COMMONWEALTH OF AUSTRALIA

National Health Act 1953

PHARMACEUTICAL BENEFITS

DECLARATION UNDER SUBSECTION 85(2)

No. PB 32 of 2007

I, STEPHEN DELLAR, Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing and Delegate of the Minister for Health and Ageing, pursuant to subsection 85(2) of the *National Health Act 1953*, hereby make the following Declaration:

1. This declaration commences on 1 May 2007.

2. Declaration No. PB 21 of 2007 under subsection 85(2) of the *National Health Act 1953* made on 12 March 2007 with effect from 1 April 2007 is repealed.

3. In this Declaration:

"Act" means the *National Health Act 1953*;

"base-priced drug" means —

(a) in relation to ranitidine hydrochloride (tablet, effervescent, equivalent to 150 mg ranitidine or syrup equivalent to 150 mg ranitidine per 10 mL, 300 mL): cimetidine or famotidine or nizatidine or ranitidine hydrochloride (tablet equivalent to 150 mg ranitidine or tablet equivalent to 300 mg ranitidine); or

(b) in relation to amlodipine besylate or lercanidipine hydrochloride or nifedipine (tablet 20 mg (controlled release)): felodipine or nifedipine (tablet 10 mg or tablet 20 mg or tablet 30 mg (controlled release) or tablet 60 mg (controlled release));

"electronic communication" has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*;

"extemporaneously-prepared pharmaceutical benefit" means a pharmaceutical benefit other than a ready-prepared pharmaceutical benefit;

"Medicare Australia CEO" means the Chief Executive Officer of Medicare Australia;

"PBS" means Pharmaceutical Benefits Scheme;

"palliative care patient", in relation to a circumstance specified in Schedule 1A, means a patient with an active, progressive, far-advanced disease, and for whom the prognosis is limited and the focus of care is the quality of life;

"ready-prepared pharmaceutical benefit" means a drug or medicinal preparation in respect of which there is in force a determination under subsection 85(6) of the Act;

"Regulations" means the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.

4. Part VII of the Act applies in relation to each of the drugs and medicinal preparations the name of which is specified in column 1 of Schedule 1 or 1A and the circumstances (if any) specified in column 2 of Schedule 1 or 1A opposite the name of that drug or medicinal preparation apply when the drug or medicinal preparation is prescribed by a medical practitioner.

4A. Part VII of the Act applies in relation to each of the drugs and medicinal preparations the name of which is specified in column 1 of Schedule 2 and the circumstances (if any) specified in column 2 of Schedule 2 opposite the name of that drug or medicinal preparation apply when the drug or medicinal preparation is prescribed by a participating dental practitioner.

5. A medicinal preparation composed of a compound that includes a pharmaceutical benefit the name of which is specified in column 1 of Schedule 3, other than a compound the name of which is specified in column 2 of that Schedule opposite the name of that pharmaceutical benefit, is not a medicinal preparation to which Part VII of the Act applies, unless the name of that pharmaceutical benefit is also specified in Schedule 4, in which case the provisions of paragraphs 7 and 8 apply.

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6. Part VII of the Act does not apply in relation to a medicinal preparation composed of a compound that includes a ready-prepared pharmaceutical benefit, other than a pharmaceutical benefit the name of which is specified in column 1 of Schedule 3.

7. Part VII of the Act applies in relation to medicinal preparations composed of one or more of the drugs or medicinal preparations the names of which are specified in Schedule 4.

8. Part VII of the Act applies in relation to medicinal preparations composed of one or more of the drugs or medicinal preparations the names of which are specified in Schedule 4 with the addition of one or more of the substances the names of which are specified in Schedule 5.

9. The substances the names of which are specified in Schedule 5 are additives for the purposes of paragraph 85(2)(b) of the Act.

10. Part VII of the Act applies in relation to each of the drugs and medicinal preparations the name of which is specified in Schedule 6.

11. The drugs and medicinal preparations the names of which are specified in Schedule 6 are additional pharmaceutical benefits made available under arrangements provided for by section 100 of the Act.

12. Where circumstances are specified in column 2 of Schedule 1, 1A, 2 or 4 opposite the name of a pharmaceutical benefit specified in column 1 of any of those Schedules, that pharmaceutical benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act.

13. Where circumstances are specified in column 2 of Schedule 4 opposite the name of a pharmaceutical benefit specified in column 1 of that Schedule, those circumstances are also specified in relation to any medicinal preparation containing that pharmaceutical benefit.

14. Subject to paragraph 16, the following circumstances are specified in relation to each relevant pharmaceutical benefit for the purposes of section 88A of the Act:

    (a) where a class of persons is specified in column 2 of Schedule 1, 1A, 2 or 4 — that the pharmaceutical benefit is to be supplied for the treatment of a person included in that class of persons;

    (b) where a disease or condition is specified in column 2 of Schedule 1, 1A, 2 or 4 —

        (i) if subsubparagraph (ii) does not apply — that the pharmaceutical benefit is to be supplied for the treatment of that disease or condition in relation to any person; or

        (ii) if the disease or condition is specified in relation to a specified class of persons — that the pharmaceutical benefit is to be supplied for the treatment of that disease or condition in a person included in that class of persons;

    (c) where a purpose is specified in column 2 of Schedule 1, 1A, 2 or 4 — that the pharmaceutical benefit is to be supplied for that purpose;

    (d) where it is specified in column 2 of Schedule 1 or 1A that compliance with authority procedures set out in subparagraph 14(d) is required — that a medical practitioner has submitted to the Medicare Australia CEO a prescription for the supply of the pharmaceutical benefit:

        (i) by preparing and signing the prescription:

            (A) in a form approved by the Secretary and completed by the medical practitioner in ink in his or her own handwriting; or

            (B) in a form, prepared by means of a computer, that is in accordance with the form approved by the Secretary under subsubsubparagraph (A); or

            (C) in a form, prepared by means of a computer, approved in writing for the purpose by the Secretary and in the format approved in writing by the Secretary; or

            (D) by a method approved in writing by the Secretary; or

        (ii) by submitting the prescription by giving the Medicare Australia CEO, by telephone, details of the prescription which has been prepared and signed by the medical practitioner in accordance with subsubparagraph (i); or

(iii) where the medical practitioner has attempted to obtain an authorisation by submitting details of the prescription to the Medicare Australia CEO in accordance with subsubparagraph (ii) but has been unable to do so because of a failure or other form of unavailability in the telephone system established by the Medicare Australia CEO for the provision of such authorisations, by submitting the prescription in accordance with the instructions stipulated in an emergency telephone message provided to the medical practitioner by the Medicare Australia CEO; or

(iv) by submitting the prescription by giving the Medicare Australia CEO, by means of an electronic communication of a kind approved in writing by the Medicare Australia CEO, details of the prescription which has been prepared and signed by the medical practitioner in accordance with subsubparagraph (i).

14A. For the purposes of subsubparagraph 14(d)(i), a prescription that has been prepared and signed by the medical practitioner in accordance with that subparagraph is taken to have been submitted by him or her if it is submitted by one of his or her employees.

15. Subject to paragraph 15B, the authorisation of a prescription submitted under subparagraph 14(d) may be made:

(a) if the prescription was submitted in accordance with subsubparagraph 14(d)(i) — by the Medicare Australia CEO signing his or her authorisation of the prescription on it and:

(i) if the Medicare Australia CEO requires the medical practitioner to alter the prescription — by returning it to the medical practitioner for alteration before the medical practitioner gives it to the person in respect of whom it was prepared; or

(ii) in any other case:

(A) by returning it to the medical practitioner; or

(B) by sending it to the person in respect of whom it was prepared; or

(b) if the prescription was submitted in accordance with subsubparagraph 14(d)(ii) — orally, at the time the Medicare Australia CEO is given details of the prescription; or

(c) if the prescription was submitted in accordance with subsubparagraph 14(d)(iv) — by the Medicare Australia CEO sending his or her authorisation, by electronic communication, to the medical practitioner.

15A. If the Medicare Australia CEO authorises a prescription in accordance with subparagraph 15(b) or (c):

(a) the Medicare Australia CEO must tell the medical practitioner, orally or by electronic communication, the number that has been allotted to the authorised prescription; and

(b) the medical practitioner must:

(i) mark that number on the prescription; and

(ii) retain a copy of the prescription for 1 year from the date on which the prescription was authorised.

15B. Notwithstanding paragraph 15, if the prescription was submitted in accordance with subsubparagraph 14(d)(iii), authorisation shall be deemed to have been granted upon completion by the medical practitioner of the prescription in accordance with the instructions stipulated in the emergency telephone message provided to the medical practitioner by the Medicare Australia CEO.

16. Where the circumstances “For use in accordance with paragraph 16” are specified in column 2 of Schedule 1, the circumstances specified for the purpose of subparagraph 14(c) are:

(a) that the pharmaceutical benefit is to be supplied for the treatment, in conjunction with dietary therapy, of a patient identified as being in one of the following very high risk categories:

(i) coronary heart disease which has become symptomatic;

(ii) cerebrovascular disease which has become symptomatic;

(iii) peripheral vascular disease which has become symptomatic;

(iv) diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of greater than 20 micrograms per minute, or urinary albumin to creatinine ratio of greater than 2.5 for males or greater than 3.5 for females);

(v) diabetes mellitus in Aboriginal or Torres Strait Islander patients;

(vi) diabetes mellitus in patients aged 60 years or more;

(vii) family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives;

(viii) family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives; or

(b) if subparagraph 16(a) does not apply — that the pharmaceutical benefit is to be supplied for the treatment, in conjunction with dietary therapy, of a patient who, after at least 6 weeks of dietary therapy, qualifies for the supply of the benefit in accordance with the following table:

Category of patient	*Fasting lipid level*
Patients with diabetes mellitus not otherwise included	total cholesterol greater than 5.5 mmol per L
Aboriginal or Torres Strait Islander patients; Patients with hypertension	total cholesterol greater than 6.5 mmol per L; or total cholesterol greater than 5.5 mmol per L and high density lipoprotein cholesterol less than 1 mmol per L
Patients with high density lipoprotein cholesterol less than 1 mmol per L	total cholesterol greater than 6.5 mmol per L
Patients with familial hypercholesterolaemia identified by: (1) DNA mutation; or (2) tendon xanthomas in the patient or their first or second degree relative	If aged 18 years or less at treatment initiation: low density lipoprotein cholesterol greater than 4 mmol per L If aged more than 18 years at treatment initiation: low density lipoprotein cholesterol greater than 5 mmol per L;
Patients with: (1) family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or (2) family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives	or total cholesterol greater than 6.5 mmol per L; or total cholesterol greater than 5.5 mmol per L and high density lipoprotein cholesterol less than 1 mmol per L
Patients not eligible under the above: (1) men over 34 but less than 76 years of age; or (2) post-menopausal women less than 76 years of age	total cholesterol greater than 7.5 mmol per L; or triglyceride greater than 4 mmol per L
Patients not otherwise included	total cholesterol greater than 9 mmol per L; or triglyceride greater than 8 mmol per L

SCHEDULE 1 – READY-PREPARED PHARMACEUTICAL BENEFITS WHEN PRESCRIBED BY A MEDICAL PRACTITIONER

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Abciximab	In compliance with authority procedures set out in subparagraph 14 (d):
	Patients undergoing percutaneous coronary balloon angioplasty
	Patients undergoing percutaneous coronary atherectomy
	Patients undergoing percutaneous coronary stent placement
Acamprosate Calcium	In compliance with authority procedures set out in subparagraph 14 (d):
	For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence
Acarbose	—
Acetazolamide	—
Acetylcysteine Sodium	Bronchiectasis
	Cystic fibrosis
Aciclovir	In respect of the tablet 200 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe initial genital herpes
	Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	In respect of the tablet 800 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of patients with herpes zoster within 72 hours of the onset of the rash
	Herpes zoster ophthalmicus
	Patients with advanced human immunodeficiency virus disease (CD4 cell counts of less than 150 million per L)
	In respect of the eye ointment 30 mg per g, 4.5 g:
	Herpes simplex keratitis
Acitretin	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe intractable psoriasis
	Severe forms of disorders of keratinisation
Adalimumab	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Initial treatment in a biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and:
	(a) (i) who have not previously received treatment with a bDMARD for this condition subsidised under the Pharmaceutical Benefits Scheme (PBS); or
	(ii) who, where the patient has previously received PBS-subsidised bDMARD treatment, have received no PBS-subsidised treatment with a bDMARD for this condition for a period of 5 years or more starting from the date the last course of PBS-subsidised bDMARD therapy was approved; and
	(b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly, have failed to achieve an adequate response to methotrexate (at a dose of at least 7.5 mg weekly) in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs) for a minimum of 3 months, and have failed to achieve an adequate response following a minimum of 3 months' treatment with leflunomide alone or with leflunomide in combination with methotrexate or with cyclosporin alone, unless:
	(i) treatment with any of the above-mentioned drugs is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, in which case the patient is exempted from demonstrating an inadequate response to that particular agent (or agents) only; or
	(ii) the patient has had a break in PBS-subsidised bDMARD treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months; and
	(c) who have signed a patient acknowledgement form declaring that they understand and acknowledge that, within a single bDMARD treatment cycle, PBS-subsidised treatment with any bDMARD will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and
	where bDMARD means a drug included in the following list of drugs:
	adalimumab, anakinra, etanercept or infliximab; and

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response to the treatment regimens specified at (b) above is demonstrated by an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L, and either a total active joint count of at least 20 active (swollen and tender) joints, or at least 4 active joints from the following list of major joints: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; where the patient is exempted from demonstrating an inadequate response to a treatment regimen specified at (b) above on the basis of contraindication or intolerance, the authority application includes details of the contraindication or intolerance, including the degree of toxicity; the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form which includes details of the patient's ESR and CRP measurements, and an assessment of the patient's active joint count, conducted no earlier than 1 month prior to the date of application, and a copy of the signed patient acknowledgment form; a course of treatment is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment in a bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment or recommencement of treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who have received prior PBS-subsidised treatment with a bDMARD for this condition in this bDMARD treatment cycle and who are eligible to receive further bDMARD therapy within this treatment cycle; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle; patients are eligible to commence therapy with adalimumab within this bDMARD treatment cycle provided they have not already tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 bDMARDs within this treatment cycle, and provided they also meet the conditions applying to recommencement of adalimumab therapy specified below, if applicable;

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	patients who have previously commenced, and subsequently ceased, PBS-subsidised treatment with adalimumab within this bDMARD treatment cycle are eligible to recommence therapy with this drug within this same cycle if: (i) they have demonstrated an adequate response to their most recent course of PBS-subsidised adalimumab treatment; and (ii) the response was assessed, and the assessment was provided to the Medicare Australia CEO, no later than 4 weeks from the date that course ceased; and (iii) the response was assessed following a minimum of 12 weeks of therapy when the most recent course of PBS-subsidised treatment was an initial 16 week course; and (iv) response to treatment was determined using the same indices of disease severity used to establish baseline at the commencement of treatment; an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form and, where this is required, evidence of the patient's response to their most recent course of adalimumab therapy; a course of treatment is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment, or of a course which recommences treatment, within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Commencement of adalimumab treatment in a bDMARD treatment cycle with an initial supply subsidised under the Pharmaceutical Benefits Scheme (PBS) for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who were receiving treatment with adalimumab prior to 1 November 2004, who failed to qualify for PBS-subsidised therapy after 1 May 2004 due to an inability to receive concomitant methotrexate, and who have demonstrated a response to adalimumab treatment as specified in the criteria for continuing PBS-subsidised treatment with adalimumab detailed below; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient; the course of treatment is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Commencement of adalimumab treatment in a bDMARD treatment cycle with an initial supply subsidised under the Pharmaceutical Benefits Scheme (PBS) for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who were receiving treatment with adalimumab prior to 1 March 2005, who failed to qualify for PBS-subsidised therapy after 1 May 2004 due to testing negative for rheumatoid factor, and who have demonstrated a response to adalimumab treatment as specified in the criteria for continuing PBS-subsidised treatment with adalimumab detailed below; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient; the course of treatment is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight Continuing treatment within an ongoing biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and: (a) who have demonstrated an adequate response to treatment with adalimumab; and (b) whose most recent course of bDMARD treatment subsidised under the Pharmaceutical Benefits Scheme (PBS) in this bDMARD treatment cycle was with adalimumab; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle; an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of treatment are used to determine response; the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with adalimumab, where response is assessed, and this assessment is provided to the Medicare Australia CEO, no later than 4 weeks from the cessation of that treatment course; if the most recent course of adalimumab therapy was an initial 16 week course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course;

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	a course of treatment is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and (2) have not previously received PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (3) have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months and to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months, unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with either methotrexate or sulfasalazine, at an adequate dose, for a minimum of 3 months; and (4) have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time; and (5) have signed a patient acknowledgement form declaring that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where biological agent means adalimumab or etanercept or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L, and either an active joint count of at least 20 active (swollen and tender) joints, or at least 4 active joints from the following list of major joints: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form which includes details of the patient's ESR and CRP measurements, and an assessment of the patient's active joint count, conducted no earlier than 1 month prior to the date of application, and a copy of the signed patient acknowledgment form;

a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment in a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and

(2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and who are eligible to receive further therapy with a biological agent within this Treatment Cycle; and

(3) have not failed treatment with adalimumab during the current Treatment Cycle; and

where biological agent means adalimumab or etanercept or infliximab; and

where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle;

patients who have previously commenced, and subsequently ceased, PBS-subsidised treatment with adalimumab within this Treatment Cycle are eligible to recommence therapy with this drug within this same cycle if:

(i) they have demonstrated an adequate response, as specified in the criteria for continuing PBS-subsidised treatment with adalimumab, to their most recent course of PBS-subsidised adalimumab treatment; and

(ii) the response was assessed, and the assessment was provided to the Medicare Australia CEO, no later than 4 weeks from the date that course ceased; and

(iii) the response was assessed following a minimum of 12 weeks of therapy, where the most recent course of PBS-subsidised treatment was a 16-week initial treatment course; and

(iv) response to treatment was determined using the same indices of disease severity used to establish baseline at the commencement of treatment;

the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form;

a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Commencement of a Biological Treatment Cycle, with an initial PBS-subsidised course of adalimumab for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and (2) were receiving treatment with adalimumab prior to 16 March 2006; and (3) have demonstrated a response to adalimumab treatment as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and (4) have signed a patient acknowledgement form declaring that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where biological agent means adalimumab or etanercept or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form which includes a copy of the signed patient acknowledgment form; the course of treatment is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight; patients are eligible for PBS-subsidised treatment under the above criteria once only In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of a course of initial PBS-subsidised treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults: (1) who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status; and (2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with adalimumab; and (3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab; and where biological agent means adalimumab or etanercept or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to treatment with adalimumab is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	— shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of treatment are used to determine response; the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with adalimumab, where response is assessed, and this assessment is provided to the Medicare Australia CEO, no later than 4 weeks from the cessation of that treatment course; if the most recent course of adalimumab therapy was a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment commencing a treatment cycle, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, and: (a) who has not received any treatment with adalimumab, etanercept or infliximab subsidised under the Pharmaceutical Benefits Scheme (PBS), or, where the patient has previously received PBS-subsidised treatment with one of these drugs, has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for this condition for a period of 5 years or more starting from the date the last course of PBS-subsidised treatment was approved; and (b) who has at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; and (c) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of at least 3 months, unless the patient has had a break in PBS-subsidised therapy with adalimumab, etanercept and infliximab of at least 5 years duration, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months; and (d) who has signed a patient acknowledgment form declaring that they understand and acknowledge that PBS-subsidised treatment with adalimumab, etanercept and infliximab for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response is demonstrated by:

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	(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale, where the BASDAI score is determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment, and is no more than 1 month old at the time of application; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L; both ESR and CRP measurements are included in the authority application and are no more than 1 month old; if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reason why this criterion cannot be satisfied; the authority application includes details of the NSAIDs trialled, their doses and duration of treatment; if the NSAID dose is less than the maximum recommended dose in the relevant Therapeutic Goods Administration (TGA)-approved Product Information, the authority application includes the reason why a higher dose cannot be used; if treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the authority application includes details of the contraindication; if intolerance to NSAID treatment develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the nature and severity of this intolerance; an appropriate minimum exercise program includes stretch and range of motion exercises at least 5 times per week, and either aerobic exercise of at least 20 minutes duration at least 3 times per week or a group exercise class at least once per week; if a patient is unable to complete the minimum exercise program, the authority application includes the clinical reasons for this and details what, if any, exercise program has been followed; the application for authorisation includes: (a) a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a signed patient acknowledgment form; and (iv) a completed Exercise Program Self Certification Form detailing the program followed and the dates over which it was followed, and including confirmation by the prescribing doctor that, to the best of their knowledge, the patient has followed the exercise program detailed; a course of initial treatment commencing a treatment cycle is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment in a treatment cycle, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, and who, qualifying under the criteria specified above has previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment, or recommencement of treatment, with adalimumab within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with adalimumab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: a patient who commenced PBS-subsidised treatment of ankylosing spondylitis with etanercept or infliximab prior to 1 March 2007 is deemed to have commenced their first treatment cycle with that therapy;

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	the authority application includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment; the application is accompanied by the results of the patient's most recent course of PBS-subsidised adalimumab, etanercept or infliximab therapy, where: (a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; and (b) (i) if the course of therapy is a 16 week initial course, the assessment of response is made following a minimum of 12 weeks of treatment; or (ii) if the course of therapy is a 6 week initial course approved prior to 1 March 2007, the assessment of response is made following at least 4 weeks of treatment; if the response assessment to the previous course of treatment with adalimumab, etanercept or infliximab is not submitted as detailed above, the patient is deemed to have failed therapy with that particular course of treatment; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 16 weeks of treatment at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment, or of a course which recommences treatment, with adalimumab within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, qualifying under the criteria specified above, has previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Commencement of a treatment cycle with an initial PBS-subsidised course of adalimumab for continuing treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who was receiving treatment with adalimumab prior to 1 November 2006; and (a) who is receiving treatment with adalimumab at the time of application; and (b) who has not received prior PBS-subsidised treatment with infliximab or etanercept; and (c) whose current Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is either less than or equal to 5 on a 0-10 scale or improved by at least 2 from baseline; and (d) who has: (i) an erythrocyte sedimentation rate (ESR) measurement no greater than 25 mm per hour; or (ii) a C-reactive protein (CRP) measurement no greater than 10 mg per L; or (iii) an ESR or CRP measurement reduced by at least 20% from pre-treatment baseline; and (e) who has signed a patient acknowledgment form declaring that they understand and acknowledge that PBS-subsidised treatment with adalimumab, etanercept and infliximab for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: the BASDAI assessment and the ESR and CRP measurements provided are no more than 1 month old at the time of application; the application for authorisation includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

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	(ii) a completed BASDAI Assessment Form; and (iii) a signed patient acknowledgment form; the course of treatment is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight; patients are eligible for PBS-subsidised treatment under the above criteria once only
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of a course of initial PBS-subsidised treatment commencing a treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who was receiving non-PBS-subsidised treatment with adalimumab prior to 1 November 2006 and at the time of the initial application for PBS-subsidised therapy and who, qualifying under the criteria specified above, has previously been issued with an authority prescription for initial PBS-subsidised treatment with adalimumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has demonstrated a response to treatment with adalimumab, and whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: a patient who commenced PBS-subsidised treatment with etanercept or infliximab prior to 1 March 2007 is deemed to have commenced their first treatment cycle with that therapy; response is defined as an improvement from baseline of at least 2 in the patient's Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and 1 of the following: (a) an erythrocyte sedimentation rate (ESR) measurement no greater than 25 mm per hour; or (b) a C-reactive protein (CRP) measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline; if the patient commenced treatment with adalimumab prior to 1 November 2006, was subsequently commenced on PBS-subsidised treatment and is continuing to receive PBS-subsidised treatment in their first treatment cycle, and where pre-treatment baselines are not available, response to treatment is defined as a BASDAI score no more than 20% greater than the score included in the initial application for PBS-subsidised treatment, or no greater than 2, and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; all measurements provided are no more than 1 month old at the time of application; the same acute phase reactant used to establish baseline at the commencement of an initial treatment course is measured and supplied for all subsequent continuing treatment applications for the patient; patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless: (a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course of treatment ceased; and (b) if the course of therapy is a 16 week initial course, the assessment of response is made following a minimum of 12 weeks of treatment; the application for authorisation includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment at a dose that does not exceed 40 mg per fortnight

