Louisiana Medicaid
Elexacaftor/Tezacaftor/Ivacaftor (Trikafta®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for elexacaftor/tezacaftor/ivacaftor combination tablets and ivacaftor tablets (Trikafta®).

Additional Point-of-Sale edits may apply.

NOTE: This agent is a mutation-specific targeted therapy that is indicated to treat only the CFTR mutation that is listed herein. Identification of the indicated genotype is required in order to receive treatment with this agent. If the recipient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation in the CFTR gene.

Approval Criteria

- Recipient is 12 years of age or older on the date of the request with a documented diagnosis of cystic fibrosis; **AND**
- Recipient has **AT LEAST ONE F508del mutation** in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, [mutation(s) identified and date of testing is **documented on the request**]; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred drug that is appropriate to use for the condition being treated; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred drug that is appropriate to use for the condition being treated; **OR**
    - The recipient has *documented contraindication(s)* to the preferred drugs that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber states that the recipient is currently using the requested medication and has had a positive clinical response to treatment; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no inappropriate concomitant drug therapies or disease states that limit the use of Trikafta® and will not receive Trikafta® in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient has had a **positive response** to treatment with Trikafta® as demonstrated by a reduction in disease severity when compared to baseline.

Duration of authorization approval, both initial and reauthorization: 12 months

Reference

Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; October 2019. Retrieved from https://pi.vrtx.com/files/uspi_elexacaftor_tezacaftor_ivacaftor.pdf

Revision	Date
Policy created.	January 2020
Policy implemented.	May 2020