carolina complete health™

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 F508del 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:** _____ ***Continued on next page***

Requests for Trikafta:

20. Does the Member been diagnosed with Cystic Fibrosis? ☐ **Yes** ☐ **No**
21. Is the Member 6 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.