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 information provided is not complete, correct, or legible, authorization may be delayed.**

Drug Requested: Trikafta® (elexacaftor/tezacaftor/ivacaftor and 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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing:

- **Children ≥ 2 years to < 6 years weighing < 14 kg:** Oral: 1 packet (containing elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg) in the morning and 1 packet (containing ivacaftor 59.5 mg) in the evening
- **Children ≥ 2 years to < 6 years weighing > 14 kg:** Oral: 1 packet (containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) in the morning and 1 packet (containing ivacaftor 75 mg) in the evening
- **Children ≥ 6 years to < 12 years weighing < 30 kg:** Oral: 2 tablets (each containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) in the morning and ivacaftor 75 mg in the evening, approximately 12 hours apart
- **Children ≥ 6 years to < 12 years weighing ≥ 30 kg:** Oral: 2 tablets (each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) in the morning and ivacaftor 150 mg in the evening, approximately 12 hours apart
- **Children ≥ 12 years, Adolescents and Adults:** Oral: 2 tablets (each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) in the morning and one ivacaftor 150 mg tablet in the evening, approximately 12 hours apart

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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: 6 months

- ❑ Member is **2 years of age or older** with a diagnosis of Cystic Fibrosis
- ❑ Member has **at least one** of the F508del mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene as confirmed by an FDA-cleared test that is responsive to elexacaftor/tezacaftor/ivacaftor **(test results must be attached)**
- ❑ Prescribing physician is a pulmonologist or has consulted with a pulmonologist who specializes in the treatment of Cystic Fibrosis
- ❑ Baseline FEV_1 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)**
- ❑ Number of pulmonary exacerbations or hospitalizations in the preceding 6 months must be noted:

  _____
- ❑ Baseline body mass index must be noted: _____
- ❑ Baseline liver function tests have been completed prior to initiating therapy and will be completed annually **(labs must be attached)**
- ❑ Provider attests a baseline ophthalmic examination to monitor lens opacities/cataracts has been completed for pediatric members
- ❑ Member does **NOT** have severe hepatic impairment (Child-Pugh Class C)
- ❑ Member will **NOT** be taking Trikafta® in combination with any other CFTR modulator therapy (i.e., Symdeko®, Orkambi®, Kalydeco®, Alyftrek™) **NOTE**: 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) and strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole)

Reauthorization: 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 all initial authorization 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

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- ❑ Member has **NOT** received a lung transplant
- ❑ Member has experienced an absence of unacceptable toxicity from therapy (i.e., elevated transaminases (ALT or AST), development of cataracts or lens opacities)

Date of initiation of Trikafta® therapy: _____	Reauthorization Date: _____
Baseline FEV1 **(last FEV1 prior to starting Trikafta®)**: _____	Current FEV1 **(FEV1 AFTER last dose of Trikafta®)**: _____
Baseline Weight: _____	Current weight: _____
Baseline BMI: _____	Current BMI: _____
Number of hospitalizations since last approval of Trikafta® must be noted _____	

Medication being provided by a Specialty Pharmacy – Proprium Rx

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**: ~~1/16/2020;~~ **5/25/2023**
REVISED/UPDATED/REFORMATTED: ~~3/02/2020; 4/1/2021; 10/11/2021;6/15/2023; 11/20/2023;~~ **4/15/2025**