Texas Standard Prior Authorization Form Addendum

Molina Healthcare of Texas

Orkambi (Lumacaftor/Ivacaftor) (Medicaid)

This fax machine is located in a secure location as required by HIPAA Regulations. Complete / Review information, sign, and date. Fax signed forms to Molina Pharmacy Prior Authorization Department at **1-888-487-9251**. Please contact Molina Pharmacy Prior Authorization Department at **1-855-322-4080** with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of Orkambi (Medicaid).

Drug Name (select from list of drugs shown / provide drug information)	
ORKAMBI 100MG-125MG TABLET	ORKAMBI 100-125MG GRANULE PKT
ORKAMBI 150-188MG GRANULE PKT	ORKAMBI 200MG-125MG TABLET

Patient Information	
Patient Name:	
Patient ID:	
Patient DOB:	

Prescribing Physician	
Physician Name:	
Physician Phone:	
Physician Fax:	
Physician Address:	
City, State, Zip:	

Diagnosis:	ICD Code:
Directions for administration:	

*****Please include all relevant clinical notes, lab work, medication history and any other applicable documentation.**

Please circle the appropriate answer for each question.

1. Is the requested drug required per court order? (court order required) Y N
   If the answer to this question is yes, approved for 365 days.
   If the answer to this question is no, go to question 2.

2. Is the request for Orkambi 100mg-125mg tablets/granules or Orkambi 150-188mg granules? Y N
   If the answer to this question is yes, go to question 3.
   If the answer to this question is no, go to question 4.

3. Is the patient greater than or equal to 2 years of age and less than 12 years of age? Y N
   If the answer to this question is yes, go to question 6.
   If the answer to this question is no, denied.

4. Is the request for Orkambi 200mg-125mg tablets? Y N
   If the answer to this question is yes, go to question 5.
   If the answer to this question is no, denied.

5. Is the patient greater than or equal to 12 years of age? Y N
   If the answer to this question is yes, go to question 6.
   If the answer to this question is no, denied.

6. Does the patient have a claim for a narrow therapeutic index CYP3A4 substrate in the last 90 days? Y N
   If the answer to this question is yes, denied.
   If the answer to this question is no, go to question 7.

7. Does the patient have a claim for a strong CYP3A4 inducer in the last 90 days? Y N
   If the answer to this question is yes, denied.
   If the answer to this question is no, go to question 8.

8. Is the requested quantity greater than 4 tablets/packets per day? Y N
   If the answer to this question is yes, denied.
   If the answer to this question is no, go to question 9.

9. Will the patient have concurrent therapy with Kalydeco, Symdeko and/or Trikafta? Y N
   If the answer to this question is yes, denied.
   If the answer to this question is no, go to question 10.

10. Is Orkambi being used for the treatment of cystic fibrosis in a patient that is homozygous for the F508del mutation in the CFTR gene? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of the F508del mutation of both alleles of the CFTR gene. Y N
    If the answer to this question is yes, go to question 11.
    If the answer to this question is no, denied.

11. Is this request for a non-preferred drug? Y N
    If the answer to this question is yes, go to question 12.
    If the answer to this question is no, approved for 365 days.

12. Has the patient failed a treatment trial with at least 1 preferred agent? Y N
    If the answer to this question is yes, approved for 365 days.
    If the answer to this question is no, go to question 13.

13. Is there a documented allergy or contraindication to preferred agents in this class? Y N
    If the answer to this question is yes, approved for 365 days.
    If the answer to this question is no, go to question 14.

14. Is the drug necessary for treatment of stage-4 advanced metastatic cancer and associated conditions? Y N
    If the answer to this question is yes, approved for 365 days.
    If the answer to this question is no, denied.

Comments:

I affirm that the information given on this form is true and accurate as of this date.

_____ _____

Prescriber (or Authorized) Signature Date