

Policy Name:	Symdeko (tezacaftor-ivacaftor)	Policy #:	2640P
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Purpose of the Policy

The purpose of this policy is to establish prior authorization criteria for coverage of Symdeko (tezacaftor-ivacaftor).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Symdeko (tezacaftor-ivacaftor) under the specialty pharmacy benefit for the following mutations when the following criteria are met.

List of CFTR gene mutations that produce CFTR protein and are responsive to tezacaftor/ivacaftor include (this is not an all-inclusive list and is subject to change): A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, F508del (two copies of mutation or at least 1 copy of a responsive mutation), K1060T, L206W, P67L, R74W, R1070W, R117C, R347H, R352Q, 51070W, S945L, S977F, 711+3A→G, 2789+5G→A, 3272-26A→G, 3849+10kbC→T

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of cystic fibrosis with
- 1.2 Documentation that member is homozygous for the F508del mutation OR member has at least one mutation in the CFTR gene that is responsive to Symdeko
- 1.3 Age 6 years of age or older
- 1.4 Prescribed by a provider specializing in the treatment of cystic fibrosis
- 1.5 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Symdeko by both a pharmacist and medical director

2. Approval Period

- 2.1 Initial Approval: 12 months
- 2.2 Subsequent Approvals: 2 years

CPT Codes

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HCPCS Codes

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References

1. Symdeko (tezacaftor/ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; August 2023.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. *Ann Am Thorac Soc*. 2018 Mar. doi: 10.1513/AnnalsATS.201707-539OT.PMID: 29342367.
3. Southern KW, Castellani C, Lammertyn E, et al. Standards of care for CFTR variant-specific therapy (including modulators) for people with cystic fibrosis. *J Cyst Fibros*. 2023 Jan;22(1):17-30.
4. Kapnadak SG, Dimango E, Hempstead SE, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. *J Cyst Fibros*. 2020 May;19(3):344-354

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DISCLAIMER

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