Louisiana ~~Fee-for-Service~~ Medicaid
Ivacaftor ~~(~~(Kalydeco®)

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

Additional Point-of-Sale edits may apply.

NOTE: This agent is a mutation-specific targeted therapy that is indicated to treat only the CTFR mutations that are 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 a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

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

Approval Criteria

- ~~1. R~~The ~~r~~ecipient is 6 months old or older on the date of the request with a documented diagnosis of cystic fibrosis; **AND**
- Recipient is **not homozygous for the F508del mutation** in the CFTR gene; **AND**

~~2. The following is true and is **noted on the request**:~~

- ~~a. The r~~Recipient has at least ONE~~one~~ of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, [mutation(s) identified ~~and the mutation is listed~~ and date of testing is **documented on the request**]; **AND**

List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to KALYDECO					
E56K	G178R	S549R	S977F	F1074L	2789+5G→A
P67L	E193K	G551D	F1052V	D1152H	3272-26A→G
R74W	L206W	G551S	K1060T	G1244E	3849+10kbC→T
D110E	R347H	D579G	A1067T	S1251N	
D110H	R352Q	711+3A→G	G1069R	S1255P	
R117C	A455E	E831X	R1070Q	D1270N	
R117H	S549N	S945L	R1070W	G1349D	

~~b. The recipient is **not homozygous** for the F508del mutation in the CFTR gene; **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**

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- 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:
  - 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 ivacaftor and will not receive ivacaftor in combination with any medication that is contraindicated or not recommended per FDA labeling.

~~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~~

~~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 concomitant drug therapies or disease states that limit the use of Kalydeco® and will not be receiving Kalydeco® 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 ivacaftor as demonstrated by a reduction in disease severity when compared to baseline.

~~By submitting the reauthorization request, the prescriber attests to the following:~~

- ~~The recipient has had a **positive response** to treatment with 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**~~

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

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)~~

Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; April ~~-~~2019. ~~Retrieved from~~ https://pi.vrtx.com/files/uspi_ivacaftor.pdf~~https://pi.vrtx.com/files/uspi_ivacaftor.pdf~~

~~Revision Table~~

Revision	Date
Policy created.~~.Policy created.~~	April 2015
Expanded ~~indication for use in patients 6 months of~~ age ~~and older added~~range~~.~~	May 2019
Added nonpreferred wording, added ~~PA questions for nonpreferred drugs added.~~ reauthorization criteria, 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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