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 and ≤ 50 years of age on the date of the request; **AND**
- The recipient has a diagnosis of sickle cell disease (SCD), with either β^S/β^S or β^S/β^0 or β^S/β^+ genotype; **AND**
- The provider **states on the request** that the recipient has experienced at least 4 severe VOEs in the previous 24 months; **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**
    - 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: 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
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