



**PB 94 of 2023**

# **National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2023**

*National Health Act 1953*

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

Dated                    28 September 2023

**NIKOLAI TSYGANOV**  
Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division

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## 1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2023*.
- (2) This instrument may also be cited as PB 94 of 2023.

## 2 Commencement

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

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. <i>The whole of this instrument</i>	<i>1 October 2023</i>	<i>1 October 2023</i>

Note: This table relates only to the provisions of this instrument as originally made.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

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

## 3 Authority

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

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

## Schedule 1—Amendments

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

**[1] Schedule 1, entry for Azacitidine**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

	Azacitidine Dr.Reddy's	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029	See Schedule 2	See Schedule 2
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**[2] Schedule 1, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

	Entecavir Viatrix	C4993 C5036	60	5
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**[3] Schedule 1, entry for Infliximab**

*substitute:*

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	C4524 C7777 C8296 C8646 C8745 C8844 C8881 C8883 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9400 C9402 C9472 C9481 C9487 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803	See Schedule 2	See Schedule 2
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	C11158 C12003 C12004 C12025 C12042 C12043 C12049 C12051 C12058 C12059 C12063 C12067 C12069 C12074 C12075 C12313 C13518 C13522 C13526 C13584 C13586 C13587 C13589 C13639 C13640 C13641 C13689 C13691 C13692 C13702 C13714 C13719 C14141 C14359 C14360	
Remicade	C4524 C7777 C8296 C8646 C8745 C8881 C8883 C8941 C8962 C9065 C9067 C9068 C9111 C9400 C9402 C9487 C9559 C9587 C9632 C9669 C9677 C9719 C9721 C9751 C9754 C9779 C9783 C9803 C11158 C12003 C12004 C12025 C12043 C12049 C12058 C12059 C12063 C12313 C13518 C13522 C13526 C13584 C13586 C13587 C13589 C13639 C13640 C13641 C13689 C13691	See Schedule 2    See Schedule 2

		C13692 C13702 C13714 C13719 C14141 C14359 C14360	
	Renflexis	C4524 C7777 C8296 C8646 C8745 C8844 C8881 C8883 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9400 C9402 C9472 C9481 C9487 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803 C11158 C12003 C12004 C12025 C12042 C12043 C12049 C12051 C12058 C12059 C12063 C12067 C12069 C12074 C12075 C12313 C13518 C13522 C13526 C13584 C13586 C13587 C13589 C13639 C13640 C13641 C13689 C13691 C13692 C13702 C13714 C13719 C14141 C14359 C14360	See Schedule 2    See Schedule 2

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[4] **Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; Capsule 10 mg; Capsule 15 mg; and Capsule 25 mg**

*insert in numerical order in the column headed "Circumstances" (all instances): C14362*

[5] **Schedule 1, entry for Nusinersen**

(a) *omit from the column headed "Circumstances": C13198*

(b) *omit from the column headed "Circumstances": C13254*

(c) *insert in numerical order in the column headed "Circumstances": C14370 C14421 C14433 C14459*

[6] **Schedule 1, entry for Octreotide in the form Injection 50 micrograms (as acetate) in 1 mL**

*omit:*

	Octreotide MaxRx	C6369 C6390 C8165 C9232 C9233 C9289	90	11
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[7] **Schedule 1, entry for Onasemnogene abeparvovec**

(a) *omit from the column headed "Circumstances" (all instances): C12641*

(b) *insert in numerical order in the column headed "Circumstances" (all instances): C14468 C14469*

[8] **Schedule 1, entry for Risdiplam**

*omit from the column headed "Circumstances": C12678 C12679 C13048 substitute: C14368 C14372 C14392 C14408 C14420 C14424 C14435 C14458*

[9] **Schedule 2, entry for Infliximab [Maximum quantity: 1 dose of 5 mg per kg of patient weight; Maximum repeats: 3]**

*substitute:*

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Infliximab	C9111 C9400 C9402 C9487 C9559 C9587 C11158 C13518 C13584 C13586 C13587 C13589 C13640 C13689 C13692 C13719 C14359 C14360	1 dose of 5 mg per kg of patient weight 3
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[10] **Schedule 2, entry for Lenalidomide [Maximum quantity: 21 tablets; Maximum repeats: 2]**

*insert in numerical order in the column headed "Circumstances": C14362*

[11] **Schedule 2, entry for Nusinersen**

*substitute:*

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Nusinersen	C13064 C14433 C14459	1 dose	0
	C12667 C12672 C12676 C13222 C13270 C14370 C14421	1 dose	3

