PB 116 of 2026

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2026

National Health Act 1953

I, MIKE POPE, 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 30 September 2026

MIKE POPE
Assistant Secretary
PBS Listing, Pricing and 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 (October Update) Instrument 2026*.

(2) This Instrument may also be cited as PB 116 of 2026.

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 2026	1 October 2026

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

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

[1] Schedule 1, entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Yuflyma	C12120 C17707 C17713 C17717 C17719 C17733 C17734	See Schedule 2	See Schedule 2

[2] Schedule 1, entry for Dupilumab in each of the forms: Injection 200 mg in 1.14 mL single dose pre-filled pen; Injection 200 mg in 1.14 mL single dose pre-filled syringe; Injection 300 mg in 2 mL single dose pre-filled pen; and Injection 300 mg in 2 mL single dose pre-filled syringe

(a) omit from the column headed "Circumstances": C17073 C17113

(b) insert in numerical order in the column headed "Circumstances": C19236

[3] Schedule 1, entry for Eculizumab

(a) omit from the column headed "Circumstances": C14753 C14754 C14781

(b) omit from the column headed "Circumstances": C14793 C14799 C14805

(c) insert in numerical order in the column headed "Circumstances": C19249 C19258 C19263 C19270 C19273 C19274

[4] Schedule 1, entry for Edaravone *[Maximum quantity: 20; Maximum repeats: 2]*

(a) omit from the column headed "Circumstances": C16479 C18480 *substitute:* C19252 C19267

(b) omit from the column headed "Purposes": P16479 *substitute:* P19267

[5] Schedule 1, entry for Edaravone *[Maximum quantity: 28; Maximum repeats: 0]*

(a) omit from the column headed "Circumstances": C16479 C18480 *substitute:* C19252 C19267

(b) omit from the column headed "Purposes": P18480 *substitute:* P19252

[6] Schedule 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit:

		Nepexto	C12120 C17706 C17707	See Schedule 2	See Schedule 2

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		C17713 C17724 C17725		

[7] Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; and Capsule 10 mg

omit:

	Lenalidomide Dr.Reddy's	C13782 C13787 C13804 C13805 C13811 C13813 C14362 C17414 C18932 C19062 C19065 C19066 C19067 C19076 C19079 C19119	See Schedule 2	See Schedule 2

[8] Schedule 1, entry for Lenalidomide in the form Capsule 15 mg

omit:

	Lenalidomide Dr.Reddy's	C13782 C13787 C13804 C13805 C13811 C13813 C14362 C17414 C18932 C19062 C19067 C19076 C19079 C19119	See Schedule 2	See Schedule 2

[9] Schedule 1, entry for Lenalidomide in the form Capsule 25 mg

omit:

	Lenalidomide Dr.Reddy's	C13782 C13787 C13805 C13811 C13813 C14362 C17414 C19062 C19067 C19079 C19119	See Schedule 2	See Schedule 2

[10] Schedule 1, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled pen

insert as first entry:

	Omlyclo	C15376 C19080 C19083 C19135 C19161 C19214	See Schedule 2	See Schedule 2

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

insert as first entry:

	Omlyclo	C7046 C15376 C16905	See Schedule 2	See Schedule 2

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		C16906 C16960 C19080 C19083 C19135 C19161 C19214		

[12] Schedule 1, entry for Pomalidomide in each of the forms: Capsule 1 mg; Capsule 2 mg; Capsule 3 mg; and Capsule 4 mg

(a) omit from the column headed "Circumstances" (all instances): C13746

(b) insert in numerical order in the column headed "Circumstances" (all instances): C19229

[13] 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

(a) omit from the column headed "Circumstances": C18351

(b) insert in numerical order in the column headed "Circumstances": C19240

[14] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL

(a) omit from the column headed "Circumstances": C9380

(b) omit from the column headed "Circumstances": C18279

(c) insert in numerical order in the column headed "Circumstances": C18945 C18946 C18947

