



Fax completed form to Navitus at: 855-668-8553
 For questions, please call: 877-908-6023

TEXAS MEDICAID

Drug Prior Authorization

Cystic Fibrosis Agents: lumacaftor/ivacaftor (ORKAMBI)

Request Information (required)

This request is:

- Expedited* (Urgent)**
- Standard (Non-Urgent)**

*Expedited means the standard review time may seriously harm the member's life, health, or ability to regain maximum function.

Member Information (required)

Prescriber Information (required)

Member Name:			Prescriber Name:		
Member Insurance ID #:			NPI # :		Specialty:
Date of Birth:			Office Phone:		
Member Phone:			Office Fax:		
Member Street Address:			Office Street Address:		
City:	State:	Zip:	City:	State:	Zip:

Please fill out the following information:

1. Medication Requested (Name):
(Go to #2)

Drug Prior Authorization

Cystic Fibrosis Agents: lumacaftor/ivacaftor (ORKAMBI)

2. Quantity Requested:
(Go to #3)

3. Dose Requested (Strength):
(Go to #4)

4. Dosing Instructions:
(Go to #5)

Required Criteria

5. Provide primary diagnosis including ICD-10 code(s):
(Go to #6)

Please complete the following clinical assessment:

6. Is the request for ORKAMBI 75-94mg granules, ORKAMBI 100-125mg tablets/granules, or ORKAMBI 150-188mg granules?

Yes

(Go to #7)

No

(Go to #8)

7. Is the member greater than or equal to (\geq) one (1) years of age and less than ($<$) 12 years of age?

Yes

(Go to #10)

No (Deny)

(Go to #8)

8. Is the request for ORKAMBI 200-125mg tablets?

Yes

(Go to #9)

No (Deny)

(Go to #9)

9. Is the member greater than or equal to (\geq) 12 years of age?

Yes

(Go to #10)

No (Deny)

(Go to #10)

10. Does the member have a claim for narrow therapeutic index CYP3A4 substrate in the last 90 days?

Examples of narrow therapeutic index CYP3A4 substrates include: AFINITOR, cyclosporine (GENGRAF, NEORAL, SANDIMMUNE), sirolimus (RAPAMUNE), tacrolimus (ENVARUSUS, PROGRAF), triazolam, and ZORTRESS.

Yes (Deny)

(Go to #11)

No

(Go to #11)

11. Does the member have a claim for a strong CYP3A4 inducer in the last 90 days?

Examples of strong CYP3A4 inducers include: alogliptin/pioglitazone (OSENI), ATRIPLA, carbamazepine (CARBATROL, EPITOL, EQUETRO, TEGRETOL), nevirapine (VIRAMUNE), phenobarbital, phenytoin (DILANTIN, PHENYTEK), pioglitazone (ACTOS), pioglitazone/glimepiride (DUETACT), pioglitazone/metformin (ACTOPLUS MET), rifabutin (MYCOBUTIN), RIFAMATE, rifampin (RIFADIN), RIFATER, SUSTIVA, and XTANDI.

Yes (Deny)
(Go to #12)

No
(Go to #12)

12. Is the requested quantity greater than (>) four (4) tablets/packets per day?

Yes (Deny)
(Go to #13)

No
(Go to #13)

13. Will the member have a concurrent therapy with KALYDECO, SYMDEKO, and/or TRIKAFTA?

Yes (Deny)
(Go to #14)

No
(Go to #14)

14. Manual Step - Is ORKAMBI being used for the treatment of cystic fibrosis in a member that is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene? If the genotype is unknown, a United States Food and Drug Administration (FDA) cleared cystic fibrosis mutation test should be used to detect the presence of the F508del mutation of both alleles of the CFTR gene.

Yes (Approve - 365 days)
(Go to #15)

No (Deny)
(Go to #15)

Additional Information

15. Please provide any additional information we should consider (or attach any supporting documents):
(END)

Submission Information (required)

Prescriber Signature: _____ **Date:** _____

**** PLEASE FAX COMPLETED FORM TO: 855-668-8553 ****

If criteria not met, submit chart documentation with form citing complex medical circumstances.
For questions, please call Customer Care at 877-908-6023

For questions, please call Navitus Customer Care at 1-877-908-6023.