

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Exagamglogene autotemcel (Casgevy) – PA Criteria

HCPC: J3392

Exagamglogene autotemcel (Casgevy) is an autologous cellular gene therapy indicated for the treatment of sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) and transfusion-dependent beta-thalassemia in adults and pediatric patients ≥ 12 years of age. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

**** All requests under this policy require SD medical director review in addition to meeting specified criteria below ****

• Initial Therapy (must meet all):

- Therapy is prescribed by a hematologist
- Individual meets the following criteria as specified per indication
 - For SCD:
 - Individual has a diagnosis of SCD with a β^S/β^S , β^S/β^0 , or β^S/β^+ genotype
 - Documentation is provided that the individual has had ≥ 2 *severe VOCs (as defined below) per year, while receiving appropriate supportive care, for the previous 24 months prior to therapy request
 - Individual has a documented failure (or contraindication) of ≥ 6 months with hydroxyurea within the last 24 months
 - For beta-thalassemia
 - Individual has a diagnosis of beta thalassemia with a β^0/β^0 , β^0/β^0 -like or non- β^0/β^0 -like genotype
 - Individual does not have associated α -thalassemia and >1 alpha deletion, or alpha multiplications
 - Individual is transfusion-dependent as defined by a history of ≥ 100 ml/kg/year or 10 units of packed red blood cell (RBC) transfusions/year in the prior 24 months before therapy request
- Attestation from provider that member is clinically stable and able to undergo gene therapy
- Individual does not have a known, human leukocyte antigen (HLA)-matched donor
- Screening has been done within the last 6 months and documentation is provided indicating that the individual is negative for the following active diseases: HIV, Hepatitis B, and Hepatitis C
- Individual has not previously received a hematopoietic stem cell transplant or prior gene therapy
- Individual does not have advanced liver disease (defined as ALT $>3X$ upper limit of normal, direct bilirubin $>2.5x$ upper limit of normal, baseline prothrombin time $>1.5x$ upper limit of normal or history of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on liver biopsy)
- If female, documentation of negative pregnancy test must be submitted prior to therapy
- Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Casgevy administration
- Individual is 12-35 years of age
- Approval duration: one dose

• Continuation of Therapy: not authorized

*Severe VOC defined as one of the following:

- Acute pain event that required a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] nonsteroidal anti-inflammatory drugs [NSAIDs]) or red blood cell (RBC) transfusions

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- Acute chest syndrome (ACS), as indicated by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever
- Priapism lasting >two hours and requiring a visit to a medical facility
- Splenic sequestration
- Hepatic sequestration