PB 43 of 2015

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2015 (No. 5)

National Health Act 1953

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

Dated 24 April 2015

TONY WYND
Acting Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health

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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 2015 (No.5).*

(2) This Instrument may also be cited as PB 43 of 2015.

2 Commencement

This Instrument commences on 1 May 2015.

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).

Schedule 1 Amendments

[1] Schedule 1, entry for Omalizumab in each of the forms Injection 75 mg in 0.5 mL single dose pre-filled syringe, Injection 150 mg in 1 mL single dose pre-filled syringe

(a) *omit from the column headed "Circumstances":* **C3740 C3742 C3822**

(b) *insert in numerical order in the column headed "Circumstances":* **C4875 C4879 C4880 C4886**

(c) *omit from the column headed "Purposes":* **P3740 P3742 P3822**

(d) *insert in numerical order in the column headed "Purposes":* **P4875 P4879 P4880 P4886**

Schedule 3 Amendments

[2] Schedule 3, entry for Omalizumab

substitute:

Omalizumab	C4875	P4875	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.	Compliance with modified Authority Required procedures
	C4879	P4879	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Initial treatment - balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.	Compliance with modified Authority Required procedures
	C4880	P4880	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Continuing treatment Patient must have a documented history of severe allergic asthma, AND Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (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. 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 18 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 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 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 will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. 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 IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. 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.	Compliance with modified Authority Required procedures

	C4886	P4886	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Initial treatment Patient must be under the care of the same physician for at least 12 months, AND Patient must have 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 the following standard clinical features: (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 Patient must have a duration of asthma of at least 1 year, AND Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months, AND Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL, AND Patient must have 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 Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 12 years or older. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. 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 bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant 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. 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 (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy 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 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 22 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 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	Compliance with modified Authority Required procedures

			a response assessment is not undertaken and submitted 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 will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. 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. 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 in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the signed patient acknowledgement; and (c) the IgE pathology report; and (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.	