(d) insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Avtozma	C9386 C10570 C12120 C14085 C14091 C14093 C14148 C14179 C14485 C14488 C14507 C14621 C17707 C17712 C17713 C17714 C17729 C18172 C18174 C18177 C18180 C18275 C18276 C18280 C18282 C18346 C18348 C18933 C18934 C18936 C18938 C18939 C18941 C18945 C18946 C18947 C18978 C18980 C19000 C19024 C19046	See Schedule 2	See Schedule 2

[15] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL

(a) omit from the column headed "Circumstances": C9380

(b) omit from the column headed "Circumstances": C18279

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(c) *insert in numerical order in the column headed "Circumstances":* C18945 C18946 C18947

(d) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

	Avtozma	C9386 C10570 C12120 C14085 C14091 C14093 C14148 C14179 C14485 C14488 C14507 C14621 C17707 C17712 C17713 C17714 C17729 C18172 C18174 C18177 C18180 C18275 C18276 C18280 C18282 C18346 C18348 C18933 C18934 C18936 C18938 C18939 C18941 C18945 C18946 C18947 C18978 C18980 C19000 C19024 C19046	See Schedule 2	See Schedule 2

[16] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL

(a) *omit from the column headed "Circumstances":* C9380

(b) *omit from the column headed "Circumstances":* C18279

(c) *insert in numerical order in the column headed "Circumstances":* C18945 C18946 C18947

(d) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

	Avtozma	C9386 C10570 C12120 C14085 C14091 C14093 C14148 C14179 C14485 C14488 C14507 C14621 C17707 C17712 C17713 C17714 C17729 C18172 C18174 C18177 C18180 C18275 C18276 C18280 C18282 C18346 C18348 C18933 C18934 C18936 C18938 C18939 C18941 C18945 C18946 C18947 C18978 C18980 C19000 C19024 C19046	See Schedule 2	See Schedule 2

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[17] Schedule 1, after entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL *[Brand: Avtozma]*

insert:

Tofersen	Solution for intrathecal injection 100 mg in 15 mL	Injection	Qalsody	C19231 C19237 C19243 C19253 C19261	P19261	1	2
				C19231 C19237 C19243 C19253 C19261	P19237 P19253	1	5
				C19231 C19237 C19243 C19253 C19261	P19231 P19243	1	6

[18] Schedule 2, entry for Dupilumab *[Maximum quantity: 1 pack; Maximum repeats: Sufficient for 24 weeks of treatment]*

omit from the column headed "Circumstances": C17113

[19] Schedule 2, entry for Dupilumab *[Maximum quantity: 1 pack; Maximum repeats: Sufficient for 32 weeks of treatment]*

(a) omit from the column headed "Circumstances": C17073

(b) insert in numerical order in the column headed "Circumstances": C19236

[20] Schedule 2, entry for Eculizumab *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 0]*

omit from the column headed "Circumstances": C14781 *substitute:* C19273

[21] Schedule 2, entry for Eculizumab *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 5]*

omit from the column headed "Circumstances": C14753 C14754 C14793 C14799 C14805 *substitute:* C19249 C19258 C19263 C19270 C19274

[22] Schedule 2, entry for Pomalidomide *[Maximum quantity: 1 pack (21 capsules); Maximum repeats: 0]*

(a) omit from the column headed "Circumstances": C13746

(b) insert in numerical order in the column headed "Circumstances": C19229

[23] Schedule 2, entry for Ravulizumab *[Maximum quantity: 1 dose; Maximum repeats: 0]*

(a) omit from the column headed "Circumstances": C18351

(b) insert in numerical order in the column headed "Circumstances": C19240

[24] Schedule 2, entry for Tocilizumab *[Maximum quantity: 1 infusion; Maximum repeats: 3]*

insert in numerical order in the column headed "Circumstances": C18933 C18934 C18936 C18980 C19000

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[25] Schedule 2, entry for Tocilizumab *[Maximum quantity: 1 infusion; Maximum repeats: 5]*

(a) omit from the column headed "Circumstances": C9380

(b) omit from the column headed "Circumstances": C18279

(c) insert in numerical order in the column headed "Circumstances": C18938 C18946 C18978 C19024 C19046

