Louisiana Medicaid
Sickle Cell Anemia

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred sickle cell anemia agents
- Clinical authorization for crizanlizumab-tmca (Adakveo®), L-glutamine oral powder (Endari®), or voxelotor (Oxbryta®).

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Non-Preferred Sickle Cell Anemia Agents (Except Adakveo®, Endari®, and Oxbryta®)

Approval Criteria

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products 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**
- 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 the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Crizanlizumab-tmca (Adakveo®)

Approval Criteria

- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products 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**
- The recipient is 16 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease; **AND**
- If possible, crizanlizumab-tmca (Adakveo®) is prescribed by, or the request states that this medication is being prescribed in consultation with, a hematologist or oncologist; **AND**
- The request lists dates of **TWO** or more sickle cell-related pain crises within the previous 12 months, where painful crisis is defined by **EITHER**:
  - a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac; **OR**
  - the occurrence of chest syndrome, priapism, or splenic sequestration; **AND**
- **ONE** of the following is **stated on the request**:
  - The recipient is currently receiving hydroxyurea therapy; **OR**
  - The recipient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy; **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 the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

L-glutamine oral powder (Endari®)

Approval Criteria

- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products 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**
- The recipient is 5 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease (SCD); **AND**
- The request **lists dates of TWO or more painful crises within the previous 12 months**, where painful crisis is defined by **EITHER**:
  - a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac; **OR**
  - the occurrence of chest syndrome, priapism, or splenic sequestration; **AND**
- The request **lists the beginning date of current hydroxyurea treatment showing the recipient has been stabilized on hydroxyurea for at least 3 months OR lists a medical reason why the recipient is unable to use hydroxyurea; AND**
- Th<u>is medication is prescribed</u> ~~e request is submitted~~ by, or <u>the request states that this medication is being prescribed</u> in consultation with, a hematologist/oncologist; **AND**
- The request **lists the recipient's current weight and dose**, which follows recommended dosing found in the prescribing information and does not exceed 30 grams per day; **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 is not pregnant, is not breastfeeding, and does not have renal or hepatic impairment; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of Endari™ and will not be receiving Endari™ in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient has had positive clinical outcomes, and this is **stated on the request**; **AND**
- The dose for the recipient's weight follows recommended dosing found in the prescribing information and does not exceed 30 grams per day.

Duration of initial and reauthorization approval: 12 months

Voxelotor (Oxbryta®)

Approval Criteria

- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products 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**
- The recipient is 4~~12~~ years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease; **AND**
- If possible, voxelotor (Oxbryta®) is prescribed by, or the request states that this medication is being prescribed in consultation with, a hematologist or oncologist; **AND**
- The recipient's baseline hemoglobin level is ≥5.5 to ≤10.5 g/dL and is **stated on the request**; **AND**
- For recipients who are 12 years of age or older on the date of the request, ~~T~~the request lists dates of **ONE** or more vaso-occlusive crises within the previous 12 months; **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 the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient's most current hemoglobin level is **stated on the request** and shows an increase of >1 g/dL from baseline.

Duration of reauthorization approval: 12 months

References

Adakveo (crizanlizumab-tmca) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021~~November 2019~~.
https://www.novartis.us/sites/www.novartis.us/files/adakveo.pdf

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; https://www.clinicalkey.com/pharmacology/" https://www.clinicalkey.com/pharmacology/

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Endari (L-glutamine) [package insert]. Torrance, CA: Emmaus Medical, Inc.; October 2020. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d5a783f4-12ef-4326-8faa-40018e45ba3b&type=display

Oxbryta (voxelotor) [package insert]. South San Francisco, CA: Global Blood Therapeutics Inc; December 2021~~November 2019~~. https://oxbryta.com/pdf/prescribing-information.pdf

U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. (2014). Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Retrieved from http://www.nhlbi.nih.gov/guidelines

Revision / Date	Implementation Date
Policy created for Endari® / May 2019	August 2019
Policy created for Adakveo® / April 2020	August 2020
Policy created for Oxbryta® / July 2020	October 2020
Policies combined; added non-preferred criteria wording, updated references / November 2020	January 2021
For Oxbryta®, removed hydroxyurea use requirement, modified from two or more pain crises to at least one vaso-occlusive crisis (VOC), added hemoglobin requirements / November 2020	April 2021
Formatting changes / April 2021	July 2021
Updated minimum age for Oxbryta®, added age specifications to VOC requirement, updated references / December 2021	July 2022