**[12] Schedule 2, entry for Onasemnogene abeparvovec**

- (a) omit from the column headed "Circumstances": **C12641**  
(b) insert in numerical order in the column headed "Circumstances": **C14468 C14469**

**[13] Schedule 2, entry for Risdiplam**

substitute:

Risdiplam	C14372 C14435 C14458	1	0
	C14424	1	5
	C14392 C14408 C14420	3	5
	C14368	3	7

**[14] Schedule 3, entry for Infliximab**

- (a) omit:

C8886	Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than	Compliance with Authority Required procedures
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		<p>5 years) restriction to complete 22 weeks treatment; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.  Must be treated by a dermatologist.</p>	
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**(b)** omit:

	C13529	<p>Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 1 month old at the time of application.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include:  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  The PASI assessment for first continuing or subsequent continuing treatment must be performed</p>	Compliance with Written Authority Required procedures
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		<p>on the same affected area as assessed at baseline.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
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(c) omit:

	C13590	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be</p>	Compliance with Written Authority Required procedures
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			<p>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.</p> <p>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 within this treatment cycle.</p>	
	C13591		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;</p>	Compliance with Written Authority Required procedures

		<p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
	C13592	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this</p>	Compliance with Written Authority Required procedures

		<p>drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.  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.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include:  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.</p>	
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			<p>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 within this treatment cycle.</p> <p>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.</p>	
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**(d)** omit:

	C13679		<p>Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  An adequate response to treatment is defined as:  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  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</p>	Compliance with Written Authority Required procedures
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		<p>treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>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 within this treatment cycle.</p> <p>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.</p>	
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(e) omit:

	C13705	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin,</p>	Compliance with Written Authority Required procedures
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		<p>apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>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.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
	C13706	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area</p>	Compliance with Written Authority Required procedures



		<p>and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of</p>	
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			<p>commencement and duration of therapy].</p> <p>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.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
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(f) omit:

	C13715		<p>Severe chronic plaque psoriasis Initial 1 - Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies</p>	Compliance with Written Authority Required procedures
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		<p>until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
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**(g)** insert in numerical order after existing text:

	C14359	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot</p>	<p>Compliance with Written Authority Required procedures</p>
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		<p>where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 22 weeks of treatment under this restriction.  Patient must be at least 18 years of age.  Must be treated by a dermatologist.  Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.  Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.  The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:  (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:  (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or  (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;  (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.  (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include:  (a) a completed authority prescription form(s); and</p>	
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		<p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>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.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
	C14360	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast,</p>	Compliance with Written Authority Required procedures

		<p>deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>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.</p> <p>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.</p> <p>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 within this treatment cycle.</p>	
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**[15] Schedule 3, entry for Lenalidomide**

*insert in numerical order after existing text:*

	C14362		Relapsed and/or refractory multiple myeloma Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS; AND Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.	Compliance with Authority Required procedures
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**[16] Schedule 3, entry for Nusinersen**

**(a) omit:**

	C13198		<p>Spinal muscular atrophy (SMA) Continuing/maintenance treatment in an adult where treatment was initiated in adulthood The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR The treatment must be occurring within the first 104 weeks from the first administered dose; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing continuing PBS-subsidised treatment that was initiated through the Initial treatment listing for SMA initiated in adulthood; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response. A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline. PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present. Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records. In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	Compliance with Authority Required procedures
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**(b)** *omit:*

	C13254		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must be undergoing continuing/maintenance treatment initiated through this drug's Initial treatment listing for SMA type IIIB/IIIC in childhood; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p>	Compliance with Authority Required procedures
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**(c)** *insert in numerical order after existing text:*

	C14370		<p>Spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. Patient must be untreated with gene therapy; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	Compliance with Written Authority Required procedures
	C14421		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC; AND</p>	Compliance with Written Authority Required procedures



			<p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Patient must be untreated with gene therapy; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	
	C14433		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p>	Compliance with Authority Required procedures
	C14459		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in an adult where treatment was initiated in adulthood</p> <p>The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR</p> <p>The treatment must be occurring within the first 104 weeks from the first administered dose; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p>	Compliance with Authority Required procedures

		<p>Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.</p> <p>A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.</p> <p>PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.</p> <p>Undertake re-assessments for a clinically meaningful response at least every six months.</p> <p>Document these re-assessments in the patient's medical records.</p> <p>In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	
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**[17] Schedule 3, entry for Onasemnogene abeparvovec**

