PB 46 of 2011

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2011 (No. 6)

National Health Act 1953

I, FELICITY MCNEILL, Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing, delegate of the Minister for Health and Ageing, make this Amendment Instrument under subsections 100(1) and 100(2) of the *National Health Act 1953*.

Dated 16 June 2011

FELICITY MCNEILL
Acting First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health and Ageing

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1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2011 (No.6).*

(2) This Instrument may also be cited as PB 46 of 2011.

2 Commencement

This Instrument commences on 1 July 2011.

3 Amendments to PB 116 of 2010

Schedule 1 amends the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* (PB 116 of 2010)

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Schedule 1 Amendments

[1] Section 4, definition of *CAR drug*

omit:

(k) rituximab;
(l) romiplostin;
(m) sildenafil; and
(n) tocilizumab

and substitute:

(k) omalizumab;
(l) rituximab;
(m) romiplostin;
(n) sildenafil; and
(o) tocilizumab

[2] Section 24, after paragraph 24(2)(n)

insert:

(o) for HSD pharmaceutical benefits that have the drug omalizumab, for initial treatment of uncontrolled severe allergic asthma – a quantity of units that are sufficient to provide for 28 weeks treatment;
(p) for HSD pharmaceutical benefits that have the drug omalizumab, for initial PBS-subsidised treatment of uncontrolled severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients) – a quantity of units that are sufficient to provide for 24 weeks treatment;
(q) for HSD pharmaceutical benefits that have the drug omalizumab, for continuing treatment – a quantity of units that are sufficient to provide for 24 weeks treatment.

[3] Section 25, after paragraph 25(2)(s)

insert:

(t) for omalizumab – where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the authority application – sufficient repeat supplies to complete 24 weeks of treatment.

(u) for omalizumab – where at least 24 weeks treatment was requested at the time of the application – 0 repeat supplies.

[4] Schedule 1, entry for Interferon Alfa-2b

omit from the column headed Responsible person (all instances):

SH

and substitute (all instances):

MK

[5] Schedule 1, after entry for Octreotide

insert:

Omalizumab	Powder for injection 150 mg with diluent	Injection	Xolair	NV	EMP	C3740 C3741 C3742		See Note 1	See Note 2	D

[6] Schedule 1, entry for Peginterferon Alfa-2b

omit from the column headed Responsible person (all instances):

SH

and substitute (all instances):

MK

[7] Schedule 1, entry for Ribavirin and Peginterferon Alfa-2b

omit from the column headed Responsible person (all instances):

SH

and substitute (all instances):

MK

[8] Schedule 1, entry for Valaciclovir

substitute:

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APO-Valaciclovir	TX	EMP	C1494 C3419		500	2	C
			Valaciclovir RBX	RA	EMP	C1494 C3419		500	2	C
			Valtrex	GK	EMP	C1494 C3419		500	2	C
			Valvala	NV	EMP	C1494 C3419		500	2	C
			Zelitrex	GM	EMP	C1494 C3419		500	2	C

[9] Schedule 2, after:

GK	GlaxoSmithKline Australia Pty Ltd	47 100 162 481

insert:

GM	Aspen Pharma Pty Ltd	88 004 118 594

[10] Schedule 2, after:

PF	Pfizer Australia Pty Ltd	50 008 422 348

omit:

RE	GlaxoSmithKline Australia Pty Ltd	47 100 162 481

and substitute:

RA	Ranbaxy Australia Pty Ltd	17 110 871 826

[11] Schedule 3, after entry for Octreotide

insert:

Omalizumab	C3740		Where the patient is receiving treatment at/from a private or public hospital Initial treatment of uncontrolled severe allergic asthma Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria: (a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and (b) duration of asthma of at least 1 year; and (c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and (d) past or current evidence of atopy, documented by skin prick testing or radioallergosorbent test (RAST); and (e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and (f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented. Optimised asthma therapy includes: (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms twice a day or eformoterol 12 micrograms twice a day) for at least 12 months, unless contraindicated or not tolerated, AND (ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant Therapeutic Goods Administration (TGA)-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-	Compliance with modified Authority Required procedures

			commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used. The IgE pathology report must be provided with the authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (5 item version) (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and (iii) the signed patient acknowledgement; and (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the written application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Medicare Australia CEO within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response	

			assessment is not undertaken and submitted to the Medicare Australia CEO within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma is not eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased	
	C3741		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who: (a) has a documented history of severe allergic asthma; and (b) has demonstrated or sustained an adequate response to treatment with omalizumab. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (5 item version) (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Medicare Australia CEO within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to the Medicare Australia CEO within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.	Compliance with modified Authority Required procedures

			At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline serum human immunoglobulin E (IgE) level and body weight of the patient (refer to the Therapeutic Goods Administration-approved Product Information), sufficient for 24 weeks of therapy. Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the written application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma is not eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased	
	C3742		Where the patient is receiving treatment at/from a private or public hospital Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria: (a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and (b) duration of asthma of at least 1 year; and (c) past or current evidence of atopy, documented by skin prick testing or radioallergosorbent test (RAST); and (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes: (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms twice a day or eformoterol 12 micrograms twice a day) for at least 12 months, and (ii) may have included maintenance dose oral corticosteroids; and (f) has demonstrated an adequate response to treatment with omalizumab.	Compliance with modified Authority Required procedures

			A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include: (i) a reduction in Asthma Control Questionnaire (5 item version) (ACQ-5) score of at least 0.5; (ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ); (iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or (iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant Therapeutic Goods Administration (TGA)-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and (iii) the signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline serum human immunoglobulin E (IgE) level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the written application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks. An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Medicare Australia CEO within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response	

			assessment is not undertaken and submitted to the Medicare Australia CEO within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma is not eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased	

Note

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