

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

Trikafta (elexacaftor/tezacaftor/ivacaftor)

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

Medications	Quantity Limit
Trikafta (elexacaftor/tezacaftor/ivacaftor) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Trikafta (elexacaftor/tezacaftor/ivacaftor) may be approved if the following are met:

- I. Individual has a diagnosis of cystic fibrosis (CF); **AND**
- II. Individual is 12 years of age or older; **AND**
- III. Mutation testing confirms the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; **OR**
- IV. Mutation testing confirms the individual has at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and one other mutation that is unresponsive to Kalydeco (ivacaftor) or Symdeko (tezacaftor/ivacaftor) .

Trikafta (elexacaftor/tezacaftor/ivacaftor) may not be approved for the following:

- I. Concurrent use with Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor) or Symdeko (tezacaftor/ivacaftor); **OR**
- II. Individual with severe hepatic impairment (Child-Pugh Class C).

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

Key References:

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. CRX-ALL-0489-20

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Applicable	X	X	X	X	X	X	NA

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 22, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medication for maintenance of lung health. *Am J Respir Crit Care Med*. 2013; 187:680-89.
5. Ren, CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Use of cystic fibrosis transmembrane conductance regulator modulator therapy in patients with cystic fibrosis. *Ann Am Thorac Soc*. 2018; 15:271-280.
6. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Last updated: May 4, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: May 31, 2019.
7. Simon RH. Cystic fibrosis: Treatment with CFTR modulators. Last updated: May 30, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: May 31, 2019.

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