[26] Schedule 2, entry for Tocilizumab *[Maximum quantity: 2 infusions; Maximum repeats: 5]*

insert in numerical order in the column headed "Circumstances": C18939 C18941 C18945 C18947

[27] Schedule 3, entry for Abatacept

omit entry for Circumstances Code "C18272" and substitute:

C18272	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.	Compliance with Written Authority Required procedures

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	An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-

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	subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[28] Schedule 3, entry for Dupilumab

(a) omit entry for Circumstances Code "C17073"

(b) omit entry for Circumstances Code "C17113"

(c) insert in numerical order after existing text:

C19236	Uncontrolled severe asthma Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment - Balance of Supply in a patient aged 6 to 12 years Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; OR The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing restriction. 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.	Compliance with Authority Required procedures

[29] Schedule 3, entry for Eculizumab

(a) omit entry for Circumstances Code "C14753"

(b) omit entry for Circumstances Code "C14754"

(c) omit entry for Circumstances Code "C14781"

(d) omit entry for Circumstances Code "C14793"

(e) omit entry for Circumstances Code "C14799"

(f) omit entry for Circumstances Code "C14805"

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(g) insert in numerical order after existing text:

C19249	Atypical haemolytic uraemic syndrome (aHUS) Continuing treatment Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; OR Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.	Compliance with Authority Required procedures

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	A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of kidney transplant if applicable (especially if required due to aHUS); (7) An inclusion of the individual consequences of recurrent disease, if applicable; (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
C19258	Atypical haemolytic uraemic syndrome (aHUS) Recommencement of treatment Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND	Compliance with Authority Required procedures

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	Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A measurement of body weight at the time of application;

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	(4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS if applicable; (6) A history of multiple episodes of aHUS following the treatment break, if applicable; (7) A history of kidney transplant if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy; (10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.	
C19263	Atypical haemolytic uraemic syndrome (aHUS) Continuing recommencement of treatment Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition; AND Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and	Compliance with Authority Required procedures

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	(2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; (7) A history of kidney transplant if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease, if applicable; (9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; (10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

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	This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
C19270	Atypical haemolytic uraemic syndrome (aHUS) Extended Continuing treatment Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition; AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR Patient must have severe TMA-related neurological impairment; OR Patient must have severe TMA-related gastrointestinal impairment; OR Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or	Compliance with Authority Required procedures

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	b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; (7) A history of kidney transplant, if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application; (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior

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	treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
C19273	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L; AND Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND Patient must have clinical features of active organ damage or impairment; AND Patient must not receive more than 4 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. Evidence of active and progressing TMA is defined by the following: (1) a platelet count of less than 150x10^9/L; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy consistent with aHUS;	Compliance with Authority Required procedures

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	(b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A detailed cover letter from the prescriber; (4) A measurement of body weight at the time of application; (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion (if available); the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply; (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply; (7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; (8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application; (9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.	
C19274	Atypical haemolytic uraemic syndrome (aHUS)	Compliance with Authority

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			Switch from PBS-subsidised ravulizumab (all phases) - loading dose	Required procedures
			Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; OR	
			Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; OR	
			Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; OR	
			Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR	
			Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; OR	
			Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition; AND	
			Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND	
			Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction.	
			Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR	
			Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND	
			Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.	
			The application must indicate the most recent treatment phase that the patient is switching from.	
			For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.	
			Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.	
			The authority application must be in writing and must include all of the following:	
			(1) Details of the proposed prescription(s);	
			(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);	
			(3) A measurement of body weight at the time of application;	
			(4) Results of genetic testing, if not previously submitted.	