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):
	Continuing treatment within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, qualifying under the criteria specified above, has previously been issued with an authority prescription for continuing treatment with adalimumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total, at a dose that does not exceed 40 mg per fortnight
Adrenaline	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician, where the name of the specialist consulted is included in the authority application
	Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis
	Continuing supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug
Adrenaline Acid Tartrate	—
Albendazole	In respect of the tablet 200 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person
	Treatment of tapeworm infestation
	In respect of the tablet 400 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used
Alendronate Sodium	In respect of the tablet equivalent to 70 mg alendronic acid:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older with a bone mineral density T-score of negative 3.0 or less, and where the date, site (femoral neck or lumbar spine) and score of the qualifying bone mineral density measurement are stated in the authority application
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older with a bone mineral density T-score of negative 3.0 or less, where the patient has previously been issued with an authority prescription for this drug
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
	In respect of the tablet equivalent to 40 mg alendronic acid:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Symptomatic Paget's disease of bone
Alendronate Sodium with Colecalciferol	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older with a bone mineral density T-score of negative 3.0 or less, and where the date, site (femoral neck or lumbar spine) and score of the qualifying bone mineral density measurement are stated in the authority application
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older with a bone mineral density T-score of negative 3.0 or less, where the patient has previously been issued with an authority prescription for this drug

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
"Alfaré"	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 3 months, for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years, where intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet, and where the date of birth of the patient is included in the authority application
	Continuing treatment for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides, and where the date of birth of the patient is included in the authority application
	Continuing treatment for intolerance (not infant colic) to cows' milk protein in a child aged 2 years or over, where the child has been assessed by a suitably qualified allergist or paediatrician, and where the date of birth of the patient is included in the authority application
	Biliary atresia
	Chronic liver failure with fat malabsorption
	Chylous ascites
	Chylothorax
	Cystic fibrosis
	Enterokinase deficiency
	Proven fat malabsorption
	Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months, where the date of birth of the patient is included in the authority application
	Severe intestinal malabsorption including short bowel syndrome
Allopurinol	—
Alprazolam	In compliance with authority procedures set out in subparagraph 14 (d):
	Panic disorder where other treatments have failed or are inappropriate
Aluminium Hydroxide - Dried with Magnesium Hydroxide	—
Aluminium Hydroxide - Dried with Magnesium Trisilicate and Magnesium Hydroxide	—
Amantadine Hydrochloride	Parkinson's disease which is not drug induced
Amiloride Hydrochloride	—
Aminoglutethimide	—
Amiodarone Hydrochloride	Severe cardiac arrhythmias
Amisulpride	In compliance with authority procedures set out in subparagraph 14 (d):
	Schizophrenia
Amitriptyline Hydrochloride	—
Amlodipine Besylate	—
Amlodipine Besylate with Atorvastatin Calcium	For use in accordance with paragraph 16 in patients who have hypertension and/or angina, and who are currently receiving treatment with a dihydropyridine calcium channel blocker
	For use in accordance with paragraph 16 in patients who have hypertension and/or angina, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate
	For use in accordance with paragraph 16 in patients who have hypertension and/or angina, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate
Amoxycillin Trihydrate	In respect of the tablet, chewable, equivalent to 250 mg amoxycillin, capsule equivalent to 250 mg amoxycillin, capsule equivalent to 500 mg amoxycillin and sachet containing oral powder equivalent to 3 g amoxycillin:
	—

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	In respect of the tablet equivalent to 1 g amoxycillin:
	Acute exacerbations of chronic bronchitis
Amoxycillin Trihydrate with Potassium Clavulanate	Infections where resistance to amoxycillin trihydrate is suspected
	Infections where resistance to amoxycillin trihydrate is proven
Amoxycillin Trihydrate with Potassium Clavulanate and Water - Purified BP	Infections where resistance to amoxycillin trihydrate is suspected
	Infections where resistance to amoxycillin trihydrate is proven
Amoxycillin Trihydrate with Water - Purified BP	—
Amphotericin	—
Ampicillin Sodium	—
Ampicillin Trihydrate	—
Anakinra	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment in a biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and: (a) (i) who have not previously received treatment with a bDMARD for this condition subsidised under the Pharmaceutical Benefits Scheme (PBS); or (ii) who, where the patient has previously received PBS-subsidised bDMARD treatment, have received no PBS-subsidised treatment with a bDMARD for this condition for a period of 5 years or more starting from the date the last course of PBS-subsidised bDMARD therapy was approved; and (b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly, have failed to achieve an adequate response to methotrexate (at a dose of at least 7.5 mg weekly) in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs) for a minimum of 3 months, and have failed to achieve an adequate response following a minimum of 3 months' treatment with leflunomide alone or with leflunomide in combination with methotrexate or with cyclosporin alone, unless: (i) treatment with any of the above-mentioned drugs is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, in which case the patient is exempted from demonstrating an inadequate response to that particular agent (or agents) only; or (ii) the patient has had a break in PBS-subsidised bDMARD treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months; and (c) who have signed a patient acknowledgement form declaring that they understand and acknowledge that, within a single bDMARD treatment cycle, PBS-subsidised treatment with any bDMARD will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the patient receives concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly; failure to achieve an adequate response to the treatment regimens specified at (b) above is demonstrated by an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L, and either a total active joint count of at least 20 active (swollen and tender) joints, or at least 4 active joints from the following list of major joints: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied;

where the patient is exempted from demonstrating an inadequate response to a treatment regimen specified at (b) above on the basis of contraindication or intolerance, the authority application includes details of the contraindication or intolerance, including the degree of toxicity;

the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form which includes details of the patient's ESR and CRP measurements, and an assessment of the patient's active joint count, conducted no earlier than 1 month prior to the date of application, and a copy of the signed patient acknowledgment form;

a course of treatment is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment in a bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who are receiving concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment or recommencement of treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who have received prior PBS-subsidised treatment with a bDMARD for this condition in this bDMARD treatment cycle and who are eligible to receive further bDMARD therapy within this treatment cycle; and

where bDMARD means a drug included in the following list of drugs:

adalimumab, anakinra, etanercept or infliximab; and

where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

the patient receives concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly;

patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle;

patients are eligible to commence therapy with anakinra within this bDMARD treatment cycle provided they have not already tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 bDMARDs within this treatment cycle, and provided they also meet the conditions applying to recommencement of anakinra therapy specified below, if applicable; unless this treatment cycle is the patient's first bDMARD treatment cycle and the patient has failed to demonstrate a response to PBS-subsidised treatment with adalimumab, etanercept and infliximab commenced prior to 1 December 2004, in which case the patient is eligible to commence therapy with anakinra in this first treatment cycle, despite having previously failed to respond to 3 bDMARDs;

patients who have previously commenced, and subsequently ceased, PBS-subsidised treatment with anakinra within this bDMARD treatment cycle are eligible to recommence therapy with this drug within this same cycle if:

(i) they have demonstrated an adequate response to their most recent course of PBS-subsidised anakinra treatment; and

(ii) the response was assessed, and the assessment was provided to the Medicare Australia CEO, no later than 4 weeks from the date that course ceased; and

(iii) the response was assessed following a minimum of 12 weeks of therapy when the most recent course of PBS-subsidised treatment was an initial 16 week course; and

(iv) response to treatment was determined using the same indices of disease severity used to establish baseline at the commencement of treatment;

an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%:

— elbow, wrist, knee or ankle (assessed as active if swollen and tender); or

— shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth);

the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form and, where this is required, evidence of the patient's response to their most recent course of anakinra therapy;

a course of treatment is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who are receiving concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Commencement of anakinra treatment in a bDMARD treatment cycle with an initial supply subsidised under the Pharmaceutical Benefits Scheme (PBS) for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who were receiving treatment with anakinra prior to 1 July 2004 and who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with anakinra detailed below; and

where bDMARD means a drug included in the following list of drugs:

adalimumab, anakinra, etanercept or infliximab; and

where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

the patient receives concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly;

the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient;

the course of treatment is limited to a maximum of 24 weeks of treatment

Commencement of anakinra treatment in a bDMARD treatment cycle with an initial supply subsidised under the Pharmaceutical Benefits Scheme (PBS) for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who were receiving treatment with anakinra prior to 1 March 2005, who failed to qualify for PBS-subsidised therapy after 1 December 2004 due to testing negative for rheumatoid factor, and who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with anakinra detailed below; and

where bDMARD means a drug included in the following list of drugs:

adalimumab, anakinra, etanercept or infliximab; and

where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	the patient receives concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly; the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient; the course of treatment is limited to a maximum of 24 weeks of treatment Continuing treatment within an ongoing biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and: (a) who have demonstrated an adequate response to treatment with anakinra; and (b) whose most recent course of bDMARD treatment subsidised under the Pharmaceutical Benefits Scheme (PBS) in this bDMARD treatment cycle was with anakinra; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the patient receives concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly; patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle; if this treatment cycle is the patient's first bDMARD treatment cycle and the patient has failed to demonstrate a response to PBS-subsidised treatment with adalimumab, etanercept and infliximab commenced prior to 1 December 2004, the patient is eligible to continue PBS-subsidised therapy with anakinra in this first treatment cycle, despite having previously failed to respond to 3 bDMARDs; an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of treatment are used to determine response; the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with anakinra, where response is assessed, and this assessment is provided to the Medicare Australia CEO, no later than 4 weeks from the cessation of that treatment course; if the most recent course of anakinra therapy was an initial 16 week course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; a course of treatment is limited to a maximum of 24 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who are receiving concomitant treatment with methotrexate at a dose of at least 7.5 mg weekly and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total
Anastrozole	Treatment of hormone-dependent breast cancer in post-menopausal women

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Anecortave Acetate	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment by an ophthalmologist, as the sole subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration, as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200), where the patient has not previously received PBS-subsidised treatment with anecortave acetate in the eye for which treatment is being sought, and where the authority application includes a completed copy of the appropriate Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram demonstrating that the CNV is predominantly (greater than or equal to 50%) classic In compliance with authority procedures set out in subsubparagraph 14 (d) (ii): Initial treatment by an ophthalmologist, as the sole subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration, as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200), where the patient has not previously received PBS-subsidised treatment with anecortave acetate in the eye for which treatment is being sought, and where the authority application includes a completed copy of the appropriate Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram demonstrating that the CNV is predominantly (greater than or equal to 50%) classic, is submitted to the Medicare Australia CEO by facsimile prior to contact by telephone and is resubmitted to the Medicare Australia CEO by post after the application has been authorised In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment by an ophthalmologist, as the sole subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation due to age-related macular degeneration, where the patient has previously been granted at least 1, but not more than 9, authority prescriptions for anecortave acetate for treatment of the same eye
Apraclonidine Hydrochloride	Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy
Aprepitant	In compliance with authority procedures set out in subparagraph 14 (d): Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, when aprepitant is used in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy, and where the cytotoxic chemotherapy to be administered to the patient includes any of the following agents: altretamine; carmustine; cisplatin, when a single dose constitutes a cycle of chemotherapy; cyclophosphamide, at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine, when a single dose constitutes a cycle of chemotherapy; streptozocin Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer where cyclophosphamide and an anthracycline are to be co-administered, when aprepitant is used in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, and where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy
Aripiprazole	In compliance with authority procedures set out in subparagraph 14 (d): Schizophrenia
Aspirin	—
Atenolol	—
Atorvastatin Calcium	For use in accordance with paragraph 16
Atovaquone	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of mild to moderate *Pneumocystis carinii* pneumonia in adult patients who are intolerant of trimethoprim with sulfamethoxazole therapy
Atropine Sulfate	—
Auranofin	—
Azathioprine	—
Azithromycin Dihydrate	Uncomplicated urethritis due to *Chlamydia trachomatis* Uncomplicated cervicitis due to *Chlamydia trachomatis* Trachoma

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Azithromycin Dihydrate with Water - Purified BP	Trachoma
Baclofen	—
Balsalazide Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Ulcerative colitis where hypersensitivity to sulfonamides exists
	Ulcerative colitis where intolerance to sulfasalazine exists
"BCG Immunotherapeutic" (Bacillus Calmette-Guérin/ Connaught strain)	Treatment of carcinoma in situ of the urinary bladder
"BCG-Tice" (Bacillus Calmette-Guérin/ Tice strain)	Primary and relapsing superficial urothelial carcinoma of the bladder
Beclomethasone Dipropionate	In respect of the pressurised inhalation 50 micrograms per dose, 200 doses (CFC-free formulation) and pressurised inhalation 100 micrograms per dose, 200 doses (CFC-free formulation):
	—
	In respect of the pressurised inhalation in breath actuated device 50 micrograms per dose, 200 doses (CFC-free formulation) and pressurised inhalation in breath actuated device 100 micrograms per dose, 200 doses (CFC-free formulation):
	Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug
Benzathine Penicillin	—
Benzhexol Hydrochloride	—
Benztropine Mesylate	—
Benzydamine Hydrochloride	Radiation induced mucositis
Benzylpenicillin Sodium	—
Betamethasone Acetate with Betamethasone Sodium Phosphate	Alopecia areata
	For local intra-articular or peri-articular infiltration
	Granulomata, dermal
	Keloid
	Lichen planus hypertrophic
	Lichen simplex chronicus
	Lupus erythematosus, chronic discoid
	Necrobiosis lipoidica
	Uveitis
Betamethasone Dipropionate	Treatment of corticosteroid-responsive dermatoses
Betamethasone Valerate	Treatment of corticosteroid-responsive dermatoses
Betaxolol Hydrochloride	—
Bethanechol Chloride	—
Bicalutamide	In compliance with authority procedures set out in subparagraph 14 (d):
	Metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) agonist therapy
Bifonazole	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
Bimatoprost	—
Biperiden Hydrochloride	—
Bisacodyl	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
	Patients receiving palliative care
	Terminal malignant neoplasia
	Anorectal congenital abnormalities
	Megacolon
Bisoprolol Fumarate	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an angiotensin-converting enzyme inhibitor if tolerated

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Bivalirudin Trifluoroacetate	In compliance with authority procedures set out in subparagraph 14 (d):
	Patients undergoing non-emergency percutaneous coronary intervention
Bleomycin Sulfate	Germ cell neoplasms
	Lymphoma
Brimonidine Tartrate	—
Brimonidine Tartrate with Timolol Maleate	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL
Brinzolamide	—
Bromocriptine Mesylate	In respect of the tablet equivalent to 2.5 mg bromocriptine:
	Prevention of the onset of lactation in the puerperium for medical reasons
	Acromegaly
	Parkinson's disease
	Pathological hyperprolactinaemia where surgery is not indicated
	Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
	Pathological hyperprolactinaemia where radiotherapy is not indicated
	Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution
	In respect of the capsule equivalent to 5 mg bromocriptine and capsule equivalent to 10 mg bromocriptine:
	Acromegaly
	Parkinson's disease
	Pathological hyperprolactinaemia where surgery is not indicated
	Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
	Pathological hyperprolactinaemia where radiotherapy is not indicated
	Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution
Budesonide	In respect of the nebuliser suspension 500 micrograms in 2 mL single dose units, 30 and nebuliser suspension 1 mg in 2 mL single dose units, 30:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy
	In respect of the powder for oral inhalation in breath actuated device 100 micrograms per dose, 200 doses, powder for oral inhalation in breath actuated device 200 micrograms per dose, 200 doses and powder for oral inhalation in breath actuated device 400 micrograms per dose, 200 doses:
	—
Budesonide with Eformoterol Fumarate Dihydrate	Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide
	Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide
Buprenorphine	Chronic severe disabling pain not responding to non-narcotic analgesics
Bupropion Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Commencement of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and who have entered a comprehensive support and counselling program, and where details of the program are specified in the authority application
	Commencement of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and who are entering a comprehensive support and counselling program during the same consultation at which the authority application is made, and where details of the program are specified in the authority application

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Completion of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and who have entered a comprehensive support and counselling program, and where the patient has previously been issued with an authority prescription for commencement of treatment with this drug
Busulfan	—
Cabergoline	In respect of the tablet 500 micrograms:
	Prevention of the onset of lactation in the puerperium for medical reasons
	In compliance with authority procedures set out in subparagraph 14 (d):
	Pathological hyperprolactinaemia where surgery is not indicated
	Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
	Pathological hyperprolactinaemia where radiotherapy is not indicated
	Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution
	In respect of the tablet 1 mg, tablet 2 mg and tablet 4 mg:
	Parkinson's disease
Calcipotriol	Chronic stable plaque type psoriasis vulgaris
Calcitriol	In compliance with authority procedures set out in subparagraph 14 (d):
	Hypocalcaemia due to renal disease
	Hypoparathyroidism
	Hypophosphataemic rickets
	Vitamin D-resistant rickets
	Initial treatment for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
Calcium Carbonate	In compliance with authority procedures set out in subparagraph 14 (d):
	Hyperphosphataemia associated with chronic renal failure
Calcium Citrate	In compliance with authority procedures set out in subparagraph 14 (d):
	Hyperphosphataemia associated with chronic renal failure
Calcium Folinate	In respect of the tablet equivalent to 15 mg folinic acid:
	Antidote to folic acid antagonists
	In respect of the injection equivalent to 50 mg folinic acid in 5 mL, injection equivalent to 100 mg folinic acid in 10 mL and injection equivalent to 300 mg folinic acid in 30 mL:
	—
Candesartan Cilexetil	—
Candesartan Cilexetil with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with 16 mg candesartan cilexetil
Capecitabine	In compliance with authority procedures set out in subparagraph 14 (d):
	Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline
	Advanced breast cancer where therapy with a taxane or an anthracycline is contraindicated
	Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy
	Treatment of advanced or metastatic colorectal cancer
	Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour
"Caprilon"	Chylous ascites
	Chylothorax
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Captopril	In respect of the tablet 12.5 mg, tablet 25 mg and tablet 50 mg:
	—
	In respect of the oral solution 5 mg per mL, 95 mL:
	For patients unable to take a solid dose form of an angiotensin-converting enzyme inhibitor
Carbamazepine	—
Carbimazole	—
"Carbohydrate Free Mixture"	Patients with intractable seizures requiring treatment with a ketogenic diet
	Glucose transport protein defects
	Pyruvate dehydrogenase deficiency
	Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance
Carbomer 974	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops
Carbomer 980	In respect of the ocular lubricating gel 2 mg per g, 10 g:
	Severe dry eye syndrome, including Sjogren's syndrome
	In respect of the eye drops 2 mg per g, single dose units 0.6 mL, 30:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops
Carboplatin	—
Carmellose Sodium	In respect of the eye drops 5 mg per mL, 15 mL and eye drops 10 mg per mL, 15 mL:
	Severe dry eye syndrome, including Sjogren's syndrome
	In respect of the eye drops 2.5 mg per mL, single dose units 0.6 mL, 24, eye drops 5 mg per mL, single dose units 0.4 mL, 30, eye drops 10 mg per mL, single dose units 0.4 mL, 30 and ocular lubricating gel 10 mg per mL, single dose units 0.6 mL, 28:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops
Carmustine	Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery
Carvedilol	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an angiotensin-converting enzyme inhibitor if tolerated
	Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002
Cefaclor Monohydrate	—
Cefaclor Monohydrate with Water - Purified BP	—
Cefepime Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of febrile neutropenia
Cefotaxime Sodium	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
Ceftriaxone Sodium	In respect of the powder for injection equivalent to 500 mg ceftriaxone:
	Gonorrhoea
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
	In respect of the powder for injection equivalent to 1 g ceftriaxone and powder for injection equivalent to 2 g ceftriaxone:
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
Cefuroxime Axetil	—
Celecoxib	Symptomatic treatment of osteoarthritis
	Symptomatic treatment of rheumatoid arthritis
Cephalexin	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Cephalexin with Water - Purified BP	—
Cephalothin Sodium	—
Cephazolin Sodium	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
Chlorambucil	—
Chloramphenicol	—
Chlorpromazine Hydrochloride	—
Chlorthalidone	—
Cholestyramine	—
Chorionic Gonadotrophin	In respect of the injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL:
	Anovulatory infertility
	For the treatment of infertility in males due to hypogonadotrophic hypogonadism
	For the treatment of infertility in males associated with isolated luteinising hormone deficiency
	For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation
	For the treatment, for a period not exceeding 6 months, of males over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty
	Cryptorchism not due to organic obstruction in boys over 12 months of age
	In respect of the injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL:
	Anovulatory infertility
	For the treatment of infertility in males due to hypogonadotrophic hypogonadism
	For the treatment of infertility in males associated with isolated luteinising hormone deficiency
	For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation
	For the treatment, for a period not exceeding 6 months, of males over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty
Ciclesonide	—
Cimetidine	—
Ciprofloxacin Hydrochloride	In respect of the tablet equivalent to 500 mg ciprofloxacin and tablet equivalent to 750 mg ciprofloxacin:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Respiratory tract infection proven or suspected to be caused by *Pseudomonas aeruginosa* in severely immunocompromised patients
	Bacterial gastroenteritis in severely immunocompromised patients
	Treatment of infections proven to be due to *Pseudomonas aeruginosa* or other gram-negative bacteria resistant to all other oral antimicrobials
	Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials
	In respect of the tablet equivalent to 250 mg ciprofloxacin:
	Gonorrhoea
	In compliance with authority procedures set out in subparagraph 14 (d):
	Respiratory tract infection proven or suspected to be caused by *Pseudomonas aeruginosa* in severely immunocompromised patients
	Bacterial gastroenteritis in severely immunocompromised patients
	Treatment of infections proven to be due to *Pseudomonas aeruginosa* or other gram-negative bacteria resistant to all other oral antimicrobials
	Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials
	In respect of the ear drops equivalent to 3 mg ciprofloxacin per mL, 5 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 year and older

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the eye drops equivalent to 3 mg ciprofloxacin per mL, 5 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Bacterial keratitis
Cisplatin	—
Citalopram Hydrobromide	Major depressive disorders
Cladribine	In compliance with authority procedures set out in subparagraph 14 (d):
	Hairy cell leukaemia
Clarithromycin	—
Clindamycin Hydrochloride	Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin
Clomiphene Citrate	Anovulatory infertility
	Patients undergoing in-vitro fertilisation
Clomipramine Hydrochloride	Cataplexy associated with narcolepsy
	Obsessive-compulsive disorder
	Phobic disorders in adults
Clonazepam	In respect of the tablet 500 micrograms, tablet 2 mg and oral liquid 2.5 mg per mL, 10 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Neurologically proven epilepsy
	In respect of the injection 1 mg in 2 mL (set containing solution 1 mg in 1 mL and 1 mL diluent):
	Epilepsy
Clonidine Hydrochloride	—
Clopidogrel Hydrogen Sulfate	In compliance with authority procedures set out in subparagraph 14 (d):
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:
	in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin
	in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding
	in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs
	Prevention of recurrence of myocardial infarction or unstable angina:
	in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin
	in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding
	in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs
Clotrimazole	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
Coal Tar - Prepared	—
Codeine Phosphate	—
Codeine Phosphate with Paracetamol	—
Colchicine	—
Colestipol Hydrochloride	—
Copper Sulfate	—
Cortisone Acetate	—
Cyclophosphamide	—
Cyclosporin	In compliance with authority procedures set out in subparagraph 14 (d):
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with organ or tissue transplants, where therapy remains under the supervision and direction of the transplant unit reviewing the patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate, where therapy remains under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient and where the name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review are included in the authority application

