Pharmacy Prior Authorization

AETNA BETTER HEALTH NEW JERSEY (MEDICAID)

Kalydeco (Medicaid)

This fax machine is located in a secure location as required by HIPAA regulations.
Complete/review information, sign and date. Fax signed forms to Aetna Better Health New Jersey at **1-855-296-0323**.
When conditions are met, we will authorize the coverage of Kalydeco (Medicaid).
Please note that all authorization requests will be reviewed as the AB rated generic (when available) unless states otherwise.

Drug Name *(circle drug)*

Kalydeco (ivacaftor)

Other, specify drug _____

Quantity _____ Frequency _____ Strength _____

Route of administration _____ Expected length of therapy _____

Member information

Member name: _____

Member ID: _____

Member Group No.: _____

Member DOB: _____

Member phone: _____

Prescribing physician

Physician name: _____

Specialty: _____ NPI number: _____

Physician fax: _____ Physician phone: _____

Physician address: _____ City, state, zip: _____

Diagnosis: _____ **ICD Code:** _____

Circle the appropriate answer for each question.

1. Has this plan authorized Kalydeco in the past for this member (i.e., previous authorization is on file under this plan)? Y N

   [If no, skip to question 7.]

2. Has documentation been submitted to support a response to therapy (symptom improvement and/or stable forced expiratory volume in one second [FEV1])? Y N

   If yes, please document response or submit records: _____

   [If no, then no further questions.]

3. Is this request for a pediatric member? Y N

   [If no, skip to question 5.]

4. Has the member had an eye exam (due to the possible development of cataracts)? Y N

   [If no, then no further questions.]

5. Are the member's transaminases (alanine transaminase [ALT], aspartate transaminase [AST]) monitored? Y N

   [If no, then no further questions.]

6. Will therapy be temporarily discontinued for any of the following: A) the member's AST or ALT levels are greater than 5 times the upper limit of normal, or B) the member's ALT or AST are greater than 3 times the upper limit of normal with bilirubin greater than 2 times the upper limit of normal? Y N

   [No further questions.]

7. Does the member have a diagnosis of cystic fibrosis? Y N

   [If no, then no further questions.]

8. Does the member have one of the following gating mutations in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor): G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R (or other mutations per the prescribing information)? Y N

   Note: Laboratory documentation must be submitted.

   [If yes, skip to question 10.]

9. Does the member have one of the following residual function mutations in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor): A1067T, A455E, D110E, D110H, D1152H D1270N, D579G, E193K,E56K, E831X, F1052V, F1074L, K1060T, L206W, P67L, R1070W, R117C, R347H, R352Q, R74W, S945L, S977F, 3272-26A—G, 3849+10kbC—T, 711+3A—G, 2789+5G—A (or other mutations per the prescribing information)? Y N

   Note: Laboratory documentation must be submitted.

   [If no, then no further questions.]

10. Is the member homozygous for the Phe508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene? Y N

[If yes, then no further questions.]

11. Is the member 1 years of age or older? Y N

    [If no, then no further questions.]

12. Does the member meet all of the following; A) transaminase (alanine transaminase [ALT], aspartate transaminase [AST]) are monitored, B) liver function tests have been evaluated, and C) the prescribed dose has been reduced if the member has moderate to severe hepatic impairment? Y N

    [If no, then no further questions.]

13. Is the request for a pediatric member? Y N

    [If no, skip to question 15.]

14. Are both of the following statements true: A) member had an eye examination at baseline, and B) member will have eye examinations performed periodically throughout therapy? Y N

    [If no, then no further questions.]

15. Is Kalydeco being prescribed by, or in consultation with, a pulmonologist? Y N

    [If no, then no further questions.]

16. Will Kalydeco be used in combination with a strong Cytochrome P450, family 3, subfamily A (CYP3A) inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort? Y N

Comments:

I affirm that the information given on this form is true and accurate as of this date.

Prescriber (Or Authorized) Signature **Date**