Sickle Cell Disease Gene Therapy - TMHP Bulletin; effective 10/01/2025

Updates to Prior Authorization Criteria for Sickle Cell Disease Gene Therapy Effective October 1, 2025

Last updated on 9/5/2025

Note: Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to Medicaid members who are enrolled in their MCO. Administrative procedures, such as prior authorization, precertification, referrals, and claims and encounter data filing, may differ from traditional Medicaid (fee-for-service) and from MCO to MCO. Providers should contact the member's specific MCO for details.

Effective for dates of service on or after October 1, 2025, the Texas Medicaid & Healthcare Partnership (TMHP) will update the initial prior authorization requirements for exagamglogene autotemcel (Casgevy) (procedure code J3392) and lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394).

This update will include the following:

- The diagnosis of sickle cell disease may be confirmed by a provider attestation.
- The requirement that a client not have a related donor who is a match to participate in an allogeneic stem hematopoietic stem cell transplant (HSCT) will be removed.
- The client has an inadequate response or contraindications to hydroxyurea per the health care provider's discretion.

The complete updated prior authorization criteria are as follows:

Exagamglogene autotemcel (Casgevy) (procedure code J3392) and lovotibeglogene autotemcel (Lyfgenia) (procedure code J3394) are benefits of Texas Medicaid and require prior authorization. Texas Medicaid will approve prior authorization for a duration of 12 months.

Exagamglogene Autotemcel (Casgevy)

Exagamglogene autotemcel (Casgevy) (procedure code J3392) is an autologous genome-edited hematopoietic stem cell-based gene therapy that is indicated for the treatment of clients who are 12 years or older with one of the following:

- Sickle cell disease with recurrent vaso-occlusive crises
- Transfusion-dependent ß-thalassemia

Initial Prior Authorization Requirements for Exagamglogene Autotemcel (Casgevy)

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Exagamglogene autotemcel (Casgevy) is a one-time infusion therapy for the treatment of clients for whom autologous hematopoietic stem cell transplantation is appropriate and who meet certain criteria:

- Clients with sickle cell disease must meet the following criteria:
    - Genetic testing confirms the client's diagnosis of sickle cell disease.
    - The client has an inadequate response to hydroxyurea or crizanlizumab.
    - The client has a history of recurrent vaso-occlusive crises and at least two vaso-occlusive crisis events per year in the past two years, as documented by provider attestation or with one of the following diagnosis codes:

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						

- Clients with transfusion-dependent ß-thalassemia must meet the following criteria:
    - Genetic testing confirms the client's diagnosis of transfusion-dependent ß-thalassemia, as documented with diagnosis code D561 or D565.
    - The client has a history of requiring at least 100 mL/kg/year or ten units/year of red blood cell transfusions in the past 24 months.
- The client is 12 years of age or older.
- The client has not previously received an allogeneic or autologous hematopoietic stem cell transplantation.
- The client has not previously received exagamglogene autotemcel (Casgevy) or any other gene therapy.
- The client has a confirmed negative serum pregnancy test.

- The client does not have active HIV-1, HIV-2, hepatitis B virus, or hepatitis C virus infection.
- The client does not have advanced liver or chronic kidney disease.

Prescriber Attestation and Monitoring Parameters

For a sickle cell disease diagnosis, a prescriber attestation will be required and must document the following:

- Hydroxyurea will be discontinued at least eight weeks before mobilization and conditioning.
- Crizanlizumab will be discontinued at least eight weeks before mobilization or conditioning.
- Iron chelators will be discontinued at least seven days before initiation of myeloablative conditioning.

For a transfusion-dependent ß-thalassemia diagnosis, the prescriber will be required to attest to discontinuation of iron chelators at least seven days prior to initiation of myeloablative conditioning.

Monitoring parameters for exagamglogene autotemcel (Casgevy) are as follows:

- Monitor for bleeding and conduct frequent platelet counts until platelet engraftment and platelet recovery are achieved.
- Monitor absolute neutrophil counts until engraftment has been achieved.

Lovotibeglogene Autotemcel (Lyfgenia)

Lovotibeglogene autotemcel (Lyfgenia) is a one-time infusion therapy for the treatment of clients for whom autologous hematopoietic stem cell transplantation is appropriate.

Initial Authorization Requirements for Lovotibeglogene Autotemcel (Lyfgenia)

Clients who are candidates for lovotibeglogene autotemcel (Lyfgenia) infusion therapy must meet the following requirements:

- The client is 12 years of age or older at the expected time of gene therapy administration.
- The client has not previously received allogeneic or autologous hematopoietic stem cell transplantation.

- The client has an inadequate response or contraindications to hydroxyurea per the health care provider's discretion.
- 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 a confirmed negative serology test for HIV-1 or HIV-2.
- The client does not have advanced liver or chronic kidney disease.
- The client has a diagnosis of sickle cell disease that has been confirmed by genetic testing.
- The client has a history of vaso-occlusive events, with at least four vaso-occlusive events in the past 24 months, or is currently receiving chronic transfusion therapy for recurrent vaso-occlusive events as documented by provider attestation or one of the following diagnosis codes:

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						

Prescriber Attestation and Monitoring Parameters

Prescribers must attest and document the following:

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

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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, at month 12, and as warranted.
- Monitor for thrombocytopenia and bleeding.
- Monitor neutrophil counts until engraftment has been achieved.

For more information, call the TMHP Contact Center at 800-925-9126.