[30] Schedule 3, entry for Edaravone

substitute:

Edaravone	C19252	P19252	Amyotrophic lateral sclerosis	Compliance with Authority

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		Initial treatment	Required procedures
		The condition must be/have been diagnosed by a neurologist; AND	
		Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug; AND	
		Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug; AND	
		Patient must not require assistance with eating or ambulation prior to commencing treatment with this drug; AND	
		Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug; AND	
		Patient must not have undergone a tracheostomy; AND	
		Patient must not have experienced respiratory failure; AND	
		Patient must not be receiving concomitant treatment with tofersen for this condition.	
		The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application.	
		Prescribers must request a quantity sufficient to cover one month per dispensing, in accordance with the patient's treatment cycle. Prescribers must request a smaller number of units than the listed maximum quantity units if it is adequate for the patient's needs.	
C19267	P19267	Amyotrophic lateral sclerosis	Compliance with Authority Required procedures
		Continuing treatment	
		Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	
		Patient must not have undergone a tracheostomy; AND	
		Patient must not have experienced respiratory failure; AND	
		Patient must not be receiving concomitant treatment with tofersen for this condition.	

[31] Schedule 3, entry for Infliximab

(a) omit entry for Circumstances Code "C14623" and substitute:

C14623		Severe active rheumatoid arthritis	Compliance with Authority Required procedures
		Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)	
		Must be treated by a rheumatologist; OR	
		Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	
		Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR	

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	Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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 treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure	

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	treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

(b) omit entry for Circumstances Code "C18345" and substitute:

C18345	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.	Compliance with Written Authority Required procedures

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	Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion

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	at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[32] Schedule 3, entry for Pomalidomide

(a) omit entry for Circumstances Code "C13746"

(b) insert in the column headed "Listed Drug" for the entry for Circumstances Code "C13755": Pomalidomide

(c) insert in numerical order after existing text:

C19229	Multiple myeloma Initial treatment - dual therapy in combination with dexamethasone The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or	Compliance with Written Authority Required procedures

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	(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and (2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information. All 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) 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).	

[33] Schedule 3, entry for Ravulizumab

(a) omit entry for Circumstances Code "C18351"

(b) insert in numerical order after existing text:

C19240	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment - Initial (new patient) loading dose Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma	Compliance with Written Authority Required procedures

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	exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L; AND Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND Patient must have clinical features of active organ damage or impairment; AND Patient must not receive more than 2 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. Evidence of active and progressing TMA is defined by the following: (1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; or (2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and (3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one or more of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe

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	thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include all of the following: (1) Details of the proposed prescription(s); (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); (3) A detailed cover letter from the prescriber; (4) A measurement of body weight at the time of application; (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion (if available); the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply; (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply; (7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; (8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application; (9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application. Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

[34] Schedule 3, entry for Tocilizumab

(a) omit entry for Circumstances Code "C9380"

(b) insert in the column headed "Listed Drug" for the entry for Circumstances Code "C9386": Tocilizumab

(c) omit entry for Circumstances Code "C18172" and substitute:

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C18172	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended	Compliance with Written Authority Required procedures

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	that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. 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). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

(d) omit entry for Circumstances Code "C18279"

(e) insert in numerical order after existing text:

C18933	Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR	Compliance with Authority Required procedures

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	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

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	(a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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 and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of results; (b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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C18934	Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the	Compliance with Authority Required procedures

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	patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of result; (b) the most recent biological agent and the date of the last continuing prescription. (c) If applicable, the new baseline scores. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C18936	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline	Compliance with Authority Required procedures

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	scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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 treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised. If a patient fails to demonstrate a response to treatment with this drug under this restriction they

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	will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
C18938	Severe active rheumatoid arthritis First continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Authority Required procedures - Streamlined Authority Code 18938
C18939	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active	Compliance with Authority Required procedures - Streamlined Authority Code 18939

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	joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
C18941	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (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	Compliance with Authority Required procedures - Streamlined Authority Code 18941

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	irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
C18945	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Written Authority Required procedures

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	(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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. 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). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
C18946	Severe active juvenile idiopathic arthritis	Compliance with Written

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	First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. 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). At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.	Authority Required procedures

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	Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C18947	Severe active juvenile idiopathic arthritis Balance of supply - Continuing treatment Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Authority Required procedures
C18978	Severe active rheumatoid arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated 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 rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either	Compliance with Authority Required procedures - Streamlined Authority Code 18978

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	marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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 treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the prescribing. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C18980	Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. If a patient has received 12 weeks or more of therapy with the alternative biological medicine as	Compliance with Authority Required procedures

