ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Kalydeco® (ivacaftor)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Kalydeco® (ivacaftor)

Diagnosis (documentation supportive of diagnosis is required)

☐ Cystic Fibrosis

☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ Confirmed G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene

☐ Age 6 or older

**Kalydeco is not effective and will not be approved for patients with CF who are homozygous for the F508del mutation in the CFTR gene*

Physician Specialty

☐ Pulmonologist

☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Kalydeco® (ivacaftor)

CLASSIFICATION

- Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator

DESCRIPTION

- Ivacaftor is a potentiator of the CFTR protein, which is a chloride channel present at the surface of epithelial cells in multiple organs. It facilitates increased chloride transport by potentiating the channel-open probability (or gating) of the G551D-CFTR protein.
- Ivacaftor is indicated for the treatment of cystic fibrosis (CF) in patients 6 years and older who have a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CF transmembrane conductance regulator (CFTR) gene; in patients whose genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence gene mutations.
- Ivacaftor is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene (the most common mutation in CF).
- Ivacaftor significantly improved FEV1, increased body weight and body mass index, improved respiratory symptom scores, and decreased the rate of pulmonary exacerbations compared with placebo in several studies of adults and children with cystic fibrosis with various specific genetic mutations
- Two randomized, double-blind, placebo-controlled clinical trials evaluated the efficacy of ivacaftor 150mg twice daily in 213 patients (109 received Kalydeco) with the G551D mutation in the CFTR gene. Trial 1 evaluated patients age 12 and older and trial 2 evaluated patients age 6 to 11 years old. Patients were excluded if Burkholderia cenocepacia, dolosa, or Mycobacterium abcessus was isolated from sputum and if liver function tests were ≥3 times the ULN. Continuation of current prescribed CF therapies was allowed (e.g. tobramycin, dornase alfa), but the use of inhaled hypertonic saline was not permitted. The primary efficacy endpoint in both studies resulted in a significant improvement in FEV1 with a treatment difference for the mean absolute change in percent predicted FEV1 from baseline through week 24 of 10.6 percentage points ($p<0.0001$) in Trial 1 and 12.5 percentage points ($p<0.0001$) in Trial 2.
- The most common adverse drug reactions that occurred in ≥8% of patients treated with Kalydeco were headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, and dizziness.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 5
Commercial Formulary: Tier 4
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Kalydeco® (ivacaftor) meets the definition of **medical necessity** for the following:

- Patients age 6 or older with Cystic Fibrosis with confirmed G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene *(documentation required).*

Kalydeco® (ivacaftor) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported.

Kalydeco® (ivacaftor) will **not be covered** for the following:

- *Kalydeco is not effective and will not be approved for patients with CF who are homozygous for the F508del mutation in the CFTR gene.*

Required Provider Specialty:

- Approval is limited to Pulmonology

DOSAGE/ADMINISTRATION

Adult and Pediatric Dosing (safety and efficacy has not been determined for pediatric patients < 6 years of age):

Cystic fibrosis, in patients with a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene:

Usual Dose:

- 150 mg ORALLY every 12 hours with fat-containing food

Dose adjustments for hepatic impairment:

- moderate (Child-Pugh Class B): 150 mg ORALLY once daily
- severe (Child-Pugh Class C): use cautiously at a dose of 150 mg ORALLY once daily or less frequently

Dose adjustments for renal impairment:

- mild to moderate, no dose adjustment necessary
- use caution in patients with severe renal impairment (CrCl ≤ to 30 mL/min) or ESRD

Dose adjustments for drug interactions:

- concomitant use with moderate CYP3A inhibitors (e.g., fluconazole or erythromycin): 150 mg ORALLY **once daily**
- concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, posaconazole, voriconazole, telithromycin): 150 mg ORALLY **twice weekly**

PRECAUTIONS

- Concomitant use with strong CYP3A4 inhibitors; dose adjustment recommended.
- Concomitant use with strong CYP3A4 inducers (e.g., rifampin, St. John's Wort) is not recommended due to substantial decreases in exposure of ivacaftor which may diminish effectiveness.
- Elevated transaminase levels have been reported. Monitoring is recommended prior to initiation of therapy, then every 3 months for 1 year, then once annually thereafter. Dose interruption may be necessary.

- Food containing grapefruit or Seville oranges should be avoided during treatment.
- Moderate hepatic impairment (Child-Pugh Class B) - dose adjustment recommended.
- Severe hepatic impairment (Child-Pugh Class C) - dose adjustment recommended and reduction in frequency of administration may be necessary.
- Severe renal impairment (CrCl less than or equal to 30 mL/min) or end stage renal disease.

Billing/Coding information

HCPCS Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

COST

- AWP (February 2012): Kalydeco 150mg PO BID (60): $29,400
- AWP (January 2013): Kalydeco 150mg PO BID (60): $30,723.60

COMMITTEE APPROVAL

- March 2012

GUIDELINE UPDATE INFORMATION

February 2012	Coverage Policy created
May 2014	Coverage Policy updated

REFERENCES

- DRUGDEX®, accessed 02/21/2012, 5/17/2014.
- Product Information: Kalydeco® (ivacaftor), oral tablet. Vertex Pharmaceuticals Inc., Cambridge, MA 02139. January 2012, February 2014.