Exagamglogene Autotemcel (Casgevy™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Casgevy is indicated for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs).
- Casgevy is indicated for the treatment of transfusion-dependent β-thalassemia (TDT) in patients 12 years and older.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Sickle Cell Disease:

- Molecular or genetic testing results documenting sickle cell disease genotype
- Chart notes or medical records documenting history of severe vaso-occlusive episodes

Transfusion-Dependent β-thalassemia:

- Molecular or genetic testing results documenting transfusion-dependent beta-thalassemia genotype
- Chart notes or medical records documenting history of blood cell transfusions

PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with a hematologist.

COVERAGE CRITERIA

Sickle Cell Disease

Authorization of 3 months for one dose total may be granted for sickle cell disease when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has a diagnosis of sickle cell disease with one of the following genotypes confirmed by molecular or genetic testing:
  - β^s/β^s
  - β^s/β^0
  - β^s/β^+
- Member has a documented history of at least 2 severe vaso-occlusive episodes per year during the previous two years (see Appendix A for examples)
- Member is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a human leukocyte antigen (HLA)-matched related donor
- Member has not received a prior hematopoietic stem cell transplant (HSCT)
- Member has not received Casgevy or any other gene therapy previously
- Member meets one of the following:
  - Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea
  - Has a contraindication to hydroxyurea

Transfusion-Dependent Beta-Thalassemia

Authorization of 3 months for one dose total may be granted for transfusion-dependent beta-thalassemia when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has a diagnosis of transfusion-dependent beta-thalassemia with a non-β0/β0 OR β0/β0 genotype confirmed via molecular or genetic testing (see Appendix B for examples).
- Member has received at least 100 milliliter per kilogram or 10 units of packed red blood cells (pRBCs) per year during the previous two years.
- Member is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a human leukocyte antigen (HLA)-matched related donor.
- Member has not received a prior hematopoietic stem cell transplant (HSCT).
- Member has not received Casgevy or any other gene therapy previously.

APPENDIX

Examples of Severe Vaso-Occlusive Events

- Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
- Acute chest syndrome
- Priapism lasting > 2 hours and requiring a visit to a medical facility
- Splenic sequestration
- Hepatic sequestration

Examples of non-β0/β0 OR β0/β0 genotypes

- β0/β0
- β0/β+
- βE/β0
- β0/IVS-I-110

- IVS-I-110/IVS-1-110

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Casgevy [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024.
2. Frangoul H, Altshuler D, Cappellini MD, et al. CRISPR-CaS9 gene editing for sickle cell disease and β-thalassemia. N Engl J Med 2021; 384:252-60.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. National Institutes of Health. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816 0.pdf. Accessed July 16, 2024.
4. Cappellini MD, Farmakis D, Porter J, Taher A. 2021 Guidelines for the management of transfusion dependent thalassaemia (TDT). Nicosia, Cyprus: Thalassaemia International Federation, 2021.

EFFECTIVE DATE 4/2/2025

ID_CHS