



# Cystic fibrosis – elexacaftor+tezacaftor+ivacaftor – initial authority application

<b>Online PBS Authorities</b>	You do not need to complete this form if you use the <b>Online PBS Authorities</b> system.
	For more information and how to access the <b>Online PBS Authorities</b> system, go to servicesaustralia.gov.au/hppbsauthorities
When to use this form	Use this form to apply for <b>initial</b> PBS-subsidised elexacaftor+tezacaftor+ivacaftor for patients 2 years or over with cystic fibrosis.
Important information	<b>Initial</b> applications to start PBS-subsidised treatment can be made using the <b>Online PBS Authorities</b> 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 <b>initial</b> treatment.
	Applications for <b>continuing</b> treatment can be made using the <b>Online PBS Authorities</b> system or in writing and must include 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:
for elexacaftor+tezacaftor	• an approved private hospital, <b>or</b>
+ivacaftor	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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PBS

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C	Online PBS Authorities	Hospital details
	You do not need to complete this form if you use the	7 Hospital name
	Online PBS Authorities system.	
	Go to servicesaustralia.gov.au/hppbsauthorities	This hospital is a:
_		public hospital
Pa	atient's details	private hospital
1	Medicare card number	
		8 Hospital provider number
	Ref no.	
	or Department of Veterans' Affairs card number	Conditions and eviteria
		Conditions and criteria
		To qualify for PBS authority approval, the following conditions
2	Dr 🗌 Mr 🗌 Mrs 🗌 Miss 🗌 Ms 🗌 Other	must be met.
	Family name	9 The patient is:
		at least 6 years old and weighs $\geq$ 30kg
	First given name	elexacaftor+tezacaftor+ivacaftor tablets
		(100mg / 50mg / 75mg + 150mg) <b>or</b>
~		$\Box$ between 6 to 11 years old and weighs < 30kg
3	Date of birth (DD MM YYYY)	elexacaftor+tezacaftor+ivacaftor tablets
		(50mg / 25mg / 37.5mg + 75mg)
_		
P	rescriber's details	between 2 to 5 years old and weighs ≥ 14kg elexacaftor+tezacaftor+ivacaftor granules
4	Prescriber number	(100mg / 50mg / 75mg + 75mg)
		or
		between 2 to 5 years old and weighs < 14kg
5	Dr 🗌 Mr 🗌 Mrs 🗌 Miss 🗌 Ms 🗌 Other 💷	elexacaftor+tezacaftor+ivacaftor granules (80mg / 40mg / 60mg + 59.5mg)
	Family name	<b>10</b> The patient is being treated:
		by a specialist respiratory physician with expertise in cystic
	First given name	fibrosis
		or
6	Business phone number (including area code)	in consultation with a specialist respiratory physician with
U		expertise in cystic fibrosis (if attendance is not possible due
		to geographic isolation).
	Alternative phone number (including area code)	<b>11</b> 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).
		,

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or   gastrointestinal and nutritional abnormalities.   Will the treatment be given concomitantly with standard therapy for this condition? Yes No Is the patient currently receiving one of the strong CYP3A4 inducers outlined in the Product Information? Yes No Provide current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics, if applicable ecklist <i>ecklist</i> The relevant attachments need to be provided with this form. Details of the proposed prescription(s).
or       gastrointestinal and nutritional abnormalities.         Will the treatment be given concomitantly with standard therapy for this condition?         Yes       No         No       Is the patient currently receiving one of the strong CYP3A4 inducers outlined in the Product Information?         Yes       No         No       Is the patient currently receiving one of the strong CYP3A4 inducers outlined in the Product Information?         Yes       No         No       Image: Provide current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics, if applicable
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or gastrointestinal and nutritional abnormalities. Will the treatment be given concomitantly with standard therapy
or
□ chronic sinopulmonary disease
Prior to initiating treatment with this drug, the patient has:
Unique identifying number/code
Date of the pathology report (DD MM YYYY)
Name of the pathology report provider
Provide details of the pathology report substantiating at least one F508del mutation:
Yes 🛄 No 🗌
cystic fibrosis transmembrane conductance regulator (CFTR) gene?
Does the patient have at least one F508del mutation in the

**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/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** 

#### 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 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)

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### **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