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life, where therapy remains under the supervision and direction of a dermatologist or specialised unit reviewing the patient and where the name of the dermatologist or specialised unit reviewing treatment and the date of the latest review are included in the authority application
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with nephrotic syndrome in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired, where therapy remains under the supervision and direction of a nephrologist or specialised unit reviewing the patient and where the name of the nephrologist or specialised unit reviewing treatment and the date of the latest review are included in the authority application
	Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate, where therapy remains under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient and where the name of the rheumatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review are included in the authority application
	Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate
	Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life
	Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate
Cyproheptadine Hydrochloride	Prevention of migraine
Cyproterone Acetate	In respect of the tablet 50 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe androgenisation, of which acne alone is not a sufficient indication, in non-pregnant women
	Advanced carcinoma of the prostate
	To reduce drive in sexual deviations in males
	In respect of the tablet 100 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Advanced carcinoma of the prostate
	To reduce drive in sexual deviations in males
Cytarabine	—
Dalteparin Sodium	—
Danazol	In compliance with authority procedures set out in subparagraph 14 (d):
	Endometriosis, visually proven
	Hereditary angio-oedema
	Treatment, for up to 6 months, of intractable primary menorrhagia
	Treatment, for up to 6 months, of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments
Dantrolene Sodium	Treatment of chronic spasticity
Dapsone	—
Desmopressin Acetate	In respect of the intranasal solution 100 micrograms per mL, 2.5 mL dropper bottle:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Cranial diabetes insipidus

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the tablet 200 micrograms and nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Primary nocturnal enuresis:
	in patients aged 6 years or older who are refractory to an enuresis alarm, where, if the application is for the tablet presentation of this drug, a period of 6 months or more has elapsed since an application was last approved for the issue of an authority prescription to the patient for the tablet presentation of this drug for this purpose
	in patients aged 6 years or older for whom an enuresis alarm is contraindicated, where the reason for the contraindication is included in the authority application, and where, if the application is for the tablet presentation of this drug, a period of 6 months or more has elapsed since an application was last approved for the issue of an authority prescription to the patient for the tablet presentation of this drug for this purpose
	Cranial diabetes insipidus
Dexamethasone	—
Dexamethasone Sodium Metasulfobenzoate with Framycetin Sulfate and Gramicidin	—
Dexamethasone Sodium Phosphate	—
Dexamphetamine Sulfate	In compliance with authority procedures set out in subparagraph 14 (d):
	Use in attention deficit hyperactivity disorder, in accordance with State/Territory law
	Narcolepsy
"Dialamine"	Gyrate atrophy of the choroid and retina
	Urea cycle disorders
Diazepam	—
Diclofenac Sodium	In respect of the tablet 25 mg (enteric coated) and tablet 50 mg (enteric coated):
	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
	In respect of the suppository 100 mg:
	—
Dicloxacillin Sodium	In respect of the capsule equivalent to 250 mg dicloxacillin and capsule equivalent to 500 mg dicloxacillin:
	Serious staphylococcal infections
	In respect of the powder for injection equivalent to 500 mg dicloxacillin and powder for injection equivalent to 1 g dicloxacillin:
	—
"Digestelact"	In compliance with authority procedures set out in subparagraph 14 (d):
	Acute lactose intolerance in children aged 1 year and over, where the date of birth of the patient is included in the authority application and where the patient has not previously been issued with an authority prescription for this medicinal preparation for this purpose
	Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished, where the date of birth of the patient is included in the authority application, and where lactose intolerance has been proven either by the relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food, or by the presence of not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet
Digoxin	—
Dihydroergotamine Mesylate	—
Diltiazem Hydrochloride	—
Diphenoxylate Hydrochloride with Atropine Sulfate	—
Diphtheria and Tetanus Vaccine - Adsorbed	—
Diphtheria and Tetanus Vaccine - Adsorbed (Diluted)	—
Dipivefrine Hydrochloride	—
Dipyridamole	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:
	in patients receiving therapy with low-dose aspirin
	in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding
	in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs
Dipyridamole with Aspirin	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Disodium Etidronate	In compliance with authority procedures set out in subparagraph 14 (d): Symptomatic Paget's disease of bone when salcatonin has been found to be unsatisfactory due to lack of efficacy Symptomatic Paget's disease of bone when salcatonin has been found to be unsatisfactory due to unacceptable side effects Heterotopic ossification
Disodium Etidronate and Calcium Carbonate	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
Disodium Pamidronate	In compliance with authority procedures set out in subparagraph 14 (d): Symptomatic Paget's disease of bone
Disopyramide	—
Docetaxel	In compliance with authority procedures set out in subparagraph 14 (d): Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide Advanced breast cancer after failure of prior therapy which includes an anthracycline Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound Locally advanced or metastatic non-small cell lung cancer Treatment of HER2 positive early breast cancer in combination with trastuzumab
Dolasetron Mesylate	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Domperidone	—
Donepezil Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the baseline scores submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more who demonstrate improvement in cognitive function following initial PBS-subsidised therapy, and where: (1) improvement in cognitive function is demonstrated by: (a) in the case of patients with a baseline MMSE or SMMSE score of 10 or more and less than 25 — an increase of at least 2 points from baseline on the MMSE or SMMSE; or

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	(b) in the case of patients with a baseline MMSE or SMMSE score of at least 25 points — an increase of at least 2 points from baseline on the MMSE or SMMSE, or, if a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) was submitted with the application for initial treatment, a decrease of at least 4 points from baseline on the ADAS-Cog; and (2) the relevant result from the MMSE, SMMSE or ADAS-Cog is included in the authority application for continuing treatment In compliance with authority procedures set out in subparagraph 14 (d): Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more and with demonstrated improvement in cognitive function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs: Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test; Intellectual (developmental or acquired) disability; Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test; Prominent dysphasia, out of proportion to other cognitive and functional impairment In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the information submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs: Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test; Intellectual (developmental or acquired) disability; Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test; Prominent dysphasia, out of proportion to other cognitive and functional impairment

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease and who demonstrate improvement in function following initial PBS-subsidised therapy, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change scale, as assessed by the same clinician who initiated treatment, and where the improvement rating achieved on the Clinicians Interview Based Impression of Change scale is stated in the authority application for continuing treatment
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less and with demonstrated improvement in function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment
Dorzolamide Hydrochloride	—
Dorzolamide Hydrochloride with Timolol Maleate	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL
Dothiepin Hydrochloride	—
Doxepin Hydrochloride	—
Doxorubicin Hydrochloride	—
Doxorubicin Hydrochloride - Pegylated Liposomal	In compliance with authority procedures set out in subparagraph 14 (d):
	Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen
	Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane
	Metastatic breast cancer, as monotherapy, where therapy with capecitabine or a taxane is contraindicated
Doxycycline Hydrochloride	In respect of the tablet equivalent to 50 mg doxycycline and capsule equivalent to 50 mg doxycycline (containing enteric coated pellets):
	Bronchiectasis in patients aged 8 years or older
	Chronic bronchitis in patients aged 8 years or older
	Severe acne
	In respect of the tablet equivalent to 100 mg doxycycline and capsule equivalent to 100 mg doxycycline (containing enteric coated pellets):
	—
Doxycycline Monohydrate	In respect of the tablet equivalent to 50 mg doxycycline:
	Bronchiectasis in patients aged 8 years or older
	Chronic bronchitis in patients aged 8 years or older
	Severe acne
	In respect of the tablet equivalent to 100 mg doxycycline:
	—
Drotrecogin Alfa (activated)	In compliance with authority procedures set out in subparagraph 14 (d):
	Adult patients with severe sepsis who have a high risk of death as determined by acute dysfunction in at least 2 organs or modified Acute Physiology and Chronic Health Evaluation II score of at least 25, where acute organ dysfunction is defined as follows:
	For cardiovascular-system dysfunction, an arterial systolic blood pressure of less than or equal to 90 mmHg or mean arterial pressure of less than or equal to 70 mmHg for at least 1 hour despite adequate fluid resuscitation, adequate intravascular volume status or the use of vasopressors in an attempt to maintain a systolic blood pressure of greater than or equal to 90 mmHg or a mean arterial pressure of greater than or equal to 70 mmHg;
	For kidney dysfunction, urine output of less than 0.5 mL per kg of body weight per hour for 1 hour despite adequate fluid resuscitation;
	For respiratory-system dysfunction, a ratio of partial pressure of oxygen in arterial blood (in mmHg) to the percentage of oxygen in the inspired air (expressed as a decimal) of less than or equal to 250;
	For haematologic dysfunction, a platelet count of less than 80,000 per cubic millimetre or which has decreased by 50 percent in the previous 3 days;

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In the case of unexplained metabolic acidosis, a pH of less than or equal to 7.30 or a base deficit of greater than or equal to 5.0 mmol per L in association with a plasma lactate level of greater than 1.5 times the upper limit of the normal value for the reporting laboratory
"Duocal"	Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae
Dydrogesterone	—
"Easiphen"	Phenylketonuria
Efalizumab	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response is indicated by a current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment, and is demonstrable in the patient at the time of the authority application; a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment; the most recent PASI assessment is no more than 1 month old at the time of application; if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) copies of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and (iii) a copy of the signed patient acknowledgement form;

a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment as systemic monotherapy, in a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with efalizumab as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with efalizumab for the treatment of this condition more than once in the current Treatment Cycle; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

patients who have previously demonstrated a response to PBS-subsidised treatment with efalizumab within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent course of PBS-subsidised efalizumab treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment;

patients who demonstrate a response to a 12-week course of PBS-subsidised treatment with etanercept and wish to transfer to treatment with efalizumab are not eligible to commence treatment with efalizumab until they have completed a period free from biological agent treatment of at least 12 weeks duration, immediately following cessation of the etanercept treatment course;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological agent treatment, including dosage, date and duration of treatment;

a course of initial treatment within a Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with efalizumab as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of efalizumab for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with efalizumab prior to 10 November 2005; and

(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with efalizumab; and

(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and

(d) have demonstrated a response as specified in the criterion included in the relevant restriction for continuing PBS-subsidised treatment with efalizumab; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of efalizumab therapy) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and

(iii) a copy of the signed patient acknowledgement form;

the most recent PASI assessment is no more than 1 month old at the time of application;

the course of treatment is limited to a maximum of 24 weeks of treatment;

patients are eligible for PBS-subsidised treatment under the above criteria once only

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy, commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis, who were receiving non-PBS-subsidised treatment with efalizumab prior to 10 November 2005, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with efalizumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with efalizumab; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

an adequate response to efalizumab treatment is defined as a Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, after at least 12 weeks of efalizumab treatment, when compared with the baseline value for this Treatment Cycle established prior to biological agent treatment;

the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score;

patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless:

(i) the assessment of response is conducted following at least 12 weeks of therapy, in the case of a 16-week initial treatment course, or is conducted within 4 weeks prior to completion of the course, in the case of a 24-week treatment course; and

(ii) the response assessment is submitted to the Medicare Australia CEO no later than 1 month from the date that course of treatment ceased;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams along with the date of the assessment of the patient's condition;

a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuing treatment as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and

(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks;

unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

failure to achieve an adequate response is demonstrable in the patient at the time of the authority application and is indicated by chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment;

a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment;

the most recent PASI assessment is no more than 1 month old at the time of application;

if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication;

if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) copies of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and

(iii) a copy of the signed patient acknowledgement form;

a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment as systemic monotherapy, in a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with efalizumab as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with efalizumab for the treatment of this condition more than once in the current Treatment Cycle; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

patients who have previously demonstrated a response to PBS-subsidised treatment with efalizumab within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent course of PBS-subsidised efalizumab treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment;

patients who demonstrate a response to a 12-week course of PBS-subsidised treatment with etanercept and wish to transfer to treatment with efalizumab are not eligible to commence treatment with efalizumab until they have completed a period free from biological agent treatment of at least 12 weeks duration, immediately following cessation of the etanercept treatment course;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological agent treatment, including dosage, date and duration of treatment;

a course of initial treatment within a Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with efalizumab as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of efalizumab for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and were receiving treatment with efalizumab prior to 10 November 2005; and

(b) whose disease, prior to treatment with efalizumab, was classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where either at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe, or the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; and

(c) who have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and

(d) who have demonstrated a response as specified in the criterion included in the relevant restriction for continuing PBS-subsidised treatment with efalizumab; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of efalizumab therapy) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and

(iii) a copy of the signed patient acknowledgement form;

the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score;

the most recent PASI assessment is no more than 1 month old at the time of application;

the course of treatment is limited to a maximum of 24 weeks of treatment;

patients are eligible for PBS-subsidised treatment under the above criteria once only

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy, commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, who were receiving non-PBS-subsidised treatment with efalizumab prior to 10 November 2005, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over: (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and (b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with efalizumab; and (c) who have demonstrated an adequate response to their most recent course of treatment with efalizumab; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to efalizumab treatment is defined as the plaque or plaques assessed prior to biological agent treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, after at least 12 weeks of efalizumab treatment, as compared to the baseline values established prior to biological agent treatment; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, after at least 12 weeks of efalizumab treatment, as compared to the baseline value established prior to biological agent treatment; the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score; patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless: (i) the assessment of response is conducted following at least 12 weeks of therapy, in the case of a 16-week initial treatment course, or is conducted within 4 weeks prior to completion of the course, in the case of a 24-week treatment course; and (ii) the response assessment is submitted to the Medicare Australia CEO no later than 1 month from the date that course of treatment ceased; the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Eformoterol Fumarate Dihydrate	Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids
	Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids
"EleCare"	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula, and where the date of birth of the patient is included in the authority application
	Continuing treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician, and where the date of birth of the patient is included in the authority application
	Treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged 2 years or over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months, and where the date of birth of the patient is included in the authority application
	Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed
	Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition
Enalapril Maleate	—
Enalapril Maleate with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with 20 mg enalapril maleate
"Energivit"	Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae
Enoxaparin Sodium	—
Entacapone	In compliance with authority procedures set out in subparagraph 14 (d):
	Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect
Epirubicin Hydrochloride	—
Eplerenone	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial therapy subsidised under the Pharmaceutical Benefits Scheme (PBS) for heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction, where the date of the acute myocardial infarction is included in the authority application, and where the treatment commences within 14 days of the acute myocardial infarction or continues treatment which was commenced in a hospital within 14 days of the acute myocardial infarction
	Continuation of therapy for heart failure with a left ventricular ejection fraction of 40% or less occurring following an acute myocardial infarction, where the patient has previously been issued with a PBS authority prescription for eplerenone
Eprosartan Mesylate	—
Eprosartan Mesylate with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or eprosartan mesylate monotherapy
Eptifibatide Acetate	In compliance with authority procedures set out in subparagraph 14 (d):
	Patients undergoing non-urgent percutaneous intervention with intracoronary stenting
Erythromycin	—
Erythromycin Ethyl Succinate	—
Erythromycin Ethyl Succinate with Water - Purified BP	—
Erythromycin Lactobionate	—
Escitalopram Oxalate	In respect of the tablet equivalent to 10 mg escitalopram and tablet equivalent to 20 mg escitalopram:
	Major depressive disorders
	In respect of the oral solution equivalent to 10 mg escitalopram per mL, 28 mL:
	Major depressive disorders
	In compliance with authority procedures set out in subparagraph 14 (d):
	Major depressive disorders, where adverse events have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Major depressive disorders, where drug interactions have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Major depressive disorders, where drug interactions are expected to occur with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Major depressive disorders, where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme would cause patient confusion resulting in problems with compliance
	Major depressive disorders, where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme is likely to result in adverse clinical consequences
Esomeprazole Magnesium Trihydrate	In respect of the tablet (enteric coated), equivalent to 20 mg esomeprazole:
	Initial treatment of gastric ulcer
	Maintenance of healed gastro-oesophageal reflux disease
	In respect of the tablet (enteric coated), equivalent to 40 mg esomeprazole:
	Healing of gastro-oesophageal reflux disease
Esomeprazole Magnesium Trihydrate and Clarithromycin and Amoxycillin Trihydrate	Eradication of *Helicobacter pylori* associated with peptic ulcer disease
Etanercept	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:
	(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
	(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and
	(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and
	(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
	(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
	(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
	(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
	(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks;
	unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and
	where biological agent means efalizumab or etanercept; and
	where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and
	where the following conditions apply:
	failure to achieve an adequate response is indicated by a current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment, and is demonstrable in the patient at the time of the authority application;
	a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment;
	the most recent PASI assessment is no more than 1 month old at the time of application;
	if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication;
	if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity;

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) copies of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and (iii) a copy of the signed patient acknowledgement form; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 12 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment as systemic monotherapy, in a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment, or recommencement of treatment, with etanercept as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis; and (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once in the current Treatment Cycle; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who have previously demonstrated a response to PBS-subsidised treatment with etanercept within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent 12-week course of PBS-subsidised etanercept treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment; the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological agent treatment, including dosage, date and duration of treatment; a course of initial treatment within a Treatment Cycle is limited to a maximum of 12 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment, or of a course which recommences treatment, with etanercept as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of etanercept for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with etanercept prior to 16 March 2006; and (b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with etanercept; and (c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and (d) have demonstrated a response as specified in the criterion included in the relevant restriction for continuing PBS-subsidised treatment with etanercept; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of etanercept therapy) and the most recent PASI assessment; and (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and (iii) a copy of the signed patient acknowledgement form; the most recent PASI assessment is no more than 1 month old at the time of application; the course of treatment is limited to a maximum of 12 weeks of treatment; patients are eligible for PBS-subsidised treatment under the above criteria once only In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy, commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis, who were receiving non-PBS-subsidised treatment with etanercept prior to 16 March 2006, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over: (a) who have a documented history of severe chronic plaque psoriasis; and (b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with etanercept; and (c) who have demonstrated an adequate response to their most recent course of treatment with etanercept; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

an adequate response to etanercept treatment is defined as a Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, after at least 12 weeks of etanercept treatment, when compared with the baseline value for this Treatment Cycle established prior to biological agent treatment;

the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score;

patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless the assessment of response is conducted at the completion of the 12-week treatment course and is submitted to the Medicare Australia CEO no later than 1 month from the date that course of treatment ceased;

patients who demonstrate a response to a 12-week course of PBS-subsidised treatment with etanercept are not eligible to commence further treatment with etanercept until they have completed a period free from biological agent therapy of at least 12 weeks duration, immediately following cessation of that course of treatment;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams along with the date of the assessment of the patient's condition;

a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 12 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuing treatment as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and

(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks;

unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

failure to achieve an adequate response is demonstrable in the patient at the time of the authority application and is indicated by chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment;

a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment;

the most recent PASI assessment is no more than 1 month old at the time of application;

if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication;

if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity;

the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) copies of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and

(iii) a copy of the signed patient acknowledgement form;

a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 12 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment as systemic monotherapy, in a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with etanercept as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once in the current Treatment Cycle; and

where biological agent means efalizumab or etanercept; and

where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

patients who have previously demonstrated a response to PBS-subsidised treatment with etanercept within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent 12-week course of PBS-subsidised etanercept treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment;

	the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
	(i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
	(ii) details of prior biological agent treatment, including dosage, date and duration of treatment;
	a course of initial treatment within a Treatment Cycle is limited to a maximum of 12 weeks of treatment
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):
	Continuation of initial treatment, or of a course which recommences treatment, with etanercept as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of etanercept for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:
	(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and were receiving treatment with etanercept prior to 16 March 2006; and
	(b) whose disease, prior to treatment with etanercept, was classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where either at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe, or the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; and
	(c) who have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the relevant restriction for continuing PBS-subsidised treatment; and
	(d) who have demonstrated a response as specified in the criterion included in the relevant restriction for continuing PBS-subsidised treatment with etanercept; and
	where biological agent means efalizumab or etanercept; and
	where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and
	where the following conditions apply:
	the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
	(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of etanercept therapy) and the most recent PASI assessment; and
	(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and
	(iii) a copy of the signed patient acknowledgement form;
	the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score;
	the most recent PASI assessment is no more than 1 month old at the time of application;
	the course of treatment is limited to a maximum of 12 weeks of treatment;
	patients are eligible for PBS-subsidised treatment under the above criteria once only

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy, commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, who were receiving non-PBS-subsidised treatment with etanercept prior to 16 March 2006, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over: (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and (b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with etanercept; and (c) who have demonstrated an adequate response to their most recent course of treatment with etanercept; and where biological agent means efalizumab or etanercept; and where a Biological Treatment Cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with a biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a biological agent up to 3 times (but with the same biological agent no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological agent treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, after at least 12 weeks of etanercept treatment, as compared to the baseline values established prior to biological agent treatment; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, after at least 12 weeks of etanercept treatment, as compared to the baseline value established prior to biological agent treatment; the PASI assessment is performed on the same affected body area assessed to establish the baseline pre-treatment PASI score; patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless the assessment of response is conducted at the completion of the 12-week treatment course and is submitted to the Medicare Australia CEO no later than 1 month from the date that course of treatment ceased; patients who demonstrate a response to a 12-week course of PBS-subsidised treatment with etanercept are not eligible to commence further treatment with etanercept until they have completed a period free from biological agent therapy of at least 12 weeks duration, immediately following cessation of that course of treatment; the application for authorisation includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 12 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment as systemic monotherapy, within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 12 weeks, and where approval of the application would enable the patient to complete a course of 12 weeks of treatment in total

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment in a biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and: (a) (i) who have not previously received treatment with a bDMARD for this condition subsidised under the Pharmaceutical Benefits Scheme (PBS); or (ii) who, where the patient has previously received PBS-subsidised bDMARD treatment, have received no PBS-subsidised treatment with a bDMARD for this condition for a period of 5 years or more starting from the date the last course of PBS-subsidised bDMARD therapy was approved; and (b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly, have failed to achieve an adequate response to methotrexate (at a dose of at least 7.5 mg weekly) in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs) for a minimum of 3 months, and have failed to achieve an adequate response following a minimum of 3 months' treatment with leflunomide alone or with leflunomide in combination with methotrexate or with cyclosporin alone, unless: (i) treatment with any of the above-mentioned drugs is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, in which case the patient is exempted from demonstrating an inadequate response to that particular agent (or agents) only; or (ii) the patient has had a break in PBS-subsidised bDMARD treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months; and (c) who have signed a patient acknowledgement form declaring that they understand and acknowledge that, within a single bDMARD treatment cycle, PBS-subsidised treatment with any bDMARD will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response to the treatment regimens specified at (b) above is demonstrated by an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L, and either a total active joint count of at least 20 active (swollen and tender) joints, or at least 4 active joints from the following list of major joints: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; where the patient is exempted from demonstrating an inadequate response to a treatment regimen specified at (b) above on the basis of contraindication or intolerance, the authority application includes details of the contraindication or intolerance, including the degree of toxicity; the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form which includes details of the patient's ESR and CRP measurements, and an assessment of the patient's active joint count, conducted no earlier than 1 month prior to the date of application, and a copy of the signed patient acknowledgment form; a course of treatment is limited to a maximum of 16 weeks of treatment

