Australian Government
Services Australia

medicare

PBS

# Symptomatic obstructive hypertrophic cardiomyopathy – mavacamten – initial grandfather 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 grandfather** PBS-subsidised mavacamten for patients 18 years or over with symptomatic obstructive hypertrophic cardiomyopathy (HCM) who have received non-PBS-subsidised treatment with mavacamten for the same condition prior to **1 May 2024**.

## Important information

**Initial grandfather** 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 symptomatic obstructive HCM **initial grandfather** 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 grandfather** treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only. After an authority application for **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.

## Treatment specifics

For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the 'maintenance treatment' criteria if at least 6 months on optimal dose of mavacamten treatment is achieved. Where a grandfathered patient has received fewer than 6 months on optimal dose, or is titrating treatment until optimal dose is achieved, they must qualify under the 'first continuing treatment' criteria.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment.

## For more information

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

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## Online PBS Authorities

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## 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, 18 years or over, is being treated by a:

☐ cardiologist

**or**

☐ consultant physician with experience in the management of hypertrophic cardiomyopathy

**8** Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 May 2024**?

Yes ☐

No ☐

**9** Prior to commencing non-PBS-subsidised treatment with this drug, did the patient have left ventricular hypertrophy due to hypertrophic cardiomyopathy (HCM) confirmed by echocardiogram (ECHO) and/or cardiac magnetic resonance imaging (MRI)?

Yes ☐

No ☐

**10** Provide details of the ECHO or MRI report

Date of the report (DD MM YYYY)

Unique identifying number/code or provider number

**11** Prior to commencing non-PBS-subsidised treatment with this drug, the patient had been symptomatic with:

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

**or**

☐ NYHA class III heart failure

**12** Prior to commencing non-PBS-subsidised treatment with this drug, the patient had maximal end-diastolic left ventricular wall thickness which was:

☐ at least 15 mm

Left ventricular wall thickness

mm

▶ *Go to 17*

**or**

☐ at least 13 mm if the patient has familial HCM (at least one first degree relative with a diagnosis of HCM)

Left ventricular wall thickness

mm

MCA0PB361 2409

**13** The patient:

☐ had a genotyping test and the report is available ▶ *Go to 14*

**or**

☐ had a genotyping test and the report is not available yet ▶ *Go to 17*

**or**

☐ has not had a genotyping test ▶ *Go to 17*

**14** Provide details of the genotyping test

Date of the report (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

Unique identifying number/code or provider number

**15** Has a gene associated with HCM been identified?

Yes ☐

No ☐

**16** Does any first-degree family relative have a confirmed diagnosis of HCM?

Yes ☐

No ☐

**17** Prior to commencing non-PBS-subsidised treatment with this drug, did the patient have confirmed peak left ventricular outflow tract (LVOT) gradient of at least 50 mm Hg?

Yes ☐

No ☐

**18** Provide details of the LVOT gradient report

Date of the report (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

Unique identifying number/code or provider number

Measured LVOT gradient

mm Hg

**19** The LVOT gradient was measured:

☐ at rest

☐ after provocation with Valsalva manoeuvre

☐ after provocation with exercise

**20** Prior to commencing non-PBS-subsidised treatment with this drug, did the patient have a left ventricular ejection fraction (LVEF) of at least 55%?

Yes ☐

No ☐

**21** Does the patient have a current LVEF of at least 50%?

Yes ☐

No ☐

**22** Prior to commencing non-PBS-subsidised treatment with this drug, the patient had:

☐ prior treatment with a beta-blocker

Name of the beta-blocker

**or**

☐ an intolerance to beta-blocker therapy

Name of the beta-blocker

Details of the intolerance

**or**

☐ a contraindication to beta-blocker therapy listed in the TGA approved Product Information (PI)

Details of the contraindication

**23** Prior to commencing non-PBS-subsidised treatment with this drug, the patient had:

☐ prior treatment with a non-dihydropyridine calcium channel blocker (CCB)

☐ diltiazem

**or**

☐ verapamil

**or**

☐ other

**or**

☐ an intolerance to non-dihydropyridine CCB therapy

☐ diltiazem

**or**

☐ verapamil

**or**

☐ other

Details of the intolerance

**or**

☐ a contraindication to non-dihydropyridine CCB therapy listed in the TGA approved PI

Details of the contraindication

**24** The patient is undergoing concomitant treatment with:

☐ a beta-blocker

Name

**and/or**

☐ a non-dihydropyridine CCB

☐ diltiazem

**or**

☐ verapamil

**or**

☐ neither of them due to a previously stated intolerance or contraindication listed in the TGA approved PI

**25** The patient has received:

☐ the optimal dose of mavacamten for at least 6 months and has demonstrated a response ▶ *Go to 26*

**or**

☐ mavacamten treatment but has not reached at least 6 months on optimal dose to demonstrate a response ▶ *Go to 27*

**26** The patient has demonstrated improvement in:

☐ symptoms

☐ quality of life

☐ exercise capacity

☐ LVOT gradient

## Checklist

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

☐ Details of the proposed prescription(s).

## Privacy notice

**28** 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**

**29 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