Australian Government
Services Australia

medicare

PBS

Cystic fibrosis – elexacaftor+tezacaftor+ivacaftor or vanzacaftor+tezacaftor+deutivacaftor – 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 treatment for cystic fibrosis with:

- elexacaftor+tezacaftor+ivacaftor for patients 2 years or over
- vanzacaftor+tezacaftor+deutivacaftor for patients 6 years or over.

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 elexacaftor+tezacaftor +ivacaftor and vanzacaftor +tezacaftor+deutivacaftor

These items are 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.

These items are 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 This application is for:

- ☐ elexacaftor+tezacaftor+ivacaftor ▶ ***Go to 10***
- ☐ vanzacaftor+tezacaftor+deutivacaft ▶ ***Go to 11***

10 The patient is:

- ☐ at least 6 years old and weighs ≥ 30kg elexacaftor+tezacaftor+ivacaftor tablets (100mg / 50mg / 75mg + 150mg)

or

- ☐ between 2 to 11 years old and weighs < 30kg elexacaftor+tezacaftor+ivacaftor tablets (50mg / 25mg / 37.5mg + 75mg)

or

- ☐ between 2 to 5 years old and weighs ≥ 14kg elexacaftor+tezacaftor+ivacaftor granules (100mg / 50mg / 75mg + 75mg)

or

- ☐ between 2 to 5 years old and weighs < 14kg elexacaftor+tezacaftor+ivacaftor granules (80mg / 40mg / 60mg + 59.5mg)

11 The patient is:

- ☐ at least 6 years old and weighs ≥ 40kg vanzacaftor+tezacaftor+deutivacaftor tablets (10mg / 50mg /125mg)

or

- ☐ at least 6 years old and weighs < 40kg vanzacaftor+tezacaftor+deutivacaftor tablets (4mg / 20mg /50mg)

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12 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).

13 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).

14 Does the patient have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor or vanzacaftor/tezacaftor/deutivacaftor potentiation based on clinical and/or in vitro assay data?

Yes ☐
No ☐

15 Is the specific mutation listed in the TGA-approved Product Information?

Yes ☐ ***Go to 17***
No ☐ ***Go to 16***

16 Does the patient harbour two Class I mutations?

Yes ☐
No ☐

17 Provide details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor or vanzacaftor/tezacaftor/deutivacaftor

List the specific mutation

Name of the pathology report provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

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

☐ chronic sinopulmonary disease

or

☐ gastrointestinal and nutritional abnormalities.

19 Is this treatment the sole PBS-subsidised CFTR modulator therapy for this condition?

Yes ☐
No ☐

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

Yes ☐
No ☐

21 Is the patient currently receiving one of the strong CYP3A4 inducers outlined in the Product Information?

Yes ☐
No ☐

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

Yes ☐ ***Go to 23***
No ☐ ***Go to 24***

23 Provide current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

25 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**

26 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