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment in a bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment or recommencement of treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who have received prior PBS-subsidised treatment with a bDMARD for this condition in this bDMARD treatment cycle and who are eligible to receive further bDMARD therapy within this treatment cycle; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle; patients are eligible to commence therapy with etanercept within this bDMARD treatment cycle provided they have not already tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 bDMARDs within this treatment cycle, and provided they also meet the conditions applying to recommencement of etanercept therapy specified below, if applicable; patients who have previously commenced, and subsequently ceased, PBS-subsidised treatment with etanercept within this bDMARD treatment cycle are eligible to recommence therapy with this drug within this same cycle if: (i) they have demonstrated an adequate response to their most recent course of PBS-subsidised etanercept treatment; and (ii) the response was assessed, and the assessment was provided to the Medicare Australia CEO, no later than 4 weeks from the date that course ceased; and (iii) the response was assessed following a minimum of 12 weeks of therapy when the most recent course of PBS-subsidised treatment was an initial 16 week course; and (iv) response to treatment was determined using the same indices of disease severity used to establish baseline at the commencement of treatment; an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form and, where this is required, evidence of the patient's response to their most recent course of etanercept therapy; a course of treatment is limited to a maximum of 16 weeks of treatment

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment, or of a course which recommences treatment, within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment, for up to 4 months, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, and who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if their response to treatment as assessed against the predetermined response criteria does not support continuation of PBS-subsidised treatment; and where the patient has failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly, has failed to achieve an adequate response to methotrexate in combination with 2 other disease modifying anti-rheumatic drugs for a minimum of 3 months, and has subsequently failed to achieve an adequate response following a minimum of 3 months' treatment with leflunomide alone or leflunomide in combination with methotrexate or cyclosporin alone, unless treatment with any of the above-mentioned drugs is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, in which case the patient is exempted from demonstrating an inadequate response to the above treatment regimens; and where the following conditions apply: failure to achieve an adequate response is demonstrated by an elevated erythrocyte sedimentation rate greater than 25 mm per hour or a C-reactive protein level greater than 15 mg per L, and either an active joint count of at least 20 active (swollen and tender) joints or at least 4 active joints from the following list: — elbow, wrist, knee or ankle (assessed as swollen and tender); — shoulder, cervical spine or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated erythrocyte sedimentation rate or C-reactive protein level cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; the authority application includes sufficient information to determine the patient's eligibility according to the above criteria and the date of joint assessment; where the patient is exempted from demonstrating an inadequate response to the treatment regimens specified above, the authority application includes details of the contraindication or intolerance, including the degree of toxicity In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Initial treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 4 months, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 4 months of uninterrupted therapy In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Commencement of etanercept treatment in a bDMARD treatment cycle with an initial supply subsidised under the Pharmaceutical Benefits Scheme (PBS) for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who were receiving treatment with etanercept prior to 1 March 2005, who failed to qualify for PBS-subsidised therapy after 1 August 2003 due to testing negative for rheumatoid factor, and who have demonstrated a response to etanercept treatment as specified in the criteria for continuing PBS-subsidised treatment with etanercept detailed below; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient; the course of treatment is limited to a maximum of 24 weeks of treatment Continuing treatment within an ongoing biological disease modifying anti-rheumatic drug (bDMARD) treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis, and: (a) who have demonstrated an adequate response to treatment with etanercept; and (b) whose most recent course of bDMARD treatment subsidised under the Pharmaceutical Benefits Scheme (PBS) in this bDMARD treatment cycle was with etanercept; and where bDMARD means a drug included in the following list of drugs: adalimumab, anakinra, etanercept or infliximab; and where a bDMARD treatment cycle is a period of treatment with successive bDMARDs which commences when an eligible patient (one who has not received PBS-subsidised treatment with a bDMARD for rheumatoid arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 bDMARD, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with a maximum of 3 bDMARDs, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who commenced PBS-subsidised bDMARD treatment prior to 1 December 2004 are deemed to have commenced their first bDMARD treatment cycle with that therapy and any PBS-subsidised treatment received prior to 1 December 2004 is deemed to be treatment received as part of the patient's first bDMARD treatment cycle; an adequate response to treatment is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of treatment are used to determine response; the authority application includes a completed copy of the appropriate Biological DMARD PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with etanercept, where response is assessed, and this assessment is provided to the Medicare Australia CEO, no later than 4 weeks from the cessation of that treatment course; if the most recent course of etanercept therapy was an initial 16 week course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; a course of treatment is limited to a maximum of 24 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment within an ongoing bDMARD treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults with severe active rheumatoid arthritis who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who were receiving treatment with etanercept prior to 1 December 2002, who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if their response to treatment as assessed against predetermined response criteria does not support continuation of PBS-subsidised treatment, and who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept; and where the authority application includes sufficient information to determine the patient's eligibility for treatment and the date of assessment of the patient Continuing PBS-subsidised treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who, at the time of application, demonstrate an adequate response to treatment with etanercept as manifested by an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and an active joint count of fewer than 10 active (swollen and tender) joints or a reduction in the active (swollen and tender) joint count by at least 50% from baseline or a reduction in the number of the following active joints, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as swollen and tender); — shoulder, cervical spine or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); and where the following conditions apply: the authority application includes sufficient information to determine the patient's response to treatment with etanercept according to the above criteria and the date of assessment of the patient; patients who have previously ceased treatment with etanercept due to failure to demonstrate an adequate response to treatment are not eligible to recommence treatment until a period of 12 months has elapsed since cessation of the previous treatment; authority applications for re-treatment with etanercept following a break in PBS-subsidised treatment with the drug include the reason for and date of cessation of the previous treatment course In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment commencing a treatment cycle, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, and: (a) who has not received any treatment with adalimumab, etanercept or infliximab subsidised under the Pharmaceutical Benefits Scheme (PBS), or, where the patient has previously received PBS-subsidised treatment with one of these drugs, has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for this condition for a period of 5 years or more starting from the date the last course of PBS-subsidised treatment was approved; and (b) who has at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; and (c) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of at least 3 months, unless the patient has had a break in PBS-subsidised therapy with adalimumab, etanercept and infliximab of at least 5 years duration, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months; and (d) who has signed a patient acknowledgment form declaring that they understand and acknowledge that PBS-subsidised treatment with adalimumab, etanercept and infliximab for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and

where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and

where the following conditions apply:

failure to achieve an adequate response is demonstrated by:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale, where the BASDAI score is determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment, and is no more than 1 month old at the time of application; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L;

both ESR and CRP measurements are included in the authority application and are no more than 1 month old;

if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reason why this criterion cannot be satisfied;

the authority application includes details of the NSAIDs trialled, their doses and duration of treatment;

if the NSAID dose is less than the maximum recommended dose in the relevant Therapeutic Goods Administration (TGA)-approved Product Information, the authority application includes the reason why a higher dose cannot be used;

if treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the authority application includes details of the contraindication;

if intolerance to NSAID treatment develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the nature and severity of this intolerance;

an appropriate minimum exercise program includes stretch and range of motion exercises at least 5 times per week, and either aerobic exercise of at least 20 minutes duration at least 3 times per week or a group exercise class at least once per week;

if a patient is unable to complete the minimum exercise program, the authority application includes the clinical reasons for this and details what, if any, exercise program has been followed;

the application for authorisation includes:

(a) a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a signed patient acknowledgment form; and

(iv) a completed Exercise Program Self Certification Form detailing the program followed and the dates over which it was followed, and including confirmation by the prescribing doctor that, to the best of their knowledge, the patient has followed the exercise program detailed;

a course of initial treatment commencing a treatment cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment in a treatment cycle, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, and who, qualifying under the criteria specified above, has previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with etanercept within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with etanercept; and

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: a patient who commenced PBS-subsidised treatment of ankylosing spondylitis with etanercept or infliximab prior to 1 March 2007 is deemed to have commenced their first treatment cycle with that therapy; the authority application includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment; the application is accompanied by the results of the patient's most recent course of PBS-subsidised adalimumab, etanercept or infliximab therapy, where: (a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; and (b) (i) if the course of therapy is a 16 week initial course, the assessment of response is made following a minimum of 12 weeks of treatment; or (ii) if the course of therapy is a 6 week initial course approved prior to 1 March 2007, the assessment of response is made following at least 4 weeks of treatment; if the response assessment to the previous course of treatment with adalimumab, etanercept or infliximab is not submitted as detailed above, the patient is deemed to have failed therapy with that particular course of treatment; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 16 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuation of initial treatment, or of a course which recommences treatment, with etanercept within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, qualifying under the criteria specified above, has previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuing treatment within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has demonstrated a response to treatment with etanercept, and whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab, etanercept or infliximab, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised courses of treatment with each of the 3 drugs once, at which point the patient is no longer eligible for treatment with adalimumab, etanercept or infliximab for ankylosing spondylitis and the period of treatment ceases; and where the following conditions apply: a patient who commenced PBS-subsidised treatment with etanercept or infliximab prior to 1 March 2007 is deemed to have commenced their first treatment cycle with that therapy; response is defined as an improvement from baseline of at least 2 in the patient's Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and 1 of the following: (a) an erythrocyte sedimentation rate (ESR) measurement no greater than 25 mm per hour; or (b) a C-reactive protein (CRP) measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline;

if the patient commenced treatment with etanercept prior to 1 July 2004, was commenced on PBS-subsidised treatment prior to 1 March 2007 and is continuing to receive PBS-subsidised treatment in their first treatment cycle, and where pre-treatment baselines are not available, response to treatment is defined as a BASDAI score no more than 20% greater than the score included in the initial application for PBS-subsidised treatment, or no greater than 2, and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L;

all measurements provided are no more than 1 month old at the time of application;

the same acute phase reactant used to establish baseline at the commencement of an initial treatment course is measured and supplied for all subsequent continuing treatment applications for the patient;

patients will be deemed to have failed to respond to treatment with a course of PBS-subsidised therapy, despite demonstrating a response as defined above, unless:

(a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course of treatment ceased; and

(b) (i) if the course of therapy is a 16 week initial course, the assessment of response is made following a minimum of 12 weeks of treatment; or

(ii) if the course of therapy is a 6 week initial course approved prior to 1 March 2007, the assessment of response is made following at least 4 weeks of treatment;

the application for authorisation includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment;

a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuing treatment within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, qualifying under the criteria specified above, has previously been issued with an authority prescription for continuing treatment with etanercept for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and

(2) have not previously received PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and

(3) have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months and to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months, unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to achieve an adequate response to treatment with either methotrexate or sulfasalazine, at an adequate dose, for a minimum of 3 months; and

(4) have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time; and

(5) have signed a patient acknowledgement form declaring that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and

where biological agent means adalimumab or etanercept or infliximab; and

where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L, and either an active joint count of at least 20 active (swollen and tender) joints, or at least 4 active joints from the following list of major joints:

— elbow, wrist, knee or ankle (assessed as active if swollen and tender); or

— shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth);

if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied;

if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication;

if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity;

the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form which includes details of the patient's ESR and CRP measurements, and an assessment of the patient's active joint count, conducted no earlier than 1 month prior to the date of application, and a copy of the signed patient acknowledgment form;

a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment in a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Initial treatment, or recommencement of treatment, with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and

(2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and who are eligible to receive further therapy with a biological agent within this Treatment Cycle; and

(3) have not failed treatment with etanercept during the current Treatment Cycle; and

where biological agent means adalimumab or etanercept or infliximab; and

where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle;

patients who have previously commenced, and subsequently ceased, PBS-subsidised treatment with etanercept within this Treatment Cycle are eligible to recommence therapy with this drug within this same cycle if:

(i) they have demonstrated an adequate response, as specified in the criteria for continuing PBS-subsidised treatment with etanercept, to their most recent course of PBS-subsidised etanercept treatment; and

(ii) the response was assessed, and the assessment was provided to the Medicare Australia CEO, no later than 4 weeks from the date that course ceased; and

(iii) the response was assessed following a minimum of 12 weeks of therapy, where the most recent course of PBS-subsidised treatment was a 16-week initial treatment course; and

(iv) response to treatment was determined using the same indices of disease severity used to establish baseline at the commencement of treatment;

the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form;

a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 16 weeks of treatment

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Commencement of a Biological Treatment Cycle, with an initial PBS-subsidised course of etanercept for continuing treatment, by a rheumatologist or by an immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and

(2) were receiving treatment with etanercept prior to 17 March 2005; and

(3) have demonstrated a response to etanercept treatment as specified in the criteria for continuing PBS-subsidised treatment with etanercept; and

(4) have signed a patient acknowledgement form declaring that they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated; and

where biological agent means adalimumab or etanercept or infliximab; and

where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and

where the following conditions apply:

the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form which includes a copy of the signed patient acknowledgement form;

the course of treatment is limited to a maximum of 24 weeks of treatment;

patients are eligible for PBS-subsidised treatment under the above criteria once only

In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):

Continuation of a course of initial PBS-subsidised treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total

In compliance with authority procedures set out in subsubparagraph 14 (d) (i):

Continuing treatment within an ongoing Biological Treatment cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status; and

(2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with etanercept; and

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept; and where biological agent means adalimumab or etanercept or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to treatment with etanercept is defined as an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline, and either a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints, or a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee or ankle (assessed as active if swollen and tender); or — shoulder or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of treatment are used to determine response; the authority application includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with etanercept, where response is assessed, and this assessment is provided to the Medicare Australia CEO, no later than 4 weeks from the cessation of that treatment course; if the most recent course of etanercept therapy was a 16 week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii): Continuing treatment within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total
Ethacrynic Acid	Patients hypersensitive to other oral diuretics
Ethosuximide	—
Etonogestrel	—
Etoposide	—
Etoposide Phosphate	—
Everolimus	In compliance with authority procedures set out in subparagraph 14 (d): Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with everolimus, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application Maintenance therapy of patients with cardiac transplants following initiation and stabilisation of treatment with everolimus, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Exemestane	Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Ezetimibe	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment in conjunction with dietary therapy and exercise, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with coronary heart disease whose cholesterol levels are inadequately controlled with a statin, and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application Initial treatment in conjunction with dietary therapy and exercise, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with diabetes mellitus whose cholesterol levels are inadequately controlled with a statin, and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application Initial treatment in conjunction with dietary therapy and exercise, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with peripheral vascular disease whose cholesterol levels are inadequately controlled with a statin, and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application Initial treatment in conjunction with dietary therapy and exercise, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with heterozygous familial hypercholesterolaemia whose cholesterol levels are inadequately controlled with a statin, and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Initial treatment in conjunction with dietary therapy and exercise, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with symptomatic cerebrovascular disease whose cholesterol levels are inadequately controlled with a statin, and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application
	Continuing treatment, when co-administered with an HMG CoA reductase inhibitor (statin), of patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this drug
	For use in accordance with paragraph 16 in patients where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated
	For use in accordance with paragraph 16 in patients where treatment with an HMG CoA reductase inhibitor (statin) is unsuitable because the patient developed a clinically important product-related adverse event during treatment with a statin and required discontinuation of all statin treatment, and where a clinically important product-related adverse event is defined as follows: Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin
	Homozygous sitosterolaemia
	For use in accordance with paragraph 16, in combination with an HMG CoA reductase inhibitor (statin), in patients with homozygous familial hypercholesterolaemia
Ezetimibe with Simvastatin	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment, in conjunction with dietary therapy and exercise, of patients with coronary heart disease whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin), and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application Initial treatment, in conjunction with dietary therapy and exercise, of patients with diabetes mellitus whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin), and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	(ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application
	Initial treatment, in conjunction with dietary therapy and exercise, of patients with peripheral vascular disease whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin), and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application
	Initial treatment, in conjunction with dietary therapy and exercise, of patients with heterozygous familial hypercholesterolaemia whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin), and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application
	Initial treatment, in conjunction with dietary therapy and exercise, of patients with symptomatic cerebrovascular disease whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin), and where: (a) inadequate control with a statin is defined as: (i) in the case of patients who fall into a category specified in subparagraph 16(a) — a cholesterol level greater than 4 mmol per L, after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; or (ii) in the case of patients who fall into a category specified in subparagraph 16(b) — a cholesterol level as specified for that category of patient in the table included in subparagraph 16(b), after at least 3 months of treatment with a statin at a daily dose of 40 mg or greater in conjunction with dietary therapy and exercise; and (b) the cholesterol level after 3 months of treatment with a statin and the dose of the statin are included in the authority application; and (c) the cholesterol level results provided are no more than 2 months old at the time of application
	Continuing treatment of patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with an HMG CoA reductase inhibitor (statin), where the patient has previously been issued with an authority prescription for ezetimibe with simvastatin or for ezetimibe used concurrently with 40 mg or greater of a statin
	For use in accordance with paragraph 16 in patients with homozygous familial hypercholesterolaemia

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Famciclovir	In respect of the tablet 125 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Episodic treatment of moderate to severe recurrent genital herpes, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	In respect of the tablet 250 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of patients with herpes zoster within 72 hours of the onset of the rash
	Suppressive therapy of moderate to severe recurrent genital herpes, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	In respect of the tablet 500 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash
	Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with human immunodeficiency virus infection and a CD4 cell count of less than 500 million per L, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with human immunodeficiency virus infection and a CD4 cell count of less than 150 million per L, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with human immunodeficiency virus infection and other opportunistic infections or Acquired Immunodeficiency Syndrome defining tumours, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
Famotidine	—
Felodipine	—
Fenofibrate	For use in accordance with paragraph 16
Fentanyl	Chronic severe disabling pain not responding to non-narcotic analgesics
Ferrous Fumarate with Folic Acid	—
Ferrous Sulfate	—
Flecainide Acetate	Serious supra-ventricular cardiac arrhythmias
	Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient)
Flucloxacillin Magnesium with Water - Purified BP	Serious staphylococcal infections
Flucloxacillin Sodium	In respect of the capsule equivalent to 250 mg flucloxacillin and capsule equivalent to 500 mg flucloxacillin:
	Serious staphylococcal infections
	In respect of the powder for injection equivalent to 500 mg flucloxacillin and powder for injection equivalent to 1 g flucloxacillin:
	—
Fluconazole	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of cryptococcal meningitis in patients unable to take or tolerate amphotericin
	Maintenance therapy in patients with cryptococcal meningitis and immunosuppression
	Treatment of oropharyngeal candidiasis in immunosuppressed patients
	Treatment of oesophageal candidiasis in immunosuppressed patients
	Secondary prophylaxis of oropharyngeal candidiasis in immunosuppressed patients
	Treatment of serious and life-threatening candida infections in patients unable to tolerate amphotericin
Fludrocortisone Acetate	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Fluorometholone	—
Fluorometholone Acetate	—
Fluorouracil	—
Fluoxetine Hydrochloride	Major depressive disorders
	Obsessive-compulsive disorder
Flupenthixol Decanoate	—
Fluphenazine Decanoate	—
Flurbiprofen Sodium	—
Flutamide	In compliance with authority procedures set out in subparagraph 14 (d):
	Metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) agonist therapy
Fluticasone Propionate	—
Fluticasone Propionate with Salmeterol Xinafoate	Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate
	Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate
Fluvastatin Sodium	For use in accordance with paragraph 16
Fluvoxamine Maleate	Major depressive disorders
	Obsessive-compulsive disorder
Folic Acid	—
Follitropin Alfa	In respect of the injection set containing 1 vial powder for injection 75 I.U. and 1 pre-filled syringe solvent 1 mL and injection set containing 1 vial powder for injection 1,050 I.U. and 1 pre-filled syringe solvent 2 mL:
	Anovulatory infertility
	In respect of the injection set containing 10 vials powder for injection 75 I.U. and 10 pre-filled syringes solvent 1 mL, injection 300 I.U. in 0.5 mL multi-dose cartridge, injection set containing 1 vial powder for injection 450 I.U. and 1 pre-filled syringe solvent 1 mL, injection 450 I.U. in 0.75 mL multi-dose cartridge and injection 900 I.U. in 1.5 mL multi-dose cartridge:
	Anovulatory infertility
	In combination with chorionic gonadotrophin, for the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with chorionic gonadotrophin to achieve adequate spermatogenesis
Follitropin Beta	Anovulatory infertility
	In combination with chorionic gonadotrophin, for the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with chorionic gonadotrophin to achieve adequate spermatogenesis
Fondaparinux Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Prevention of venous thromboembolic events in patients undergoing major hip surgery
	Prevention of venous thromboembolic events in patients undergoing total knee replacement
Fosinopril Sodium	—
Fosinopril Sodium with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or fosinopril sodium monotherapy
Fotemustine	In compliance with authority procedures set out in subparagraph 14 (d):
	Metastatic malignant melanoma
Framycetin Sulfate	—
Frusemide	—
Gabapentin	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs
Galantamine Hydrobromide	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the baseline scores submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more who demonstrate improvement in cognitive function following initial PBS-subsidised therapy, and where: (1) improvement in cognitive function is demonstrated by: (a) in the case of patients with a baseline MMSE or SMMSE score of 10 or more and less than 25 — an increase of at least 2 points from baseline on the MMSE or SMMSE; or (b) in the case of patients with a baseline MMSE or SMMSE score of at least 25 points — an increase of at least 2 points from baseline on the MMSE or SMMSE, or, if a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) was submitted with the application for initial treatment, a decrease of at least 4 points from baseline on the ADAS-Cog; and (2) the relevant result from the MMSE, SMMSE or ADAS-Cog is included in the authority application for continuing treatment In compliance with authority procedures set out in subparagraph 14 (d): Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more and with demonstrated improvement in cognitive function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs: Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test; Intellectual (developmental or acquired) disability; Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test; Prominent dysphasia, out of proportion to other cognitive and functional impairment In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the information submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs: Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test; Intellectual (developmental or acquired) disability; Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test; Prominent dysphasia, out of proportion to other cognitive and functional impairment Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease and who demonstrate improvement in function following initial PBS-subsidised therapy, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change scale, as assessed by the same clinician who initiated treatment, and where the improvement rating achieved on the Clinicians Interview Based Impression of Change scale is stated in the authority application for continuing treatment In compliance with authority procedures set out in subparagraph 14 (d): Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less and with demonstrated improvement in function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment
Gefitinib	In compliance with authority procedures set out in subsubparagraph 14 (d) (i): Initial treatment subsidised under the Pharmaceutical Benefits Scheme (PBS), as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a World Health Organisation (WHO) performance status of 2 or less, and: (a) in whom disease progression has occurred following treatment with at least 1 chemotherapy agent; and (b) where there is evidence that the patient has at least 1 activating mutation of the epidermal growth factor receptor (EGFR) gene in tumour material, unless: (i) the patient commenced treatment with gefitinib prior to 1 July 2004, in which case, although an attempt must be made to test for the presence of an activating mutation of the EGFR gene, the patient is exempt from meeting this requirement; or (ii) the patient commenced treatment with gefitinib between 1 July 2004 and 27 September 2004, in which case a test for the presence of an activating mutation of the EGFR gene with a negative result does not render the patient ineligible if a radiological assessment of the patient which is less than 1 month old at the date of the authority application demonstrates that disease progression has not occurred while the patient has been on gefitinib therapy; and where the following conditions apply: the presence of a mutation is demonstrated by analysis of the DNA sequence of the EGFR gene; the authority application includes the following: (i) a completed copy of the appropriate Gefitinib (Iressa) PBS Authority Application - Supporting Information Form; and (ii) details of the prior chemotherapy including the names of drugs and date of the most recent treatment cycle; and (iii) details of the patient's WHO performance status; and (iv) a copy of the pathology report from an Approved Pathology Authority providing the result of the test for the presence of an activating mutation, or mutations, of the EGFR gene; and

