Part B Prior Authorization Guidelines

Sickle Cell Disease

Lyfgenia (lovotibeglogene autocel) J3394

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Diagnosis of sickle cell disease confirmed by genetic testing demonstrating ONE of the following:
- ☐ Homozygous sickle cell disease (e.g., HbSS); OR
- ☐ Heterozygous sickle cell disease (e.g., HbSC, HbSβ+, HbSβ0, HbSD, HbSOArab, HbSE); AND

☐ At least 12 years of age

☐ Documented history of one of the following clinical signs or symptoms in the last 12 months in the setting of appropriate supportive care measures for sickle cell disease (e.g., pain management plan):
- ☐ Acute pain event requiring a visit to a medical facility and administration of pain medications (e.g. opioids (IV or oral) or intravenous NSAIDs), hydration therapy or red blood cell transfusions
- ☐ Acute chest syndrome
- ☐ Acute hepatic sequestration
- ☐ Acute splenic sequestration
- ☐ Priapism lasting > 2 hours and requiring a visit to a medical facility; AND

☐ Meet the institutional requirements for a stem cell transplant procedure where the individual is expected to receive gene therapy. These requirements may include:

- ☐ Adequate Karnofsky performance status or Lansky performance status;
- ☐ Absence of advanced liver disease;
- ☐ Adequate estimate glomerular filtration rate (eGFR);
- ☐ Adequate diffusing capacity of the lungs for carbon monoxide (DLCO);
- ☐ Adequate left ventricular ejection fraction (LVEF);
- ☐ Absence of clinically significant active infection(s); AND

☐ Have not received a previous allogenic hematopoietic stem cell transplant; AND

☐ Have not received any gene therapy or are under consideration for treatment for another gene therapy for sickle cell disease.

If not, please provide **clinical rationale** for formulary exception: _____
_____

Continuation Requests: Lyfgenia is a ONE-TIME infusion and will not be reauthorized.

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Lyfgenia PA

Drug Name(s):
LYFGENIA **LOVOTIBEGLOGENE AUTOTEMCEL**

Criteria for approval of Prior Authorization Drug:
1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Prescribed by or in consultation with a Hematologist

Coverage Duration:
Initial approval will be for 6 months / one infusion.

FDA Indications:
Lyfgenia
- Sickling disorder due to hemoglobin S, with a history of vaso-occlusive events

Off-Label Uses:
N/A

Age Restrictions:
12 years and older

Other Clinical Considerations:
Black Box Warning: (IV; Suspension)
Hematologic malignancy has occurred in patients treated with lovotibeglogene autotemcel. Monitor patients closely for evidence of malignancy through complete blood counts at least every 6 months and through integration site analysis at Months 6, 12, and as warranted

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/D99F6B/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/0DED32/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=lyfgenia&UserSearchTerm=lyfgenia&SearchFilter=filterNone&navitem=searchGlobal#