Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Horizon NJ Health

Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Products – Medical Necessity Request

*****Complete page 1 for Initial Requests Only*****

1. Does the member have a diagnosis of Cystic Fibrosis (CF)?
   - □ **Yes**
   - □ **No** – Please provide the diagnosis: _____

2. Is the medication being prescribed by or in consultation with a specialist in CF or a pulmonologist? **Yes or No**

3. Is the member being currently treated with another CFTR agent?
   - □ **No**
   - □ **Yes** - Will it be discontinued prior to initiating the requested drug? **Yes or No**

4. Have baseline liver function tests (e.g., ALT, AST) been performed? **Yes or No**

5. What is the member's current weight? _____ lbs or _____kg

6. For pediatric patients, has a baseline eye examination been performed and will be performed periodically during therapy? **Yes or No**

7. For members taking CYP3A inhibitors such as fluconazole, erythromycin, ketoconazole, etc., will the dose of the requested drug be reduced? **Yes or No**

8. Please answer the questions listed below for the requested drug and also submit documentation of the mutation test results.

Medication	Criteria
Ivacaftor (Kalydeco®)	• Is the member is 4 months or older? **Yes or No** • Does the member have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor based on clinical and/or *in vitro* assay data? **Yes or No**
Lumacaftor/ivacaftor (Orkambi®)	• Is the member is 2 years or older? **Yes or No** • Is the member is homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene? **Yes or No**
Tezacaftor/ivacaftor (Symdeko®)	• Is the member is 6 years or older? **Yes or No** • Is the member is homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence? **Yes or No**
Elexacaftor/tezacaftor/ivacaftor (Trikafta®)	• Is the member 6 years or older? **Yes or No** • Does the member have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on *in vitro* data? **Yes or No**

Physician office's signature*_____ Print Name_____

***Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Horizon NJ Health

Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Products – Medical Necessity Request

Complete page 2 only for Subsequent/Renewal requests*

1. Has the member demonstrated a clinical improvement or stabilization with the product being requested?
   □ **No**
   □ **Yes -** Please indicate which of the following the member has experienced.
      □ Improvement in FEV1 from baseline
      □ Increase in weight or body mass index (BMI)
      □ Improvement in quality of life as demonstrated by CF Questionnaire-Revised (CFQ-R) Respiratory Domain Score
      □ Improvement in respiratory symptoms related to members with CF (cough, sputum production, and difficulty breathing)
      □ Reduced number of pulmonary exacerbations
      □ None of the above
      □ Other: _____

2. Is the member concurrently receiving another CFTR agent? **Yes or No**

3. Is the medication being prescribed by or in consultation with a specialist in CF or a pulmonologist? **Yes or No**

4. Is monitoring of ALT and AST being done annually? **Yes or No**

5. For pediatric members: Is the member being monitored for possible development of cataracts? **Yes or No**

6. Is the dose being increased from the previous dose?
   □ **Yes -** Please provide the member's current weight: _____ lbs or _____kg
   □ **No**

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**