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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

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

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 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 will **NOT** be taking Kalydeco® in combination with any other CFTR modulator therapy (i.e., Symdeko®, Orkambi®, Trikafta®, Alyftrek™); 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.