

Cell-Based Gene Therapy
Casgevy™ (exagamglogene autotemcel)

NOTE: Prior authorization requests must be submitted on a CMS-1450 to the Utilization Review department with the following contact information. <https://humanservices.arkansas.gov/wp-content/uploads/DMSUR.docx>

Drug Description

Casgevy™ is an autologous genome edited hematopoietic stem cell-based gene therapy.

FDA Approved Indication(s)

Casgevy™ is indicated for treatment of patients aged 12 years and older with:

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

NOTE:

- **This monograph will apply only to the sickle cell disease indication not transfusion-dependent β-thalassemia (TDT).**
- **Refer to the package insert for considerations for dosage and administration, contraindications, warnings and precautions, drug interactions, and use in specific populations.**

Prescribing Considerations

- Patient is 12 years of age and older at the expected time of gene therapy administration.
- Patient has a diagnosis of sickle cell disease (SCD) confirmed by genetic testing.
- Patient has one of the following based on provider attestation:
 - Experienced recurrent vaso-occlusive crises (VOCs), defined as two (2) or more documented VOCs per year in the previous twenty-four (24) months; OR
 - Currently receiving chronic transfusion therapy for recurrent VOCs
- The request must be prescribed by, or in consultation with, a board-certified hematologist with SCD expertise in conjunction with treatment by an Arkansas Medicaid enrolled Sickle Cell treatment center.
- Patient is considered clinically stable and fit for transplantation.
- Patient must have prior use of or intolerance to hydroxyurea (per health care professional judgement) at any point in the past.
- Prior authorization approval will be valid for a time period of 12 months with one (1) single dose per lifetime.



Billing / Coding Information

Applicable Procedure Codes—see billing guide

- Casgevy™ J-code is J3392

Literature / References

- <https://clinicaltrials.gov/study/NCT03745287?intr=nct03745287&limit=10&rank=1>
- <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7c3e12ad-e2fe-4d3f-a630-ea7364d9e846>

CHANGE AUTHORIZATION REVIEWS

Any changes/updates to this information must be documented as follows: