COMMONWEALTH OF AUSTRALIA

Instrument number PB 24 of 2008

Amendment determinations under sections 85, 85A and 88 of the National Health Act 1953

I, DIANA MACDONELL, Acting Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing, delegate of the Minister for Health and Ageing, make this instrument under sections 85, 85A and 88 of the *National Health Act 1953*.

Dated 1st February 2008

DIANA MACDONELL
Acting Assistant Secretary
Pharmaceutical Evaluation Branch
Department of Health and Ageing

Amendment determination — pharmaceutical benefits

1 Commencement

This instrument commences on 1 March 2008.

2 Amendment of PB 89 of 2007

Schedule 1 amends PB 89 of 2007.

Federal Register of Legislative Instruments F2008L00282

Schedule 1 Amendments

[1] Part 1 of Schedule 1, after item dealing with Amino acid formula with vitamins and minerals without methionine in the form Oral powder 500 g (XMET Maxamum)

insert in the columns in the order indicated:

	Oral liquid 130 mL, 30 (HCU Cooler)	Oral	4	5	HCU Cooler

[2] Part 1 of Schedule 1, after item dealing with Amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form Oral powder 500 g (Xphen, TYR Maxamum)

insert in the columns in the order indicated:

	Oral liquid 130 mL, 30 (TYR Cooler)	Oral	4	5	TYR Cooler

[3] Part 1 of Schedule 1, item dealing with Amoxycillin with Clavulanic Acid in the form Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

in the column headed "Brand" insert in alphabetical order:

GA-Amclav 500/125

[4] Part 1 of Schedule 1, item dealing with Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

in the column headed "Brand" insert in alphabetical order:

GA-Amclav Forte 875/125

[5] Part 1 of Schedule 1, item dealing with Calcium in the form Tablet 250 mg (as citrate)

omit from the column headed "Maximum quantity":

120

and substitute:

240

[6] Part 1 of Schedule 1, item dealing with Calcium in the form Tablet, chewable, 500 mg (as carbonate)

omit from the column headed "Maximum quantity":

120

and substitute:

240

[7] Part 1 of Schedule 1, item dealing with Citalopram in the form Tablet 20 mg (as hydrobromide)

in the column headed "Brand" insert in alphabetical order:

Citalobell

[8] Part 1 of Schedule 1, item dealing with Ipratropium

omit from the columns in the order indicated:

	Nebuliser solution containing ipratropium bromide 250 micrograms (anhydrous) per mL, 20 mL	Inhalation	2	2	Atrovent

[9] Part 1 of Schedule 1, after item dealing with Iron Sucrose

insert in the columns in the order indicated:

Isoleucine with carbohydrate	Sachets of oral powder 4 g containing 50 mg isoleucine, 30 (Isoleucine Amino Acid Supplement)	Oral	4	5	Isoleucine Amino Acid Supplement

[10] Part 1 of Schedule 1, item dealing with Mesalazine in the form Sachet containing granules, 1 g per sachet

omit from the column headed "Maximum number of repeats":

2

and substitute:

5

[11] Part 1 of Schedule 1, item dealing with Mirtazapine in the form Tablet 30 mg

omit from the column headed "Brand":

Remeron

[12] Part 1 of Schedule 1, item dealing with Oxaliplatin in the form Powder for I.V. infusion 50 mg

in the column headed "Brand" insert in alphabetical order:

Oxaliplan 50

[13] Part 1 of Schedule 1, item dealing with Oxaliplatin in the form Powder for I.V. infusion 100 mg

in the column headed "Brand" insert in alphabetical order:

Oxaliplan 100

[14] Part 1 of Schedule 1, item dealing with Pemetrexed

insert as first entry in the columns in the order indicated:

	Powder for I.V. infusion 100 mg (as disodium heptahydrate)	Injection	1	3	Alimta

[15] Part 1 of Schedule 1, item dealing with Ranibizumab

omit from the column headed "Maximum number of repeats":

..

