AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Orkambi® (ivacaftor/lumacaftor)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing:

Age	Weight	Dose	Administration
1 through 2 years	7 kg to < 9kg	1 packet of lumacaftor 75 mg/ivacaftor 94 mg granules	Mixed with one teaspoon (5 mL) of soft food or liquid and administered orally **every 12 hours** with fat-containing food
	9kg to < 14kg	1 packet of lumacaftor 100 mg/ivacaftor 125 mg granules	
	≥ 14 kg	1 packet of lumacaftor 150 mg/ivacaftor 188 mg granules	
2 through 5 years	< 14 kg	1 packet of lumacaftor 100 mg/ivacaftor 125 mg granules	Mixed with one teaspoon (5 mL) of soft food or liquid and administered orally **every 12 hours** with fat-containing food

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Age	Weight	Dose	Administration
6 through 11 years		2 tablets of lumacaftor 100 mg/ivacaftor 125 mg (lumacaftor 200 mg/ivacaftor 250 mg per dose)	Taken orally **every 12 hours** with fat-containing food
12 years and older		2 tablets of lumacaftor 200 mg/ivacaftor 125 mg (lumacaftor 400 mg/ivacaftor 250 mg per dose)	

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is **1 years of age or older** with a diagnosis of Cystic Fibrosis
- ❑ Member is confirmed to be homozygous for the F508del gene mutation of the CFTR protein in the cystic fibrosis transmembrane conductance regulator (CFTR) confirmed by an FDA-cleared test **(test results must be attached)**
- ❑ Prescribing physician is a pulmonologist or has consulted with a pulmonologist who specializes in the treatment of Cystic Fibrosis
- ❑ Baseline FEV1 completed within the last 30 days must be submitted **(test results must be attached)**, unless the member is unable to perform a pulmonary function test **(documentation required)**
- ❑ Number of pulmonary exacerbations or hospitalizations in the preceding 6 months must be noted:

  _____
- ❑ Baseline body mass index must be noted: _____
- ❑ Baseline liver function tests have been completed prior to initiating therapy and will be completed annually **(labs must be attached)**
- ❑ Provider attests a baseline ophthalmic examination to monitor lens opacities/cataracts has been completed for pediatric members
- ❑ Member will **NOT** take Orkambi®, in combination with any other CFTR modulator therapy (i.e., Symdeko®, Kalydeco®, Trikafta®, Alyftrek™); **NOTE**: concurrent therapy with these agents will **NOT** be approved
- ❑ Member will avoid concomitant use of strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, phenobarbital, St. John's Wort) and strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole)

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has demonstrated disease response as indicated by **one or more** of the following **(must submit current labs and chart notes)**:
  - ❑ Decreased pulmonary exacerbations or hospitalizations compared to pretreatment baseline
  - ❑ Stabilization of lung function as measured by FEV1 within the last year compared to baseline
  - ❑ Improvement in quality of life, weight gain, or growth
- ❑ Member has **NOT** received a lung transplant
- ❑ Member has experienced an absence of unacceptable toxicity from therapy (i.e. elevated transaminases (ALT or AST), development of cataracts or lens opacities)

Date of initiation of Orkambi® therapy: _____	Reauthorization Date: _____
Baseline FEV_1 **(last FEV1 prior to starting Orkambi®)**: _____	Current FEV_1 **(FEV1 AFTER last dose of Orkambi®)**: _____
Baseline Weight: _____	Current Weight: _____
BMI Baseline: _____	Current BMI: _____
Number of hospitalizations since last approval of Orkambi® must be noted: _____	

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: ~~8/15/15; 10/14/2016;~~ **11/18/2022**
REVISED/UPDATED/REFORMATTED: ~~12/12/2016; 8/4/2017; 12/30/2018; 08/13/2019; 4/1/2021; 6/30/2021; 11/30/2022;11/1/2023,~~ **4/15/2025**