Australian Government
Services Australia

medicare

PBS

Cystic fibrosis – ivacaftor – 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 ivacaftor for patients 1 month or older with cystic fibrosis.

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 cystic fibrosis **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.

Applications for **continuing** 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.

Section 100 arrangements for ivacaftor

This item is 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.

This item is 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.

For more information

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

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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

- ☐ public hospital
- ☐ private hospital

8 Hospital provider number

Conditions and criteria

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

9 The patient, 1 month or older, has been assessed:

- ☐ through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis
- ☐ in consultation with a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis (if attendance at such a unit is not possible due to geographical isolation).

10 This application is for a patient with:

- ☐ gating mutations ▶ ***Go to 11***
- ☐ non-gating mutations ▶ ***Go to 13***

11 The patient has:

- ☐ G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele

or

- ☐ other gating (class III) mutation in the CFTR gene on at least 1 allele



MCA0PB120 2611

12 Provide details of the pathology report substantiating G551D or other gating (Class III) mutation on the CFTR gene:

Specific CFTR mutation listed in the TGA approved Product Information

Name of the pathology report provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

Go to 16

13 Does the patient have either G551D mutation or other gating (class III) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene?

Yes ☐
No ☐

14 Does the patient have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data?

Yes ☐
No ☐

15 Provide details of the pathology report substantiating the specific mutation responsive to ivacaftor as listed in the TGA approved Product Information (PI)

Specific mutation listed in the TGA approved PI

Name of the pathology report provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

16 Will the treatment be given concomitantly with standard therapy for this condition?

Yes ☐
No ☐

17 Is the patient currently receiving one of the CYP3A4 inducers listed in the restrictions?

Yes ☐
No ☐

18 Is the patient concomitantly receiving CYP3A4 inhibitors, CYP3A4 inducers or IV antibiotics?

Yes ☐ ***Go to 19***
No ☐ ***Go to 20***

19 Provide current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

21 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**

22 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.

Reset form

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**
- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001