

Spinal muscular atrophy adult – nusinersen or risdiplam – initial authority application

Online PBS Authorities



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

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 nusinersen or risdiplam for patients 19 years or over with the onset of spinal muscular atrophy (SMA) symptoms prior to 19 years who did not initiate PBS subsidy during childhood.

Important information

Initial applications to start PBS-subsidised treatment can be made 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 SMA **initial** authority applications.

Where the term 'disease modifying treatment' appears, it refers to nusinersen or risdiplam.

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 **initial** treatment has been approved, applications for **continuing** treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Section 100 arrangements for nusinersen and risdiplam

These items are available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- patient on discharge.

These items are not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

Treatment specifics

Patients receiving treatment with nusinersen **must not exceed 4 loading doses** (at days 0, 14, 28, 63) under this restriction.

Patients receiving treatment with risdiplam must have the quantity of drug and number of repeat prescriptions prescribed based on their weight and **must not exceed a maximum quantity of 3 and repeats of 7** under this restriction.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

14 This condition has genetic confirmation of:

5q homozygous deletion of the survival motor neuron 1 (SMN1) gene

or

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.

15 Is the patient's medical history consistent with a diagnosis of childhood onset SMA?

Yes

No

16 Has the patient experienced onset of SMA before 19 years of age and never claimed PBS subsidy for a disease modifying treatment during childhood?

Yes

No

17 Indicate at least one of the defined signs and symptoms of SMA the patient experienced at onset prior to 19 years of age:

failure to meet or regression in ability to perform age-appropriate motor milestones

proximal weakness

hypotonia

absence of deep tendon reflexes

failure to gain weight appropriate for age


any active denervation or chronic neurogenic changes found on electromyography

a compound muscle action potential below normative values for an age-matched child

18 Provide the patient's age at the onset of these signs and symptoms

years

Checklist

19  The relevant attachments need to be provided with this form.

Details of the proposed prescription(s).

Privacy notice

20 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 servicessaustralia.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 servicessaustralia.gov.au/hpos

21 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 servicessaustralia.gov.au/hpos
or
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001