

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: Commercial (Traditional) Commercial (Individual/Optimized)

Medicaid

This request is: Urgent (life threatening) Non-Urgent (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Symdeko[®] (Tezacaftor /ivacaftor)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

New request Continuation request

Drug product: Symdeko 100mg-150mg & 150mg tablet

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Drug cost information

The wholesale acquisition cost for each Symdeko tablet is \$400.00. The annual cost of treatment with this drug is more than \$288,000.00.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must be used for treatment of cystic fibrosis (documentation of a cystic fibrosis ICD10 code* within the last 12 months must be submitted to Priority Health)
2. Must be age 12 or older with laboratory confirmation of homozygous F508del mutation in the CFTR (cystic fibrosis transmembrane regulator) gene or CFTR gene mutation responsive to Symdeko.

* Approved ICD10 codes are provided in the Additional Information section

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What is the patient's diagnosis?

Cystic fibrosis (documentation of a cystic fibrosis ICD10 code from within the last 12 months must be submitted to Priority Health)

Other: _____

Rationale for use: _____

B. Which of the following mutations does the patient have? (please fax laboratory confirmation)

- | | | | |
|-------------------------------------|---------------------------------------|-----------------------------------|------------------------------------|
| <input type="checkbox"/> E56K | <input type="checkbox"/> F1052V | <input type="checkbox"/> L206W | <input type="checkbox"/> S1251N |
| <input type="checkbox"/> A1067T | <input type="checkbox"/> F1074L | <input type="checkbox"/> P67L | <input type="checkbox"/> S1255P |
| <input type="checkbox"/> A455E | <input type="checkbox"/> G1069R | <input type="checkbox"/> R1070Q | <input type="checkbox"/> S549N |
| <input type="checkbox"/> D110E | <input type="checkbox"/> G1244E | <input type="checkbox"/> R1070W | <input type="checkbox"/> S549R |
| <input type="checkbox"/> D110H | <input type="checkbox"/> G1349D | <input type="checkbox"/> R117C | <input type="checkbox"/> S945L |
| <input type="checkbox"/> D1152H | <input type="checkbox"/> G178R | <input type="checkbox"/> R117H | <input type="checkbox"/> S977F |
| <input type="checkbox"/> D1270N | <input type="checkbox"/> G551D | <input type="checkbox"/> R347H | <input type="checkbox"/> E831X |
| <input type="checkbox"/> D579G | <input type="checkbox"/> G551S | <input type="checkbox"/> R352Q | <input type="checkbox"/> 711+3A→G |
| <input type="checkbox"/> E193K | <input type="checkbox"/> K1060T | <input type="checkbox"/> R74W | <input type="checkbox"/> 2789+5G→A |
| <input type="checkbox"/> 3272-26A→G | <input type="checkbox"/> 3849+10kbC→T | <input type="checkbox"/> F508del* | |

*A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in the table above to be indicated.

Additional Information:

Approved ICD10 Codes for Cystic Fibrosis

ICD10	ICD10 Label
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis, unspecified