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	(v) where the patient is claiming exemption from the requirement to test positive for the presence of an activating mutation of the EGFR gene on the basis that treatment with gefitinib commenced between 1 July 2004 and 27 September 2004 and a radiological assessment within the month prior to the application shows disease progression has not occurred while on gefitinib therapy, a copy of that radiological assessment
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):
	Continuing treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a World Health Organisation performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib
Gelatin - Succinylated	—
Gemcitabine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline
	Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy
	Locally advanced or metastatic non-small cell lung cancer
	Locally advanced or metastatic adenocarcinoma of the pancreas
	Locally advanced or metastatic bladder cancer, when used in combination with cisplatin
Gemfibrozil	For use in accordance with paragraph 16
Gentamicin Sulfate	In respect of the injection equivalent to 80 mg gentamicin in 2 mL ampoule:
	—
	In respect of the eye drops equivalent to 3 mg gentamicin per mL, 5 mL:
	Invasive ocular infection
	Perioperative use in ophthalmic surgery
	Suspected pseudomonal eye infection
Gestrinone	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of visually proven endometriosis where the duration of treatment provided for by this prescription, in combination with any previous prescriptions, does not exceed 6 months' uninterrupted therapy
Glatiramer Acetate	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, and where the diagnosis is confirmed by magnetic resonance imaging of the brain or spinal cord and the date of the scan is included in the authority application, or where the authority application is accompanied by written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient
	Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy
Glibenclamide	—
Gliclazide	—
Glimepiride	—
Glipizide	—
Glucagon Hydrochloride	—
Glucose	—
Glucose and Ketone Indicator—Urine	—
Glucose Indicator—Blood	In respect of the electrode strips, 50 (Accu-Chek Performa), electrode strips, 50 (Advantage II), electrode strips, 50 (Freestyle Papillon), electrode strips, 50 (Glucocard 01 Sensor), electrode strips, 50 (GlucoCare), electrode strips, 50 (GlucoCare Super Sensor), electrode strips, 50 (GlucoMen Sensor), electrode strips, 50 (MWD Pen Sensor Strips), electrode strips, 50 (Omnitest EZ), electrode strips, 50 (Omnitest Plus), electrode strips, 50 (Touch-In Plus), electrode strips, 50 (TrueTrack), discs containing electrode sensors, 10 sensors per disc, 5, electrode strips, 100 (Optium glucose), electrode strips, 100 (SofTact), electrode strips, 100 (TrueSense), reagent strips, 50 (Accu-Chek Active), reagent strips, 50 (Accu-Chek Go), reagent strips, 51 (Accu-Chek Integra), reagent strips, 50 (Betachek), reagent strips, 50 (Betachek G5), reagent strips, 50 (CareSens), reagent strips, 50 (Glucoflex-R), reagent strips, 50 (Glucostix) and reagent strips, 50 (SensoCard):
	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the electrode strips, 50 (Ascensia Elite) and electrode strips, 100 (Precision Plus):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Patients who have previously received this product as a pharmaceutical benefit
	Patients who have purchased a meter to be used with this product prior to 1 August 2003
Glucose Indicator—Urine	—
Glucose with Sodium Chloride, Potassium Chloride and Sodium Acid Citrate	—
Glycerol	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
	Patients receiving palliative care
	Terminal malignant neoplasia
	Anorectal congenital abnormalities
	Megacolon
Glyceryl Trinitrate	—
Goserelin Acetate	In respect of the subcutaneous implant equivalent to 3.6 mg goserelin in pre-filled injection syringe:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate
	Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women
	Treatment of visually proven endometriosis where the duration of treatment provided for by this prescription, in combination with any previous prescriptions, does not exceed 6 months' uninterrupted therapy
	In respect of the subcutaneous implant (long acting) equivalent to 10.8 mg goserelin in pre-filled injection syringe:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate
Goserelin Acetate and Bicalutamide	In compliance with authority procedures set out in subparagraph 14 (d):
	Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) agonist is required
Granisetron Hydrochloride	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy
Griseofulvin	—
Haloperidol	—
Haloperidol Decanoate	—
"HCU express"	Pyridoxine non-responsive homocystinuria
"HCU gel"	Pyridoxine non-responsive homocystinuria
Heparin Sodium	—
Hexamine Hippurate	—
Homatropine Hydrobromide	—
Hydralazine Hydrochloride	—
Hydrochlorothiazide	—
Hydrochlorothiazide with Amiloride Hydrochloride	—
Hydrochlorothiazide with Triamterene	—
Hydrocortisone	In respect of the tablet 4 mg and tablet 20 mg:
	—
	In respect of the cream 10 mg per g, 50 g:
	Treatment of corticosteroid-responsive dermatoses

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Hydrocortisone Acetate	In respect of the eye ointment 5 mg per g, 5 g and eye ointment 10 mg per g, 5 g:
	—
	In respect of the cream 10 mg per g, 30 g, cream 10 mg per g, 50 g, ointment 10 mg per g, 30 g and ointment 10 mg per g, 50 g:
	Treatment of corticosteroid-responsive dermatoses
	In respect of the rectal foam 90 mg per applicatorful, 14 applications, aerosol 21.1 g:
	Proctitis
	Ulcerative colitis
Hydrocortisone Sodium Succinate	—
Hydromorphone Hydrochloride	In respect of the tablet 2 mg, tablet 4 mg, tablet 8 mg and oral liquid 1 mg per mL, 473 mL:
	Severe disabling pain not responding to non-narcotic analgesics
	In respect of the injection 2 mg in 1 mL ampoule, injection 10 mg in 1 mL ampoule, injection 50 mg in 5 mL ampoule and injection 500 mg in 50 mL vial:
	—
Hydroxocobalamin	Pernicious anaemia
	Other proven vitamin B_{12} deficiencies
	Prophylaxis after gastrectomy
Hydroxocobalamin Acetate	Pernicious anaemia
	Other proven vitamin B_{12} deficiencies
	Prophylaxis after gastrectomy
Hydroxychloroquine Sulfate	—
Hydroxyurea	—
Hypromellose	Severe dry eye syndrome, including Sjogren's syndrome
Hypromellose 2900 with Dextran 70	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops
Hypromellose 4500 with Dextran 70	Severe dry eye syndrome, including Sjogren's syndrome
Hypromellose with Carbomer 980	Severe dry eye syndrome, including Sjogren's syndrome
Ibuprofen	In respect of the tablet 200 mg:
	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
	In respect of the tablet 400 mg:
	—
Idarubicin Hydrochloride	Acute myelogenous leukaemia
Ifosfamide	Relapsed or refractory germ cell tumours following first-line chemotherapy
	Relapsed or refractory sarcomas following first-line chemotherapy
Imipramine Hydrochloride	—
Imiquimod	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma in immunocompetent patients who cannot have surgical excision, cryotherapy, or curettage with diathermy, and where the date of the pathology report and name of the Approved Pathology Authority are included in the authority application
Indapamide Hemihydrate	—
Indomethacin	In respect of the capsule 25 mg:
	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
	In respect of the suppository 100 mg:
	—
Influenza Vaccine (Split Virion) - Inactivated	Persons at special risk of adverse consequences from infections of the lower respiratory tract
Insect Allergen Extract—Honey Bee Venom	—
Insect Allergen Extract—Paper Wasp Venom	—
Insect Allergen Extract—Yellow Jacket Venom	—
Insulin Aspart	—
Insulin Aspart with Insulin Aspart Protamine Suspension	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Insulin Detemir	Type 1 diabetes
Insulin Glargine	—
Insulin - Isophane	—
Insulin Lispro	—
Insulin Lispro with Insulin Lispro Protamine Suspension	—
Insulin - Neutral	—
Insulin - Neutral with Insulin - Isophane	—
Interferon Alfa-2a	In respect of the injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe: In compliance with authority procedures set out in subparagraph 14 (d): Hairy cell leukaemia Myeloproliferative disease with excessive thrombocytosis Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy In respect of the injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe, injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe and injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe: In compliance with authority procedures set out in subparagraph 14 (d): Myeloproliferative disease with excessive thrombocytosis Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
Interferon Alfa-2b	In respect of the solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen: In compliance with authority procedures set out in subparagraph 14 (d): Hairy cell leukaemia Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy In respect of the solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen: In compliance with authority procedures set out in subparagraph 14 (d): Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
Interferon Beta-1a	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, and where the diagnosis is confirmed by magnetic resonance imaging of the brain or spinal cord and the date of the scan is included in the authority application, or where the authority application is accompanied by written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy
Interferon Beta-1b	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, and where the diagnosis is confirmed by magnetic resonance imaging of the brain or spinal cord and the date of the scan is included in the authority application, or where the authority application is accompanied by written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy
Ipratropium Bromide	In respect of the pressurised inhalation 21 micrograms per dose, 200 doses (CFC-free formulation): —

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the nebuliser solution 250 micrograms (anhydrous) in 1 mL single dose units, 30, nebuliser solution 500 micrograms (anhydrous) in 1 mL single dose units, 30 and nebuliser solution 250 micrograms (anhydrous) per mL, 20 mL:
	Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer
	Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer
Irbesartan	—
Irbesartan with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or irbesartan monotherapy
Irinotecan Hydrochloride Trihydrate	In compliance with authority procedures set out in subparagraph 14 (d):
	Metastatic colorectal cancer in patients with a World Health Organisation performance status of 2 or less
Iron Polymaltose Complex	—
Iron Sucrose	In compliance with authority procedures set out in subparagraph 14 (d):
	Iron deficiency anaemia, when used in combination with either epoetin alfa or darbepoetin alfa, in patients undergoing chronic haemodialysis who have had a documented hypersensitivity reaction to iron polymaltose and in whom continued intravenous iron therapy is appropriate
Isoniazid	—
Isosorbide Dinitrate	—
Isosorbide Mononitrate	—
Isotretinoin	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe cystic acne not responsive to other therapy
Itraconazole	In compliance with authority procedures set out in subparagraph 14 (d):
	Systemic aspergillosis
	Systemic sporotrichosis
	Systemic histoplasmosis
	Treatment and maintenance therapy in patients with Acquired Immunodeficiency Syndrome who have disseminated pulmonary histoplasmosis infection
	Treatment and maintenance therapy in patients with Acquired Immunodeficiency Syndrome who have chronic pulmonary histoplasmosis infection
	Treatment of oropharyngeal candidiasis in immunosuppressed patients
	Treatment of oesophageal candidiasis in immunosuppressed patients
Ivermectin	In compliance with authority procedures set out in subparagraph 14 (d):
	Onchocerciasis
	Strongyloidiasis
"Karicare De-Lact"	In compliance with authority procedures set out in subparagraph 14 (d):
	Acute lactose intolerance in patients up to the age of 12 months, where the date of birth of the patient is included in the authority application and where the patient has not previously been issued with an authority prescription for this medicinal preparation for this purpose
	Proven chronic lactose intolerance in patients up to the age of 12 months, where the date of birth of the patient is included in the authority application, and where lactose intolerance has been proven either by the relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food, or by the presence of not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet
Ketoconazole	In respect of the tablet 200 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy
	Oral candidiasis in severely immunocompromised persons where topical therapy has failed
	Systemic or deep mycoses where other forms of therapy have failed
	In respect of the cream 20 mg per g, 30 g, shampoo 10 mg per g, 100 mL and shampoo 20 mg per g, 60 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
"Ketonex-1"	Maple syrup urine disease
"Ketonex-2"	Maple syrup urine disease

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Ketoprofen	In respect of the capsule 200 mg (sustained release): Chronic arthropathies (including osteoarthritis) with an inflammatory component In respect of the suppository 100 mg: —
"Kindergen"	In compliance with authority procedures set out in subparagraph 14 (d): Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet
Labetalol Hydrochloride	—
Lactulose	Hepatic coma or precoma (chronic porto-systemic encephalopathy) Constipation in patients with malignant neoplasia
Lamotrigine	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs
Lansoprazole	In respect of the capsule 30 mg: Initial treatment of peptic ulcer Gastro-oesophageal reflux disease Scleroderma oesophagus In respect of the sachet containing granules for oral suspension, 30 mg per sachet: Initial treatment of peptic ulcer Gastro-oesophageal reflux disease Scleroderma oesophagus In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment of peptic ulcer, in patients unable to take a solid dose form of a proton pump inhibitor Gastro-oesophageal reflux disease, in patients unable to take a solid dose form of a proton pump inhibitor Scleroderma oesophagus, in patients unable to take a solid dose form of a proton pump inhibitor In respect of the capsule 15 mg: Gastro-oesophageal reflux disease Scleroderma oesophagus
Latanoprost	—
Latanoprost with Timolol Maleate	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL or latanoprost eye drops Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL or latanoprost eye drops
Leflunomide	In respect of the pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg: In compliance with authority procedures set out in subparagraph 14 (d): Initiation treatment of severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate or ineffective and where the authority application is made by a consultant physician In respect of the tablet 10 mg and tablet 20 mg: In compliance with authority procedures set out in subparagraph 14 (d): Initiation treatment of severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate or ineffective and where the authority application is made by a consultant physician Ongoing leflunomide therapy for severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate or ineffective
Lercanidipine Hydrochloride	—
Letrozole	Treatment of hormone-dependent breast cancer in post-menopausal women
Leuprorelin Acetate	In compliance with authority procedures set out in subparagraph 14 (d): Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate
Levetiracetam	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where adverse events have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where drug interactions have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where drug interactions are expected to occur with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme would cause patient confusion resulting in problems with compliance
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme is likely to result in adverse clinical consequences
Levobunolol Hydrochloride	—
Levodopa with Benserazide Hydrochloride	—
Levodopa with Carbidopa	In respect of the tablet 200 mg-50 mg (anhydrous) (modified release):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor
	In respect of the tablet 100 mg-25 mg (anhydrous) and tablet 250 mg-25 mg (anhydrous):
	—
Levodopa with Carbidopa and Entacapone	In compliance with authority procedures set out in subparagraph 14 (d):
	Parkinson's disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect
	Parkinson's disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone
Levonorgestrel	In respect of the tablets 30 micrograms, 28:
	—
	In respect of the intrauterine drug delivery system 52 mg:
	Contraception
Levonorgestrel with Ethinyloestradiol	—
Lignocaine Hydrochloride	—
Lincomycin Hydrochloride	—
Liothyronine Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of patients with thyroid cancer
	Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium
	Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium
	Initiation of thyroid therapy in severely hypothyroid patients
Lisinopril	—
Lithium Carbonate	—
"Locasol"	In compliance with authority procedures set out in subparagraph 14 (d):
	Hypercalcaemia in children under the age of 4 years
Loperamide Hydrochloride	—
"Lophlex"	Phenylketonuria
"Lophlex LQ"	Phenylketonuria
Lumiracoxib	Symptomatic treatment of osteoarthritis
Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride	Constipation in patients with malignant neoplasia
"Mapleflex"	Maple syrup urine disease
Medroxyprogesterone Acetate	In respect of the tablet 500 mg:
	Hormone-dependent advanced breast cancer
	In respect of the tablet 100 mg, tablet 200 mg and tablet 250 mg:
	Hormone-dependent breast cancer

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Endometrial cancer
	In respect of the tablet 5 mg, tablet 10 mg, injection 50 mg in 1 mL vial and injection 150 mg in 1 mL vial:
	—
Mefenamic Acid	Dysmenorrhoea
	Menorrhagia
Megestrol Acetate	Hormone-dependent advanced breast cancer
Meloxicam	Symptomatic treatment of osteoarthritis
Melphalan	—
Mercaptopurine	—
Mesalazine	In respect of the tablet 250 mg (enteric coated) and tablet 500 mg (enteric coated):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Ulcerative colitis where hypersensitivity to sulfonamides exists
	Ulcerative colitis where intolerance to sulfasalazine exists
	Crohn's disease where hypersensitivity to sulfonamides exists
	Crohn's disease where intolerance to sulfasalazine exists
	In respect of the sachet containing granules, 500 mg per sachet and sachet containing granules, 1 g per sachet:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Ulcerative colitis where hypersensitivity to sulfonamides exists
	Ulcerative colitis where intolerance to sulfasalazine exists
	In respect of the suppositories 1 g, 28:
	Acute episode of mild to moderate ulcerative proctitis
	In respect of the enemas 1 g in 100 mL, 7, enemas 2 g in 60 mL, 7, enemas 4 g in 60 mL, 7 and rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Acute episode of mild to moderate ulcerative colitis
Mesna	Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide
"Metabolic Mineral Mixture"	Metabolic disorders
Metformin Hydrochloride	—
Metformin Hydrochloride with Glibenclamide	—
Methadone Hydrochloride	Severe disabling pain not responding to non-narcotic analgesics
Methotrexate	—
Methyldopa	—
Methylphenidate Hydrochloride	In respect of the tablet 10 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Use in attention deficit hyperactivity disorder, in accordance with State/Territory law
	In respect of the tablet 18 mg (extended release), tablet 36 mg (extended release) and tablet 54 mg (extended release):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of attention deficit hyperactivity disorder (ADHD) in a child or adolescent aged between 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours
Methylprednisolone Aceponate	In respect of the cream 1 mg per g, 15 g, ointment 1 mg per g, 15 g and fatty ointment 1 mg per g, 15 g:
	Treatment of corticosteroid-responsive dermatoses
	In respect of the lotion 1 mg per g, 20 g:
	Eczema
Methylprednisolone Acetate	For local intra-articular or peri-articular infiltration
Methylprednisolone Sodium Succinate	—
Methysergide Maleate	—
Metoclopramide Hydrochloride	—
Metoprolol Succinate	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an angiotensin-converting enzyme inhibitor if tolerated
Metoprolol Tartrate	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Metronidazole	In respect of the tablet 200 mg, tablet 400 mg and suppositories 500 mg, 10:
	—
	In respect of the I.V. infusion 500 mg in 100 mL:
	Prophylaxis in large bowel surgery
	Treatment, in a hospital, of acute anaerobic sepsis
Metronidazole Benzoate	—
Mexiletine Hydrochloride	—
Mianserin Hydrochloride	Severe depression
Miconazole	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
Miconazole Nitrate	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
"Minaphlex"	Phenylketonuria
Minocycline Hydrochloride	In respect of the tablet equivalent to 50 mg minocycline:
	Severe acne not responding to other tetracyclines
	In respect of the capsule equivalent to 100 mg minocycline:
	—
Minoxidil	In compliance with authority procedures set out in subparagraph 14 (d):
	Severe refractory hypertension where treatment with minoxidil was initiated in a hospital (in-patient or out-patient)
Mirtazapine	Major depressive disorders
Misoprostol	In compliance with authority procedures set out in subparagraph 14 (d):
	Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and in whom non-steroidal anti-inflammatory drug therapy is essential
	Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery, where the date on which, and the method by which, the ulcer was proven are included in the authority application
	Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years, where the date on which, and the method by which, the ulcer was proven are included in the authority application
Mitozantrone Hydrochloride	—
Moclobemide	Major depressive disorders
Modafinil	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:
	(i) intolerance to dexamphetamine sulfate of a severity necessitating permanent treatment withdrawal develops; or
	(ii) therapy with dexamphetamine sulfate poses an unacceptable medical risk, as indicated by the presence of any 1 of the following:
	(a) a psychiatric disorder;
	(b) a cardiac disorder;
	(c) a history of substance abuse;
	(d) glaucoma;
	(e) any other absolute contraindication to dexamphetamine sulfate as specified in the Therapeutic Goods Administration-approved Product Information; and
	where the patient meets the following definition of narcolepsy:
	excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, and:
	(i) a definite history of cataplexy and a Multiple Sleep Latency Test (MSLT), conducted following at least 6 hours of sleep, with a mean sleep latency less than or equal to 8 minutes; or
	(ii) a MSLT, conducted following at least 6 hours of sleep, with a mean sleep latency less than or equal to 8 minutes and 2 or more sleep onset rapid eye movement (REM) periods; or
	(iii) an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and
	where the following conditions apply:
	the MSLT is preceded by nocturnal polysomnography;

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	the polysomnography test and the MSLT are conducted by, or under the supervision of, a qualified sleep medicine practitioner;
	the EEG is conducted by, or under the supervision of, a neurologist;
	the authority application includes the following:
	(a) a completed copy of the appropriate Modafinil (Modavigil) PBS Authority Application - Supporting Information Form; and
	(b) details of the contraindication or intolerance to dexamphetamine sulfate; and
	(c) either the result and date of the polysomnography test and the MSLT, or the result and date of the EEG;
	the polysomnography and MSLT, or the EEG, test reports are provided with the authority application
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i) or 14 (d) (ii):
	Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug
Mometasone Furoate	Treatment of corticosteroid-responsive dermatoses
"Monogen"	Chylous ascites
	Chylothorax
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders
	Hyperlipoproteinaemia type 1
	Long chain fatty acid oxidation disorders
Montelukast Sodium	In respect of the tablet, chewable, equivalent to 4 mg montelukast:
	In compliance with authority procedures set out in subparagraph 14 (d):
	First-line preventer medication, as the single preventer agent for children aged from 2 to less than 6 years with frequent episodic or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium
	In respect of the tablet, chewable, equivalent to 5 mg montelukast:
	In compliance with authority procedures set out in subparagraph 14 (d):
	First-line preventer medication, as the single preventer agent for children aged from 6 to less than 15 years with frequent episodic or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium
Morphine Hydrochloride	Severe disabling pain not responding to non-narcotic analgesics
Morphine Sulfate	In respect of the tablet 10 mg and tablet 20 mg:
	Severe disabling pain due to cancer not responding to non-narcotic analgesics
	In respect of the tablet 30 mg:
	Severe disabling pain not responding to non-narcotic analgesics
	In respect of the tablet 5 mg (controlled release), tablet 10 mg (controlled release), tablet 15 mg (controlled release), tablet 30 mg (controlled release), tablet 60 mg (controlled release), tablet 100 mg (controlled release), capsule 10 mg (containing sustained release pellets), capsule 20 mg (containing sustained release pellets), capsule 30 mg (controlled release), capsule 50 mg (containing sustained release pellets), capsule 60 mg (controlled release), capsule 90 mg (controlled release), capsule 100 mg (containing sustained release pellets), capsule 120 mg (controlled release), sachet containing controlled release granules for oral suspension, 20 mg per sachet, sachet containing controlled release granules for oral suspension, 30 mg per sachet, sachet containing controlled release granules for oral suspension, 60 mg per sachet and sachet containing controlled release granules for oral suspension, 100 mg per sachet:
	Chronic severe disabling pain not responding to non-narcotic analgesics
	In respect of the tablet 200 mg (controlled release) and sachet containing controlled release granules for oral suspension, 200 mg per sachet:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Chronic severe disabling pain due to cancer
	In respect of the injection 10 mg in 1 mL ampoule, injection 15 mg in 1 mL ampoule and injection 30 mg in 1 mL ampoule:
	—
Morphine Tartrate	—
Moxonidine	Hypertension in patients receiving concurrent antihypertensive therapy
"MSUD AID III"	Maple syrup urine disease
"MSUD Analog"	Maple syrup urine disease
"MSUD Express"	Maple syrup urine disease
"MSUD-gel"	Maple syrup urine disease

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
"MSUD Maxamaid"	Maple syrup urine disease
"MSUD Maxamum"	Maple syrup urine disease
Mycophenolate Mofetil	In compliance with authority procedures set out in subparagraph 14 (d): Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with mycophenolate mofetil, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application Maintenance therapy of patients with cardiac transplants following initiation and stabilisation of treatment with mycophenolate mofetil, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Mycophenolate Mofetil with Water - Purified BP	In compliance with authority procedures set out in subparagraph 14 (d): Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with mycophenolate mofetil, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application Maintenance therapy of patients with cardiac transplants following initiation and stabilisation of treatment with mycophenolate mofetil, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Mycophenolate Sodium	In compliance with authority procedures set out in subparagraph 14 (d): Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with mycophenolate sodium, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Nafarelin Acetate	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment, for up to 6 months, of visually proven endometriosis Subsequent treatment, for up to 6 months, of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made and where the date of the assessment is included in the authority application
Naloxone Hydrochloride	—
Naltrexone Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence
Nandrolone Decanoate	In compliance with authority procedures set out in subparagraph 14 (d): Monotherapy for osteoporosis where other treatment has failed, where monotherapy does not preclude concomitant calcium supplementation, and where, if the authority application is the initial authority application for this purpose for the patient, specialist advice has been obtained confirming that this drug is the only suitable treatment option for the patient Monotherapy for osteoporosis where other treatment is not tolerated, where monotherapy does not preclude concomitant calcium supplementation, and where, if the authority application is the initial authority application for this purpose for the patient, specialist advice has been obtained confirming that this drug is the only suitable treatment option for the patient Monotherapy for osteoporosis where other treatment is contraindicated, where monotherapy does not preclude concomitant calcium supplementation, and where, if the authority application is the initial authority application for this purpose for the patient, specialist advice has been obtained confirming that this drug is the only suitable treatment option for the patient Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004 Patients on long-term treatment with corticosteroids
Naproxen	In respect of the tablet 250 mg, tablet 500 mg, tablet 750 mg (sustained release) and tablet 1 g (sustained release): Chronic arthropathies (including osteoarthritis) with an inflammatory component Bone pain due to malignant disease

