Australian Government
Services Australia

medicare

PBS

Cystic fibrosis – elexacaftor+tezacaftor+ivacaftor initial authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised elexacaftor+tezacaftor+ivacaftor for patients aged at least 6 years old with cystic fibrosis.

Important information

Initial applications to start PBS-subsidised treatment must be 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 must be made in writing to Services Australia and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Section 100 arrangements for elexacaftor+tezacaftor +ivacaftor

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 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 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 is:

☐ at least 6 years old elexacaftor+tezacaftor+ivacaftor (100mg / 50mg / 75mg + 150mg)

or

☐ between 6 years and 11 years old elexacaftor+tezacaftor+ivacaftor (50mg / 25mg / 37.5mg + 75mg)

10 The patient is being treated:

☐ by a specialist respiratory physician with expertise in cystic fibrosis

or

☐ in consultation with a specialist respiratory physician with expertise in cystic fibrosis (if attendance is not possible due to geographic isolation).

11 The patient is being treated:

☐ in a centre with expertise in cystic fibrosis

or

☐ in consultation with a centre with expertise in cystic fibrosis (if attendance is not possible due to geographic isolation).

12 Does the patient have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene?

No ☐

Yes ☐

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

No ☐

Yes ☐

14 Prior to initiating treatment with this drug, the patient has:

☐ chronic sinopulmonary disease

or

☐ gastrointestinal and nutritional abnormalities.

15 Is the patient currently receiving a strong CYP3A4 inducer as outlined in the restrictions?

No ☐

Yes ☐

MCA0PB286 2305

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

17 Provide the following pathology report details that confirms at least one F508del mutation in the CFTR gene:

Pathology provider name

Date of pathology report (DD MM YYYY)

Unique identifying number/code

Checklist

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

☐ The completed authority prescription form(s).

Privacy notice

19 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

20 **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 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