

OPTIMA HEALTH PLAN

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 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.*

Drug Requested: Orkambi® (ivacaftor/lumacaftor)

DRUG INFORMATION: Complete information below. If incomplete, authorization process will be delayed

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

- Positive cultures for *Burkholderia cencopacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus* **will not** be covered
- Orkambi® **will NOT** be covered for patients with FEV₁ > 90 %.

CLINICAL CRITERIA: ALL boxes below **must** be checked to qualify. Lab results and chart notes **MUST** be attached. If not included, authorization process will be delayed.

- Patient is **6 years of age or older** with a diagnosis of Cystic Fibrosis.
- Patient is confirmed to be homozygous for the Phe-508del gene mutation of the CFTR protein (**Lab documentation required**)
- Baseline FEV₁ (within the last 3 months). (**Lab documentation required**)
- Recent eGFR or SCr (within the last 3 months) (**Lab documentation required**)
- Recent LFTs (within the last 3 months) (**Lab documentation required**)
- Patient does not have positive cultures for *Burkholderia cencopacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*. (**Lab documentation required within last six (6) months of THIS request.**)
- Member is currently **COMPLIANT** on at least **two (2)** of the following:
 - Dornase alfa
 - Hypertonic saline
 - Inhaled or oral antibiotics within the last three (3) months

Initial Authorization Limit to 6 months.

For **Re-authorization**, member **must** show improvement from baseline of at least FEV₁ 5% and compliance

Baseline Date: _____ (**prior to Orkambi® 1st dose**)

FEV₁: _____

(continued on next page)

Medication being provided by a Specialty Pharmacy: Briova SpecialtyRx

****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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

*Approved by Pharmacy and Therapeutics Committee: 8/15/15; 10/14/2016;

REVISED/UPDATED: 10/29/2015; 12/22/2015; 1/15/2016; 3/30/2016; 6/6/2016; 8/11/2016; 9/22/2016; 11/17/2016; 12/12/2016; 9/16/2017; 10/7/2017.