TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Lovotibeglogene autotemcel (Lyfgenia®)	**CRITERIA ID:** TX.CC.PHAR.45
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: January 1, 2025	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE:	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for lovotibeglogene autotemcel (Lyfgenia®)

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage precision drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All precision drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All precision drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J3394 (used for Lyfgenia) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
NRB = Non-Risk Based
UM = Utilization Management
CPS = Centene Pharmacy Services
SHP = Superior HealthPlan

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of lovotibeglogene autotemcel (Lyfgenia®); procedure code: J3394.

Description/Mechanism of Action:
Lovotibeglogene autotemcel (Lyfgenia®) is an autologous hematopoietic stem cell-based gene therapy.

FDA Approved Indications:
Lovotibeglogene autotemcel (Lyfgenia®) is indicated for the treatment of clients 12 years of age and older with sickle cell disease (SCD) and a history of vaso-occlusive events.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Sickle Cell Disease (SCD):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is 12 years of age or older.
4. The client has a diagnosis of sickle cell disease (SCD) as confirmed by genetic testing and a history of vaso-occlusive events, with at least four vaso-occlusive events in the past 24 months.

Diagnosis Codes:							
D5700	D5701	D5702	D5703	D5704	D5709	D571	D5720
D57211	D57212	D57213	D57214	D57218	D57219	D5740	D57411
D57412	D57413	D57414	D57418	D57419	D5742	D57431	D57432
D57433	D57434	D57438	D57439	D5744	D57451	D57452	D57453
D57454	D57458	D57459	D5780	D57811	D57812	D57813	D57814
D57818	D57819						

5. Documentation that the client has not previously received allogeneic or autologous hematopoietic stem cell transplantation and does not have a matched related donor to participate in an allogenic stem hematopoietic stem cell transplant (HSCT).
6. The client has inadequate response or contraindication to hydroxyurea.
7. The client has not previously received Lyfgenia or any other gene therapy.
8. The client has a confirmed negative serum pregnancy test and is not breastfeeding.
9. The client has a confirmed negative serology test for HIV-1 or HIV-2.
10. The client does not have advanced liver or chronic kidney disease.
11. Prescriber attestation is required to all of the following:
    - Discontinuation of hydroxyurea at 2 months prior to mobilization and two days prior to conditioning;
    - Discontinuation of anti-retroviral medication at least one month prior to mobilization and until all cycles of apheresis are completed;
    - Discontinuation of iron chelators at least 7 days prior to initiation of myeloablative conditioning.
12. Prescriber attestation to monitoring of the following parameters for clients receiving Lyfgenia:
    - Monitor 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;
    - Monitor for thrombocytopenia and bleeding;
    - Monitor neutrophil counts until engraftment has been achieved.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of provider.

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document	N/A	01/01/2025