El Paso Health

Provider Fact Sheet: Sickle Cell Disease Gene Therapy

Lovotibeglogene Autotemcel (Lyfgenia)

Reference: Texas Medicaid Provider Procedures Manual (TMPPM), Outpatient Drug Services Handbook, Section 6.116, Sickle Cell Disease Gene Therapy

Sickle Cell Disease Gene Therapy

Lovotibeglogene autotemcel (Lyfgenia) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of clients who are 12 years of age or older with sickle cell disease and a history of vaso-occlusive events with at least four vaso-occlusive events in the past 24 months or currently receiving chronic transfusion therapy for recurrent vaso-occlusive events.

Lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394) is a benefit of Texas Medicaid with prior authorization. Prior authorization is approved for a duration of 12 months.

Lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394) is limited to one transfusion treatment per lifetime.

Prior Authorization Requirements

Prior authorization requests for lovotibeglogene autotemcel (Lyfgenia) must be submitted using the **Special Medical Prior Authorization (SMPA) Request Form**.

Lovotibeglogene autotemcel (Lyfgenia) is a one-time infusion therapy indicated for the treatment of clients for whom autologous hematopoietic stem cell transplantation is appropriate and who meet the following requirements:

Sickle Cell Disease

- The client is 12 years of age or older at the expected time of gene therapy administration.
- The client has a diagnosis of sickle cell disease confirmed by genetic testing and a history of vaso-occlusive events, with at least four vaso-occlusive events in the past 24 months, or currently receiving chronic transfusion therapy for recurrent vaso-occlusive events, as documented with one of the following diagnosis codes or provider attestation:

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						

- The client has inadequate response or contraindication to hydroxyurea per the healthcare provider’s discretion.

Additional Requirements

In addition to the criteria above, all of the following criteria must be met:

- The client has not previously received allogeneic or autologous hematopoietic stem cell transplantation.
- The client has not previously received lovotibeglogene autotemcel (Lyfgenia) or any other gene therapy.
- The client has a confirmed negative serum pregnancy test and is not breastfeeding.
- The client has confirmed negative serology test for HIV-1 or HIV-2.
- The client does not have advanced liver or chronic kidney disease.

Prescriber Attestation

Prescribers must attest and document the following:

- Hydroxyurea is discontinued two months before mobilization and two days before conditioning.
- Anti-retroviral medication is discontinued at least one month before mobilization and until all cycles of apheresis are completed.
- Iron chelators are discontinued at least seven days before initiation of myeloablative conditioning.

Monitoring Parameters

Monitoring parameters for lovotibeglogene autotemcel (Lyfgenia) are as follows:

- Monitor for evidence of malignancy through complete blood counts at least every six months and through integration site analysis at month 6, month 12, and as warranted.
- Monitor for thrombocytopenia and bleeding.
- Monitor neutrophil counts until engraftment has been achieved.

Documentation Requirements

In addition to documentation requirements outlined in this section, all services are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

Contact Information

For questions specific to gene therapy criteria, documentation, or prior authorization requirements, please email: **HS_UM INQUIRIES@elpasohealth.com**