

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Kalydeco (ivacaftor)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kalydeco (ivacaftor)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Kalydeco (ivacaftor) may be approved if the following are met:

- I. Individual has a diagnosis of cystic fibrosis (CF); **AND**
- II. Individual is 6 months of age or older; **AND**
- III. A copy of the CF mutation analysis test results must be provided; **AND**
- IV. Individual has a mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene with **one** of the following mutation types:
  - A. G551D; **OR**
  - B. G1244E; **OR**
  - C. G1349D; **OR**
  - D. G178R; **OR**
  - E. G551S; **OR**
  - F. S1251N; **OR**
  - G. S1255P; **OR**
  - H. S549N; **OR**
  - I. S549R; **OR**
  - J. R117H; **OR**
  - K. E193K; **OR**
  - L. F1052V; **OR**
  - M. D1152H; **OR**
  - N. G1069R; **OR**
  - O. D579G; **OR**
  - P. K1060T; **OR**
  - Q. S945L; **OR**
  - R. R74W; **OR**
  - S. A1067T; **OR**
  - T. R1070W; **OR**
  - U. D110H; **OR**
  - V. R347H; **OR**

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

- W. D1270N; **OR**
- X. P67L; **OR**
- Y. D110E; **OR**
- Z. R352Q; **OR**
- AA. E56K; **OR**
- BB. A455E; **OR**
- CC. L206W; **OR**
- DD. F1074L; **OR**
- EE. R117C; **OR**
- FF. S977F; **OR**
- GG. R1070Q; **OR**
- HH. 2789+5G→A; **OR**
- II. 3272-26A→G; **OR**
- JJ. 3849+10kbC→T; **OR**
- KK. 711+3A→G; **OR**
- LL. E831X.

Kalydeco (ivacaftor) monotherapy, may not be approved for the following:

- I. Individual is homozygous for F508del mutation in the CFTR gene; **OR**
- II. Concurrent use with Orkambi (ivacaftor/lumacaftor), Symdeko (tezacaftor/ivacaftor) or Trikafta (elexacaftor/tezacaftor/ivacaftor).

**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 27, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
4. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Last updated: March 10, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 24, 2020.
5. Simon RH. Cystic fibrosis: Treatment with CFTR modulators. Last updated: February 13, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 24, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.