and substitute:

2

[16] Part 1 of Schedule 1, item dealing with Trandolapril in the form Capsule 500 micrograms

in the column headed "Brand" insert in alphabetical order:

Dolapril 0.5

[17] Part 1 of Schedule 1, item dealing with Trandolapril in the form Capsule 1 mg

in the column headed "Brand" insert in alphabetical order:

Dolapril 1

[18] Part 1 of Schedule 1, item dealing with Trandolapril in the form Capsule 2 mg

in the column headed "Brand" insert in alphabetical order:

Dolapril 2

[19] Part 1 of Schedule 1, item dealing with Trandolapril in the form Capsule 4 mg

in the column headed "Brand" insert in alphabetical order:

Dolapril 4

[20] Part 1 of Schedule 1, after item dealing with Valaciclovir

insert in the columns in the order indicated:

Valine with carbohydrate	Sachets of oral powder 4 g containing 50 mg valine, 30 (Valine Amino Acid Supplement)	Oral	4	5	Valine Amino Acid Supplement

[21] Part 2 of Schedule 1, item dealing with Adalimumab in the *first* instance of the form Injection 40 mg in 0.8 mL pre-filled syringe

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with adalimumab 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with adalimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with adalimumab; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised adalimumab in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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

[22] Part 2 of Schedule 1, item dealing with Adalimumab in the *second* instance of the form Injection 40 mg in 0.8 mL pre-filled syringe

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (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 either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily 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 methotrexate or sulfasalazine or leflunomide, 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 11 (d) (i) or 11 (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 11 (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 11 (d) (i) or 11 (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

[23] Part 2 of Schedule 1, item dealing with Adalimumab in the *first* instance of the form Injection 40 mg in 0.8 mL pre-filled pen

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with adalimumab 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with adalimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with adalimumab; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised adalimumab in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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

[24] Part 2 of Schedule 1, item dealing with Adalimumab in the *second* instance of the form Injection 40 mg in 0.8 mL pre-filled pen

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (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 either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily 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 methotrexate or sulfasalazine or leflunomide, 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 11 (d) (i) or 11 (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 11 (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 11 (d) (i) or 11 (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

[25] Part 2 of Schedule 1, item dealing with Amino Acids – synthetic, formula in the *first* instance of the form Oral powder 400 g (Elecare)

No change

[26] Part 2 of Schedule 1, item dealing with Amino Acids – synthetic, formula in the *second* instance of the form Oral powder 400 g (Elecare)

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 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, soy protein and protein hydrolysate formulae in a child aged 2 years and 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

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated, and where the date of birth of the patient is included in the authority application

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist 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

[27] Part 2 of Schedule 1, item dealing with Amino Acids – synthetic, formula in the form Oral powder 400 g (Neocate)

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 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, soy protein and protein hydrolysate formulae in a child aged 2 years and 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

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated, and where the date of birth of the patient is included in the authority application

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist 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

[28] Part 2 of Schedule 1, item dealing with Amino Acids – synthetic, formula in the form Oral powder 400 g (Neocate Advance)

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 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, soy protein and protein hydrolysate formulae in a child aged 2 years and 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

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated, and where the date of birth of the patient is included in the authority application

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist 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

[29] Part 2 of Schedule 1, item dealing with Amino Acids – synthetic, formula in the form Oral powder 400 g (Neocate Advance Tropical Flavour)

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 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, soy protein and protein hydrolysate formulae in a child aged 2 years and 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

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated, and where the date of birth of the patient is included in the authority application

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist 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

[30] Part 2 of Schedule 1, item dealing with Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 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, soy protein and protein hydrolysate formulae in a child aged 2 years and 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

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated, and where the date of birth of the patient is included in the authority application

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist 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

[31] Part 2 of Schedule 1, item dealing with Anakinra in the form Injection 100 mg in 0.67 mL single use pre-filled syringe

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with anakinra 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with anakinra; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with anakinra; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid Arthritis 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 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised anakinra in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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

