If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Trikafta (elexacaftor, tezacaftor and ivacaftor; ivacaftor) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/12/2019	New policy for Trikafta created.
12/31/2020	New approved FDA mutations included. Diagnosis of cystic fibrosis added to initial criteria.
08/09/2021	Changed lower age limit to 6 years.
04/27/2022	Policy transferred to new template. Added dose information for children aged 6 to 11.
05/19/2023	Lowered age limit to 2 years to align with FDA approval; removed compliance with initial criteria and adherence in claims history from reauthorization criteria; added references.

References:

1. Trikafta [prescribing information]. Boston, MA: Vertex Pharmaceuticals Inc; April 2023.

2. 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(3):271-280. doi:10.1513/AnnalsATS.201707-539OT.
3. Farrell PM, White TB, Ren CL, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation [publ