(a) *omit:*

	C12641	<p>Spinal muscular atrophy (SMA)</p> <p>Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition;</p> <p>AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing;</p> <p>AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime;</p> <p>AND</p>	Compliance with Written Authority Required procedures
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			<p>Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.</p> <p>Patient must be no older than 9 months of age; AND</p> <p>Patient must have symptomatic Type 1 SMA; OR</p> <p>Patient must have pre-symptomatic SMA.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.</p> <p>Confirm that a previous PBS authority application has been approved for one of the following:</p> <p>(i) Symptomatic Type 1 SMA; or</p> <p>(ii) Pre-symptomatic SMA treated with nusinersen</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.</p>	
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**(b)** *insert in numerical order after existing text:*

	C14468		<p>Spinal muscular atrophy (SMA)</p> <p>Use in a patient untreated with disease modifying therapies for this condition</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND</p>	Compliance with Written Authority Required procedures
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		<p>Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.  Patient must be no older than 9 months of age.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; 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).  State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.  Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:  (i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or  (ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.  Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).  Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.</p>	
	C14469	<p>Spinal muscular atrophy (SMA)  Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparovvec)  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.  Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition; AND  Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND  Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing;  AND  Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime;  AND  Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.  Patient must be no older than 9 months of age; AND  Patient must have symptomatic Type 1 SMA; OR</p>	Compliance with Written Authority Required procedures

			<p>Patient must have pre-symptomatic SMA.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; 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).  Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.  Confirm that a previous PBS authority application has been approved for one of the following:  (i) Symptomatic Type 1 SMA; or  (ii) Pre-symptomatic SMA.  State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.  Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.</p>	
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**[18] Schedule 3, entry for Risdiplam**

*substitute:*

Risdiplam	C14368		<p>Spinal muscular atrophy (SMA)  Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood  Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood; AND  Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19<sup>th</sup> birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).  Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR  Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND  Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease;  OR  Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.  The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR  The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene;  AND  Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than</p>	Compliance with Written Authority Required procedures
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		<p>or equal to 16 hours per day.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p> <p>(v) Failure to gain weight appropriate for age,</p> <p>(vi) Any active denervation or chronic neurogenic changes found on electromyography,</p> <p>(vii) A compound muscle action potential below normative values for an age-matched child.</p> <p>In this authority application, confirm:</p> <p>(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,</p> <p>(2) which of the above (i to vii) (at least 1) were present during childhood,</p> <p>(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.</p>	
	C14372	<p>Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)</p> <p>Initial treatment</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.</p> <p>Patient must be untreated with gene therapy.</p> <p>Patient must be 18 years of age or under.</p> <p>Defined signs and symptoms of type I SMA are:</p> <p>i) Onset before 6 months of age; and</p> <p>ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or</p> <p>iii) Proximal weakness; or</p>	Compliance with Written Authority Required procedures

		<p>iv) Hypotonia; or  v) Absence of deep tendon reflexes; or  vi) Failure to gain weight appropriate for age; or  vii) Any active chronic neurogenic changes; or  viii) A compound muscle action potential below normative values for an age-matched child.  Defined signs and symptoms of type II SMA are:  i) Onset between 6 and 18 months; and  ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or  iii) Proximal weakness; or  iv) Weakness in trunk righting/derotation; or  v) Hypotonia; or  vi) Absence of deep tendon reflexes; or  vii) Failure to gain weight appropriate for age; or  viii) Any active chronic neurogenic changes; or  ix) A compound muscle action potential below normative values for an age-matched child.  Defined signs and symptoms of type IIIa SMA are:  i) Onset between 18 months and 3 years of age; and  ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or  iii) Proximal weakness; or  iv) Hypotonia; or  v) Absence of deep tendon reflexes; or  vi) Failure to gain weight appropriate for age; or  vii) Any active chronic neurogenic changes; or  viii) A compound muscle action potential below normative values for an age-matched child.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  Application for authorisation of initial treatment must be in writing and must include:  (a) a completed authority prescription form; and  (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:  i) specification of SMA type (I, II or IIIa); and  (ii) sign(s) and symptom(s) that the patient has experienced; and  (iii) patient's age at the onset of sign(s) and symptom(s).  The approved Product Information recommended dosing is as follows:  (i) 16 days to less than 2 months of age: 0.15 mg/kg  (ii) 2 months to less than 2 years of age: 0.20 mg/kg  (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg  (iv) 2 years of age and older weighing 20 kg or more: 5 mg  In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:  1 unit where (i) applies;  2 units where (ii) applies;  3 units where (iii) applies;  3 units where (iv) applies.</p>	
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	C14392	<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing. The approved Product Information recommended dosing is as follows: (i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to: 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	Compliance with Authority Required procedures
	C14408	<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Initial PBS-subsidised treatment with this drug in a child Patient must be of an age that is prior to their 19<sup>th</sup> birthday at the time of this authority application; AND Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday (SMA type IIIB/IIIC). Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated</p>	Compliance with Written Authority Required procedures