[32] Part 2 of Schedule 1, item dealing with Bupropion in the form Tablet containing bupropion hydrochloride 150 mg (sustained release)

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subparagraph 11 (d):
Completion of short-term, sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program

[33] Part 2 of Schedule 1, item dealing with Etanercept in the *first* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

No change

[34] Part 2 of Schedule 1, item dealing with Etanercept in the *second* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

No change

[35] Part 2 of Schedule 1, item dealing with Etanercept in the *third* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (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 either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily 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 methotrexate or sulfasalazine or leflunomide, 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 11 (d) (i) or 11 (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 11 (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 11 (d) (i) or 11 (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

[36] Part 2 of Schedule 1, item dealing with Etanercept in the *fourth* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

No Change

[37] Part 2 of Schedule 1, item dealing with Etanercept in the *fifth* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Initial treatment commencing 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 who:

(a) have severe active rheumatoid arthritis; and

(b) have not previously received PBS-subsidised treatment with a bDMARD for this condition, or, where the patient has previously received PBS-subsidised treatment with a bDMARD 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 bDMARD treatment for this condition was approved; and

(c) 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 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

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 (c) 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);

all tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

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 (c) 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 (c) 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 Rheumatoid 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 signed patient acknowledgment;

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 11 (d) (i) or 11 (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 11 (d) (i):

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

(a) have a documented history of severe active rheumatoid arthritis; and

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

(c) have not failed previous PBS-subsidised treatment with etanercept during this Treatment Cycle; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD Treatment Cycle with that therapy;

patients are eligible to receive further bDMARD therapy within this 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;

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 provided that:

(i) they have demonstrated an adequate response, as specified in the criteria for continuing PBS-subsidised treatment of rheumatoid arthritis, 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;

patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with etanercept are not eligible to commence treatment with etanercept until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion;

the authority application includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and, in the case of patients recommencing therapy with etanercept in this Treatment Cycle, evidence of the patient's response to their most recent course of PBS-subsidised etanercept therapy;

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 11 (d) (i) or 11 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with etanercept 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 a documented history of severe active rheumatoid arthritis, 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 11 (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 11 (d) (i) or 11 (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

[38] Part 2 of Schedule 1, item dealing with Etanercept in the *sixth* instance of the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with etanercept 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with etanercept; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised etanercept in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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 11 (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

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

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

[39] Part 2 of Schedule 1, item dealing with Etanercept in the *first* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

No change

[40] Part 2 of Schedule 1, item dealing with Etanercept in the *second* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

No change

[41] Part 2 of Schedule 1, item dealing with Etanercept in the *third* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (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 either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily 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 methotrexate or sulfasalazine or leflunomide, 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 11 (d) (i) or 11 (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 11 (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 11 (d) (i) or 11 (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

[42] Part 2 of Schedule 1, item dealing with Etanercept in the *fourth* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

No change

[43] Part 2 of Schedule 1, item dealing with Etanercept in the *fifth* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Initial treatment commencing 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 who:

(a) have severe active rheumatoid arthritis; and

(b) have not previously received PBS-subsidised treatment with a bDMARD for this condition, or, where the patient has previously received PBS-subsidised treatment with a bDMARD 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 bDMARD treatment for this condition was approved; and

(c) 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 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

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 (c) 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);

all tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

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 (c) 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 (c) 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 Rheumatoid 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 signed patient acknowledgment;

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 11 (d) (i) or 11 (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 11 (d) (i):

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

(a) have a documented history of severe active rheumatoid arthritis; and

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

(c) have not failed previous PBS-subsidised treatment with etanercept during this Treatment Cycle; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD Treatment Cycle with that therapy;

patients are eligible to receive further bDMARD therapy within this 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;

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 provided that:

