

Cystic fibrosis – lumacaftor+ivacaftor or tezacaftor+ivacaftor – continuing 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 **continuing** PBS-subsidised lumacaftor+ivacaftor or tezacaftor+ivacaftor for

patients with cystic fibrosis.

Important information

Continuing authority applications 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.

applications.

The information in this form is correct at the time of publishing and may be subject to change.

Under no circumstances will phone approvals be granted for cystic fibrosis continuing authority

Continuing treatment

This form is ONLY for **continuing** treatment.

The patient remains eligible to receive continuing treatment providing they continue to sustain a response

to treatment.

Section 100 arrangements for lumacaftor+ivacaftor and tezacaftor+ivacaftor 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

PB244.2410 **1 of 3**







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Hospital details Online PBS Authorities You do not need to complete this form if you use the Hospital name Online PBS Authorities system. Go to servicesaustralia.gov.au/hppbsauthorities This hospital is a: public hospital Patient's details private hospital Medicare card number Hospital provider number Department of Veterans' Affairs card number **Conditions and criteria** To qualify for PBS authority approval, the following conditions must be met. Mr Mrs Miss Ms Family name This application is for: or First given name tezacaftor+ivacaftor **10** The patient: Date of birth (DD MM YYYY) is homozygous for the F508del mutation or has at least one residual function (RF) mutation Prescriber's details **11** The patient is being treated: Prescriber number by a specialist respiratory physician with expertise in cystic fibrosis in consultation with a specialist respiratory physician with Miss expertise in cystic fibrosis (if attendance is not possible due Family name to geographic isolation). **12** The patient is being treated: First given name in a centre with expertise in cystic fibrosis in consultation with a centre with expertise in cystic fibrosis Business phone number (including area code) (if attendance is not possible due to geographic isolation). 13 Is this treatment being used as sole PBS-subsidised cystic Alternative phone number (including area code) fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition?



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Yes No

14	Will the treatment be given concomitantly with standard therapy for this condition?	Prescriber's declaration	
	Yes	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	
15	The patient, applying for:	servicesaustralia.gov.au/hpos	
	 lumacaftor+ivacaftor, is not currently receiving one of the strong CYP3A4 inducers outlined in the Product Information tezacaftor+ivacaftor, is not currently receiving one of the CYP3A4 inducers listed in the restrictions 	 I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine. 	
16	Provide current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics, if applicable	 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. 	
Checklist		I understand that:giving false or misleading information is a serious offence.	
17	The relevant attachments need to be provided with this form.	I have read, understood and agree to the above.	
	Details of the proposed prescription(s).	Date (DD MM YYYY) (you must date this declaration)	
Privacy notice		Prescriber's signature (only required if returning by post)	
18	Personal information is protected by law (including the Privacy Act 1988) and is collected by Services Australia for the	L	
	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	Returning this form	
	where it is required or authorised by law (including for the purpose of research or conducting investigations).	Return this form, details of the proposed prescription(s) and any relevant attachments:	
	More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at servicesaustralia.gov.au/privacypolicy	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