Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health	**Submission Date:** 6/1/2020
Policy Number:	**Effective Date:** 8/1/2020 **Revision Date:** 2/2020
Policy Name: Cystic Fibrosis Medications (Non-PDL)	
Type of Submission – Check all that apply: ☐ **New Policy** ☐ **Annual Review – No Revisions** **X Revised Policy**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:**	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** 

Last Review: 02/2020
Last PARP Approval: 3/2019
Current PARP Approval: 8/2020

AETNA BETTER HEALTH®

Prior Authorization guideline for Cystic Fibrosis Medications (Non-PDL)

Kalydeco
Orkambi
Pulmozyme
Symdeko
Trikafta

Authorization guidelines

Pulmozyme may be authorized when the following are met:

A. Member has a diagnosis of Cystic Fibrosis
B. Member is at least 5 years old

   OR

C. For members less than 5 years old: Member has daily cough or has FEV_1 below the normal range

Kalydeco can be recommended for approval for patients who meet the following:

A. Prescribed by, or in consultation with, a pulmonologist
B. Member has a diagnosis of cystic fibrosis
C. Member is at least 6 months old
D. Member has one mutation in the CFTR gene that is responsive to Kalydeco (ivacaftor)
E. Member is not homozygous for the PheF508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.
F. For pediatric members, an eye examination is required at baseline and periodically throughout therapy.

Last Review: 02/2020
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G. Transaminase (ALT, AST) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment
H. Not currently using strong CYP3A inducers (ex. rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's wort)

Orkambi can be recommended for approval for patients who meet the following:

A. Prescribed by, or in consultation with, a pulmonologist
B. Member has a diagnosis of cystic fibrosis
C. Member is at least 2 years old
D. Lab results support that member is homozygous for the F508Del at the CFTR gene. (If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene)
E. For pediatric members, an eye examination is required at baseline and periodically throughout therapy
F. Transaminase (ALT, AST) monitoring at baseline and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment
G. Member is not taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducers such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort

Symdeko can be recommended for approval when the following are met:

A. Prescribed by, or in consultation with pulmonologist
B. Member has a diagnosis of Cystic Fibrosis
C. Member is at least 6years of age
D. Lab results to support ONE of the following:
    1. Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene

2. Member has at least one mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene that is responsive to Symdeko (tezacaftor-ivacaftor)

E. Transaminase (ALT and AST) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment

F. For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), dose is decreased

Trikafta can be recommended for approval when the following are met:

A. Prescribed by, or in consultation with pulmonologist

B. Member has a diagnosis of Cystic Fibrosis

C. Member is at least 12 years of age

D. Lab results to support the following:

1. Member has at least one F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene

E. Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment

F. For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Trikafta dose

Initial Approval:

Kalydeco, Orkambi, Symdeko and Trikafta: 3 months

All others: Indefinite

Renewal:

Kalydeco, Orkambi, Symdeko and Trikafta: 12 months

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Requirements

- Based on the prescriber's assessment, continues to benefit from therapy
- Pediatric members: Eye exam due to the possible development of cataracts.
- Transaminase (ALT, AST) monitoring
- Liver Function Tests (LFTs):
    - Kalydeco, Symdeko, Orkambi and Trikafta should be temporarily discontinued if AST/ALT are >5x ULN
      or
    - Orkambi and Symdeko: ALT or AST >3 x ULN with bilirubin >2 x ULN

Additional Information:

Quantity Limits

- Kalydeco tablets and granule packets: 56 tablets or packets per 28 days
- Orkambi tablets: 112 tablets per 28 days
- Orkambi granule packets: 56 packets per 28 days
- Symdeko: 56 tablets per 28 days
- Trikafta: 84 tablets per 28 days

Medications are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

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The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

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