Louisiana Medicaid
Lovotibeglogene autotemcel (Lyfgenia®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for lovotibeglogene autotemcel (Lyfgenia®).

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 years ~~and ≤ 50 years~~ of age or older at~~on~~ the expected time of gene therapy administration~~date of the request~~; **AND**
- The recipient has a diagnosis of sickle cell disease (SCD)~~,~~ confirmed via genetic testing~~with either β^S/β^S or β^S/β^0 or β^S/β^+ genotype~~; **AND**
- **ONE** of the following is true and **stated on the request**:
  - ~~T~~he provider ~~**states on the request** that the~~The recipient has experienced at least 4 severe vaso-occlusive events (VOEs) in the previous 24 months; **OR**~~**AND**~~
  - The recipient is currently receiving chronic transfusion therapy for recurrent VOEs; **AND**
- The recipient has had treatment failure, or intolerance to hydroxyurea (per health care professional judgement) at any point in the past~~HU)~~; **AND**
- This medication is prescribed by, or in consultation with a board-certified ~~a~~ hematologist with SCD experience; **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**
  - The recipient does not have inadequate bone marrow function, as defined by an absolute neutrophil count of < 1000/µL (< 500/µL for subjects on HU treatment) or a platelet count < 100,000/µL; **AND**
  - ~~The recipient does not have a history of severe cerebral vasculopathy; **AND**~~
  - The recipient does not have prior or current malignancy or immunodeficiency disorder, except previously treated, non-life threatening, cured tumors such as squamous cell carcinoma of the skin; **AND**
  - The recipient does not have an immediate family member with a known or suspected familial cancer syndrome; **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~~6~~ months – allow 1 dose per lifetime

References

ClinicalTrials.gov. A Study Evaluating the Safety and Efficacy of bb1111 in Severe Sickle Cell Disease. https://clinicaltrials.gov/study/NCT02140554

Lyfgenia (lovotibeglogene autotemcel) [package insert]. Somerville, MA: Bluebird Bio, Inc; December 2023. https://www.bluebirdbio.com/-/media/bluebirdbio/Corporate%20COM/Files/Lyfgenia/LYFGENIA_Prescribing_Information.pdf

Revision / Date	Implementation Date
Policy created / February 2024	July 2024
Modified the following criteria – age, timing of administration, specific genotypes removed / confirmed genetic testing added, included chronic transfusion therapy for recurrent VOEs, included hydroxyurea failure/intolerance in the past per health care professional judgement, included consultation with board-certified hematologist with SCD experience, increased approval duration to 12 months	July 2025