

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

Beneficiary Information

1. Beneficiary Last Name: _____ 2. First Name: _____
3. Beneficiary ID #: _____ 4. Beneficiary Date of Birth: _____ 5. Beneficiary 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 beneficiary have a diagnosis of cystic fibrosis? Yes No
2. Is the beneficiary 1 month of age or older? Yes No
3. Does the beneficiary have a documented mutation in the CFTR gene that is responsive to ivacaftor? Yes No
4. If the beneficiary'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 beneficiary 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 beneficiary 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 beneficiary have a diagnosis of cystic fibrosis? Yes No
9. Is the beneficiary 2 years of age or older? Yes No
10. Is the beneficiary documented as homozygous for the F508del mutation in the CFTR gene? Yes No
11. If the beneficiary'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 beneficiary 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 beneficiary 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 beneficiary have a diagnosis of cystic fibrosis? Yes No
15. Is the beneficiary 6 years of age or older? Yes No
16. Is the beneficiary 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 beneficiary'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 beneficiary receive 1 tablet in the morning and 1 tablet in the evening? Yes No
19. Did the beneficiary have a baseline ALT and AST assessed prior to beginning therapy? Yes No **ALT Result and Date:** _____ **AST Result and Date:** _____
- Requests for Trikafta:**
20. Has the beneficiary been diagnosed with Cystic Fibrosis? Yes No
21. Is the beneficiary 2 years of age or older? Yes No
22. If the beneficiary'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 beneficiary have a documented mutation in the CFTR gene that is response to Trikafta? Yes No
23. Will the beneficiary 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 beneficiary 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 beneficiary 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.