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the oral suspension 125 mg per 5 mL, 474 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Chronic arthropathies (including osteoarthritis) with an inflammatory component in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent
	Bone pain due to malignant disease in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent
Naproxen Sodium	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
Naratriptan Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where adverse events have occurred with other suitable PBS-listed drugs
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where drug interactions have occurred with other suitable PBS-listed drugs
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where drug interactions are expected to occur with other suitable PBS-listed drugs
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences
Nedocromil Sodium	—
"Neocate"	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula, and where the date of birth of the patient is included in the authority application
	Continuing treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician, and where the date of birth of the patient is included in the authority application
	Treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged 2 years or over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months, and where the date of birth of the patient is included in the authority application
	Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed
	Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition
"Neocate Advance"	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula, and where the date of birth of the patient is included in the authority application

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Continuing treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician, and where the date of birth of the patient is included in the authority application
	Treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged 2 years or over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months, and where the date of birth of the patient is included in the authority application
	Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed
	Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition
Neomycin Sulfate	—
Neomycin Undecenoate with Bacitracin Zinc	—
Nicorandil	—
Nifedipine	—
Nilutamide	In compliance with authority procedures set out in subparagraph 14 (d):
	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) agonist therapy
	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, when used in conjunction with surgical orchidectomy
Nitrazepam	—
Nitrofurantoin	—
Nizatidine	—
Norethisterone	—
Norethisterone with Ethinyloestradiol	—
Norethisterone with Mestranol	—
Norfloxacin	In compliance with authority procedures set out in subparagraph 14 (d):
	Acute bacterial enterocolitis
	Complicated urinary tract infection
Nortriptyline Hydrochloride	Major depression where other antidepressant therapy has failed
	Major depression where other antidepressant therapy is contraindicated
Nystatin	In respect of the tablet 500,000 units, capsule 500,000 units and oral suspension 100,000 units per mL, 24 mL:
	—
	In respect of the cream 100,000 units per g, 15 g:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person
Oestradiol	In respect of the tablet 2 mg and vaginal tablets 25 micrograms, 15:
	—
	In respect of the transdermal patches 390 micrograms, 8, transdermal patches 2 mg, 4, transdermal patches 2 mg, 8, transdermal patches 585 micrograms, 8, transdermal patches 3.28 mg, 8, transdermal patches 3.8 mg, 4, transdermal patches 4 mg, 8, transdermal patches 780 micrograms, 8, transdermal patches 4.33 mg, 8, transdermal patches 5.7 mg, 4, transdermal patches 1.17 mg, 8, transdermal patches 6.57 mg, 8, transdermal patches 7.6 mg, 4, transdermal patches 8 mg, 8, transdermal patches 1.56 mg, 8 and transdermal patches 8.66 mg, 8:
	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens
Oestradiol and Oestradiol with Dydrogesterone	—
Oestradiol and Oestradiol with Norethisterone Acetate	In respect of the pack containing 12 tablets oestradiol 2 mg, 10 tablets oestradiol 2 mg with norethisterone acetate 1 mg and 6 tablets oestradiol 1 mg:
	—
	In respect of the pack containing 4 transdermal patches oestradiol 4 mg and 4 transdermal patches oestradiol 10 mg with norethisterone acetate 30 mg:
	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens
Oestradiol Hemihydrate	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Oestradiol Hemihydrate and Oestradiol Hemihydrate with Norethisterone Acetate	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens
Oestradiol Hemihydrate with Norethisterone Acetate	In respect of the tablets equivalent to 1 mg oestradiol with 500 micrograms norethisterone acetate, 28 and tablets equivalent to 2 mg oestradiol with 1 mg norethisterone acetate, 28:
	—
	In respect of the transdermal patches equivalent to 620 micrograms oestradiol with 2.7 mg norethisterone acetate, 8 and transdermal patches equivalent to 510 micrograms oestradiol with 4.8 mg norethisterone acetate, 8:
	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens
Oestradiol Valerate	—
Oestriol	—
Oestrogens—Conjugated	—
Oestrogens—Conjugated with Medroxyprogesterone Acetate	—
Ofloxacin	In compliance with authority procedures set out in subparagraph 14 (d):
	Bacterial keratitis
Olanzapine	In compliance with authority procedures set out in subparagraph 14 (d):
	Schizophrenia
	Maintenance treatment of bipolar I disorder
Olsalazine Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Ulcerative colitis where hypersensitivity to sulfonamides exists
	Ulcerative colitis where intolerance to sulfasalazine exists
Omeprazole	Initial treatment of peptic ulcer
	Gastro-oesophageal reflux disease
	Scleroderma oesophagus
	Zollinger-Ellison syndrome
Omeprazole and Clarithromycin and Amoxycillin Trihydrate	Eradication of *Helicobacter pylori* associated with peptic ulcer disease
Omeprazole Magnesium	In respect of the tablet equivalent to 20 mg omeprazole:
	Initial treatment of peptic ulcer
	Gastro-oesophageal reflux disease
	Scleroderma oesophagus
	Zollinger-Ellison syndrome
	In respect of the tablet equivalent to 10 mg omeprazole:
	Gastro-oesophageal reflux disease
	Scleroderma oesophagus
	Zollinger-Ellison syndrome
Ondansetron	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy
Ondansetron Hydrochloride Dihydrate	In respect of the tablet equivalent to 4 mg ondansetron, tablet equivalent to 8 mg ondansetron, I.V. injection equivalent to 4 mg ondansetron in 2 mL ampoule and I.V. injection equivalent to 8 mg ondansetron in 4 mL ampoule:
	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy
	In respect of the syrup equivalent to 4 mg ondansetron per 5 mL, 50 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Oxaliplatin	In compliance with authority procedures set out in subparagraph 14 (d): Metastatic colorectal cancer in patients with a World Health Organisation performance status of 2 or less, when used in combination with fluorouracil sodium and calcium folinate Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with fluorouracil sodium and calcium folinate, following complete resection of the primary tumour
Oxazepam	—
Oxcarbazepine	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs
Oxprenolol Hydrochloride	—
Oxybutynin Hydrochloride	Detrusor overactivity where propantheline bromide has failed
Oxycodone Hydrochloride	In respect of the tablet 5 mg, capsule 5 mg, capsule 10 mg, capsule 20 mg and oral solution 5 mg per 5 mL, 250 mL: Severe disabling pain not responding to non-narcotic analgesics In respect of the tablet 5 mg (controlled release), tablet 10 mg (controlled release), tablet 20 mg (controlled release), tablet 40 mg (controlled release) and tablet 80 mg (controlled release): Chronic severe disabling pain not responding to non-narcotic analgesics
Oxycodone Pectinate	Severe disabling pain not responding to non-narcotic analgesics
Paclitaxel	In compliance with authority procedures set out in subparagraph 14 (d): Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide Advanced breast cancer after failure of prior therapy which includes an anthracycline Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound Primary treatment of ovarian cancer in combination with a platinum compound Locally advanced or metastatic non-small cell lung cancer Treatment of HER2 positive early breast cancer in combination with trastuzumab
Pancreatic Extract	—
Pancrelipase	—
Pantoprazole Sodium Sesquihydrate	In respect of the tablet (enteric coated), equivalent to 40 mg pantoprazole: Initial treatment of peptic ulcer Gastro-oesophageal reflux disease Scleroderma oesophagus Zollinger-Ellison syndrome In respect of the tablet (enteric coated), equivalent to 20 mg pantoprazole: Gastro-oesophageal reflux disease
Paracetamol	In respect of the tablet 500 mg, oral liquid 120 mg per 5 mL, 100 mL and oral liquid 240 mg per 5 mL, 200 mL: — In respect of the tablet 665 mg (modified release): Relief of persistent pain associated with osteoarthritis
Paraffin - Soft White with Paraffin - Liquid	—
Paroxetine Hydrochloride	Major depressive disorders Obsessive-compulsive disorder Panic disorder
Pemetrexed Disodium Heptahydrate	In compliance with authority procedures set out in subparagraph 14 (d): Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with paclitaxel or docetaxel is contraindicated Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where intolerance to treatment with either docetaxel or paclitaxel has developed Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with either docetaxel or paclitaxel has been unsuccessful

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where transfer to docetaxel or paclitaxel is likely to result in adverse clinical consequences
Penicillamine	—
"Pepti-Junior"	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment, for up to 3 months, for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years, where intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet, and where the date of birth of the patient is included in the authority application Continuing treatment for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides, and where the date of birth of the patient is included in the authority application Continuing treatment for intolerance (not infant colic) to cows' milk protein in a child aged 2 years or over, where the child has been assessed by a suitably qualified allergist or paediatrician, and where the date of birth of the patient is included in the authority application Biliary atresia Chronic liver failure with fat malabsorption Chylous ascites Cystic fibrosis Enterokinase deficiency Proven fat malabsorption Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months, where the date of birth of the patient is included in the authority application Severe intestinal malabsorption including short bowel syndrome
Pergolide Mesylate	Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations
Perhexiline Maleate	In compliance with authority procedures set out in subparagraph 14 (d): Angina not responding to other therapy
Pericyazine	—
Perindopril Arginine	—
Perindopril Arginine with Indapamide Hemihydrate	Hypertension in patients who are not adequately controlled with either indapamide hemihydrate or perindopril monotherapy
Perindopril Erbumine	—
Perindopril Erbumine with Indapamide Hemihydrate	Hypertension in patients who are not adequately controlled with either indapamide hemihydrate or perindopril monotherapy
Permethrin	—
Phenelzine Sulfate	Depression where all other anti-depressant therapy has failed or is inappropriate
"Phenex-1"	Phenylketonuria
"Phenex-2"	Phenylketonuria
Phenobarbitone	Epilepsy
Phenobarbitone Sodium	Epilepsy
Phenoxybenzamine Hydrochloride	Phaeochromocytoma Neurogenic urinary retention
Phenoxymethylpenicillin Benzathine	—
Phenoxymethylpenicillin Potassium	—
Phenytoin	—
Phenytoin Sodium	—
"Phlexy-10"	Phenylketonuria
"Phlexy-10 Drink Mix"	Phenylketonuria
Pilocarpine Hydrochloride	—
Pimecrolimus	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months who have 1 or more of the following contraindications to topical corticosteroids: perioral dermatitis; periorbital dermatitis; rosacea; epidermal atrophy; dermal atrophy; allergy to topical corticosteroids;

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	cataracts; glaucoma; raised intraocular pressure; and where a period of 6 months or more has elapsed since an application was last approved for the issue of an authority prescription to the patient for this purpose Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy and where more than 3 months have passed since the initial diagnosis of atopic dermatitis; and where failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by: failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; and where a period of 6 months or more has elapsed since an application was last approved for the issue of an authority prescription to the patient for this purpose
Pindolol	—
Pioglitazone Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): Initiation of therapy, in combination with either metformin hydrochloride or a sulfonylurea, in type 2 diabetes mellitus patients in whom a combination of metformin hydrochloride and a sulfonylurea is contraindicated or not tolerated, and: (a) who have glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Continuation of therapy, in combination with either metformin hydrochloride or a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for pioglitazone hydrochloride or rosiglitazone maleate Initiation of therapy, in combination with insulin, in type 2 diabetes mellitus patients who, despite treatment with insulin and oral anti-diabetic agents, or with insulin alone where metformin hydrochloride is contraindicated, have either: (a) glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolyic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, blood glucose levels greater than 10 mmol per L in more than 20% of tests conducted during blood glucose monitoring over a 2 week period; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Continuation of therapy, in combination with insulin, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for pioglitazone hydrochloride or rosiglitazone maleate
Piperazine Oestrone Sulfate	—
Piroxicam	Chronic arthropathies (including osteoarthritis) with an inflammatory component
Pizotifen Malate	—
"PK AID II"	Phenylketonuria
"PKU-Express"	Phenylketonuria
"PKU Express Liquid"	Phenylketonuria
"PKU-gel"	Phenylketonuria

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Pneumococcal Vaccine - Polyvalent	Splenectomised persons over 2 years of age
	Persons with Hodgkin's disease
	Persons at high risk of pneumococcal infections
Polyethylene Glycol 400 with Propylene Glycol	Severe dry eye syndrome, including Sjogren's syndrome
Polygeline	—
Polyvinyl Alcohol	Severe dry eye syndrome, including Sjogren's syndrome
Potassium Chloride	—
Potassium Chloride with Potassium Bicarbonate	—
Pravastatin Sodium	For use in accordance with paragraph 16
Prazosin Hydrochloride	—
Prednisolone	—
Prednisolone Acetate with Phenylephrine Hydrochloride	Corneal grafts
	Uveitis
Prednisolone Sodium Phosphate	In respect of the oral solution equivalent to 5 mg prednisolone per mL, 30 mL and enema, retention, equivalent to 20 mg prednisolone in 100 mL:
	—
	In respect of the suppositories equivalent to 5 mg prednisolone, 10:
	Proctitis
	Ulcerative colitis
Prednisone	—
Primidone	—
Probenecid	—
Procaine Penicillin	—
Prochlorperazine	—
Prochlorperazine Maleate	—
Prochlorperazine Mesylate	—
Promethazine Hydrochloride	—
Propantheline Bromide	Detrusor overactivity
"Pro-Phree"	Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae
Propranolol Hydrochloride	—
Propylthiouracil	—
Pyrantel Embonate	—
Pyridostigmine Bromide	—
Pyrimethamine	—
Quetiapine Fumarate	In compliance with authority procedures set out in subparagraph 14 (d):
	Schizophrenia
Quinagolide Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Pathological hyperprolactinaemia where surgery is not indicated
	Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
	Pathological hyperprolactinaemia where radiotherapy is not indicated
	Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution
Quinapril Hydrochloride	—
Quinapril Hydrochloride with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or quinapril hydrochloride monotherapy
Quinine Bisulfate	In compliance with authority procedures set out in subparagraph 14 (d):
	Malaria
Quinine Sulfate	In compliance with authority procedures set out in subparagraph 14 (d):
	Malaria
Rabeprazole Sodium	In respect of the tablet 20 mg (enteric coated):
	Initial treatment of peptic ulcer
	Gastro-oesophageal reflux disease
	Scleroderma oesophagus

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In respect of the tablet 10 mg (enteric coated):
	Gastro-oesophageal reflux disease
	Scleroderma oesophagus
Raloxifene Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
Raltitrexed	In compliance with authority procedures set out in subparagraph 14 (d):
	For use as a single agent in the treatment of advanced colorectal cancer
Ramipril	—
Ranitidine Hydrochloride	—
"RCF"	Patients with intractable seizures requiring treatment with a ketogenic diet
	Glucose transport protein defects
	Pyruvate dehydrogenase deficiency
	Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance
Reboxetine Mesilate	Major depressive disorders
Reteplase	Treatment of acute myocardial infarction within 6 hours of onset of attack
Rifampicin	In respect of the capsule 150 mg and capsule 300 mg:
	Prophylaxis of meningococcal disease in close contacts and carriers
	Prophylactic treatment of contacts of patients with *Haemophilus influenzae* type B
	In compliance with authority procedures set out in subparagraph 14 (d):
	Leprosy in adults
	In respect of the syrup 100 mg per 5 mL, 60 mL:
	Prophylaxis of meningococcal disease in close contacts and carriers
	Prophylactic treatment of contacts of patients with *Haemophilus influenzae* type B
Riluzole	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 2 years or less who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy, and who have not undergone tracheostomy, have not experienced respiratory failure and, if not ambulatory, are either able to use upper limbs or able to swallow, and where the date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) are included in the authority application
	Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who have not undergone tracheostomy, have not experienced respiratory failure and, if not ambulatory, are either able to use upper limbs or able to swallow
Risedronate Sodium	In respect of the tablet 5 mg and tablet 35 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
	In respect of the tablet 30 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Symptomatic Paget's disease of bone

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Risedronate Sodium and Calcium Carbonate	In compliance with authority procedures set out in subparagraph 14 (d): Initial treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
Risperidone	In respect of the tablet 0.5 mg and tablet 0.5 mg (orally disintegrating): In compliance with authority procedures set out in subparagraph 14 (d): Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a child or adolescent aged less than 18 years with autism, where behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful, and where the diagnosis of autism has been made based on either the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or the International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) international classification of mental and behavioural disorders Schizophrenia In respect of the tablet 1 mg and tablet 1 mg (orally disintegrating): In compliance with authority procedures set out in subparagraph 14 (d): Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a child or adolescent aged less than 18 years with autism, where behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful, and where the diagnosis of autism has been made based on either the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or the International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) international classification of mental and behavioural disorders Schizophrenia Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder In respect of the tablet 2 mg and tablet 2 mg (orally disintegrating): In compliance with authority procedures set out in subparagraph 14 (d): Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a child or adolescent aged less than 18 years with autism, where behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful, and where the diagnosis of autism has been made based on either the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or the International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) international classification of mental and behavioural disorders Schizophrenia Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder In respect of the tablet 3 mg, tablet 3 mg (orally disintegrating), tablet 4 mg, tablet 4 mg (orally disintegrating) and oral solution 1 mg per mL, 100 mL: In compliance with authority procedures set out in subparagraph 14 (d): Schizophrenia Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder In respect of the oral solution 1 mg per mL, 30 mL: In compliance with authority procedures set out in subparagraph 14 (d): Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a child or adolescent aged less than 18 years with autism, where behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful, and where the diagnosis of autism has been made based on either the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or the International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) international classification of mental and behavioural disorders
	In respect of the I.M. injection (modified release), set containing 1 vial powder for injection 25 mg and 1 pre-filled syringe diluent 2 mL, I.M. injection (modified release), set containing 1 vial powder for injection 37.5 mg and 1 pre-filled syringe diluent 2 mL and I.M. injection (modified release), set containing 1 vial powder for injection 50 mg and 1 pre-filled syringe diluent 2 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Schizophrenia
Rituximab	In compliance with authority procedures set out in subparagraph 14 (d):
	Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma
	Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma
	Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy
	Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy
Rivastigmine Hydrogen Tartrate	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the baseline scores submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total
	Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, where the diagnosis is confirmed by a specialist or consultant physician, where the result of the baseline MMSE or SMMSE is included in the authority application, and where, if the patient's baseline MMSE or SMMSE is 25 to 30 points and it is so desired, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale, is also included in the authority application
	Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more who demonstrate improvement in cognitive function following initial PBS-subsidised therapy, and where:
	(1) improvement in cognitive function is demonstrated by:
	(a) in the case of patients with a baseline MMSE or SMMSE score of 10 or more and less than 25 — an increase of at least 2 points from baseline on the MMSE or SMMSE; or
	(b) in the case of patients with a baseline MMSE or SMMSE score of at least 25 points — an increase of at least 2 points from baseline on the MMSE or SMMSE, or, if a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) was submitted with the application for initial treatment, a decrease of at least 4 points from baseline on the ADAS-Cog; and
	(2) the relevant result from the MMSE, SMMSE or ADAS-Cog is included in the authority application for continuing treatment

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more and with demonstrated improvement in cognitive function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment
	Initial treatment, for up to 2 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs:
	Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
	Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
	Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test;
	Intellectual (developmental or acquired) disability;
	Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test;
	Prominent dysphasia, out of proportion to other cognitive and functional impairment
	In compliance with authority procedures set out in subsubparagraph 14 (d) (i):
	Continuation of initial treatment of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, where the patient has previously been issued with an authority prescription for initial treatment with this drug for a period of up to 2 months, where the application includes the information submitted with the first application for initial treatment, and where approval of the application would enable the patient to complete a period of initial treatment of not more than 6 months' duration in total
	Initial treatment, for up to 6 months, of mild to moderately severe Alzheimer's disease in patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease as they are from 1 or more of the qualifying groups specified below, where the patient is assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale and the diagnosis is confirmed by a specialist or consultant physician, and where the authority application includes the result of the baseline MMSE or SMMSE and specifies to which of the following qualifying groups the patient belongs:
	Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
	Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
	Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an MMSE or SMMSE test;
	Intellectual (developmental or acquired) disability;
	Significant sensory impairment despite best correction, which precludes completion of an MMSE or SMMSE test;
	Prominent dysphasia, out of proportion to other cognitive and functional impairment
	Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease and who demonstrate improvement in function following initial PBS-subsidised therapy, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change scale, as assessed by the same clinician who initiated treatment, and where the improvement rating achieved on the Clinicians Interview Based Impression of Change scale is stated in the authority application for continuing treatment

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	In compliance with authority procedures set out in subparagraph 14 (d): Continuing treatment of mild to moderately severe Alzheimer's disease in eligible patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less and with demonstrated improvement in function following initial PBS-subsidised therapy, where the patient has previously been issued with an authority prescription for continuing treatment
Rosiglitazone Maleate	In compliance with authority procedures set out in subparagraph 14 (d): Initiation of therapy, in combination with either metformin hydrochloride or a sulfonylurea, in type 2 diabetes mellitus patients in whom a combination of metformin hydrochloride and a sulfonylurea is contraindicated or not tolerated, and: (a) who have glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Continuation of therapy, in combination with either metformin hydrochloride or a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride Initiation of therapy, in combination with metformin hydrochloride and a sulfonylurea, in type 2 diabetes mellitus patients who, despite maximally tolerated doses of metformin hydrochloride and a sulfonylurea, have either: (a) glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, blood glucose levels greater than 10 mmol per L in more than 20% of tests conducted during blood glucose monitoring over a 2 week period; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Continuation of therapy, in combination with metformin hydrochloride and a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride Initiation of therapy, in combination with insulin, in type 2 diabetes mellitus patients who, despite treatment with insulin and oral anti-diabetic agents, or with insulin alone where metformin hydrochloride is contraindicated, have either: (a) glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolyic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, blood glucose levels greater than 10 mmol per L in more than 20% of tests conducted during blood glucose monitoring over a 2 week period; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Continuation of therapy, in combination with insulin, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride
Rosiglitazone Maleate with Metformin Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): Initiation of therapy in type 2 diabetes mellitus patients in whom a combination of metformin hydrochloride with a sulfonylurea is contraindicated or not tolerated, and: (a) who have glycosylated haemoglobin (HbA1c) greater than 7%; or (b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests; and where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application Initiation of therapy in type 2 diabetes mellitus patients who are stabilised on PBS-subsidised rosiglitazone maleate and metformin hydrochloride

