BlueCross BlueShield
Federal Employee Program

TRIKAFTA
(elexacaftor/tezacaftor/ivacaftor)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 2 years of age and older

Diagnosis

Patient must have the following:

Cystic fibrosis (CF)

AND ALL the following:

1. At least one *F508del* mutation in the *CFTR* gene confirmed by an FDA-cleared CF mutation test or a mutation that is responsive to Trikafta (see Appendix 2)
2. Patients 6 years of age or older **only**: Pretreatment percent predicted forced expiratory volume (ppFEV) must be provided
3. Baseline ALT, AST, alkaline phosphatase, and bilirubin levels will be obtained and prescriber agrees to monitor every month for the first 6 months of treatment, every 3 months for the next 12 months, and annually thereafter
4. Must be prescribed by a pulmonologist or gastroenterologist
5. **NO** severe hepatic impairment (Child-Pugh Class C)
6. **NO** dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator (see Appendix 1)

Prior - Approval Limits

Quantity

Dosage Form	Quantity Limit	Details
Tablets	12 blister packs (252 tablets) per 84 days	Blister packs contain 14 tablets of elexacaftor, tezacaftor, and ivacaftor and 7 tablets of ivacaftor for a 7 day supply
Oral granules	12 wallets (168 packets of granules) per 84 days	Wallets contain 7 packets of elexacaftor, tezacaftor, and ivacaftor and 7 packets of ivacaftor for a 7 day supply

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Duration 12 months

Prior – Approval *Renewal* Requirements

Age 2 years of age and older

Diagnosis

Patient must have the following:

Cystic fibrosis (CF)

AND ALL of the following:

1. Patients less than 6 years of age **only**: Patient's symptoms have improved or stabilized from baseline **OR** reduced number of pulmonary exacerbations
2. Patients 6 years of age or older **only**: Stable or improvement of ppFEV$_1$ from baseline **OR** reduced number of pulmonary exacerbations
3. Prescriber agrees to monitor ALT, AST, alkaline phosphatase, and bilirubin levels annually
4. **NO** severe hepatic impairment (Child-Pugh Class C)
5. **NO** dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator (see Appendix 1)

Prior - Approval *Renewal* Limits

Same as above

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Appendix 1 - List of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Potentiators

Generic Name	Brand Name
ivacaftor	Kalydeco
ivacaftor/lumacaftor	Orkambi
ivacaftor/tezacaftor	Symdeko
ivacaftor/tezacaftor/elexacaftor	Trikafta