

Provider Fact Sheet: Sickle Cell Disease Gene Therapy

Exagamglogene Autotemcel (Casgevy)

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

Sickle Cell Disease Gene Therapy

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

- Sickle cell disease (SCD) with recurrent vaso-occlusive crises, or
- Transfusion-dependent β -thalassemia

Exagamglogene autotemcel (Casgevy) (procedure code J3392) is a benefit of Texas Medicaid with prior authorization. Prior authorization is approved for a duration of 12 months.

Exagamglogene autotemcel (Casgevy) (procedure code J3392) is limited to one transfusion treatment per lifetime.

Prior Authorization Requirements

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

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

Sickle Cell Disease

- The client is 12 years of age or older and has been diagnosed with sickle cell disease.
- The client has a diagnosis of sickle cell disease as confirmed by genetic testing with recurrent vaso-occlusive crises, with at least two vaso-occlusive crisis events per year in the past 2 years, 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 to hydroxyurea or crizanlizumab.

Transfusion-Dependent β -Thalassemia

- The client is 12 years of age or older and has been diagnosed with transfusion-dependent β -thalassemia, and the following additional criteria must be met:

- Genetic testing confirms the client's diagnosis of transfusion-dependent β -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 (RBC) transfusions in the past 24 months.

Diagnosis Codes	
D561	D565

All Clients

In addition to the criteria for the applicable diagnosis 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 exagamlogene 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, HBV, or HCV.
- The client does not have advanced liver or chronic kidney disease.

Prescriber Attestation

For diagnosis of sickle cell disease, the prescriber attestation is required for the following:

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

For transfusion-dependent β -thalassemia diagnosis, prescriber attestation will be required to discontinue iron chelators at least 7 days prior to initiation of myeloablative conditioning.

Monitoring Parameters

Monitoring parameters for exagamlogene 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.

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