

### medicare



# Symptomatic obstructive hypertrophic cardiomyopathy - mavacamten 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 mayacamten for patients 18 years or over with

symptomatic obstructive hypertrophic cardiomyopathy (HCM).

**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 symptomatic obstructive HCM 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** treatment.

After an authority application for the 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.

**Treatment specifics** Initial treatment covers the first 12 weeks of therapy. First continuing treatment continues until at least

6 months on optimal dose is achieved.

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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## medicare



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**Conditions and criteria** 

#### **Online PBS Authorities**



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Pa	tient'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)				
Pr	escriber's details				
4	Prescriber number				
5	Dr				
	Family name				
	First given name				
6	Business phone number (including area code)				
	Alternative phone number (including area code)				

	qualify for PBS authority approval, the following conditions ust 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	Does the patient have left ventricular hypertrophy due to hypertrophic cardiomyopathy (HCM) confirmed by echocardiogram (ECHO) and/or cardiac magnetic resonance imaging (MRI)?  Yes  No
9	Provide details of the ECHO or MRI report  Date of the report (DD MM YYYY)  Unique identifying number/code or provider number
10	The patient is symptomatic with:  New York Heart Association (NYHA) class II heart failure  or  NYHA class III heart failure
11	The patient has maximal end-diastolic left ventricular wall thickness which is:  at least 15 mm  Left ventricular wall thickness  mm  Go to 16
	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



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12	The patient:	1	<b>20</b> The	patient had:
	had a genotyping test and the			prior treatment with a beta-blocker
	report is available	Go to 13		Name of the beta-blocker
	or			
	had a genotyping test and the report		or	
	is not available yet	Go to 16		an intolerance to beta-blocker therapy
	or			Name of the beta-blocker
	has not had a genotyping test	Go to 16		Number of the beta blocker
13	Provide details of the genotyping test			
	Date of the report (DD MM YYYY)			Details of the intolerance
	Unique identifying number/code or provider number			
			or	
1/	Has a gene associated with HCM been identified?			a contraindication to beta-blocker therapy listed in the TGA
14				approved Product Information (PI)
	Yes No			Details of the contraindication
15	Does any first-degree family relative have a confirme	ed diagnosis		
	of HCM?		<b>91</b> The	patient had:
	Yes		ZI IIIe	
	No 📖			prior treatment with a non-dihydropyridine calcium channel blocker (CCB)
16	Does the patient have confirmed peak left ventricular	routflow		diltiazem
	tract (LVOT) gradient of at least 50 mm Hg?			or
	Yes			verapamil
	No 🗔			or
17	Provide details of the LVOT gradient report			other
	Date of the report (DD MM YYYY)		or	otto:
				an intolerance to non-dihydropyridine CCB therapy
	Unique identifying number/code or provider number			diltiazem
				or
	Measured LVOT gradient			verapamil
	mm Hg			or
				other
18	The LVOT gradient was measured:			Details of the intolerance
	at rest			
	after provocation with Valsalva manoeuvre			
	after provocation with exercise		or	
19	Does the patient have a current left ventricular ejection	on fraction		a contraindication to non-dihydropyridine CCB therapy
	(LVEF) of at least 55%?			listed in the TGA approved PI
	Yes			Details of the contraindication
	No 🗀			

22	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				
Che	eck	list				
23	G	The relevant attachments need to be provided with this form.				
		Details of the proposed prescription(s).				
Driv	120	v notice				

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

#### 25 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.

#### Lunderstand that:

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$\bullet $ giving false or misleading information is a serious offence.		
☐ I have read, understood and agree to the above.		
Date (DD MM YYYY) (you <b>must</b> 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 servicesaustralia.gov.au/hpos

or

by post (signature required) to

Services Australia Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001