REALRx

PRIOR AUTHORIZATION REQUEST FORM

CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) AGENTS

Kalydeco®, Orkambi®, Symdeko®, Trikafta™

For authorization, please answer each question and fax this form PLUS chart notes back to Real Rx at 385-425-4052.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have prior authorization questions, please call for assistance 385-425-5094.

Disclaimer: Prior authorization request forms are subject to change in accordance with Federal and State notice requirements.

Date:	Member Name:	ID#:
DOB:	Gender:	Physician:
Office Phone:	Office Fax:	Office Contact:

Height/Weight:

Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.

Product being requested: ☐ Kalydeco® (ivacaftor), ☐ Orkambi® (lumacaftor/ivacaftor), ☐ Symdeko® (tezacaftor/ivacaftor and ivacaftor), ☐ Trikafta™ (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

Dosing/Frequency:_____

If the request is for reauthorization, proceed to reauthorization section.

Questions	Yes	No	Comments/Notes
1. Is this request for an **expedited** review? By checking the **"Yes"** box to request an expedited review (24 hours), you are certifying that applying the standard review time frame (72 hours) may place the member's life, health, or ability to regain maximum function in serious jeopardy.			
2. Does the member have a documented diagnosis of cystic fibrosis (CF) as listed below? • Cystic fibrosis with pulmonary manifestations • Cystic fibrosis with other intestinal manifestations • Cystic fibrosis with other manifestations • Cystic fibrosis, unspecified	☐	☐	**Please provide documentation**
3. Is the requesting provider a cystic fibrosis specialist?	☐	☐	
4. Does the provided documentation show that the member has a CF mutation that the requested medication is indicated to treat?	☐	☐	**Please provide documentation**
5. Does the member have a baseline forced expiratory volume in one second (FEV1) between 40% and 90% of predicted normal value?	☐	☐	**Please provide documentation**
6. Does the member demonstrate at least a 75% history of compliance with the Cystic Fibrosis Center clinic visits over the	☐	☐	**Please provide documentation**

last 12 months? Documentation of adherence must be provided with the request.			
7. Does the member demonstrate at least 80% adherence to prescribed medication therapies over the last 12 months? Adherence to prescribed medications will be verified by claim review and fill history, if available.	☐	☐	**Please provide documentation**
REAUTHORIZATION			
1. Is the request for reauthorization of therapy?	☐	☐	
2. Does the member have a continued medical need for therapy and has the therapy been effective and tolerable?	☐	☐	**Please provide documentation**
3. Has member achieved a clinically significant response to therapy with documentation of at least ONE of the following? • Improvement or stabilization in lung function as demonstrated by a current FEV1 as compared to pre-treatment values. • Improvement or stabilization in Body Mass Index (BMI) as compared to pre-treatment BMI. • Member has a decrease in pulmonary exacerbations as demonstrated by a decrease in hospitalizations, emergency room visits and/or IV antibiotic use.	☐	☐	**Please provide documentation**
4. Is member's ALT or AST not > 5 times the upper limit of normal (UNL) and ALT or AST is not > 3 times the UNL and bilirubin is not > 2 times the UNL?	☐	☐	**Please provide documentation**
5. Does documentation show yearly ophthalmic examinations are performed to assess for possible non-congenital lens opacities for adolescent members between the ages of 12 – 18 years of age?	☐	☐	**Please provide documentation**
6. Did member demonstrate at least 80% adherence to prescribed medication therapies over at least the last 6 months prior to continuation of therapy requests? Adherence to prescribed medications will be verified by claim review and fill history.	☐	☐	**Please provide documentation**
7. Is the member followed at least annually by a practitioner who specializes in the care of patients with cystic fibrosis?	☐	☐	
What medications and/or treatment modalities have been tried in the past for this condition? Please document name of treatment, reason for failure, treatment dates, etc.			
Additional information:			

Physician Signature:

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Policy PHARM- 014
Origination Date: 12/05/2019
Reviewed/Revised Date: 01/18/2023
Next Review Date: 01/18/2024
Current Effective Date: 02/01/2023