PB 77 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July 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, 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 26 June 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 (July Update) Instrument 2025.*

(2) This instrument may also be cited as PB 77 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 July 2025	1 July 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Schedule 1, entry for Anifrolumab

omit from the column headed "Circumstances": **C15426**

[2] Schedule 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)

omit:

	Bosentan Mylan	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632	See Schedule 2	See Schedule 2

[3] Schedule 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor in each of the forms: Pack containing 28 sachets containing granules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg; and Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg

omit from the column headed "Circumstances": **C15482 C15511** *substitute:* **C16706 C16734**

[4] Schedule 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor in the form Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg

omit from the column headed "Circumstances": **C13932 C13991** *substitute:* **C16703 C16704**

[5] Schedule 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor in the form Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg

omit from the column headed "Circumstances": **C13962 C13980** *substitute:* **C16799 C16800**

[6] Schedule 1, after entry for Etanercept in the form Injection 50 mg in 1 mL single use-auto injector, 4 *[Brand: Enbrel]*

insert:

	Nepexto	C9417 C14068 C14070 C14071	See Schedule 2	See Schedule 2

				C14154 C14155		

[7] Schedule 1, after entry for Maraviroc in the form Tablet 300 mg *[Brand: Maraviroc Waymade]*

insert:

Maribavir	Tablet 200 mg	Oral	Livtencity	C16735 C16806	112	1

[8] Schedule 1, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg

omit:

			Sevelamer Apotex	C5530 C9762	360	5

[9] Schedule 2, entry for Anifrolumab

omit from the column headed "Circumstances": **C15426**

[10] Schedule 2, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor

omit from the column headed "Circumstances": **C13932 C13962 C13980 C13991 C15482 C15511** *substitute:* **C16703 C16704 C16706 C16734 C16799 C16800**

[11] Schedule 3, entry for Anifrolumab

omit:

	C15426		Systemic lupus erythematosus Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2024; AND Patient must have had a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019 prior to commencing therapy with this drug for this condition; AND Patient must have had persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points prior to commencing therapy with this drug for this condition; AND Patient must have been receiving hydroxychloroquine for at least 12 weeks prior to commencing therapy with this drug for this condition; AND Patient must have been receiving immunosuppressant medication for at least 12 weeks with either (i) minimum dose of methotrexate 20 mg per week (ii) azathioprine 100 mg per day	Compliance with Written Authority Required procedures

			(iii)mycophenolate 1,000 mg per day, prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal; AND Patient must have been receiving prednisolone or equivalent of at least 7.5 mg per day for at least 4 weeks prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal; AND Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus. Must be treated by a specialist physician experienced in the management of this condition. If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day. Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above. If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application. The authority application must be made in writing via HPOS form upload or mail and must include: (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE; (b) details (date and score) of the completed SLEDAI-2K score sheet; (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use); (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose). All the reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) 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). For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	

[12] Schedule 3, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor

substitute:

Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	C16703		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be aged between 2 and 11 years inclusive. For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and (2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	Compliance with Written Authority Required procedures
	C16704		Cystic fibrosis	Compliance with Written

			Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged between 2 and 11 years inclusive. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	Authority Required procedures
	C16706		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be 2 to 5 years of age. For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.	Compliance with Written Authority Required procedures

			This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and (2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	
	C16734		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 2 to 5 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	Compliance with Written Authority Required procedures
	C16799		Cystic fibrosis	Compliance with Written Authority Required

			Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be at least 6 years of age. For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and (2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	procedures
	C16800		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with	Compliance with Written Authority Required procedures

			expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be at least 6 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) 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).	

[13] Schedule 3, entry for Eltrombopag

omit:

	C15482		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be 2 to 5 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) details of the proposed prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and	Compliance with Written Authority Required procedures

			(3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.	
	C15511		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 2 to 5 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) details of the proposed prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.	Compliance with Written Authority Required procedures

[14] Schedule 3, after entry for Maraviroc

insert:

Maribavir	C16735		Cytomegalovirus infection and disease Patient must have received a hematopoietic stem-cell transplant; OR Patient must have received a solid-organ transplant; AND Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; OR Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; AND The treatment must be used as monotherapy for this condition under this restriction; AND Patient must not have previously demonstrated resistance to this drug; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16735

			Patient must not have cytomegalovirus disease that involves the central nervous system; AND Patient must not have cytomegalovirus retinitis. For the purpose of administering this restriction: (i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level. (ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet. (iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.	
	C16806		Cytomegalovirus infection and disease Patient must have received a hematopoietic stem-cell transplant; OR Patient must have received a solid-organ transplant; AND Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; OR Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; AND The treatment must be used as monotherapy for this condition under this restriction; AND Patient must not have previously demonstrated resistance to this drug; AND Patient must not have cytomegalovirus disease that involves the central nervous system; AND Patient must not have cytomegalovirus retinitis. For the purpose of administering this restriction: (i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level. (ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet. (iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.	Compliance with Authority Required procedures - Streamlined Authority Code 16806