

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Kalydeco (ivacaftor)**

A. Prescriptions That Require Prior Authorization

All prescriptions for Kalydeco (ivacaftor) must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Kalydeco (ivacaftor), the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is 6 years of age or older

**AND**

2. Has a diagnosis of cystic fibrosis

**AND**

3. Has a documented genetic mutation as noted in the package labeling

**AND**

4. Is not homozygous for the F508del mutation in the CFTR gene

**AND**

5. Is not taking a strong CYP3A4 inducer

**AND**

6. Dose has been adjusted if necessary according to package labeling

**AND**

7. Has a baseline FEV<sub>1</sub>

**AND**

8. Has a baseline ALT and AST

**AND**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

9. Will have repeat ALT and AST every 3 months during the first year of therapy then annually thereafter

**AND**

10. Does not have a contraindication to Kalydeco (ivacaftor)

**OR**

11. Does not meet the clinical review guidelines listed above but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

FOR RENEWALS OF PRESCRIPTIONS FOR KALYDECO (ivacaftor):  
Requests for prior authorization of renewals of prescriptions for Kalydeco that were previously approved will take into account whether the recipient:

1. Is not taking a strong CYP3A4 inducer

**AND**

2. Dose has been adjusted if necessary according to package labeling

**AND**

3. Has had improvement or stabilization of their Cystic Fibrosis as documented by their FEV<sub>1</sub>

**AND**

4. Has had a repeat ALT and AST that is not greater than 5 times the upper limit of normal

**AND**

5. Does not have a contraindication to Kalydeco (ivacaftor)

**OR**

6. Does not meet the clinical review guidelines listed above but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

C Clinical Review Process

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Kalydeco (ivacaftor). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

D. Dose and Duration of Therapy

Requests for prior authorization of Kalydeco (ivacaftor) will be approved as follows:

1. Initial approvals of requests for prior authorization of Kalydeco (ivacaftor), and subsequent requests during the first year of therapy, will be limited to 3 months of therapy
2. Renewals of requests for prior authorization of Kalydeco (ivacaftor) after the first year of therapy that were previously approved will be approved for up to 12 months

E. References:

1. Kalydeco (package insert). Vertex Pharmaceuticals Incorporated, Cambridge, MA; January 2012