Reference number(s)
C28137-A

CAREFIRST: CASGEVY (exagamglogene autotemcel)

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

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

1. Casgevy is indicated for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs).
2. 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.

I. CRITERIA FOR INITIAL APPROVAL

A. Sickle Cell Disease

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

1. Member is 12 years of age or older.
2. Member has a confirmed diagnosis of sickle-cell disease. Examples of genotypes include, but not limited to are βS/βS or βS/β0 or βS/β+.
3. 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).
4. Member is eligible for a hematopoietic stem cell transplant (HSCT).
5. Member does NOT have a known 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic HSCT.
6. Member has not received a prior hematopoietic stem cell transplant (HSCT).
7. Member has not received Casgevy or any other gene therapy previously.

B. Transfusion-Dependent β-Thalassemia

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

1. Member is 12 years of age or older.
2. Member has a diagnosis of transfusion-dependent β-thalassemia with a non-β0/β0 OR β0/β0 genotype confirmed via molecular or genetic testing (see Appendix B for examples).
3. 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.
4. Member is eligible for a hematopoietic stem cell transplant (HSCT)
5. Member does NOT have a known 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic HSCT.
6. Member has not received a prior hematopoietic stem cell transplant (HSCT).
7. Member has not received Casgevy or any other gene therapy previously.

APPENDICES

Appendix A: Examples of Severe Vaso-Occlusive Events

1. 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
2. Acute chest syndrome
3. Priapism lasting > 2 hours and requiring a visit to a medical facility
4. Splenic sequestration

5. Hepatic sequestration

Appendix B: Examples of non-β0/β0 OR β0/β0 genotypes

1. β0/β0
2. β0/β+
3. βE/β0
4. β0/IVS-I-110
5. IVS-I-110/IVS-1-110

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 December 13, 2023.
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.