

# Cystic Fibrosis – Lumacaftor+Ivacaftor Continuing PBS authority application

## Supporting information

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<b>When to use this form</b>	Use this authority application form (this form) to apply for <b>continuing</b> Pharmaceutical Benefits Scheme (PBS) subsidised treatment with lumacaftor+ivacaftor for cystic fibrosis.
<b>Important information</b>	<p>Authority applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.</p> <p>Under no circumstances will phone approvals be granted for <b>continuing</b> authority applications.</p> <p>The patient must be registered in the Australian Cystic Fibrosis Database Registry.</p> <p>The information in this form is correct at the time of publishing and may be subject to change.</p>
<b>Continuing treatment</b>	<p>This form is ONLY for <b>continuing</b> treatment.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional 1 month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p>
<b>Section 100 arrangements for lumacaftor+ivacaftor</b>	<p>This item is available to a patient who is attending:</p> <ul style="list-style-type: none"><li>• an approved private hospital</li><li>• a public participating hospital, <b>or</b></li><li>• a public hospital</li></ul> <p><b>and is:</b></p> <ul style="list-style-type: none"><li>• a day admitted patient</li><li>• a non-admitted patient, <b>or</b></li><li>• a patient on discharge.</li></ul> <p>This item is not available as a PBS benefit for in-patients of a hospital.</p> <p>The hospital name and provider number must be included in this form.</p>
<b>For more information</b>	Go to <a href="https://humanservices.gov.au/healthprofessionals">humanservices.gov.au/healthprofessionals</a>

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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  
 /  /

## Prescriber's details

- 4 Prescriber number
- 5 Dr  Mr  Mrs  Miss  Ms  Other   
Family name
- First given name
- 6 Business phone number  
 ( )
- Alternative phone number
- Fax number  
 ( )

## Hospital details


- 7 Hospital name
- 8 Hospital provider number

## Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

- 9 The patient is:  
 6 to 11 years of age  
 12 years of age and above.
- 10 Has the patient previously received PBS subsidised treatment with this drug for this condition?  
No   
Yes
- 11 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).
- 12 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).
- 13 Will treatment be given concomitantly with standard therapy for this condition?  
No   
Yes
- 14 Provide details of intravenous (IV) antibiotics received by the patient, if applicable

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 Provide a copy of the patient's full current medication history.

**15** Provide the following patient details:

- a) Patient's current weight and height

Weight	Height
<input type="text"/> kg	<input type="text"/> cm

- b) Measurement of the number of days of cystic fibrosis hospitalisation (including hospital-in-the-home) in the previous 6 months

 days

- c) Result of Forced Expiratory Volume in 1 second (FEV<sub>1</sub>) measurement performed within the month prior to the date of application

Test result	Date of test
<input type="text"/> %	<input type="text"/> / /

**Note:** FEV<sub>1</sub> must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time of measurement.

### Checklist

- 16**  The relevant attachments need to be provided with this form.

- The completed authority prescription form(s).
- A copy of the full current medication history including any IV antibiotics.

### Privacy notice

- 17** Personal information is protected by law (including the *Privacy Act 1988*) and is collected by the Australian Government Department of Human Services for the purposes of assessing and processing this authority application.

Personal information may be used by the department, 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 the department manages personal information, including our privacy policy, can be found at [humanservices.gov.au/privacy](http://humanservices.gov.au/privacy)

### Prescriber's declaration

**18 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 the Australian Government Department of Human Services 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

Date

### Returning your form

You can 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 [humanservices.gov.au/hpos](http://humanservices.gov.au/hpos)
- **By mail**, send this form, the authority prescription form(s) and any relevant attachments to:

**Department of Human Services  
Complex Drugs Programs  
PO Box 9826  
HOBART TAS 7001**