



PB 28 of 2025

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

National Health Act 1953

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

Dated 27 March 2025

REBECCA RICHARDSON

Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2025*.
- (2) This instrument may also be cited as PB 28 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. <i>The whole of this instrument</i>	<i>1 April 2025</i>	<i>1 April 2025</i>

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Schedule 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Humira]

insert:

	Hyrimoz	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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[2] Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; and Capsule 10 mg

omit:

	Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362	See Schedule 2	See Schedule 2
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[3] Schedule 1, entry for Lenalidomide in the form Capsule 15 mg

omit:

	Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362	See Schedule 2	See Schedule 2
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[4] Schedule 1, entry for Lenalidomide in the form Capsule 25 mg

omit:

	Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812	See Schedule 2	See Schedule 2
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C13813 C14362

[5] Schedule 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

	Mycophenolate APOTEX	C5554 C5795 C9691 C9693	300	5
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[6] Schedule 1, entry for Ravulizumab in each of the forms: Solution concentrate for I.V. infusion 300 mg in 3 mL; and Solution concentrate for I.V. infusion 1,100 mg in 11 mL

insert in numerical order in the column headed "Circumstances": C16368 C16398 C16400

[7] Schedule 1, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg

omit:

	Tenofovir/Emtricitabine 300/200 APOTEX	C6985 C6986	60	5
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[8] Schedule 2, entry for Ravulizumab [Maximum quantity: 1 dose; Maximum repeats: 0]

insert in numerical order in the column headed "Circumstances": C16400

[9] Schedule 2, entry for Ravulizumab [Maximum quantity: 1 dose; Maximum repeats: 2]

insert in numerical order in the column headed "Circumstances": C16368 C16398

[10] Schedule 3, entry for Ravulizumab

insert in numerical order after existing text:

	C16368		Neuromyelitis optica spectrum disorder (NMOSD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7; AND Patient must not have experienced a relapse while receiving treatment with this drug for this condition; AND	Compliance with Authority Required procedures
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			<p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Must be treated by a neurologist; OR</p> <p>Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.</p> <p>Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.</p> <p>An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
	C16398		<p>Neuromyelitis optica spectrum disorder (NMOSD)</p> <p>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025; AND</p> <p>Patient must have a confirmed diagnosis of NMOSD with AQP4-IgG prior to commencing treatment with this drug; AND</p> <p>Patient must have a recorded baseline Expanded Disability Status Scale (EDSS) score of no higher than 7 prior to commencing treatment with this drug; AND</p> <p>Patient must have had at least one relapse in the 12 months prior to commencing treatment with this drug for this condition; AND</p> <p>Patient must have received treatment with rituximab immediately prior to the most recent relapse prior to initiation of ravulizumab; OR</p> <p>Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR</p> <p>Patient must have a documented contraindication to rituximab therapy; AND</p> <p>Patient must have a current Expanded Disability Status Scale (EDSS) score of no higher than 7; AND</p> <p>Patient must not have experienced a relapse while receiving treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a neurologist; OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.</p> <p>Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.</p> <p>An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) details of the proposed authority prescription; and</p> <p>(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) which includes:</p> <p>(i) the patient's baseline Expanded Disability Status Scale (EDSS) score before commencement with this drug for this condition; and</p> <p>(ii) the patient's current Expanded Disability Status Scale (EDSS) score; and</p> <p>(iii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
	C16400	<p>Neuromyelitis optica spectrum disorder (NMOSD)</p> <p>Initial treatment - loading dose</p> <p>Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG); AND</p> <p>Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7; AND</p> <p>Patient must have had at least one relapse in the last 12 months; AND</p> <p>Patient must have experienced the most recent relapse while receiving treatment with rituximab; OR</p> <p>Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR</p> <p>Patient must have a documented contraindication to rituximab therapy; AND</p> <p>Patient must not receive more than 2 weeks of treatment under this restriction.</p> <p>Must be treated by a neurologist; OR</p> <p>Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.</p>	Compliance with Written Authority Required procedures

			<p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).</p> <p>An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.</p> <p>Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) details of the proposed authority prescription; and</p> <p>(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) which includes:</p> <p>(i) the patient's Expanded Disability Status Scale (EDSS) score; and</p> <p>(ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
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