

**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

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1. Name
2. This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2024.*
3. This instrument may also be cited as PB 18 of 2024.
4. Commencement
5. 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Note: This table relates only to the provisions of this instrument as originally made.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.

1. 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.
2. Authority

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

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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

1. 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 |

1. Schedule 1, entry for Filgrastim
	1. *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 |

* 1. *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 |

1. Schedule 1, entry for Nusinersen
2. *omit from the column headed “Circumstances”:* **C12667**
3. *insert in numerical order in the column headed “Circumstances”:* **C15053**
4. Schedule 2, entry for Nusinersen *[Maximum Quantity: 1 dose; Maximum Repeats: 3]*
5. *omit from the column headed “Circumstances”:* **C12667**
6. *insert in numerical order in the column headed “Circumstances”:* **C15053**
7. Schedule 3, entry for Nusinersen
8. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C12667 |  | Pre‑symptomatic spinal muscular atrophy (SMA)Initial treatment of pre‑symptomatic spinal muscular atrophy (SMA) ‑ Loading dosesMust 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; ORThe 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; ANDThe condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; ANDThe condition must be pre‑symptomatic; ANDThe treatment must be given concomitantly with best supportive care for this condition; ANDThe treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; ANDPatient 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 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C15053 |  | Pre-symptomatic spinal muscular atrophy (SMA)Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading dosesMust 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; ORThe 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; ANDThe condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; ORThe condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; ANDThe condition must be pre-symptomatic; ANDThe treatment must be given concomitantly with best supportive care for this condition; ANDThe treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; ANDPatient 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 |