

**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  $\beta$ -thalassemia (TDT)

**NOTE:**

- **This monograph will apply only to the sickle cell disease indication not transfusion-dependent  $\beta$ -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.



**ARKANSAS DEPARTMENT OF  
HUMAN SERVICES**  
Division of  
Medical Services

### 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:

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