CareSource

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Kalydeco (ivacaftor)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 150 mg tablets - 60 per 30 days 25 mg, 50 mg & 75 mg granules - 56 per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kalydeco (ivacaftor) will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For **initial** authorization:

1. Member must be 4 months of age or older; AND
2. Member has a diagnosis of cystic fibrosis; AND
3. Member has had genetic testing documented in chart notes with one of the following mutations in the CFTR gene: 711+3A→G, F311del, I148T, R75Q, S589N, 2789+5G→A, F311L, I175V, R117C,S737F, 3272-26A→G, F508C, I807M, R117G, S945L, 3849+10kbC→T, F508C;S1251N, I1027T, R117H, S977F, A120T, F1052V, I1139V, R117L, S1159F, A234D, F1074L, K1060T, R117P, S1159P, A349V, G178E, L206W, R170H, S1251N, A455E, G178R, L320V, R347H, S1255P, A1067T, G194R, L967S, R347L, T338I, D110E, G314E, L997F, R352Q, T1053I, D110H, G551D, L1480P, R553Q, V232D, D192G, G551S, M152V, R668C, V562I, D579G, G576A, M952I, R792G, V754M, D924N, G970D, M952T, R933G, V1293G, D1152H, G1069R, P67L, R1070Q, W1282R, D1270N, G1244E, Q237E, R1070W, Y1014C, E56K, G1249R, Q237H, R1162L, Y1032C, E193K, G1349D, Q359R, R1283M, E822K, H939R, Q1291R, S549N, E831X, H1375P, R74W, S549R.
4. **Dosage allowed:**
   a) Adult and pediatric members 6 years of age or older: Up to 150 mg every 12 hours.
   b) Pediatrics under 6 years of age:

Age	Dosage Allowed	
Infants 4 to <6 months old and weighing ≥5 kg	25 mg granule packet every 12 hours	
Infants ≥6 months and <6 years old	Weight	Dosage Allowed
	5 to <7 kg	25 mg packet every 12 hours
	7 to <14 kg	50 mg packet every 12 hours
	≥14 kg	75 mg packet every 12 hours

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member's adherence to medication is confirmed by claims history; AND
3. Chart notes submitted with any of the following:
   a) Improved FEV1 and/or other lung function tests;
   b) Improvement in sweat chloride;
   c) Decrease in pulmonary exacerbations;
   d) Decrease in pulmonary infections;
   e) Increase in weight-gain;
   f) Decrease in hospitalizations.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kalydeco (ivacaftor) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Kalydeco created.
10/05/2018	New CFTD gene mutations added. Age coverage expanded (approved for 12 months old members and older).
05/16/2019	Age coverage expanded (approved for 6 months old members and older).
12/30/2020	Policy reviewed. New age limit expanded to 4 months of age (previously 6 months). List of approved mutations expanded. Added dosing chart for patients 6 years of age and younger. Reauthorization criteria updated to ask for evidence of disease stability or improvement.
12/21/2021	Removed prescriber specialty requirement.

References:

1. Kalydeco [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; December, 2020.
2. Kalydeco. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 6, 2017.
3. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. Available: https://www.atsjournals.org/doi/full/10.1164/rccm.201207-1160OE. Accessed November 27, 2018.

Effective date: 01/01/2022
Revised date: 12/21/2021