Gateway Health℠ It's Wholecare.

Updated: 06/2021
PARP Approved: 07/2021

Prior Authorization Criteria

Cystic Fibrosis Biologic Response Modifiers

All requests for Cystic Fibrosis Biologic Response Modifiers require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Cystic Fibrosis Biologic Response Modifiers include Kalydeco (ivacaftor), Symdeko (tezacaftor/ivacaftor), Orkambi (lumacaftor/ivacaftor), and Trikafta (elexacaftor, tezacaftor, ivacaftor). New products with this classification will require the same documentation.

Coverage may be provided with a diagnosis of Cystic Fibrosis and the following criteria is met:

- Must be prescribed by or in consultation with a pulmonologist or Cystic Fibrosis specialist
- Has a documented genetic mutation as noted in the package labeling.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- **Initial Duration of Approval:** 3 months
- **Reauthorization Criteria**
    - Continues to benefit from treatment based on the prescriber's assessment
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health℠ It's Wholecare.

Updated: 06/2021
PARP Approved: 07/2021

CYSTIC FIBROSIS BIOLOGIC RESPONSE MODIFIERS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Is there a genetic mutation as noted in the package labeling? ☐ Yes, please indicate the mutation: _____ ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date