

# Casgevy (exagamglogene-autotemcel) Criteria

Revised: 11/01/2024

## CASGEVY (EXAGAMGLOGENE-AUTOTEMCEL)

**Length of Authorization:** One treatment course

## CRITERIA TO APPROVE

All the following:

- Confirmed diagnosis of sickle cell disease with **one** of the following genotypes:
  - $\beta S/\beta S$
  - $\beta S/\beta 0$
  - $\beta S/\beta +$
  - **Note:** Additional genotypes will be considered on an individual consideration (IC) basis based on disease severity.
- Age 12 years or older
- Prescriber is a specialist at a qualified treatment center for Casgevy
- Patient does not have a contraindication to the prescribed medication
- Patient does not have clinically suitable, known and available 10/10 human leukocyte antigen matched sibling donor willing to participate in an allogenic hematopoietic stem cell transplant
- Patient must not have received prior treatment with any gene therapy for sickle cell disease or an allogenic hematopoietic stem cell transplant
- Patient has history of intolerance or failure of hydroxyurea treatment **or** patient use of hydroxyurea is contraindicated
- Prior to treatment, patient must have experienced at least four severe vaso-occlusive crises in the past 24 months **or** is currently receiving chronic red blood cell (RBC) transfusion therapy for the prevention of severe vaso-occlusive episodes
  - **Note:** Severe VOC is defined as an occurrence of at least one of the following events requiring an evaluation at a medical facility with no medically determined cause other than vaso-occlusion requiring administration of pain medications such as opioids or intravenous (IV) non-steroidal anti-inflammatory drugs (NSAIDs) or RBC transfusions:
    - Acute pain
    - Acute chest syndrome
    - Acute hepatic sequestration
    - Priapism > 2 hours
    - Splenic sequestration
- Patient has a negative serologic test for HIV infection

## RENEWAL CRITERIA

Not applicable as no further authorizations will be provided

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## REVISION HISTORY

Date	Issues/Updates
11/01/2024	• Criteria created