Louisiana ~~Fee for Service~~ Medicaid
Tezacaftor/Ivacaftor (Symdeko®~~o~~™)

~~Tezacaftor/ivacaftor (Symdeko™) requires clinical authorization.~~ The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tezacaftor/ivacaftor (Symdeko®™).

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 will be considered for approval if all of the following criteria are met:~~

Approval ~~uthorization~~ Criteria

~~:~~

- ~~Recipient is 12 years of age or older; **AND**~~
- ~~Recipient has a diagnosis of cystic fibrosis (CF) and ONE of the following is documented on the request:~~
  - ~~a. The recipient is homozygous for the F508del mutation; **OR**~~
  - ~~b. The recipient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data or clinical evidence.~~

- Recipient is 6 years of age or older on the date of the request; **AND**
- Recipient has ONE of the following mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene [mutation(s) identified and date of genetic testing is **documented on the request**]:
  - The recipient is **homozygous for the F508del** mutation; **OR**
  - The recipient has at least **ONE** of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation is listed on the request; **AND**

The following mutations in the CFTR gene are responsive to tezacaftor/ivacaftor:

A1067T	A455E	D110E	D110H	D1152H	D1270N	D579G	E193K
E56K	E831X	F1052V	F1074L	K1060T	L206W	P67L	R1070W
R117C	R347H	R352Q	R74W	S945L	S977F	F508del (2 copies)	
2789+5G→A		3272-26A→G		3849+10kbC→T		711+3A→G	

- If the request is for a non-preferred agent - **ONE** of the following is required:

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- 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 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 concomitant drug therapies or disease states that limit the use of tezacaftor/ivacaftor and will not receive tezacaftor/ivacaftor in combination with any medication that is contraindicated or not recommended per FDA labeling.

~~Requests to continue treatment with tezacaftor/ivacaftor will be considered for approval if all of the following criteria are met:~~

Reauthorization Criteria

~~:~~

- ~~All of the initial request criteria are met; AND~~
- ~~The prescriber attests that the patient has achieved a clinically significant response while on tezacaftor/ivacaftor.~~
- 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 tezacaftor/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 tezacaftor/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**~~

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~~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 tezacaftor/ivacaftor and will not receive tezacaftor/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)~~

Symdeko™ (tezacaftor / ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; December 201~~8~~9. Retrieved from https://pi.vrtx.com/files/uspi_tezacaftor_ivacaftor.pdf

~~**Revision Table**~~

Revision	**Date**
~~Policy created.~~Policy created.~~,~~	September 2018
Expanded age range, added nonpreferred wording, ~~indication for use in patients 6 years of age and older added, PA questions for nonpreferred drugs added,~~ added reauthorization criteria ~~added~~, added revision table ~~added and~~, removed footer ~~removed.~~	January 2020~~September 2019~~
~~RAdded requirement for identification of indicated genotype added and citation for prescribing information updated.~~	~~December 2019~~

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