SENTARA COMMUNITY PLAN
(MEDICAID)

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: 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:** _____

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:** _____

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 – 1 year

1. Does the member have a diagnosis of cystic fibrosis? ❑ Yes ❑ No

AND

2. Is the member 2 years of age or older? ❑ Yes ❑ No

AND

3. Does the member have at least one F508del mutation in the CFTR gene as confirmed by an FDA cleared CF mutation test? **(Documentation required – include a copy of the test with this fax)**

❑ Yes ❑ No

AND

(Continued on next page)

4. Is there confirmation that the member is **NOT** receiving concurrent treatment with any other CFTR targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor or elexacaftor?
   ❑ Yes ❑ No

AND

5. Is there confirmation that the member will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort)? ❑ Yes ❑ No

AND

6. Does the member have a baseline percent predicted forced expiratory volume (ppFEV1) **(reported measurements may be used on renewal)**? ❑ Yes ❑ No

AND

7. Has baseline liver function tests (e.g., ALT, AST, bilirubin) been performed and will be reassessed every 3 months? **(Documentation required – include a copy of the test with this fax)**
   ❑ Yes ❑ No

AND

8. Is there confirmation that the member does **NOT** have severe hepatic impairment (Child-Pugh Class C)?
   ❑ Yes ❑ No

AND

9. Has a baseline ophthalmic examination been performed to monitor lens opacities/cataracts if the member is 2 years to ≤ 18 years of age **(not required in adults)**? ❑ Yes ❑ No

Reauthorization Approval – 1 year. 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.

10. Does the member continue to meet the above criteria? ❑ Yes ❑ No

AND

11. Does the member demonstrate disease response as indicated by ≥ 1 of the following:
    - ❑ Decreased pulmonary exacerbations compared to pretreatment baseline; **OR**
    - ❑ Improvement or stabilization of lung function compared to baseline; **OR**
    - ❑ Decrease in decline of lung function; **OR**
    - ❑ Improvement in quality of life, weight gain, or growth?

    ❑ Yes ❑ No

AND

(Continued on next page)

12. Is there confirmation that the member has **NOT** received a lung transplant? ❑ Yes ❑ No

AND

13. Is there confirmation that the prescriber reassessed liver function tests (ALT, AST, bilirubin) every 3 months in the first year, and annually thereafter? ❑ Yes ❑ No

AND

14. Does the member have absence of unacceptable toxicity from the drug (e.g., elevated transaminases [ALT or AST], cataracts or lens opacities)? ❑ Yes ❑ No

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.*