PB 92 of 2022

National Health (Growth Hormone Program) Special Arrangement Amendment (Mecasermin and Somatrogon) Instrument 2022

I, David Laffan, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 23 September 2022

David Laffan
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health and Aged Care

OPC66097 - A

Contents

1 Name

(1) This instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment (Mecasermin and Somatrogon) Instrument 2022*.

(2) This instrument may also be cited as PB 92 of 2022.

2 Commencement

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

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 October 2022.	1 October 2022

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Growth Hormone Program) Special Arrangement 2015

1 Subsection 4(1) (after paragraph (c) of the definition of *authorised prescriber*)

Insert:

(ca) for the changing drug treatment phase for a child means:
- a specialist or consultant physician in paediatric endocrinology; or
- a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

(cb) for the non-PBS subsidised to PBS subsidised supply treatment phase for a child in relation to a pharmaceutical benefit that has the drug mecasermin or somatrogon means:
- a specialist or consultant physician in paediatric endocrinology; or
- a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

2 Subsection 4(1)

Insert:

changing drug treatment phase for a child means a treatment phase to facilitate a change in the prescribed pharmaceutical benefit for a child:

(a) from a pharmaceutical benefit that has the drug somatrogon to a pharmaceutical benefit that has the drug somatropin; or

(b) from a pharmaceutical benefit that has the drug somatropin to a pharmaceutical benefit that has the drug somatrogon.

3 Subsection 4(1)

Insert:

pharmaceutical benefit has a drug has the same meaning as in Part VII of the Act.

4 Sections 8 and 9

Repeal the sections, substitute:

8 Prescription for child—maximum quantity

Somatrogon and somatropin

(1) Subject to subsection (2), the maximum quantity or number of units of a pharmaceutical benefit that has the drug somatrogon or somatropin that may, in one prescription for a child, be directed to be supplied during an initial treatment phase, a recommencement treatment phase, or a recommencement of treatment

as a reclassified patient phase is an amount that is sufficient for 16 weeks of treatment of the child.

(2) The total quantity or number of units (including any repeats) of a pharmaceutical benefit that has the drug somatrogon or somatropin that may, in prescriptions for a child, be directed to be supplied for a phase referred to in subsection (1) is an amount that is sufficient for 32 weeks of treatment of the child.

(3) Subject to subsection (4), the maximum quantity or number of units of a pharmaceutical benefit that has the drug somatrogon or somatropin that may, in one prescription for a child, be directed to be supplied during a continuing treatment phase, a continuing treatment as a reclassified patient phase, a changing drug treatment phase, or a non-PBS subsidised to PBS subsidised supply treatment phase is an amount that is sufficient for 13 weeks of treatment of the child.

(4) The total quantity or number of units (including any repeats) of a pharmaceutical benefit that has the drug somatrogon or somatropin that may, in prescriptions for a child, be directed to be supplied for a phase referred to in subsection (3) is an amount that is sufficient for 26 weeks of treatment of the child.

Mecasermin

(5) The maximum quantity or number of units of a pharmaceutical benefit that has the drug mecasermin that may, in one prescription for a child, be directed to be supplied during an initial treatment phase, a continuing treatment phase or a non-PBS subsidised to PBS subsidised supply treatment phase is an amount that is sufficient for the first month of treatment of the child in that phase.

9 Prescription for child—maximum number of repeats

Somatrogon and somatropin

(1) The maximum number of occasions on which the supply of a pharmaceutical benefit that has the drug somatrogon or somatropin may, in one prescription for a child, be directed to be repeated is one.

Mecasermin

(2) The maximum number of occasions on which the supply of a pharmaceutical benefit that has the drug mecasermin may, in one prescription for a child, be directed to be repeated is 5, with each direction for a repeated supply directing a supply, on one occasion, of pharmaceutical benefit sufficient for one month.

5 Section 10 (heading)

Repeal the heading, substitute:

10 Definitions relating to doses of somatropin

6 Subsection 10(1)

Omit "In this Part", substitute "For the purposes of table items 1 to 4 of the table in section 11".

7 Subsection 10(2)

Omit "The", substitute "For the purposes of table items 1 to 3 of the table in section 11, the".

8 Subsection 10(3)

Omit "The", substitute "For the purposes of table item 4 of the table in section 11, the".

9 Section 11

Repeal the section, substitute:

11 Assessment of dosage of pharmaceutical benefit

(1) The dose of a pharmaceutical benefit that has a drug mentioned in column 1 of an item in the following table and that is prescribed by an authorised prescriber for a person's condition mentioned in column 2 of that item must:

(a) be appropriate for treatment of the person under this Special Arrangement; and

(b) subject to subsections (2) and (3), not exceed the dose calculated in accordance with column 3 of that item.

Dose of pharmaceutical benefit

Item	Column 1 Drug	Column 2 Condition	Column 3 Maximum dose
1	Somatropin	In the category of: (a) short stature and slow growth; or (b) short stature associated with biochemical growth hormone deficiency; or (c) growth retardation secondary to an intracranial lesion or cranial irradiation; or (d) risk of hypoglycaemia secondary to biochemical growth hormone deficiency in neonates/infants; or (e) biochemical growth hormone deficiency and precocious puberty; or (f) hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth	7.5 mg/m^2/week
2	Somatropin	In the category of: (a) short stature associated with Turner Syndrome; or (b) short stature due to short stature homeobox (SHOX) gene disorders; or (c) short stature associated with chronic renal insufficiency	9.5 mg/m^2/week
3	Somatropin	In the category of short stature and poor body composition due to Prader-Willi Syndrome, where the person has a non-mature skeleton	7.5 mg/m^2/week
4	Somatropin	In the category of short stature and poor body	0.04 mg/kg/week

Dose of pharmaceutical benefit			
Item	**Column 1** **Drug**	**Column 2** **Condition**	**Column 3** **Maximum dose**
		composition due to Prader-Willi Syndrome, where the person has a mature skeleton	
5	Mecasermin	In the category of severe primary insulin-like growth factor 1 deficiency (Primary IGFD)	0.12 mg/kg twice daily
6	Somatrogon	In the category of: (a) short stature associated with biochemical growth hormone deficiency; or (b) short stature and slow growth	0.66 mg/kg/week

(2) If:

(a) the dose is of a pharmaceutical benefit that has the drug somatropin; and

(b) the form of the pharmaceutical benefit and the manufacturer's pack is unable to accommodate the dose calculated in accordance with column 3 of the applicable item of the table;

the dose may be up to 3% greater than the dose calculated in accordance with that item of the table.

(3) If:

(a) the dose is of a pharmaceutical benefit that has the drug somatrogon; and

(b) the form of the pharmaceutical benefit and the manufacturer's pack is unable to accommodate the dose calculated in accordance with column 3 of the applicable item of the table;

the dose, once calculated in accordance with that item of the table, may be rounded up to the nearest 0.2 mg or 0.5 mg.