Pharmacy Drug Policy & Procedure

Policy Name:	Kalydeco (ivacaftor)	Policy #:	1962P

Purpose of the Policy

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

Statement of the Policy

Health Alliance Medical Plans will approve the use of Kalydeco (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 ivacaftor include (this is not an all-inclusive list and is subject to change): A455E, D579G, D1152H, E831X, F508C / S1251N, G178R, G551D, G551S, G1244E, G1349D, L206W, P67L, R1070W, R117C, R117H, R347H, R352Q, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A→G, 2789+5G→A, 3272-26A→G, 3849+10kbC→T

Criteria

1. Coverage Criteria for Kalydeco

1.1 Prescribed by a provider specializing in the treatment of cystic fibrosis
1.2 Member has a diagnosis of cystic fibrosis
1.3 Member is 1 month of age or older
1.4 Documentation of a CFTR gene mutation that produces the CFTR protein and is responsive to Kalydeco
1.5 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Kalydeco by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Member homozygous for F508del mutation in the CFTR gene

3. Approval Period

3.1 Initial Approval: 12 months
3.2 Subsequent Approvals: 2 years

CPT Codes

HCPCS Codes

References

1. Kalydeco (ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Inc; 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;15(3):271-280.
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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