

#### medicare



## 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

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### **Online services** 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 Medicare card number Department of Veterans' Affairs card number Mr Miss | Ms Family name First given name Date of birth (DD MM YYYY) Prescriber's details Prescriber number Mr Family name First given name Business phone number (including area code) Alternative phone number (including area code)

nuspitai uetalis		
7	Hospital name	
	This hospital is a:	
	public hospital	
	private hospital	
8	Hospital provider number	
Co	nditions and criteria	
	qualify for PBS authority approval, the following conditions ust be met.	
9	The patient is being treated by a:	
	specialist medical practitioner experienced in the diagnosis/ management of SMA	
	or  medical practitioner directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.	
10	The patient:	
	$\hfill \Box$ is initiating PBS-subsidised treatment for untreated disease $\hfill {\bf or}$	
	has initiated treatment via non-PBS supply.	
11	Is this the sole PBS-subsidised disease modifying treatment?  Yes  No	
12	Will the treatment be given concomitantly with best supportive care for this condition?  Yes  No	
13	Will PBS-subsidised treatment with this drug be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause?  Yes  No	



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14	This condition has genetic confirmation of:	Prescriber's declaration
	<ul> <li>□ 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene</li> <li>or</li> <li>□ deletion of one copy of the SMN1 gene, in addition to a pathogonic/likely pothogonic varient in the remaining single.</li> </ul>	You do not need to <b>sign</b> the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at <b>servicesaustralia.gov.au/hpos</b>
	pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene.	21 I declare that:
15	Is the patient's medical history consistent with a diagnosis of childhood onset SMA?  Yes	<ul> <li>I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.</li> <li>I have informed the patient that their personal information</li> </ul>
16	No  Has the patient experienced onset of SMA before 19 years of age and never claimed PBS subsidy for a disease modifying treatment during childhood?	(including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
	Yes No	<ul> <li>I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.</li> </ul>
17	Indicate at least one of the defined signs and symptoms of SMA the patient experienced at onset prior to 19 years of age:	<ul> <li>the information I have provided in this form is complete and correct.</li> </ul>
	failure to meet or regression in ability to perform age-	I understand that:
	appropriate motor milestones	• giving false or misleading information is a serious offence.
	proximal weakness	I have read, understood and agree to the above.
	hypotonia	Date (DD MM YYYY) (you must date this declaration)
	absence of deep tendon reflexes	
	failure to gain weight appropriate for age	Prescriber's signature ( <b>only</b> required if returning by post)
	any active denervation or chronic neurogenic changes found on electromyography	r resember a signature ( <b>omy</b> required in returning by post)
	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	Returning this form
	years	Return this form, details of the proposed prescription(s) and any relevant attachments:
<b>Ch</b> ⁄	ecklist	online (no signature required), upload through HPOS at servicesaustralia.gov.au/hpos
UIII	DONIIST	or
19	The relevant attachments need to be provided with this form.	by post (signature required) to
	Details of the proposed prescription(s).	Services Australia Complex Drugs Programs Reply Paid 9826
Pri	vacy notice	HOBART TAS 7001
20	Personal information is protected by law (including the <i>Privacy Act 1988</i> ) 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	