Clinical Policy Title:	tezacaftor/ivacaftor
Policy Number:	RxA.487
Drug(s) Applied:	Symdeko®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all)**:**

1. Diagnosis of cystic fibrosis (CF) confirmed by one of the following (a or b):
   a. Homozygous for F508del mutation in the CFTR gene;
   b. Presence of at least one mutation in the CFTR gene that is responsive to Symdeko® based on in vitro data or clinical evidence.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Cystic Fibrosis (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member is responding positively to therapy as evidenced by a stabilization in ppFEV1 if baseline was $\geq$ 70% or increase in ppFEV1 if baseline was < 70%.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation pulmonary guidelines: Use of cystic fibrosis transmembrane conductance regulator modulator therapy in patients with cystic fibrosis. Ann Am Thorac Soc. 2018; 15(3): 271-280. Available at: https://pubmed.ncbi.nlm.nih.gov/29342367/. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to all lines of business. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…".	10/01/2020	12/07/2020

3. References were updated.		
Policy was reviewed: 1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	09/4/2021	12/7/2021
Policy was reviewed: 1. References were reviewed and updated.	04/05/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1.a and 1.A.1.b: Updated to remove diagnostic criteria " a. Clinical symptoms consistent with CF in at least one organ system, or positive newborn screen or genetic testing for siblings of patients with CF; b. Evidence of cystic fibrosis transmembrane conductance regulator (CFTR) dysfunction confirmed by one of the following (i or ii): i. Elevated sweat chloride $\geq$ 60 mmol/L; ii. Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parental allele." 2. Initial Approval Criteria, I.A.4: Update to remove documentation criteria "Chart notes indicate that pulmonary function tests, performed within the last 90 days, show a percent predicted forced expiratory volume in 1 second (ppFEV1) that is between 40-90%." 3. Initial Approval Criteria, I.A.5: Update to remove prior cuncurrent therapy criteria "Symdeko® is not prescribed concurrently with other CFTR modulators (e.g., Kalydeco®, Orkambi®, Trikafta®)." 4. Initial Approval Criteria, I.A: Updated Approval duration from 6 to 12 months for Commercial and Medicaid. 5. Continued Therapy Approval Criteria II.A.3: Update to remove prior cuncurrent therapy criteria "Symdeko® is not prescribed concurrently with other CFTR modulators (e.g., Kalydeco®, Orkambi®, Trikafta®)."	04/28/2023	07/13/2023

6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024