Louisiana Medicaid
Exagamglogene autotemcel (Casgevy™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for exagamglogene autotemcel (Casgevy™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria

- The recipient is ≥ 12 and ≤ 35 years of age on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease (SCD); **AND**
- The provider **states on the request** that the recipient has experienced at least two severe vaso-occlusive crisis events per year for the previous two years; **AND**
- The recipient has had treatment failure or intolerance to hydroxyurea (HU); **AND**
- This medication is prescribed by a hematologist; **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 product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of 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**; AND**
- The following are true and **stated on the request:**
    - The recipient does not have advanced liver disease; **AND**
    - The recipient has not tested positive for human immunodeficiency virus [HIV] infection, hepatitis B virus [HBV] or hepatitis C virus [HCV]; **AND**
    - Recipients ≥ 12 to ≤ 16 years of age have a normal transcranial doppler (TCD); **AND**
    - Recipients ≥ 12 and ≤ 18 years of age do not have a history of an abnormal transcranial doppler (TCD) in the middle cerebral artery and the internal carotid artery; **AND**
    - The recipient is not pregnant or breastfeeding; **AND**
    - The recipient is eligible to receive hematopoietic stem cell (HSC) transplantation; **AND**
    - The recipient has no known and available HLA matched family donor; **AND**
    - The recipient has not received prior HSC transplantation; **AND**
    - The recipient **has never received a dose** of any gene therapy; **AND**
    - The recipient does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection;

OR

- The recipient is ≥ 12 and ≤ 35 years of age on the date of the request; **AND**
- The recipient has a diagnosis of homozygous β-thalassemia or compound heterozygous β-thalassemia including β-thalassemia/hemoglobin E (HbE); **AND**

- The provider **states on the request** that the recipient is transfusion-dependent defined by a history of **ONE** of the following in the 2-year period prior to the request:
    - At least 10 units/year of packed red blood cells (pRBCs); **OR**
    - At least 100 mL/kg/year of pRBCs; **AND**
- This medication is prescribed by a hematologist; **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 product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of 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**; AND**
- The following are true and **stated on the request:**
    - The recipient does not have severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction [LVEF] < 45% by echocardiogram); **AND**
    - The recipient does not have α-thalassemia and >1 alpha deletion or alpha multiplications; **AND**
    - The recipient does not have sickle cell beta thalassemia variant; **AND**
    - The recipient does not have advanced liver disease; **AND**
    - The recipient has not tested positive for human immunodeficiency virus [HIV] infection, hepatitis B virus [HBV] or hepatitis C virus [HCV]; **AND**
    - The recipient does not have white blood cell (WBC) counts < $3X10^9$/liter (L) and/or platelet counts < $50X10^9$/L (not due to hypersplenism); **AND**
    - The recipient is not pregnant or breastfeeding; **AND**
    - The recipient is eligible to receive hematopoietic stem cell (HSC) transplantation; **AND**
    - The recipient has no known and available HLA matched family donor; **AND**
    - The recipient has not received prior HSC transplantation; **AND**
    - The recipient **has never received a dose** of any gene therapy; **AND**
    - The recipient does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection.

Duration of approval: 6 months – allow 1 dose per lifetime

References

Casgevy (exagamglogene autotemcel) [package insert]. Boston, MA: Vertex Pharmaceuticals; January 2024. https://pi.vrtx.com/files/uspi_exagamglogene_autotemcel.pdf

ClinicalTrials.gov. A Safety and Efficacy Study Evaluating CTX001 in Subjects With Severe Sickle Cell Disease. https://clinicaltrials.gov/study/NCT03745287

ClinicalTrials.gov. A Safety and Efficacy Study Evaluating CTX001 in Subjects With Transfusion-Dependent β-Thalassemia. https://clinicaltrials.gov/study/NCT03655678

Frangoul H, et al. CRISPR-Cas9 Gene Editing for Sickle Cell Disease and β-Thalassemia. N Engl J Med. 2021 Jan 21;384(3):252-260. doi: 10.1056/NEJMoa2031054. Epub 2020 Dec 5. PMID: 33283989.

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 https://www.nhlbi.nih.gov/sites/default/files/media/docs/Evd-Bsd_SickleCellDis_Rep2014.pdf

Revision / Date	**Implementation Date**
Policy created / February 2024	July 2024