



Tafamidis is a novel transthyretin stabilizer which is PBS listed for the treatment of **transthyretin cardiac amyloidosis**. Tafamidis can be prescribed by any cardiologist or amyloid specialist. Applications for initial and ongoing prescriptions are managed via PRODA:

1. Sign in to **PRODA/HPOS**: <https://www.servicesaustralia.gov.au/proda-provider-digital-access>
2. From your HPOS home page, select **My Programs**
3. Select **PBS Authorities**
4. Select **Request Authority** to start recording a new authority for your patient

You will need your patient's **Medicare number** and an **authority script pad** to complete the process.

NB: The 'Authority Prescription Number' is listed in the top right hand corner of your authority script pad.

For more information, please review the full PBS listing and product information for tafamidis:

- <https://www.pbs.gov.au/medicine/item/14100D>
- <https://www.tga.gov.au/resources/artg/314813>

Clinical Information for Initial Application

For the authority application, you will need to confirm that there is **documented evidence of transthyretin precursor protein**. This can be done via the following diagnostic tests:

1 Amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry

OR

2 Bone scintigraphy with grade 2–3 finding

PLUS

3 Confirmed negative results for monoclonal protein on each of the following tests:

1. Serum immunofixation (EPG/iEPG)
2. Urine immunofixation (EPG/iEPG)
3. Serum free light chain blood test

You will also need the following information:

- Date and unique imaging/pathology report number for each of the patient's diagnostic tests
- Septal wall thickness (TTE/CMR, measured in mm)
- Imaging report must be stored in patient's record
- Name of the amyloid expert centre where immunohistochemistry or mass spectrometry was reviewed where relevant

**If a patient's heart failure has worsened to NYHA class III/IV, the prescriber must review the patient within 3 months to determine if worsening heart failure is persistent. No more than two repeat prescriptions should be issued in such an instance.*

First PBS-subsidised prescription (Code 15412)

Clinical criteria:

- ✓ The patient must have **documented evidence of transthyretin amyloid cardiomyopathy**, AND
- ✓ Patient must have experienced at least one **hospitalisation due to heart failure**; OR had clinical evidence of heart failure that **required treatment with a diuretic**, AND
- ✓ Patient must have **NYHA class I or II heart failure** at the time of commencing this drug, AND
- ✓ Patient must have an **end-diastolic ventricular septal thickness of ≥ 12 mm**, AND
- ✓ Patient must have an **eGFR > 25 mL/min/1.73 m²**

Exclusion criteria:

Tafamidis should not be prescribed if the patient has:

- ✗ Severe renal impairment (eGFR < 25 mL/min/1.73 m²)
- ✗ Severe liver impairment (transaminases $> 2.0 \times$ ULN)
- ✗ Established (> 3 months) NYHA Class III or IV* heart failure

Subsequent PBS-subsidised prescription (Code 15327)

- ✓ Patient has **previously received PBS-subsidised treatment** with tafamidis, AND
- ✓ Patient has an **eGFR > 25 mL/min/1.73 m²**, AND
- ✓ Tafamidis must be **ceased** if the patient's heart failure has worsened to **persistent NYHA class III/IV***, AND
- ✓ Tafamidis must be **ceased** if the patient has received: (i) a **heart transplant**, (ii) a **liver transplant**, (iii) an **implanted ventricular assist device**



For more information or individual patient advice:

1. Visit our website via the QR code
2. Email us at amyloidreferrals@svha.org.au
3. Telephone the St Vincent's Hospital switchboard (p) 8382 1111 and ask for the Cardiac Amyloidosis Fellow