Louisiana ~~Fee-for-Service~~ Medicaid
Lumacaftor/Ivacaftor (Orkambi®)

~~Lumacaftor/Ivacaftor (Orkambi®) requires clinical authorization.~~The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for lumacaftor/ivacaftor (Orkambi®).

Additional Point-of-Sale edits may apply.

NOTE: This agent is a mutation-specific targeted therapy that is indicated to treat only the CTFR 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 detect the presence of the F508del mutation on both alleles of the CFTR gene.

~~Requests for lumacaftor/ivacaftor, both initial and reauthorization, will be considered for approval if all of the following criteria are met:~~

Approval Criteria

- ~~1.~~ Recipient is 2 years of age or older on the date of the request with a documented diagnosis of cystic fibrosis; **AND**
- ~~2. The following is true and is **noted on the request**: The recipient~~Recipient is **homozygous for the F508del mutation** in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, [mutation(s) ~~identified~~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**~~,~~

- ~~3.~~ By submitting the authorization request, the prescriber attests to the following:
  - ~~a.~~ 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**
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~~b.~~ 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**

- ~~c.~~ The recipient has no inappropriate concomitant drug therapies or disease states that limit the use of lumacaftor/ivacaftor ~~.~~and will not receive lumacaftor/ivacaftor in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

~~By submitting the reauthorization request, the prescriber attests to the following:~~
~~The recipient has had a **positive response** to treatment with lumacaftor/ivacaftor as demonstrated by a reduction in disease severity when compared to baseline; **AND**~~
~~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 concomitant drug therapies or disease states that limit the use of lumacaftor/ivacaftor and will not receive lumacaftor/ivacaftor in combination with any medication that is contraindicated or not recommended per FDA labeling.~~

- 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 lumacaftor/ivacaftor as demonstrated by a reduction in disease severity when compared to baseline.

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

~~*Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf*~~

Reference~~(s)~~

Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; July 2019~~8~~. Retrieved from https://pi.vrtx.com/files/uspi_lumacaftor_ivacaftor.pdf ~~https://pi.vrtx.com/files/uspi_lumacaftor_ivacaftor.pdf~~

~~**Revision Table**~~

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Revision	Date
Policy created. Policy created.	March 2017
PA questions for Added nonpreferred drugs added wording, added reauthorization criteria added, added revision table added, and removed footer removed.	January 2020 September 2019
RAdded requirement for identification of indicated genotype added.	December 2019

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