SENTARA HEALTH PLANS

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. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Symdeko® (tezacaftor/ivacaftor)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Maximum Approved Dose: Adults and children ≥6 years: Max 2 tablets daily. Children ≥6 years to < 12 years weighing <30kg: tezacaftor 50mg/ivacaftor 75mg in the morning and ivacaftor 75mg in the evening, 12 hours apart. Children ≥6 years to < 12 years weighing >30kg & Children > 12 years, and adolescents: tezacaftor 100mg/ivacaftor 150mg in the morning and ivacaftor 150mg in the evening, 12 hours apart.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 months

- ❑ Member is **6 years of age or older** with a diagnosis of Cystic Fibrosis

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- ❑ Member must have ONE of the following mutation types in the cystic fibrosis transmembrane conductance regulator (CFTR) gene:
  - ❑ Member is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene **(Test result must be attached)**

    OR
  - ❑ Member has **at least one mutation** in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko® detected by an FDA-cleared test **(Test result must be attached)**
- ❑ Prescribing physician is a pulmonologist or has consulted with a pulmonologist who specializes in the treatment of Cystic Fibrosis
- ❑ Baseline FEV1 within the last 30 days must be submitted **(Test results must be attached),** unless the member is unable to perform a pulmonary function test **(documentation required)**
- ❑ Baseline LFTs have been completed prior to initiating therapy and will be completed annually **(Labs must be attached)**
- ❑ Attestation that baseline ophthalmic examination to monitor lens opacities/cataracts has been completed for pediatric members
- ❑ Number of pulmonary exacerbations or hospitalizations in the preceding 6 months must be noted: _____
- ❑ Baseline body mass index must be noted: _____
- ❑ Member will not be taking Symdeko®, in combination with any other CFTR modulator therapy (i.e. Orkambi®, Kalydeco®, Trikafta™); concurrent therapy with these agents will not be approved
- ❑ Member will avoid concomitant use of strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, phenobarbital, St. John's Wort; etc.) and strong or moderate CYP3A inhibitors (i.e. fluconazole, itraconazole)

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the initial criteria
- ❑ Member has demonstrated disease response as indicated by **one or more** of the following **(must submit current labs and chart notes)**:
  - ❑ Decreased pulmonary exacerbations or hospitalizations compared to pretreatment baseline
  - ❑ Stabilization of lung function as measured by FEV1 within the last year compared to baseline
  - ❑ Improvement in quality of life, weight gain, or growth
- ❑ Patient has not received a lung transplant
- ❑ Absence of unacceptable toxicity from therapy the drug i.e. elevated transaminases (ALT or AST), development of cataracts or lens opacities)

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Date of initiation of Symdeko® therapy: _____	Re-Authorization Date: _____
Baseline FEV_1 (**last FEV_1 prior to starting Symdeko®**): _____	Current FEV_1 (**FEV_1 AFTER last dose of Symdeko®**): _____
Baseline Weight: _____	Current weight: _____
Baseline BMI: _____	Current BMI: _____
Number of hospitalizations since last approval of Symdeko® must be noted _____	

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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.****

***Approved by Pharmacy and Therapeutics Committee**: 4/19/2018
REVISED/UPDATED: ~~6/20/2018; 9/12/2019; 4/1/20211;10/11/2021;~~ **10/30/2023**;