

Pharmacy Prior Approval Request for Cystic Fibrosis: Kalydeco, Orkambi, Symdeko, and Trikafta

Member Information

1. Member Last Name: _____ 2. First Name: _____
 3. Member ID #: _____ 4. Member Date of Birth: _____ 5. Member Gender: _____

Prescriber Information

6. Prescribing Provider NPI #: _____
 7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days: _____
 11. Length of Therapy (in days): up to 30 Days 60 Days 90 Days 120 Days 180 Days 365 Days Other _____

Clinical Information

Requests for Kalydeco:

1. Does the Member have a diagnosis of cystic fibrosis? Yes No
2. Is the Member 4 months of age or older? Yes No
3. Does the Member have a documented mutation in the CFTR gene that is responsive to ivacaftor? Yes No
4. If the Member's genotype is unknown, has an FDA-cleared CF mutation test been used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instruction?
 Yes No
5. Does the Member have CF with homozygous for F508del mutation in the CFTR gene? Yes No
6. Is the total daily dose prescribed 300mg/day total or less? Yes No
7. Did the Member have a baseline ALT and AST assessed prior to beginning therapy? Yes No
ALT Result and Date: _____ **AST Result and Date:** _____

Requests for Orkambi:

8. Does the Member have a diagnosis of cystic fibrosis? Yes No
9. Is the Member 2 years of age or older? Yes No
10. Is the Member documented as homozygous for the F508del mutation in the CFTR gene? Yes No
11. If the Member's genotype is unknown, has an FDA-cleared CF mutation test been used to detect the presence of the F508del mutation on both alleles of the CFTR gene? Yes No
12. Will the Member receive a dose of two tablets (each containing lumacaftor 200mg/ivacaftor 125mg) or less taken orally every 12 hours with fat containing food? Yes No
13. Did the Member have a baseline ALT and AST assessed prior to beginning therapy? Yes No
ALT Result and Date: _____ **AST Result and Date:** _____

Requests for Symdeko:

14. Does the Member have a diagnosis of cystic fibrosis? Yes No
15. Is the Member 6 years of age or older? Yes No
16. Is the Member documented as homozygous for the F508del mutation in the CFTR gene or have one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor? Yes No
17. If the Member's genotype is unknown, has an FDA-cleared CF mutation test been used to detect the presence of the F507del mutation on both alleles of the CFTR gene? Yes No
18. Will the Member receive 1 tablet in the morning and 1 tablet in the evening? Yes No
19. Did the Member have a baseline ALT and AST assessed prior to beginning therapy? Yes No
ALT Result and Date: _____ **AST Result and Date:** _____

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Requests for Trikafta:

20. Does the Member been diagnosed with Cystic Fibrosis? **Yes** **No**
21. Is the Member 12 years of age or older? **Yes** **No**
22. If the Member's genotype is unknown, has an FDA-cleared CF mutation test been used to confirm the presence of at least one F508del mutation? **Yes** **No**
23. Will the Member receive a dose of one tablet (containing tezacaftor 100 mg/ivacaftor 150 mg) in the morning and one tablet (containing ivacaftor 150 mg) in the evening? **Yes** **No**
24. Did the Member have a baseline ALT, AST, and bilirubin assessed prior to beginning therapy? **Yes** **No**
ALT Result and Date: _____ **AST Result and Date:** _____ **Bilirubin Result and Date:** _____
25. If the Member is less than 18 years of age, has a baseline ophthalmic examination been performed? **Yes** **No**

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

Fax all form/lab work to: (866) 399-0929

Pharmacy PA Call Center: (833) 585-4309