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Initiation of therapy in type 2 diabetes mellitus patients who are stabilised on PBS-subsidised pioglitazone hydrochloride and metformin hydrochloride
	Continuation of therapy in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate and metformin hydrochloride fixed dose combination tablet
	Initiation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients who, despite maximally tolerated doses of metformin hydrochloride and a sulfonylurea, have either:
	(a) glycosylated haemoglobin (HbA1c) greater than 7%; or
	(b) in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months, blood glucose levels greater than 10 mmol per L in more than 20% of tests conducted during blood glucose monitoring over a 2 week period; and
	where the date of the HbA1c measurement or the most recent blood glucose level, whichever is applicable in the circumstance, is included in the authority application and is no greater than 4 months old at the time of application
	Initiation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients who are stabilised on PBS-subsidised rosiglitazone maleate and metformin hydrochloride
	Initiation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients who are stabilised on PBS-subsidised pioglitazone hydrochloride and metformin hydrochloride
	Continuation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate and metformin hydrochloride fixed dose combination tablet
Rosuvastatin Calcium	For use in accordance with paragraph 16
Roxithromycin	—
"S-26 LF"	In compliance with authority procedures set out in subparagraph 14 (d):
	Acute lactose intolerance in patients up to the age of 12 months, where the date of birth of the patient is included in the authority application and where the patient has not previously been issued with an authority prescription for this medicinal preparation for this purpose
	Proven chronic lactose intolerance in patients up to the age of 12 months, where the date of birth of the patient is included in the authority application, and where lactose intolerance has been proven either by the relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food, or by the presence of not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet
Salbutamol Sulfate	In respect of the oral solution equivalent to 2 mg salbutamol per 5 mL, 150 mL, capsule containing powder for oral inhalation equivalent to 200 micrograms salbutamol (for use in Ventolin Rotahaler) and pressurised inhalation equivalent to 100 micrograms salbutamol per dose, 200 doses (CFC-free formulation):
	—
	In respect of the pressurised inhalation in breath actuated device equivalent to 100 micrograms salbutamol per dose, 200 doses (CFC-free formulation):
	Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug
	In respect of the nebuliser solution equivalent to 2.5 mg salbutamol in 2.5 mL single dose units, 30, nebuliser solution equivalent to 5 mg salbutamol in 2.5 mL single dose units, 30 and nebuliser solution equivalent to 5 mg salbutamol per mL, 30 mL:
	Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer
	Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer
Salcatonin	In compliance with authority procedures set out in subparagraph 14 (d):
	Symptomatic Paget's disease of bone
	Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia
Salmeterol Xinafoate	Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids
	Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids
Selegiline Hydrochloride	Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Sertraline Hydrochloride	Major depressive disorders
	Obsessive-compulsive disorder
	Panic disorder where other treatments have failed or are inappropriate
Silver Sulfadiazine with Chlorhexidine Gluconate	Prevention and treatment of infection in partial or full skin thickness loss due to burns
	Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa
	Stasis ulcers
Simvastatin	For use in accordance with paragraph 16
Sirolimus	In compliance with authority procedures set out in subparagraph 14 (d):
	Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with sirolimus, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Sodium Acid Phosphate	In compliance with authority procedures set out in subparagraph 14 (d):
	Familial hypophosphataemia
	Hypercalcaemia
	Hypophosphataemic rickets
	Vitamin D-resistant rickets
Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate	—
Sodium Aurothiomalate	—
Sodium Chloride	—
Sodium Chloride with Glucose	—
Sodium Chloride with Potassium Chloride and Calcium Chloride	—
Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride	—
Sodium Clodronate Tetrahydrate	Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy
	Multiple myeloma
	Bone metastases from breast cancer
Sodium Cromoglycate	In respect of the capsule containing powder for oral inhalation 20 mg (for use in Intal Spinhaler or Intal Halermatic), pressurised inhalation 1 mg per dose, 200 doses, pressurised inhalation 1 mg per dose, 200 doses (CFC-free formulation) and pressurised inhalation 5 mg per dose, 112 doses (CFC-free formulation):
	—
	In respect of the eye drops 20 mg per mL, 10 mL:
	Vernal kerato-conjunctivitis
Sodium Fusidate	For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections
Sodium Lactate with Sodium Chloride, Potassium Chloride and Calcium Chloride	—
Sodium Valproate	—
Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
	Patients receiving palliative care
	Terminal malignant neoplasia
	Anorectal congenital abnormalities
	Megacolon
Sotalol Hydrochloride	Severe cardiac arrhythmias
Spironolactone	—
Sterculia with Frangula Bark	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
	Patients receiving palliative care
	Terminal malignant neoplasia
	Anorectal congenital abnormalities
	Megacolon
Strontium Ranelate	In compliance with authority procedures set out in subparagraph 14 (d):
	Initial treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the fracture has been demonstrated radiologically and the year of plain x-ray or computed tomography scan or magnetic resonance imaging scan is included in the authority application, provided that if the fracture is a vertebral fracture, there is a 20% or greater reduction in height of the anterior or mid portion of the affected vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
	Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug
Sucralfate	—
Sulfacetamide Sodium	—
Sulfasalazine	—
Sulindac	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
Sulthiame	—
Sumatriptan	In compliance with authority procedures set out in subparagraph 14 (d):
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated
Sumatriptan Succinate	In compliance with authority procedures set out in subparagraph 14 (d):
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated
Tacrolimus	In compliance with authority procedures set out in subparagraph 14 (d):
	Maintenance therapy of patients with liver transplants following initiation and stabilisation of treatment with tacrolimus, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
	Maintenance therapy of patients with renal transplants following initiation and stabilisation of treatment with tacrolimus, where therapy remains under the supervision and direction of the transplant unit reviewing that patient and where the name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application
Tamoxifen Citrate	Treatment of hormone-dependent breast cancer
Telmisartan	—
Telmisartan with Hydrochlorothiazide	Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or telmisartan monotherapy
Temazepam	—
Temozolomide	In respect of the capsule 5 mg, capsule 20 mg and capsule 100 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Glioblastoma multiforme concomitantly with radiotherapy
	Recurrence of anaplastic astrocytoma following standard therapy
	Recurrence of glioblastoma multiforme following standard therapy
	Glioblastoma multiforme following radiotherapy
	In respect of the capsule 250 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Recurrence of anaplastic astrocytoma following standard therapy
	Recurrence of glioblastoma multiforme following standard therapy
	Glioblastoma multiforme following radiotherapy
Tenecteplase	Treatment of acute myocardial infarction within 12 hours of onset of attack

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Terbinafine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed, where the infection is proven by microscopy or culture and confirmed by an Approved Pathology Authority not more than 12 months prior to the date of the authority application and where the date of the pathology report is included in the authority application
Terbutaline Sulfate	In respect of the injection 500 micrograms in 1 mL ampoule and powder for oral inhalation in breath actuated device 500 micrograms per dose, 200 doses: — In respect of the nebuliser solution 5 mg in 2 mL single dose units, 30: Asthma in patients unable to use this drug delivered from a breath actuated device Chronic obstructive pulmonary disease in patients unable to use this drug delivered from a breath actuated device
Testosterone	In compliance with authority procedures set out in subparagraph 14 (d): Androgen deficiency in males with established pituitary or testicular disorders Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings, where androgen deficiency is confirmed by testosterone less than 8 nmol per L, or from 8 to 15 nmol per L with luteinising hormone greater than 1.5 times the upper limit of the eugonadal reference range for young men Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age
Testosterone Enanthate	In compliance with authority procedures set out in subparagraph 14 (d): Androgen deficiency in males with established pituitary or testicular disorders Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings, where androgen deficiency is confirmed by testosterone less than 8 nmol per L, or from 8 to 15 nmol per L with luteinising hormone greater than 1.5 times the upper limit of the eugonadal reference range for young men Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age
Testosterone Propionate with Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate	In compliance with authority procedures set out in subparagraph 14 (d): Androgen deficiency in males with established pituitary or testicular disorders Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings, where androgen deficiency is confirmed by testosterone less than 8 nmol per L, or from 8 to 15 nmol per L with luteinising hormone greater than 1.5 times the upper limit of the eugonadal reference range for young men Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age
Testosterone Propionate with Testosterone Phenylpropionate and Testosterone Isocaproate	In compliance with authority procedures set out in subparagraph 14 (d): Androgen deficiency in males with established pituitary or testicular disorders Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings, where androgen deficiency is confirmed by testosterone less than 8 nmol per L, or from 8 to 15 nmol per L with luteinising hormone greater than 1.5 times the upper limit of the eugonadal reference range for young men Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age
Testosterone Undecanoate	In compliance with authority procedures set out in subparagraph 14 (d): Androgen deficiency in males with established pituitary or testicular disorders Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings, where androgen deficiency is confirmed by testosterone less than 8 nmol per L, or from 8 to 15 nmol per L with luteinising hormone greater than 1.5 times the upper limit of the eugonadal reference range for young men Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age
Tetrabenazine	In compliance with authority procedures set out in subparagraph 14 (d): Hyperkinetic extrapyramidal disorders
Tetracosactrin	—
Theophylline	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Thiamine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person
Thioguanine	—
Thioridazine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Management of patients with schizophrenia who have failed to respond adequately to treatment with appropriate courses of at least 2 other antipsychotic drugs, at an adequate dose and for an adequate duration, because of insufficient effectiveness
	Management of patients with schizophrenia who have failed to respond adequately to treatment with appropriate courses of at least 2 other antipsychotic drugs, at an adequate dose and for an adequate duration, because of the inability to achieve an effective dose due to intolerable adverse effects from those drugs
Thiotepa	—
Thyroxine Sodium	—
Tiagabine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs
Tiaprofenic Acid	Chronic arthropathies (including osteoarthritis) with an inflammatory component
Ticarcillin Sodium with Potassium Clavulanate	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
Ticlopidine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:
	in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin
	in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding
	in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs
	Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999
Tiludronate Disodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Symptomatic Paget's disease of bone
Timolol Maleate	—
Tinidazole	—
Tiotropium Bromide Monohydrate	For the long-term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease
Tirofiban Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes
	Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours
	Patients with non-Q-wave myocardial infarction
Tobramycin	Invasive ocular infection
	Perioperative use in ophthalmic surgery
	Suspected pseudomonal eye infection
Tobramycin Sulfate	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
	Septicaemia, suspected
	Septicaemia, proven
Topiramate	In respect of the tablet 25 mg, tablet 50 mg, tablet 100 mg and tablet 200 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs, and where adverse events have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs, and where drug interactions have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs, and where drug interactions are expected to occur with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme would cause patient confusion resulting in problems with compliance
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme is likely to result in adverse clinical consequences
	In respect of the capsule 15 mg, capsule 25 mg and capsule 50 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate, and where adverse events have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate, and where drug interactions have occurred with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate, and where drug interactions are expected to occur with other suitable drugs available under the Pharmaceutical Benefits Scheme
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme would cause patient confusion resulting in problems with compliance
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid form dose of topiramate, and where transfer to another suitable drug available under the Pharmaceutical Benefits Scheme is likely to result in adverse clinical consequences
Topotecan Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound
Toremifene Citrate	Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients
Tramadol Hydrochloride	In respect of the capsule 50 mg:
	For acute pain where aspirin or paracetamol alone is inappropriate or has failed
	For dosage titration in chronic pain where aspirin or paracetamol alone is inappropriate or has failed
	In respect of the tablet 50 mg (sustained release), tablet 100 mg (sustained release), tablet 150 mg (sustained release), tablet 200 mg (sustained release) and oral drops 100 mg per mL, 10 mL:
	For pain where aspirin or paracetamol alone is inappropriate or has failed
	In respect of the injection 100 mg in 2 mL ampoule:
	Short-term treatment of acute pain
Trandolapril	—
Trandolapril with Verapamil Hydrochloride	Hypertension in a patient who is stabilised on treatment with trandolapril 4 mg and verapamil hydrochloride sustained release 240 mg

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Tranexamic Acid	—
Tranylcypromine Sulfate	—
Travoprost	—
Travoprost with Timolol Maleate	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL or travoprost eye drops
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate eye drops equivalent to 5 mg timolol per mL or travoprost eye drops
Triamcinolone Acetonide	In respect of the injection 10 mg in 1 mL ampoule:
	Alopecia areata
	For local intra-articular or peri-articular infiltration
	Granulomata, dermal
	Keloid
	Lichen planus hypertrophic
	Lichen simplex chronicus
	Lupus erythematosus, chronic discoid
	Necrobiosis lipoidica
	Psoriasis
	In respect of the cream 200 micrograms per g, 100 g and ointment 200 micrograms per g, 100 g:
	Treatment of corticosteroid-responsive dermatoses
Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin	—
Trifluoperazine Hydrochloride	—
Triglycerides Oil - Medium Chain	In compliance with authority procedures set out in subparagraph 14 (d):
	Chylous ascites
	Chylothorax
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders
	Hyperlipoproteinaemia type 1
	Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet
	Long chain fatty acid oxidation disorders
Trimethoprim	—
Trimethoprim with Sulfamethoxazole	—
Tropisetron Hydrochloride	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
"TYR Express"	Tyrosinaemia
"TYR gel"	Tyrosinaemia
Ursodeoxycholic Acid	In compliance with authority procedures set out in subparagraph 14 (d):
	Primary biliary cirrhosis
Valaciclovir Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Moderate to severe initial genital herpes
	Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes, where the diagnosis is confirmed microbiologically (by viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction) but where commencement of treatment need not await confirmation of diagnosis
	Treatment of patients with herpes zoster within 72 hours of the onset of the rash
	Herpes zoster ophthalmicus
Vancomycin Hydrochloride	In respect of the capsule equivalent to 125 mg (125,000 I.U.) vancomycin activity and capsule equivalent to 250 mg (250,000 I.U.) vancomycin activity:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Antibiotic associated pseudomembranous colitis due to *Clostridium difficile* which is unresponsive to metronidazole
	Antibiotic associated pseudomembranous colitis due to *Clostridium difficile* where there is intolerance to metronidazole
	In respect of the powder for injection equivalent to 500 mg (500,000 I.U.) vancomycin activity:
	Prophylaxis of endocarditis in patients hypersensitive to penicillin
	Endophthalmitis

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Use initiated in a hospital for infections where vancomycin hydrochloride is an appropriate antibiotic
Venlafaxine Hydrochloride	Major depressive disorders
Verapamil Hydrochloride	—
Vigabatrin	In compliance with authority procedures set out in subparagraph 14 (d): Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs
Vinblastine Sulfate	—
Vincristine Sulfate	—
Vinorelbine Tartrate	In respect of the capsule equivalent to 20 mg vinorelbine and capsule equivalent to 30 mg vinorelbine: In compliance with authority procedures set out in subparagraph 14 (d): Locally advanced or metastatic non-small cell lung cancer In respect of the solution for I.V. infusion equivalent to 10 mg vinorelbine in 1 mL and solution for I.V. infusion equivalent to 50 mg vinorelbine in 5 mL: In compliance with authority procedures set out in subparagraph 14 (d): Advanced breast cancer after failure of prior therapy which includes an anthracycline Locally advanced or metastatic non-small cell lung cancer
Warfarin Sodium	—
"XLYS, LOW TRY Analog"	An infant or young child with proven glutaric aciduria type 1
"XLYS, LOW TRY Maxamaid"	A child aged less than 7 years with proven glutaric aciduria type 1
"XMET Analog"	For infants and very young children with pyridoxine non-responsive homocystinuria
"XMET Maxamaid"	Pyridoxine non-responsive homocystinuria
"XMET Maxamum"	Pyridoxine non-responsive homocystinuria
"XMTVI Analog"	Methylmalonic acidaemia Propionic acidaemia
"XMTVI Asadon"	Methylmalonic acidaemia Propionic acidaemia
"XMTVI Maxamaid"	Methylmalonic acidaemia Propionic acidaemia
"XMTVI Maxamum"	Methylmalonic acidaemia Propionic acidaemia
"XP Analog"	Phenylketonuria
"XP Analog LCP"	Phenylketonuria
"XPhen, Tyr Analog"	Tyrosinaemia
"XPhen, Tyr Maxamaid"	Tyrosinaemia
"XPhen, Tyr Maxamum"	Tyrosinaemia
"XP Maxamaid"	Phenylketonuria
"XP Maxamum"	Phenylketonuria
"XPTM Tyrosidon"	Tyrosinaemia
Ziprasidone Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d): Schizophrenia
Zolmitriptan	In compliance with authority procedures set out in subparagraph 14 (d): Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where adverse events have occurred with other suitable PBS-listed drugs Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where drug interactions have occurred with other suitable PBS-listed drugs

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where drug interactions are expected to occur with other suitable PBS-listed drugs
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences
Zuclopenthixol Decanoate	—

SCHEDULE 1A – READY-PREPARED PHARMACEUTICAL BENEFITS WHEN PRESCRIBED BY A MEDICAL PRACTITIONER FOR PATIENTS RECEIVING PALLIATIVE CARE

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Benzydamine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where a painful mouth is a problem
	Initial supply, for up to 4 months, for palliative care patients where a painful mouth is a problem
	Continuing supply for palliative care patients where a painful mouth is a problem, and where consultation with a palliative care specialist or service has occurred
Bisacodyl	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Carmellose Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where dry mouth is a symptom
	Initial supply, for up to 4 months, for palliative care patients where dry mouth is a symptom
	Continuing supply for palliative care patients where dry mouth is a symptom, and where consultation with a palliative care specialist or service has occurred
Clonazepam	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients for the prevention of epilepsy
	Initial supply, for up to 4 months, for palliative care patients for the prevention of epilepsy
	Continuing supply for palliative care patients for the prevention of epilepsy, where consultation with a palliative care specialist or service has occurred
Diazepam	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where anxiety is a problem
	Initial supply, for up to 4 months, for palliative care patients where anxiety is a problem
	Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred
Diclofenac Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred
Glycerol	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Hyoscine Butylbromide	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where colicky pain is a symptom
	Initial supply, for up to 4 months, for palliative care patients where colicky pain is a symptom
	Continuing supply for palliative care patients where colicky pain is a symptom, and where consultation with a palliative care specialist or service has occurred
Ibuprofen	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred
Indomethacin	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Lactulose	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Methadone Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply, for up to 1 month, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics
	Initial supply, for up to 3 months, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics
	Continuing supply, for up to 3 months, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred
Morphine Sulfate	In respect of the tablet 10 mg and tablet 20 mg:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply, for up to 1 month, for palliative care patients with severe disabling pain not responding to non-narcotic analgesics
	Initial supply, for up to 3 months, for palliative care patients with severe disabling pain not responding to non-narcotic analgesics
	Continuing supply, for up to 3 months, for palliative care patients with severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred
	In respect of the tablet 200 mg (controlled release):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply, for up to 1 month, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics
	Initial supply, for up to 3 months, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics
	Continuing supply, for up to 3 months, for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred
Naproxen	In respect of the tablet 250 mg, tablet 500 mg, tablet 750 mg (sustained release) and tablet 1 g (sustained release):
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred
	In respect of the oral suspension 125 mg per 5 mL, 474 mL:
	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent
	Continuing supply for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent, and where consultation with a palliative care specialist or service has occurred
Naproxen Sodium	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Nitrazepam	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where insomnia is a problem
	Initial supply, for up to 4 months, for palliative care patients where insomnia is a problem
	Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred
Oxazepam	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where anxiety is a problem
	Initial supply, for up to 4 months, for palliative care patients where anxiety is a problem
	Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred
Paracetamol	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated
	Initial supply, for up to 4 months, for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated
	Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated, and where consultation with a palliative care specialist or service has occurred
Promethazine Hydrochloride	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where nausea and/or vomiting is a problem
	Initial supply, for up to 4 months, for palliative care patients where nausea and/or vomiting is a problem
	Continuing supply for palliative care patients where nausea and/or vomiting is a problem, and where consultation with a palliative care specialist or service has occurred
Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Sterculia with Frangula Bark	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where constipation is a problem
	Initial supply, for up to 4 months, for palliative care patients where constipation is a problem
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred
Sulindac	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where severe pain is a problem
	Initial supply, for up to 4 months, for palliative care patients where severe pain is a problem
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred
Temazepam	In compliance with authority procedures set out in subparagraph 14 (d):
	Continuing supply for palliative care patients where insomnia is a problem
	Initial supply, for up to 4 months, for palliative care patients where insomnia is a problem
	Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred

SCHEDULE 2 – READY-PREPARED PHARMACEUTICAL BENEFITS WHEN PRESCRIBED BY A PARTICIPATING DENTAL PRACTITIONER

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Adrenaline Acid Tartrate	—
Amoxycillin Trihydrate	—
Amoxycillin Trihydrate with Potassium Clavulanate	Infections where resistance to amoxycillin trihydrate is suspected Infections where resistance to amoxycillin trihydrate is proven
Amoxycillin Trihydrate with Potassium Clavulanate and Water - Purified BP	Infections where resistance to amoxycillin trihydrate is suspected Infections where resistance to amoxycillin trihydrate is proven
Amoxycillin Trihydrate with Water - Purified BP	—
Amphotericin	—
Ampicillin Sodium	—
Ampicillin Trihydrate	—
Aspirin	—
Atropine Sulfate	—
Benzathine Penicillin	—
Benztropine Mesylate	—
Benzydamine Hydrochloride	Radiation induced mucositis
Benzylpenicillin Sodium	—
Betamethasone Acetate with Betamethasone Sodium Phosphate	For local intra-articular or peri-articular infiltration Keloid Lichen planus hypertrophic
Carbamazepine	—
Cefaclor Monohydrate	—
Cefaclor Monohydrate with Water - Purified BP	—
Cefotaxime Sodium	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
Cefuroxime Axetil	—
Cephalexin	—
Cephalexin with Water - Purified BP	—
Cephalothin Sodium	—
Chloramphenicol	—
Clindamycin Hydrochloride	Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin
Codeine Phosphate	—
Codeine Phosphate with Paracetamol	—
Diazepam	—
Diclofenac Sodium	In respect of the tablet 25 mg (enteric coated) and tablet 50 mg (enteric coated): Chronic arthropathies (including osteoarthritis) with an inflammatory component Bone pain due to malignant disease In respect of the suppository 100 mg: —
Dicloxacillin Sodium	In respect of the capsule equivalent to 250 mg dicloxacillin and capsule equivalent to 500 mg dicloxacillin: Serious staphylococcal infections In respect of the powder for injection equivalent to 500 mg dicloxacillin and powder for injection equivalent to 1 g dicloxacillin: —
Doxycycline Hydrochloride	—
Doxycycline Monohydrate	—
Erythromycin	—
Erythromycin Ethyl Succinate	—
Erythromycin Ethyl Succinate with Water - Purified BP	—
Erythromycin Lactobionate	—
Flucloxacillin Magnesium with Water - Purified BP	Serious staphylococcal infections

