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~~with 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 cystic fibrosis transmembrane conductance regulator (CFTR) mutation that is listed ~~here~~in the prescribing information. 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~~ The recipient is 12 years of age or older on the date of the request with a documented diagnosis of cystic fibrosis; **AND**
- ~~Recipient~~ The following is true and is **stated on the request**: The recipient has **AT LEAST ONE** *F508del* mutation in the ~~cystic fibrosis transmembrane conductance regulator (~~CFTR~~)~~ gene, or a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor with ivacaftor based on *in vitro* data ~~[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 there is evidence of a ~~recipient has had a~~ positive response to treatment ~~with Trikafta® as demonstrated by a reduction in disease severity when compared to baseline~~.

Duration of initial and reauthorization approval: 12 months

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

Reference

Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2020~~October 2019~~. ~~Retrieved from~~ https://pi.vrtx.com/files/uspi_elexacaftor_tezacaftor_ivacaftor.pdf

Revision	**Implementation Date**
Policy created / January 2020	May 2020
Updated indication and reference, formatting changes	February 2021