

Severe growth failure with primary insulin-like growth factor-1 deficiency – mecasermin – initial authority application

Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to servicesaustralia.gov.au/hppbsauthorities

When to use this form

Use this form to apply for **initial** PBS-subsidised mecasermin for patients aged from 2 to 17 years old (inclusive) with severe growth failure with primary insulin-like growth factor-1 deficiency (IGFD).

Important information

Initial applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for severe growth failure with IGFD **initial** authority applications.

The information in this form is correct at the time of publishing and may be subject to change.

Continuing treatment

This form is ONLY for **initial** treatment.

After an authority application for the **initial** treatment has been approved, applications for **continuing** treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Treatment specifics

An older child is defined as a:

- male with a chronological age of **at least 12 years** or a bone age of **at least 10 years**, or
- female with a chronological age of **at least 10 years** or a bone age of **at least 8 years**.

Current height, growth velocity and weight measurements must not be more than **3 months** old at the time of application.

The Centers for Disease Control and Prevention (U.S. Department of Health and Human Services) publishes Clinical Growth Charts which this restriction refers to. Both the 'length-for-age' (birth to 36 months) and 'stature-for-age' (children 2 years to 20 years) growth charts can be viewed, printed and reproduced at the following website cdc.gov/growthcharts/clinical_charts.htm

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to servicesaustralia.gov.au/hppbsauthorities

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

 kg

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Dosage details

8 Number of vials requested for 30 days of treatment
(= $7.2 \times \text{weight (kg)} \div 40$)

9 Dose

mg/kg twice daily

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

10 The patient is being treated by, and this authority application is completed by:

☐ a paediatric endocrinologist

or

☐ a paediatrician in consultation with a paediatric endocrinologist

11 The patient aged between 2 and 17 years old (inclusive) is:

☐ a female with a bone age less than 13.5 years

or

☐ a male with a bone age less than 15.5 years

12 Provide the following details:

Patient's bone age performed within the last 12 months, if the patient's current chronological age is ≥ 2.5 years.

years months

Date of assessment (DD MM YYYY)

13 Is the patient's condition caused by severe primary insulin-like growth factor-1 (IGF-1) deficiency, with a basal IGF-1 level below the 2.5th percentile adjusted for both age and sex?

No ☐

Yes ☐



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14 Provide the following details:

Most recent basal IGF-1 level

ng/mL

Date of the pathology report (DD MM YYYY)

Name of the pathology report provider

15 Is the patient's condition caused by secondary causes of IGFD?

No ☐

Yes ☐

16 Prior to initiating treatment with this drug for this condition, have malnutrition, hypopituitarism, hypothyroidism and medication side-effects been excluded as secondary causes of IGFD?

No ☐

Yes ☐

17 Does the patient have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)?

No ☐

Yes ☐

18 Has the condition resulted in the patient experiencing short stature, with a height at least 3 standard deviations below the norm, adjusted for both age and sex?

No ☐

Yes ☐ Patient's current height

cm

19 Is the patient's condition caused by growth hormone deficiency?

No ☐

Yes ☐

20 Provide the patient's most recent growth hormone level

mcg/L

21 Is the patient known to have epiphyseal closure/growth plate fusion?

No ☐

Yes ☐

Checklist

- 22**  The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s)

Privacy notice

23 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application. Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at servicesaustralia.gov.au/privacypolicy

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at servicesaustralia.gov.au/hpos

24 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)



Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- online** (no signature required), upload through HPOS at servicesaustralia.gov.au/hpos
or
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001