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	their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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). At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C19000	Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological	Compliance with Authority Required procedures

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	medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must be under 18 years of age. If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (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). At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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	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. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C19024	Severe active rheumatoid arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated 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 rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder 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 treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the prescribing. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be	Compliance with Authority Required procedures - Streamlined Authority Code 19024

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			determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C19046		Severe active rheumatoid arthritis First continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Authority Required procedures - Streamlined Authority Code 19046

[35] Schedule 3, after entry for Tocilizumab

insert:

Tofersen	C19231	P19231	Amyotrophic lateral sclerosis Initial treatment Patient must have/have had one or more clinical symptoms of amyotrophic lateral sclerosis prior to commencing treatment with this drug; AND The condition must have been diagnosed by a neurologist; AND The condition must have a confirmed pathogenic (class 5) or likely pathogenic (class 4) superoxide dismutase 1 (SOD1) gene variant; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure; AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition; AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis.	Compliance with Authority Required procedures

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		The following must be documented in the patient's medical records: a) date and details of the patient's genetic testing confirming the presence of the SOD1 pathogenic gene variant; and b) baseline score of Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised (ALSFRS-R) at treatment initiation.	
C19237	P19237	Amyotrophic lateral sclerosis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the first continuing treatment, the extended first continuing treatment or the grandfather treatment restriction; AND Patient must have demonstrated an adequate response to treatment defined as any improvement or stabilisation in the ALSFRS-R score (i.e. no more than a 20% decline from the baseline ALSFRS-R score), if they have received treatment under the first continuing or extended first continuing restriction; OR Patient must have demonstrated a clinical benefit from treatment, based on clinician judgment, within 12 months of treatment initiation, if they have received treatment under the grandfather listing; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure; AND Patient must not be receiving palliative (end of life) care; AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition; AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis.	Compliance with Authority Required procedures
C19243	P19243	Amyotrophic lateral sclerosis First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure; AND Patient must not be receiving palliative (end of life) care; AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition; AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis.	Compliance with Authority Required procedures

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		Assessment of response must be conducted after 6 months of the first continuing treatment (i.e. at 12 months from treatment initiation). If a response to treatment cannot be demonstrated at this assessment, prescribers may apply for up to a maximum of three months (i.e. 2 repeats) of additional continuing treatment under the extended first continuing treatment phase to verify non-response. Reassessment of response must be conducted after the additional three months of therapy to determine the patient's eligibility for further treatment. If this reassessment is not undertaken, the patient will not be eligible for ongoing treatment. All the assessments of response must be documented in the patient's medical records. Adequate response to treatment is defined as any improvement or stabilisation (no more than 20% decline) from baseline score of ALSFRS-R.	
C19253	P19253	Amyotrophic lateral sclerosis Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2026; AND Patient must have had one or more clinical symptoms of amyotrophic lateral sclerosis prior to commencing non-PBS-subsidised treatment with this drug; AND The condition must have been diagnosed by a neurologist; AND The condition must have a confirmed pathogenic (class 5) or likely pathogenic (class 4) superoxide dismutase 1 (SOD1) gene variant; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure; AND Patient must not be receiving palliative (end of life) care; AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition; AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. The date and details of the patient's genetic testing confirming the presence of the SOD1 pathogenic gene variant must be documented in the patient's medical records. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria.	Compliance with Authority Required procedures
C19261	P19261	Amyotrophic lateral sclerosis Extended first continuing treatment (additional 3 doses) Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND	Compliance with Authority Required procedures

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	Patient must not have demonstrated an adequate response to treatment with this drug for this condition; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure; AND Patient must not be receiving palliative (end of life) care; AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition; AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. Reassessment of response must be conducted after the additional three months of therapy to determine the patient's eligibility for further treatment. If this reassessment is not undertaken, the patient will not be eligible for ongoing treatment. All the assessments of response must be documented in the patient's medical records. Patient may qualify for this treatment phase once only. Adequate response to treatment is defined as any improvement or stabilisation (no more than 20% decline) from baseline score of ALSFRS-R.

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