PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**ORKAMBI**
(Generic)	**(lumacaftor/ivacaftor)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 1279-A***

FDA-Approved Indication[1]

Orkambi is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene.

Limitation of use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the *F508del* mutation.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of cystic fibrosis? [If no, no further questions.]	Yes	No
2	Does the patient have the F508del mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR)* gene? [If no, no further questions.]	Yes	No
3	Is the patient homozygous for the F508del mutation? [If no, no further questions.]	Yes	No
4	Will Orkambi be used in combination with Kalydeco? [If yes, no further questions.]	Yes	No
5	Is the patient 6 years of age or older?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1: Cystic Fibrosis	
Yes to question(s)	**No to question(s)**
1	4
2	
3	
5	

Mapping Instructions		
	Yes	**No**
1.	Go to 2	Deny
2.	Go to 3	Deny
3.	Go to 4	Deny
4.	Deny	Go to 5
5.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCE

1. Orkambi [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; September 2016.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (TS) 07/2015
Revised:	TS 08/2015 (CMS), IP 01/2016, 07/2016 (CMS), 09/2016 (label update), DK 12/2016, 07/2017 (CMS)
Reviewed:	CDPR / KRU 07/2015, DHR 01/2016; GAD 10/2016, LMS 01/2017
External Review:	07/2015, 03/2016, 03/2017