Australian Government
Services Australia

medicare

PBS

Cystic fibrosis – ivacaftor initial authority application

When to use this form

Use this authority application form to apply for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised treatment with ivacaftor for patients 12 months or older with cystic fibrosis.

Important information

Initial applications must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for **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 must be made in writing to Services Australia and must include a continuing treatment authority application form that provides sufficient information to determine the patient's eligibility according to the PBS criteria.

Section 100 arrangements

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a hospital.

The hospital name and provider number must be included in this form.

Treatment specifics

The patient must not receive **more than 24 weeks** treatment under this restriction.

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 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)

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 aged 12 months 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

or

☐ 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 as clinic is not possible due to geographical isolation).

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

No ☐

Yes ☐

11 The patient:

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

or

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

and

☐ has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis.

Sweat chloride result

mmol/L

12 Is the patient currently receiving a CYP3A4 inducer as outlined in the restriction?

No ☐

Yes ☐

13 Provide details of the patient's current CYP3A4 inhibitors, inducers and IV antibiotics medications if applicable

MCA0PB120 220405

14 Provide the following pathology report details confirming the G551D mutation or other gating (class III) mutation:

a) Pathology provider name

Date of pathology report (DD MM YYYY)

b) Unique identifying number/code

Checklist

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

☐ The completed authority prescription form(s).

Privacy notice

16 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/privacy**

Prescriber's declaration

17 **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 attached the completed authority prescription form(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.

Prescriber's signature

On completion, print and sign by hand.

Date (DD MM YYYY)

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form Print form