# 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: Kalydeco®** (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:** _____

**Quantity Limit: 2 packets or tablets per day (all strengths)**

**Recommended Dosage:**

| Age | Weight | Dosage |
|---|---|---|
| 1 month to < 2 months | 3 kg or greater | one 5.8 mg packet every 12 hours |
| 2 months to < 4 months | 3 kg or greater | one 13.4 mg packet every 12 hours |
| 4 months to < 6 months | 5 kg or greater | one 25 mg packet every 12 hours |
| 6 months to < 6 years | 5 kg to < 7 kg | one 25 mg packet every 12 hours |
| | 7 kg to < 14 kg | one 50 mg packet every 12 hours |
| | 14 kg or greater | one 75 mg packet every 12 hours |
| 6 years and older | N/A | one 150 mg tablet every 12 hours |

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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 **1 month of age** or older with a diagnosis of Cystic Fibrosis
- ❑ Member has **at least one** mutation in the Cystic Fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor as detected by an FDA cleared test **(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 LFTs 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 will **NOT** be taking Kalydeco® in combination with any other CFTR modulator therapy (i.e., Symdeko®, Orkambi®, 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) 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 compared to pretreatment baseline
  - ❑ Stabilization of lung function as measured by $FEV_1$ within the last year as 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 Kalydeco® therapy: _____** | **Re-Authorization Date: _____** |
| **Baseline $FEV_1$ (last $FEV_1$ prior to starting Kalydeco®): _____** | **Current $FEV_1$ ($FEV_1$ after last dose of Kalydeco®): _____** |
| **Baseline weight: _____** | **Current weight: _____** |
| **Baseline BMI: _____** | **Current BMI: _____** |
| **Number of hospitalizations since last approval of Kalydeco® 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.***