PAC Instructions

Cystic Fibrosis, CFTR Modulators

Policy Type: PA/SP

Length of Authorization

- Initial: Length of Benefit
- Renewal: Length of Benefit

Quantity limits

Product Name	Indication	Dosage Form	Quantity Limit
ivacaftor (Kalydeco)	Cystic fibrosis, one mutation in the CFTR gene[a] that is responsive to ivacaftor[b]	150 mg tablet	56 tablets/28 days
		5.8 mg/ packet oral granules	56 packets/28 days
		13.4 mg/packet oral granules	56 packets/28 days
		25 mg/packet oral granules	56 packets/28 days
		50 mg/packet oral granules	56 packets/28 days
		75 mg/packet oral granules	56 packets/28 days
ivacaftor/ lumacaftor (Orkambi)	Cystic fibrosis, homozygous for F508del mutation	125/200 mg tablet	112 tablets/28 days
		125/100 mg tablet	112 tablets/28 days
		94/75 mg oral granule packet	28 packets/28 days
		125/100 mg oral granule packet	56 packets/28 days
		188/150 mg oral granule packet	56 packets/28 days
ivacaftor/ tezacaftor (Symdeko)	Cystic fibrosis, homozygous F508del mutation or at least one mutation in the CFTR gene[a] that is responsive to ivacaftor/tezacaftor[b]	Kit: (ivacaftor; ivacaftor/tezacaftor) 150mg; 150/100mg	56 tablets/28 days
		Kit: (ivacaftor; ivacaftor/tezacaftor) 75mg; 75/50 mg	56 tablets/28 days
elexacaftor/ tezacaftor/ ivacaftor (Trikafta)		Kit (elexacaftor/ tezacaftor/ ivacaftor; ivacaftor) 100/50/75mg; 150 mg	84 tablets/28 days

	Cystic fibrosis, one F508del mutation or at least mutation if the CFTR gene[a] that is responsive[b]	Kit (elexacaftor/ tezacaftor/ ivacaftor; ivacaftor) 50/37.5/25mg; 75 mg	84 tablets/28 days
		Kit (elexacaftor/ tezacaftor/ ivacaftor; ivacaftor) 100/50/75mg; 75mg	56 packets/28 days
		Kit (elexacaftor/ tezacaftor/ ivacaftor; ivacaftor) 80/40/60mg; 59.5mg	56 packets/28 days

[a] Specific mutations listed below in policy criteria

[b] Based on clinical and/or *in vitro* assay data

Additional Notes:

1. The mutation listed in CMM matches to the Gene Mutation Table in the Package Insert for the Requested Medication
   a. Ivacaftor (Kalydeco) KALYDECO® (ivacaftor)
   b. Ivacaftor/Tezacaftor (Symdeko) SYMDEKO® (tezacaftor/ivacaftor and ivacaftor)
   c. Ivacaftor/Tezacaftor/Elexacaftor (Trikafta) TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

PAC Note: If approvable and the following are met:

1. Member has an EXISTING ACTIVE prior authorization for a medication within this criteria AND

2. Provider marks NO to using in combination with another CTFR CF/specialty medication OR

Indicates within chart notes that the previous medication shall be “discontinued” or “change therapy”

ADD the following statement to approval letter and de-activate existing “old” PA

“The medical provider indicates the intent to change therapy. With the initiation of this approval, the prior authorization for [PRIOR AGENT] will be deactivated as of [MO/DA/YEAR]. A new prior authorization request must be submitted and approved in the event this medication is required in the future.”

Cystic Fibrosis, CFTR Modulators