(i) they have demonstrated an adequate response, as specified in the criteria for continuing PBS-subsidised treatment of rheumatoid arthritis, 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;

patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with etanercept are not eligible to commence treatment with etanercept until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion;

the authority application includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and, in the case of patients recommencing therapy with etanercept in this Treatment Cycle, evidence of the patient's response to their most recent course of PBS-subsidised etanercept therapy;

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 11 (d) (i) or 11 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with etanercept 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 a documented history of severe active rheumatoid arthritis, 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 11 (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 11 (d) (i) or 11 (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

[44] Part 2 of Schedule 1, item dealing with Etanercept in the *sixth* instance of the form Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with etanercept 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with etanercept; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised etanercept in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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 11 (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

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

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

[45] Part 2 of Schedule 1, item dealing with Etanercept in the *first* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

No change

[46] Part 2 of Schedule 1, item dealing with Etanercept in the *second* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

No change

[47] Part 2 of Schedule 1, item dealing with Etanercept in the *third* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (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 either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily 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 methotrexate or sulfasalazine or leflunomide, 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 11 (d) (i) or 11 (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 11 (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 11 (d) (i) or 11 (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

[48] Part 2 of Schedule 1, item dealing with Etanercept in the *fourth* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

No change

[49] Part 2 of Schedule 1, item dealing with Etanercept in the *fifth* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Initial treatment commencing 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 who:

(a) have severe active rheumatoid arthritis; and

(b) have not previously received PBS-subsidised treatment with a bDMARD for this condition, or, where the patient has previously received PBS-subsidised treatment with a bDMARD 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 bDMARD treatment for this condition was approved; and

(c) 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 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

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 (c) 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);

all tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

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 (c) 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 (c) 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 Rheumatoid 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 signed patient acknowledgment;

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 11 (d) (i) or 11 (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 11 (d) (i):

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

(a) have a documented history of severe active rheumatoid arthritis; and

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

(c) have not failed previous PBS-subsidised treatment with etanercept during this Treatment Cycle; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD Treatment Cycle with that therapy;

patients are eligible to receive further bDMARD therapy within this 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;

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 provided that:

(i) they have demonstrated an adequate response, as specified in the criteria for continuing PBS-subsidised treatment of rheumatoid arthritis, 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;

patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with etanercept are not eligible to commence treatment with etanercept until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion;

the authority application includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and, in the case of patients recommencing therapy with etanercept in this Treatment Cycle, evidence of the patient's response to their most recent course of PBS-subsidised etanercept therapy;

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 11 (d) (i) or 11 (d) (ii):

Continuation of initial treatment, or of a course which recommences treatment, with etanercept 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 a documented history of severe active rheumatoid arthritis, 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 11 (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 11 (d) (i) or 11 (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

[50] Part 2 of Schedule 1, item dealing with Etanercept in the *sixth* instance of the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit all text from the column headed "Purposes" and substitute:

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

Continuing treatment with etanercept 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:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this bDMARD Treatment Cycle was with etanercept; and

where bDMARD means abatacept, adalimumab, anakinra, etanercept, infliximab or rituximab; 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 March 2008 are deemed to have commenced their first bDMARD treatment cycle with that therapy;

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;

a patient 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 treatment course, the assessment of response is made following a minimum of 12 weeks of treatment;

the authority application includes a completed copy of the appropriate Rheumatoid 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;

the patient has not failed to demonstrate response to a course of PBS-subsidised etanercept in this Treatment Cycle;

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 11 (d) (i) or 11 (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 a documented history of severe active rheumatoid arthritis, 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 11 (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

In compliance with authority procedures set out in subsubparagraph 11 (d) (i):

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

[51] Part 2 of Schedule 1, omit item dealing with Ranibizumab

[52] Part 1 of Schedule 3, item dealing with Amoxycillin with Clavulanic Acid in the form Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

in the column headed "Brand" insert in alphabetical order:

GA-Amclav 500/125

[53] Part 1 of Schedule 3, item dealing with Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

in the column headed "Brand" insert in alphabetical order:

GA-Amclav Forte 875/125