Australian Government
Services Australia

medicare

PBS

Transthyretin amyloid cardiomyopathy – tafamidis – 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 tafamidis for patients with transthyretin amyloid cardiomyopathy.

You can also use this form to apply for **initial grandfather** PBS-subsidised tafamidis for patients who have received non-PBS-subsidised treatment with tafamidis for the same condition prior to **1 May 2024**.

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 transthyretin amyloid cardiomyopathy **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** or **initial grandfather** treatment.

After an authority application for **initial** or **initial grandfather** 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.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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Online PBS Authorities

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 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Conditions and criteria

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

7 The patient is being treated by, and this application is being completed by a:

☐ cardiologist

☐ consultant physician with experience in the management of amyloid disorders

8 This application is for:

☐ initial treatment ▶ ***Go to 9***

or

☐ initial grandfather treatment (the patient has initiated treatment via non-PBS supply) ▶ ***Go to 10***

9 The patient has:

☐ New York Heart Association (NYHA) class I heart failure

or

☐ NYHA class II heart failure

▶ ***Go to 12***

10 At the time of commencing treatment with this drug, the patient had:

☐ New York Heart Association (NYHA) class I heart failure

or

☐ NYHA class II heart failure

11 Has the patient's heart failure worsened to persistent NYHA Class III/IV heart failure while taking this drug?

Yes ☐

No ☐

12 The patient has:

☐ experienced at least one episode of hospitalisation that was a direct result of heart failure

or

☐ clinical evidence of heart failure without hospitalisation that required treatment with diuretic for improvement

13 Does the patient have documented evidence of transthyretin precursor protein present?

Yes ☐

No ☐

MCA0PB358 2411

14 The patient has a diagnosis confirmed by:

☐ amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry

▶ *Go to 15*

or

☐ bone scintigraphy with grade 2-3 finding and confirmed negative results for monoclonal protein on serum and urine immunofixation and serum free light chains blood test

▶ *Go to 16*

15 Provide details of amyloid expert centre histology findings

Date of the findings (DD MM YYYY)

Unique imaging/pathology report number/code

Name of the amyloid expert centre

▶ *Go to 20*

16 Provide details of bone scintigraphy finding

Date of the finding (DD MM YYYY)

Unique imaging/pathology report number/code

17 Provide details of serum immunofixation test

Date of the test (DD MM YYYY)

Unique imaging/pathology report number/code

18 Provide details of urine immunofixation test

Date of the test (DD MM YYYY)

Unique imaging/pathology report number/code

19 Provide details of serum free light chains blood test

Date of the test (DD MM YYYY)

Unique imaging/pathology report number/code

20 Does the patient have an estimated glomerular filtration rate (eGFR) greater than 25mL/minute/1.73 m^2?

Yes ☐

No ☐

21 Does the patient have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging (echocardiogram or magnetic resonance imaging)?

Yes ☐

No ☐

22 Provide details of the imaging report

Date of the report (DD MM YYYY)

End-diastolic interventricular septal wall thickness (in mm)

mm

23 Is the imaging report stored in the patient's medical records?

Yes ☐

No ☐

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

25 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**

26 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)

If returning by post, print and sign by hand.

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

Reset form