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Flucloxacillin Sodium	In respect of the capsule equivalent to 250 mg flucloxacillin and capsule equivalent to 500 mg flucloxacillin: Serious staphylococcal infections In respect of the powder for injection equivalent to 500 mg flucloxacillin and powder for injection equivalent to 1 g flucloxacillin: —
Glucagon Hydrochloride	—
Glucose	—
Glyceryl Trinitrate	—
Hydrocortisone Acetate	Treatment of corticosteroid-responsive dermatoses
Hydrocortisone Sodium Succinate	For use in a hospital
Hydromorphone Hydrochloride	In respect of the tablet 2 mg, tablet 4 mg, tablet 8 mg and oral liquid 1 mg per mL, 473 mL: Severe disabling pain not responding to non-narcotic analgesics In respect of the injection 2 mg in 1 mL ampoule, injection 10 mg in 1 mL ampoule and injection 50 mg in 5 mL ampoule: —
Ibuprofen	In respect of the tablet 200 mg: Chronic arthropathies (including osteoarthritis) with an inflammatory component Bone pain due to malignant disease In respect of the tablet 400 mg: —
Indomethacin	In respect of the capsule 25 mg: Chronic arthropathies (including osteoarthritis) with an inflammatory component Bone pain due to malignant disease In respect of the suppository 100 mg: —
Ketoprofen	In respect of the capsule 200 mg (sustained release): Chronic arthropathies (including osteoarthritis) with an inflammatory component In respect of the suppository 100 mg: —
Lignocaine Hydrochloride	—
Lincomycin Hydrochloride	—
Methylprednisolone Acetate	For local intra-articular or peri-articular infiltration
Metoclopramide Hydrochloride	—
Metronidazole	In respect of the tablet 200 mg, tablet 400 mg and suppositories 500 mg, 10: — In respect of the I.V. infusion 500 mg in 100 mL: Treatment, in a hospital, of acute anaerobic sepsis
Metronidazole Benzoate	—
Morphine Hydrochloride	Severe disabling pain not responding to non-narcotic analgesics
Morphine Sulfate	In respect of the tablet 30 mg: Severe disabling pain not responding to non-narcotic analgesics In respect of the tablet 5 mg (controlled release), tablet 10 mg (controlled release), tablet 15 mg (controlled release), tablet 30 mg (controlled release), tablet 60 mg (controlled release), tablet 100 mg (controlled release), capsule 10 mg (containing sustained release pellets), capsule 20 mg (containing sustained release pellets), capsule 30 mg (controlled release), capsule 50 mg (containing sustained release pellets), capsule 60 mg (controlled release), capsule 90 mg (controlled release), capsule 100 mg (containing sustained release pellets), capsule 120 mg (controlled release), sachet containing controlled release granules for oral suspension, 20 mg per sachet, sachet containing controlled release granules for oral suspension, 30 mg per sachet, sachet containing controlled release granules for oral suspension, 60 mg per sachet and sachet containing controlled release granules for oral suspension, 100 mg per sachet: Chronic severe disabling pain not responding to non-narcotic analgesics In respect of the injection 10 mg in 1 mL ampoule, injection 15 mg in 1 mL ampoule and injection 30 mg in 1 mL ampoule: —
Naloxone Hydrochloride	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Naproxen	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
Naproxen Sodium	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
Nitrazepam	—
Nystatin	—
Oxazepam	—
Oxycodone Hydrochloride	In respect of the tablet 5 mg, capsule 5 mg, capsule 10 mg, capsule 20 mg and oral solution 5 mg per 5 mL, 250 mL:
	Severe disabling pain not responding to non-narcotic analgesics
	In respect of the tablet 5 mg (controlled release), tablet 10 mg (controlled release), tablet 20 mg (controlled release), tablet 40 mg (controlled release) and tablet 80 mg (controlled release):
	Chronic severe disabling pain not responding to non-narcotic analgesics
Oxycodone Pectinate	Severe disabling pain not responding to non-narcotic analgesics
Paracetamol	—
Phenoxymethylpenicillin Benzathine	—
Phenoxymethylpenicillin Potassium	—
Piroxicam	Chronic arthropathies (including osteoarthritis) with an inflammatory component
Procaine Penicillin	—
Prochlorperazine	—
Prochlorperazine Maleate	—
Prochlorperazine Mesylate	—
Promethazine Hydrochloride	—
Sodium Chloride	—
Sodium Chloride with Glucose	—
Sulindac	Chronic arthropathies (including osteoarthritis) with an inflammatory component
	Bone pain due to malignant disease
Temazepam	—
Ticarcillin Sodium with Potassium Clavulanate	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
Tramadol Hydrochloride	In respect of the capsule 50 mg:
	For acute pain where aspirin or paracetamol alone is inappropriate or has failed
	For dosage titration in chronic pain where aspirin or paracetamol alone is inappropriate or has failed
	In respect of the tablet 50 mg (sustained release), tablet 100 mg (sustained release), tablet 150 mg (sustained release), tablet 200 mg (sustained release) and oral drops 100 mg per mL, 10 mL:
	For pain where aspirin or paracetamol alone is inappropriate or has failed
	In respect of the injection 100 mg in 2 mL ampoule:
	Short-term treatment of acute pain
Triamcinolone Acetonide	For local intra-articular or peri-articular infiltration
	Keloid
	Lichen planus hypertrophic
Trimethoprim with Sulfamethoxazole	—
Vancomycin Hydrochloride	Prophylaxis of endocarditis in patients hypersensitive to penicillin

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Allowable compounds*
Abacavir Sulfate	Abacavir Sulfate with Lamivudine
	Abacavir Sulfate with Lamivudine and Zidovudine
Alendronate Sodium	Alendronate Sodium with Colecalciferol
Aluminium Hydroxide - Dried	Aluminium Hydroxide - Dried with Magnesium Hydroxide
	Aluminium Hydroxide - Dried with Magnesium Trisilicate and Magnesium Hydroxide
Amiloride Hydrochloride	Hydrochlorothiazide with Amiloride Hydrochloride
Amlodipine Besylate	Amlodipine Besylate with Atorvastatin Calcium
Amoxycillin Trihydrate	Amoxycillin Trihydrate with Potassium Clavulanate
	Amoxycillin Trihydrate with Potassium Clavulanate and Water - Purified BP
	Amoxycillin Trihydrate with Water - Purified BP
Aspirin	Dipyridamole with Aspirin
Atorvastatin Calcium	Amlodipine Besylate with Atorvastatin Calcium
Atropine Sulfate	Diphenoxylate Hydrochloride with Atropine Sulfate
Azithromycin Dihydrate	Azithromycin Dihydrate with Water - Purified BP
Bacitracin Zinc	Neomycin Undecenoate with Bacitracin Zinc
Benserazide Hydrochloride	Levodopa with Benserazide Hydrochloride
Betamethasone Acetate	Betamethasone Acetate with Betamethasone Sodium Phosphate
Betamethasone Sodium Phosphate	Betamethasone Acetate with Betamethasone Sodium Phosphate
Brimonidine Tartrate	Brimonidine Tartrate with Timolol Maleate
Budesonide	Budesonide with Eformoterol Fumarate Dihydrate
Buprenorphine Hydrochloride	Buprenorphine Hydrochloride with Naloxone Hydrochloride
Calcium Carbonate	Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate
Calcium Chloride	Sodium Chloride with Potassium Chloride and Calcium Chloride
	Sodium Lactate with Sodium Chloride, Potassium Chloride and Calcium Chloride
Candesartan Cilexetil	Candesartan Cilexetil with Hydrochlorothiazide
Carbidopa	Levodopa with Carbidopa
	Levodopa with Carbidopa and Entacapone
Carbomer 980	Hypromellose with Carbomer 980
Cefaclor Monohydrate	Cefaclor Monohydrate with Water - Purified BP
Cephalexin	Cephalexin with Water - Purified BP
Chlorhexidine Gluconate	Silver Sulfadiazine with Chlorhexidine Gluconate
Codeine Phosphate	Codeine Phosphate with Paracetamol
Colecalciferol	Alendronate Sodium with Colecalciferol
Dexamethasone Sodium Metasulfobenzoate	Dexamethasone Sodium Metasulfobenzoate with Framycetin Sulfate and Gramicidin
Dextran 70	Hypromellose 2900 with Dextran 70
	Hypromellose 4500 with Dextran 70
Diphenoxylate Hydrochloride	Diphenoxylate Hydrochloride with Atropine Sulfate
Dipyridamole	Dipyridamole with Aspirin
Dorzolamide Hydrochloride	Dorzolamide Hydrochloride with Timolol Maleate
Dydrogesterone	Oestradiol with Dydrogesterone
Eformoterol Fumarate Dihydrate	Budesonide with Eformoterol Fumarate Dihydrate
Emtricitabine	Tenofovir Disoproxil Fumarate with Emtricitabine
Enalapril Maleate	Enalapril Maleate with Hydrochlorothiazide
Entacapone	Levodopa with Carbidopa and Entacapone
Eprosartan Mesylate	Eprosartan Mesylate with Hydrochlorothiazide
Erythromycin Ethyl Succinate	Erythromycin Ethyl Succinate with Water - Purified BP
Ethinyloestradiol	Levonorgestrel with Ethinyloestradiol
	Norethisterone with Ethinyloestradiol
Ezetimibe	Ezetimibe with Simvastatin
Ferrous Fumarate	Ferrous Fumarate with Folic Acid
Flucloxacillin Magnesium	Flucloxacillin Magnesium with Water - Purified BP
Fluticasone Propionate	Fluticasone Propionate with Salmeterol Xinafoate
Folic Acid	Ferrous Fumarate with Folic Acid
Fosinopril Sodium	Fosinopril Sodium with Hydrochlorothiazide
Framycetin Sulfate	Dexamethasone Sodium Metasulfobenzoate with Framycetin Sulfate and Gramicidin
Frangula Bark	Sterculia with Frangula Bark
Glibenclamide	Metformin Hydrochloride with Glibenclamide

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Allowable compounds*
Glucose	Glucose with Sodium Chloride, Potassium Chloride and Sodium Acid Citrate
	Sodium Chloride with Glucose
Gramicidin	Dexamethasone Sodium Metasulfobenzoate with Framycetin Sulfate and Gramicidin
	Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin
Hydrochlorothiazide	Candesartan Cilexetil with Hydrochlorothiazide
	Enalapril Maleate with Hydrochlorothiazide
	Eprosartan Mesylate with Hydrochlorothiazide
	Fosinopril Sodium with Hydrochlorothiazide
	Hydrochlorothiazide with Amiloride Hydrochloride
	Hydrochlorothiazide with Triamterene
	Irbesartan with Hydrochlorothiazide
	Quinapril Hydrochloride with Hydrochlorothiazide
	Telmisartan with Hydrochlorothiazide
Hypromellose	Hypromellose with Carbomer 980
Hypromellose 2900	Hypromellose 2900 with Dextran 70
Hypromellose 4500	Hypromellose 4500 with Dextran 70
Indapamide Hemihydrate	Perindopril Arginine with Indapamide Hemihydrate
	Perindopril Erbumine with Indapamide Hemihydrate
Insulin Aspart	Insulin Aspart with Insulin Aspart Protamine Suspension
Insulin Aspart Protamine Suspension	Insulin Aspart with Insulin Aspart Protamine Suspension
Insulin - Isophane	Insulin - Neutral with Insulin - Isophane
Insulin Lispro	Insulin Lispro with Insulin Lispro Protamine Suspension
Insulin Lispro Protamine Suspension	Insulin Lispro with Insulin Lispro Protamine Suspension
Insulin - Neutral	Insulin - Neutral with Insulin - Isophane
Irbesartan	Irbesartan with Hydrochlorothiazide
Lamivudine	Abacavir Sulfate with Lamivudine
	Abacavir Sulfate with Lamivudine and Zidovudine
	Lamivudine with Zidovudine
Latanoprost	Latanoprost with Timolol Maleate
Levodopa	Levodopa with Benserazide Hydrochloride
	Levodopa with Carbidopa
	Levodopa with Carbidopa and Entacapone
Levonorgestrel	Levonorgestrel with Ethinyloestradiol
Lopinavir	Lopinavir with Ritonavir
Macrogol 3350	Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride
Magnesium Chloride	Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride
Magnesium Hydroxide	Aluminium Hydroxide - Dried with Magnesium Hydroxide
	Aluminium Hydroxide - Dried with Magnesium Trisilicate and Magnesium Hydroxide
Magnesium Trisilicate	Aluminium Hydroxide - Dried with Magnesium Trisilicate and Magnesium Hydroxide
Medroxyprogesterone Acetate	Oestrogens—Conjugated with Medroxyprogesterone Acetate
Mestranol	Norethisterone with Mestranol
Metformin Hydrochloride	Metformin Hydrochloride with Glibenclamide
	Rosiglitazone Maleate with Metformin Hydrochloride
Mycophenolate Mofetil	Mycophenolate Mofetil with Water - Purified BP
Naloxone Hydrochloride	Buprenorphine Hydrochloride with Naloxone Hydrochloride
Neomycin Sulfate	Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin
Neomycin Undecenoate	Neomycin Undecenoate with Bacitracin Zinc
Norethisterone	Norethisterone with Ethinyloestradiol
	Norethisterone with Mestranol
Norethisterone Acetate	Oestradiol Hemihydrate with Norethisterone Acetate
	Oestradiol with Norethisterone Acetate
Nystatin	Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin
Oestradiol	Oestradiol with Dydrogesterone
	Oestradiol with Norethisterone Acetate
Oestradiol Hemihydrate	Oestradiol Hemihydrate with Norethisterone Acetate
Oestrogens—Conjugated	Oestrogens—Conjugated with Medroxyprogesterone Acetate

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Allowable compounds*
Paracetamol	Codeine Phosphate with Paracetamol
Paraffin - Liquid	Paraffin - Soft White with Paraffin - Liquid
Paraffin - Soft White	Paraffin - Soft White with Paraffin - Liquid
Perindopril Arginine	Perindopril Arginine with Indapamide Hemihydrate
Perindopril Erbumine	Perindopril Erbumine with Indapamide Hemihydrate
Phenylephrine Hydrochloride	Prednisolone Acetate with Phenylephrine Hydrochloride
Polyethylene Glycol 400	Polyethylene Glycol 400 with Propylene Glycol
Potassium Bicarbonate	Potassium Chloride with Potassium Bicarbonate
Potassium Chloride	Glucose with Sodium Chloride, Potassium Chloride and Sodium Acid Citrate
	Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride
	Potassium Chloride with Potassium Bicarbonate
	Sodium Chloride with Potassium Chloride and Calcium Chloride
	Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride
	Sodium Lactate with Sodium Chloride, Potassium Chloride and Calcium Chloride
Potassium Clavulanate	Amoxycillin Trihydrate with Potassium Clavulanate
	Amoxycillin Trihydrate with Potassium Clavulanate and Water - Purified BP
	Ticarcillin Sodium with Potassium Clavulanate
Prednisolone Acetate	Prednisolone Acetate with Phenylephrine Hydrochloride
Propylene Glycol	Polyethylene Glycol 400 with Propylene Glycol
Quinapril Hydrochloride	Quinapril Hydrochloride with Hydrochlorothiazide
Ritonavir	Lopinavir with Ritonavir
Rosiglitazone Maleate	Rosiglitazone Maleate with Metformin Hydrochloride
Salmeterol Xinafoate	Fluticasone Propionate with Salmeterol Xinafoate
Silver Sulfadiazine	Silver Sulfadiazine with Chlorhexidine Gluconate
Simvastatin	Ezetimibe with Simvastatin
Sodium Acetate	Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride
Sodium Acid Citrate	Glucose with Sodium Chloride, Potassium Chloride and Sodium Acid Citrate
Sodium Alginate	Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate
Sodium Bicarbonate	Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride
	Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate
Sodium Chloride	Glucose with Sodium Chloride, Potassium Chloride and Sodium Acid Citrate
	Macrogol 3350 with Sodium Chloride, Sodium Bicarbonate and Potassium Chloride
	Sodium Chloride with Glucose
	Sodium Chloride with Potassium Chloride and Calcium Chloride
	Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride
	Sodium Lactate with Sodium Chloride, Potassium Chloride and Calcium Chloride
Sodium Citrate	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate
Sodium Gluconate	Sodium Chloride with Sodium Acetate, Sodium Gluconate, Potassium Chloride and Magnesium Chloride
Sodium Lactate	Sodium Lactate with Sodium Chloride, Potassium Chloride and Calcium Chloride
Sodium Lauryl Sulfoacetate	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate
Sorbitol	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate
Stavudine	Stavudine with Water - Purified BP
Sterculia	Sterculia with Frangula Bark
Sulfamethoxazole	Trimethoprim with Sulfamethoxazole
Telmisartan	Telmisartan with Hydrochlorothiazide
Tenofovir Disoproxil Fumarate	Tenofovir Disoproxil Fumarate with Emtricitabine
Testosterone Decanoate	Testosterone Propionate with Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate
Testosterone Isocaproate	Testosterone Propionate with Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate
	Testosterone Propionate with Testosterone Phenylpropionate and Testosterone Isocaproate

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Allowable compounds*
Testosterone Phenylpropionate	Testosterone Propionate with Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate
	Testosterone Propionate with Testosterone Phenylpropionate and Testosterone Isocaproate
Testosterone Propionate	Testosterone Propionate with Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate
	Testosterone Propionate with Testosterone Phenylpropionate and Testosterone Isocaproate
Ticarcillin Sodium	Ticarcillin Sodium with Potassium Clavulanate
Timolol Maleate	Brimonidine Tartrate with Timolol Maleate
	Dorzolamide Hydrochloride with Timolol Maleate
	Latanoprost with Timolol Maleate
	Travoprost with Timolol Maleate
Trandolapril	Trandolapril with Verapamil Hydrochloride
Travoprost	Travoprost with Timolol Maleate
Triamcinolone Acetonide	Triamcinolone Acetonide with Neomycin Sulfate, Gramicidin and Nystatin
Triamterene	Hydrochlorothiazide with Triamterene
Trimethoprim	Trimethoprim with Sulfamethoxazole
Verapamil Hydrochloride	Trandolapril with Verapamil Hydrochloride
Water - Purified BP	Amoxycillin Trihydrate with Potassium Clavulanate and Water - Purified BP
	Amoxycillin Trihydrate with Water - Purified BP
	Azithromycin Dihydrate with Water - Purified BP
	Cefaclor Monohydrate with Water - Purified BP
	Cephalexin with Water - Purified BP
	Erythromycin Ethyl Succinate with Water - Purified BP
	Flucloxacillin Magnesium with Water - Purified BP
	Mycophenolate Mofetil with Water - Purified BP
	Stavudine with Water - Purified BP
Zidovudine	Abacavir Sulfate with Lamivudine and Zidovudine
	Lamivudine with Zidovudine

SCHEDULE 4 – DRUGS OR MEDICINAL PREPARATIONS THAT MAY BE USED AS INGREDIENTS OF EXTEMPORANEOUSLY-PREPARED PHARMACEUTICAL BENEFITS

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Acacia BP, powdered	—
Acetic Acid (33 per cent) BP	—
Alum BP	—
Aluminium Acetate Solution BP	—
Aqueous Cream APF	For use only as a base combined with active ingredients
Ascorbic Acid BP	For use only as an ingredient of ferrous sulfate mixtures
Aspirin BP	—
Belladonna Tincture BP	—
Benzocaine BP	—
Benzoic Acid BP	—
Benzoin Tincture Compound BP	—
Boric Acid, Olive Oil and Zinc Oxide Ointment QHF	—
Calcium Hydroxide BP	—
Cetomacrogol Cream, Aqueous APF	For use only as a base combined with active ingredients
Cetrimide Cream, Aqueous APF	For use only as a base combined with active ingredients
Chlorhexidine Cream, Aqueous APF	For use only as a base combined with active ingredients
Citric Acid Monohydrate BP	—
Coal Tar BP	—
Coal Tar Solution BP	—
Cocaine Hydrochloride BP	—
Coconut Oil BP	—
Codeine Phosphate BP	May only be prescribed in linctuses, mixtures and mixtures for children
Collodion Flexible BP	—
Dithranol BP	—
Emulsifying Ointment BP	For use only as a base combined with active ingredients
Ephedrine Hydrochloride BP	May only be prescribed in nasal instillations
Ferrous Sulfate BP	—
Formaldehyde Solution BP	—
Gentian Alkaline Mixture APF	—
Glycerol BP	—
Iodine BP	—
Kaolin Mixture BPC 1968	—
Kaolin and Opium Mixture APF 14	—
Lactic Acid BP	—
Lavender Oil, Spike BPC 1968	—
Levomenthol BP	—
Liquorice Liquid Extract BP	—
Magnesium Carbonate, Light BP	—
Magnesium Sulfate BP	May only be prescribed for other than oral use
Magnesium Trisilicate BP	—
Menthol, Racemic BP	—
Methyl Hydroxybenzoate BP	—
Paraffin, Hard BP	—
Paraffin, Light Liquid BP	—
Paraffin, Liquid BP	May only be prescribed for other than oral use
Paraffin, Soft White BP	—
Paraffin, Soft Yellow BP	—
Phenobarbitone Sodium BP	May only be prescribed for the treatment of epilepsy
Phenol, Liquefied BP	Not available for ear drops
Podophyllum Resin BP	—
Potassium Citrate BP	—
Potassium Iodide BP	—
Potassium Permanganate BP	—
Propyl Hydroxybenzoate BP	—
Propylene Glycol BP	—

Column 1 *Name of pharmaceutical benefit*	*Column 2* *Circumstances (if any) specified for the purposes of section 88A of the Act*
Red Syrup APF 15	—
Resorcinol BP	—
Salicylic Acid BP	—
Simple Ointment (white) BP	For use only as a base combined with active ingredients
Simple Ointment (yellow) BP	For use only as a base combined with active ingredients
Sodium Bicarbonate BP	—
Sodium Chloride BP	—
Sodium Citrate BP	—
Starches BP	—
Sulfur, Precipitated BP 1980	—
Syrup BP	—
Talc, Purified BP, sterilised	—
Thymol BP	—
Thymol Mouth Wash, Compound APF 15	—
Tragacanth BP, powdered	—
Tragacanth Powder, Compound BP 1980	—
Trichloroacetic Acid BP 1980	—
Triethanolamine BP	—
Water For Injections, sterilised BP	May only be prescribed in eye drops and eye lotions
Water, Purified BP	—
Wool Alcohols Ointment (white) BP	For use only as a base combined with active ingredients
Wool Alcohols Ointment (yellow) BP	For use only as a base combined with active ingredients
Wool Fat BP	—
Wool Fat, Hydrous BP	—
Zinc Cream BP	For use only as a base combined with active ingredients
Zinc Oxide BP	—
Zinc Sulfate BP	—

Acetone BP
Anise Water, Concentrated BP
Boric Acid BP
Castor Oil BP
Chlorhexidine Acetate BP
Chloroform BP
Ethanol (96 per cent) BP
Ethanols, Dilute BP
Ether, Solvent BP
Eucalyptus Oil BP
Honey, Purified BP 1993
Industrial Methylated Spirit BP
Olive Oil BP
Peppermint Oil BP
Peppermint Water, Concentrated APF
Pholcodine Citrate Syrup BPC 1959
Sodium Thiosulfate BP

Abacavir Sulfate
Abacavir Sulfate with Lamivudine
Abacavir Sulfate with Lamivudine and Zidovudine
Adefovir Dipivoxil
Apomorphine Hydrochloride
Atazanavir Sulfate
Bosentan Monohydrate
Botulinum Toxin Type A Purified Neurotoxin Complex
Buprenorphine Hydrochloride
Buprenorphine Hydrochloride with Naloxone Hydrochloride
Charcoal - Activated
Choriogonadotropin Alfa
Cidofovir
Clostridium Botulinum Type A Toxin—Haemagglutinin Complex
Clozapine
Darbepoetin Alfa
Deferasirox
Deferiprone
Delavirdine Mesylate
Desferrioxamine Mesylate
Didanosine
Dornase Alfa
Efavirenz
Emtricitabine
Enfuvirtide
Entecavir Monohydrate
Epoetin Alfa
Epoetin Beta
Epoprostenol Sodium
Filgrastim
Fosamprenavir Calcium
Foscarnet Sodium
Ganciclovir
Ganciclovir Sodium
Iloprost Trometamol
Imatinib Mesylate
Indinavir Sulfate
Infliximab
Interferon Gamma-1b
Lamivudine
Lamivudine with Zidovudine
Lanreotide Acetate
Lenograstim
Lopinavir with Ritonavir
Nelfinavir Mesylate
Nevirapine
Octreotide Acetate
Pegfilgrastim
Peginterferon Alfa-2a
Peginterferon Alfa-2b
Progesterone
Ribavirin and Peginterferon Alfa-2a
Ribavirin and Peginterferon Alfa-2b
Rifabutin
Ritonavir
Saquinavir Mesylate
Sildenafil Citrate

Somatropin
Stavudine
Stavudine with Water - Purified BP
Tenofovir Disoproxil Fumarate
Tenofovir Disoproxil Fumarate with Emtricitabine
Thalidomide
Trastuzumab
Valganciclovir Hydrochloride
Zidovudine
Zoledronic Acid

Dated this 30 day of March. 2007.

STEPHEN DELLAR
Assistant Secretary
Pharmaceutical Evaluation Branch
Department of Health and Ageing
Delegate of the Minister for Health and Ageing