Kalydeco (ivacaftor)
Prior Authorization Request Form

Caterpillar Prescription Drug Benefit
Phone: 877-228-7909 Fax: 800-424-7640

Instructions: Please fill out all applicable sections completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the authorization request). Information contained in this form is Protected Health Information under HIPAA.

☐ **URGENT**

MEMBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PHONE NUMBER:	**DATE OF BIRTH:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
PATIENT INSURANCE ID NUMBER:	

☐ **MALE** ☐ **FEMALE** **HEIGHT (IN/CM):** _____ **WEIGHT (LB/KG):** _____ **ALLERGIES:** _____

IF YOU ARE NOT THE PATIENT OR THE PRESCRIBER, YOU WILL NEED TO SUBMIT A PHI DISCLOSURE AUTHORIZATION FORM WITH THIS REQUEST WHICH CAN BE FOUND AT THE FOLLOWING LINK: HTTPS://MAGELLANRX.COM/MEMBER/EXTERNAL/COMMERCIAL/COMMON/DOC/EN-US/PHI_DISCLOSURE_AUTHORIZATION.PDF

PATIENT'S AUTHORIZED REPRESENTATIVE (IF APPLICABLE): _____
AUTHORIZED REPRESENTATIVE'S PHONE NUMBER: _____

PRESCRIBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PRESCRIBER SPECIALTY:	**EMAIL ADDRESS:**
NPI NUMBER:	**DEA NUMBER:**
PHONE NUMBER:	**FAX NUMBER:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
REQUESTOR (if different than prescriber)**:**	**OFFICE CONTACT PERSON:**

MEDICATION OR MEDICAL DISPENSING INFORMATION			
MEDICATION NAME:			
DOSE/STRENGTH:	**FREQUENCY:**	**LENGTH OF THERAPY/REFILLS:**	**QUANTITY:**
☐ **NEW THERAPY** ☐ **RENEWAL** DURATION OF THERAPY (SPECIFIC DATES):		**IF RENEWAL:** DATE THERAPY INITIATED:	

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Revision Date: 6.1.2023
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MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

1. HAS THE PATIENT TRIED ANY OTHER MEDICATIONS FOR THIS CONDITION? ☐ YES (if yes, complete below) ☐ NO		
MEDICATION/THERAPY (SPECIFY DRUG NAME AND DOSAGE):	**DURATION OF THERAPY** (SPECIFY DATES):	**RESPONSE/REASON FOR FAILURE/ALLERGY:**

2. LIST DIAGNOSES:	**ICD-10:**
☐ **Cystic fibrosis**	

3. REQUIRED CLINICAL INFORMATION: PLEASE PROVIDE ALL RELEVANT CLINICAL INFORMATION TO SUPPORT A PRIOR AUTHORIZATION.

Clinical Information:
Will drug be used as part of a clinical trial? ☐ Yes ☐ No

Is this request for initial therapy (meaning the patient has not received therapy with Kalydeco in the past AND there are no paid claims for Kalydeco in member's history)? ☐ Yes ☐ No
If No, please complete "Renewal Therapy" section below.

Initial Request:
Does the patient have a diagnosis of cystic fibrosis? ☐ Yes ☐ No

Does the patient have a CFTR gene mutation listed within the current FDA prescribing information?
☐ Yes ☐ No *Test documentation must be provided*

If patient is under the age of 6 years, please answer the following:
Does patient have documentation of compromised lung function either with: ☐ Yes ☐ No *Documentation must be provided.*
☐ Infant Pulmonary Function Test(IPFT)
☐ Number of or history of cystic fibrosis(CF) exacerbations requiring antibiotics either outpatient or inpatient
☐ CT evidence of persistent bronchiectasis

If patient is 6 years of age or older, please answer the following:
Is documentation available showing this patient's most recent (baseline) FVC measurement, obtained within the past 30 days, to be greater than or equal to 40% predicted? ☐ Yes ☐ No
Please submit this documentation, e.g., chart notes.

Is documentation available showing this patient's most recent (baseline) measurements for FEV1 and FEV1 percentage of predicted, obtained within the past 30 days while the patient is NOT receiving treatment with Kalydeco? ☐ Yes ☐ No *Please submit this documentation, e.g., chart notes*

MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

Renewal Therapy

You must answer ALL of the following questions:

Is this request for renewal of therapy (meaning the patient is currently receiving therapy AND paid claims are in member's history)? □ Yes □ No

Note: use of samples only and/or access through patient assistance program only does not qualify as current therapy subject to renewal; those should be submitted as initial therapy instead.

If No, please complete "Initial Therapy" section above.

Has patient had a lung transplant? □ Yes □ No

For patients under 6 years of age, please answer the following:

Does patient have a disease response as indicated by one or more of the following: □ Yes □ No ***Please submit this documentation, e.g., chart notes***

□ Decreased pulmonary exacerbations compared to pre-treatment baseline

□ Decrease in decline of lung function as measured by percent predicated FEV1 from date of start of Kalydeco(ivacaftor)

□ Improvement in quality of life demonstrated by at least 2 of the following:

- **□ Cystic Fibrosis Questionnaire-Revised Score(CFQ-R)**
- **□ Weight gain**
- **□ Increase in height.**

For patients 6 years of age or older, please answer the following

Is documentation available which shows the patient's current FEV1 measurements? □ Yes □ No

Current FEV1 measurements are defined as the most recent FEV1 and FEV1 percentage of predicted that were measured within the previous 30 days while the patient is receiving treatment with Kalydeco.

Please submit this documentation, such as chart notes.

Does the patient have the R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene? □ Yes □ No

Does the patient have the G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene? □ Yes □ No

Is the patient's current FEV1 percentage of predicted increased by at least 5 absolute percentage points greater than the baseline FEV1 percentage of predicted? □ Yes □ No

Baseline FEV1 percentage of predicted is defined as the most recent FEV1 percentage of predicted that was measured while the patient was not receiving treatment with Kalydeco.

Please submit this documentation, such as chart notes

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Is the patient's current FEV1 percentage of predicted increased by at least 8.60 absolute percentage points greater than the baseline FEV1 percentage of predicted? □ **Yes** □ **No**

Baseline FEV1 percentage of predicted is defined as the most recent FEV1 percentage of predicted that was measured while the patient was not receiving treatment with Kalydeco.
Please submit this documentation, such as chart notes

Is the patient's current FEV1 percentage of predicted increased by at least 10 absolute percentage points greater than the baseline FEV1 percentage of predicted? □ **Yes** □ **No**

Baseline FEV1 percentage of predicted is defined as the most recent FEV1 percentage of predicted that was measured while the patient was not receiving treatment with Kalydeco.
Please submit this documentation, such as chart notes

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

Please note: Not all drugs/diagnosis are covered on all plans. This request may be denied unless all required information is received.

ATTESTATION: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ **Date:** _____

FAX THIS FORM TO: 800-424-7640
MAIL REQUESTS TO: Magellan Rx Management Prior Authorization Program
Attn: CP - 4201
P.O. Box 64811
St. Paul, MN 55164-0811