

| Market Applicability |    |          |        |        |    |    |    |    |    |    |    |    |    |    |    |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | X  | NA | NA | NA |

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## Kalydeco (ivacaftor)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>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 2 years 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**

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.

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| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | X  | NA | NA | NA |

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- U. D110H; **OR**
- V. R347H; **OR**
- 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, without concurrent use of lumacaftor, may not be approved for the following:

- I. Individual is homozygous for F508del mutation in the CFTR gene.

| State Specific Mandates |                |   |
|-------------------------|----------------|---|
| State name              | Date effective | Mandate details (including specific bill if applicable) |
| N/A                     | N/A            | N/A   |

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 9, 2017.

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|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | X  | NA | NA | NA |

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DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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