PB 18 of 2024

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2024

National Health Act 1953

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 February 2024

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

Contents

1 Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2024.*

(2) This instrument may also be cited as PB 18 of 2024.

2 Commencement

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

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 March 2024*	*1 March 2024*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Cinacalcet in the form Tablet 30 mg (as hydrochloride)

omit:

			Cinacalcet Mylan	C10063 C10067 C10073	56	5

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

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

			Entecavir Viatris	C5037 C5044	60	5

[3] Schedule 1, entry for Filgrastim

(a) *omit:*

	Injection 300 micrograms in 1 mL	Injection	Neupogen	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696	20	11

(b) *omit:*

	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696	20	11

[4] Schedule 1, entry for Nusinersen

(a) *omit from the column headed "Circumstances":* **C12667**

(b) *insert in numerical order in the column headed "Circumstances":* **C15053**

[6] Schedule 2, entry for Nusinersen *[Maximum Quantity: 1 dose; Maximum Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C12667**

(b) *insert in numerical order in the column headed "Circumstances":* **C15053**

[7] Schedule 3, entry for Nusinersen

(a) *omit:*

	C12667		Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses 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. 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 The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND The condition must be pre-symptomatic; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND Patient must be untreated with gene therapy. Patient must be aged under 36 months prior to commencing treatment. Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) 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) confirmation of genetic diagnosis of SMA; and (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)	Compliance with Written Authority Required procedures

(b) *insert in numerical order after existing text:*

	C15053		Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses 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. 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 The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; OR The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND The condition must be pre-symptomatic; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND Patient must be untreated with gene therapy. Patient must be aged under 36 months prior to commencing treatment. Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) 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) confirmation of genetic diagnosis of SMA; and (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)	Compliance with Written Authority Required procedures

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