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: Alyftrek™ (vanzacaftor/tezacaftor/deutivacaftor)

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 ≥ 6 years to < 12 years weighing < 40 kg:** Oral: Three tablets of vanzacaftor 4 mg/tezacaftor 20 mg/deutivacaftor 50 mg once daily
- **Children ≥ 6 years to < 12 years weighing ≥ 40 kg:** Oral: Two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg once daily
- **12 years and older:** Oral: Two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg once daily

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 **6 years of age or older** with a diagnosis of Cystic Fibrosis

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- ❑ Member has **at least one** variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on clinical and/or in vitro data, results in production of CFTR protein, or is confirmed by an FDA-cleared test to be responsive to vanzacaftor/tezacaftor/deutivacaftor **(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 FEV1 within the last 30 days must be submitted, unless the member is unable to perform a pulmonary function test **(Test results must be attached)**
- ❑ 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 that 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 Alyftrek™ in combination with any other CFTR modulator therapy (i.e., Trikafta®, Symdeko®, Orkambi®, or Kalydeco®) **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 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
- ❑ 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)

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

Medication being provided by 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.*