Updated: 06/2024
DMMA Approved: 06/2024

Request for Prior Authorization for Cystic Fibrosis Biologic Response Modifiers
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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 Prior Authorization Criteria:

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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK HEALTH OPTIONS

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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 Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

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