PB 109 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 29 September 2025

REBECCA RICHARDSON
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

Contents

1. Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 109 of 2025.

2. Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 October 2025	1 October 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3. Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)

[1] Part 1, Division 1, Section 6 (definition of *medication for the treatment of hepatitis B)*

repeal the definition, substitute:

medication for the treatment of hepatitis B means any of the following:

(a) entecavir;

(b) lamivudine;

(c) tenofovir.

[2] Schedule 1, entry for Abacavir with Lamivudine

omit:

			Kivexa	C4527 C4528	60	5

[3] Schedule 1, omit entry for Adefovir

[4] Schedule 1, entry for Etanercept

substitute:

Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2
			Erelzi	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2
			Nepexto	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2
			Erelzi	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2
	Injection set containing 4 vials powder for injection 25 mg and	Injection	Enbrel	C9417 C14068 C14071 C14154 C14155 C17280	See Schedule 2	See Schedule 2

	4 pre-filled syringes solvent 1 mL					

[5] Schedule 1, entry for Lamivudine in the form Tablet 150 mg

omit:

		Lamivudine Alphapharm	C4454 C4512	120	5

[6] Schedule 1, entry for Nevirapine

omit:

Tablet 400 mg (extended release)	Oral	Viramune XR	C4454 C4526	60	5

[7] Schedule 1, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled syringe *[Brand: Omlyclo]*

(a) omit from the column headed "Circumstances": C17049

(b) insert in numerical order in the column headed "Circumstances": C17284

[8] Schedule 1, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled syringe *[Brand: Xolair]*

(a) omit from the column headed "Circumstances": C17049

(b) insert in numerical order in the column headed "Circumstances": C17284

[9] Schedule 1, entry for Omalizumab in the form Injection 150 mg in 1 mL single dose pre-filled syringe

(a) omit from the column headed "Circumstances": C17049

(b) insert in numerical order in the column headed "Circumstances": C17284

[10] Schedule 2, entry for Etanercept *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 3]*

(a) omit from the column headed "Circumstances": C14070

(b) insert in numerical order in the column headed "Circumstances": C17280

[11] Schedule 2, entry for Omalizumab *[Maximum quantity: Sufficient for 4 weeks of treatment; Maximum repeats: 6]*

(a) omit from the column headed "Circumstances": C17049

(b) insert in numerical order in the column headed "Circumstances": C17284

[12] Schedule 3, omit entry for Adefovir

[13] Schedule 3, entry for Etanercept

(a) omit:

C14070	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/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). The assessment of response to prior treatment must be documented in the patient's medical records.	Compliance with Authority Required procedures

	The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

(b) insert in numerical order after existing text:

C17280	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.	Compliance with Authority Required procedures

	Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/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). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

[14] Schedule 3, entry for Nevirapine

omit:

	C4526	HIV infection Initial Patient must have been stabilised on nevirapine immediate release; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4526

[15] Schedule 3, entry for Omalizumab

(a) omit:

	C17049	Uncontrolled severe allergic asthma Initial treatment - Initial 2 (Change of treatment) Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction. Patient must be aged 6 to less than 12 years. The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be under the care of the same physician for at least 6 months. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first	Compliance with Written Authority Required procedures

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	continuing therapy to be processed. This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine. A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. 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 of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE 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: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (a) the IgE result and date; and (b) Asthma Control Questionnaire (ACQ-5) score; or (c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. (d) the details of prior biological medicine treatment including the details of date and duration of treatment; and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	

(b) insert in numerical order after existing text:

C17284	Uncontrolled severe allergic asthma Initial treatment - Initial 2 (Change of treatment) Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma; AND	Compliance with Written Authority Required procedures

	Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 6 to less than 12 years. The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be under the care of the same physician for at least 6 months. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine. A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for

	recommencement of treatment with a biological medicine under the new treatment cycle. 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 of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE 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: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (a) the IgE result and date; and (b) Asthma Control Questionnaire (ACQ-5) score; or (c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. (d) the details of prior biological medicine treatment including the details of date and duration of treatment; and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).