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.

The Louisiana Department of Health (LDH) / Louisiana Medicaid participates in the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy Access Model. Under this model, treatment centers that provide gene therapies for sickle cell disease (gene therapies for beta-thalassemia are not included at this time) must be members of the CMS Designated Registry through the Center for International Blood and Marrow Transplant Research (CIBMTR). Treatment centers must be enrolled in CIBMTR before administering gene therapies for sickle cell disease to Louisiana Medicaid recipients.

Approval Criteria for Specific Diagnoses:

Sickle Cell Disease (SCD)

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease (SCD) confirmed by genetic testing; **AND**
- **ONE** of the following is true and **stated on the request**:
    - ~~The provider **states on the request** that t~~The recipient has experienced recurrent vaso-occlusive crisis (VOCs) events (defined as more than or equal to two VOCs per year for the previous two years); **OR**~~**AND**~~
    - The recipient is currently receiving chronic transfusion therapy for recurrent VOCs; **AND**
- The recipient has had treatment failure, or intolerance to hydroxyurea (per health care professional judgement) at any point in the past; **AND**
- This medication is prescribed by, or in consultation with a board-certified hematologist with SCD experience; **AND**
- The following are true and **stated on the request:**
    - The recipient is clinically stable and fit for hematopoietic stem cell (HSC) transplantation; **AND**
    - The recipient is eligible to receive HSC transplantation; **AND**
    - The recipient has not received prior HSC transplantation.~~;~~

Transfusion-Dependent β-Thalassemia (TDT)

~~**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: 12 months – allow 1 dose per lifetime

References

Casgevy (exagamglogene autotemcel) [package insert]. Boston, MA: Vertex Pharmaceuticals; SeptemberJanuary 20254. 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
Added CMMI Cell and Gene Therapy Access Model statement, modified the following criteria – age, specific genotypes removed / confirmed genetic testing added, defined of VOCs, included hydroxyurea failure/intolerance in the past per health care professional judgement, included consultation with board-certified hematologist with SCD experience, included clinically stable and fit for HSC transplant, increased approval duration to 12 months, simplified the wording for patient eligibility for HSC transplantation / June 2025	June 2025
Removed VOC severity / December 2025	January 2026
Formatting changes, expanded VOC criterion to include current chronic transfusion therapy, updated references / November 2025	April 2026