Trillium Health Resources
Pharmacy Prior Approval Request for

Trillium HEALTH RESOURCES
Transforming Lives. Building Community Well-Being.

Cystic Fibrosis: Kalydeco, Orkambi, Symdeko, and Trikafta

Member Information

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

Prescriber Information

1. Prescriber Name: _____ 2. NPI #: _____
3. Requestor Name (Nurse/Office Staff): _____
4. Mailing Address: _____ City: _____ State: ____ Zip: _____
5. Phone #: _____ Ext. _____ Fax #: _____

Drug Information

1. Drug Name:_____ 2. Strength: _____ 3. Quantity per 30 Days: _____
4. 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 1 month 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 being 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 mutuation 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 2 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 or does the member have a documented mutation in the CFTR gene that is response to Trikafta? ☐ **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.