		<p>treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.  The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR  The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND  Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  The authority application must be made in writing and must include:  (1) a completed authority prescription form; 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).  Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:  (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,  (ii) Proximal weakness,  (iii) Hypotonia,  (iv) Absence of deep tendon reflexes,  (v) Any active denervation or chronic neurogenic changes found on electromyography,  (vi) A compound muscle action potential below normative values for an age-matched child.  In this authority application, confirm:  (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,  (2) which of the above (i to vi) (at least 1) were present after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday,  (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.  The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.  The approved Product Information recommended dosing is as follows:  (i) 16 days to less than 2 months of age: 0.15 mg/kg  (ii) 2 months to less than 2 years of age: 0.20 mg/kg  (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg  (iv) 2 years of age and older weighing 20 kg or more: 5 mg  In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:  1 unit where (i) applies;  2 units where (ii) applies;  3 units where (iii) applies;  3 units where (iv) applies.</p>	
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C14420		<p>Spinal muscular atrophy (SMA)  Continuing/maintenance treatment in an adult where treatment was initiated in adulthood  Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR  Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday; AND  Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR  Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.  The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR  The treatment must be occurring within the first 104 weeks from the first administered dose; AND  Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.  A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.  PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.  Undertake re-assessments for a clinically meaningful response at least every six months.  Document these re-assessments in the patient's medical records.  In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	Compliance with Authority Required procedures
C14424		<p>Spinal muscular atrophy (SMA)  Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA  Patient must have previously received PBS-subsidised treatment with this drug for this condition;  OR  Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND</p>	Compliance with Written Authority Required procedures

		<p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
	C14435	<p>Spinal muscular atrophy (SMA)</p> <p>Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA</p> <p>Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples); AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.</p> <p>Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA. Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.</p> <p>Definition:</p> <p>Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.</p> <p>0. Absence of developmental states (1 to 9) listed below:</p> <p>1. Rolls from side to side on back;</p> <p>2. Child holds head erect for at least 3 seconds unsupported;</p> <p>3. Sitting, but with assistance;</p> <p>4. Sitting without assistance:</p> <p>(a) Child sits up straight with the head erect for at least 10 seconds;</p> <p>(b) Child does not use arms or hands to balance body or support position.</p> <p>5. Hands and knees crawling:</p> <p>(a) Child alternately moves forward or backwards on hands and knees;</p> <p>(b) The stomach does not touch the supporting surface;</p> <p>(c) There are continuous and consecutive movements at least 3 in a row.</p> <p>6. Standing with assistance:</p> <p>(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;</p> <p>(b)The body does not touch the stable object, and the legs support most of the body weight;</p> <p>(c) Child thus stands with assistance for at least 10 seconds.</p> <p>7. Standing alone:</p> <p>(a) Child stands in upright position on both feet (not on the toes) with the back straight;</p> <p>(b) The leg supports 100% of the child's weight;</p> <p>(c) There is no contact with a person or object;</p> <p>(d) Child stands alone for at least 10 seconds.</p> <p>8. Walking with assistance:</p> <p>(a) Child is in an upright position with the back straight;</p> <p>(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or</p>	
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		<p>both hands;</p> <p>(c) One leg moves forward while the other supports part of the body weight;</p> <p>(d) Child takes at least 5 steps in this manner.</p> <p>9. Walking alone:</p> <p>(a) Child takes at least 5 steps independently in upright position with the back straight;</p> <p>(b) One leg moves forward while the other supports most of the body weight;</p> <p>(c) There is no contact with a person or object.</p> <p>Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).</p> <p>Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
	C14458	<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene;</p> <p>AND</p> <p>The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The condition must be pre-symptomatic; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>Patient must be untreated with gene therapy.</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or</p>	Compliance with Written Authority Required procedures

		<p>electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p> <p>(i) confirmation of genetic diagnosis of SMA; and</p> <p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
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