exagamglogene autotemcel (Casgevy)

Commercial Medical Benefit Drug Policy

Place of Service

Hospital Administration
Hospital Outpatient Facility

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: Autologous genome edited hematopoietic stem cell-based gene therapy
HCPCS:
J3392:Injection, exagamglogene autotemcel, per treatment
How Supplied:
Casgevy is supplied in one or more vials containing a frozen suspension of genome edited autologous CD34+ cells. Casgevy is supplied in vials packaged in cartons. One carton contains a single lot of Casgevy consisting of 1 to 9 vials. A single dose of Casgevy may consist of multiple Casgevy lots, and therefore may consist of multiple cartons.

NDC: 51167-290-09

Condition(s) listed in policy *(see coverage criteria for details)*

- Sickle Cell Disease
- Transfusion-dependent Beta-thalassemia (TDT)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Sickle Cell Disease
Meets medical necessity if all the following are met:
1. Diagnosis of sickle cell disease
2. Patient is 12 years of age or older
3. Prescribed by or in consultation with a hematologist or transplantation specialist
4. Patient has experienced at least four vaso-occlusive crises (VOCs) in the past 2 years
5. Patient is clinically stable and eligible to undergo myeloablative conditioning and hematopoietic stem cell transplantation
6. Inadequate response, intolerable side effect, or contraindication to hydroxyurea

7. Patient does not have a known 10/10 human leukocyte matched related donor willing to participate in an allogeneic hematopoietic stem cell transplantation
8. Patient has not previously received allogeneic hematopoietic stem cell transplantation
9. Patient has not previously received gene therapy
10. Patient does not have any prior or current malignancy or immunodeficiency disorder, with the exception of non-melanoma skin cancers or immediate family member with a known or suspected Familial Cancer Syndrome
11. Patient does not have advanced liver disease (e.g., liver cirrhosis, active hepatitis, significant fibrosis, liver iron concentration of ≥15 mg/g)
12. Patient does not have evidence of chronic kidney disease
13. Patient does not have a history or presence of Moyamoya disease
14. Patient does not have any of the following viruses:
    a. HIV-1 or HIV-2
    b. Hepatitis B virus (HBV), unless one of the following:
        i. Patient has received previous vaccination against hepatitis B (e.g., positive for hepatitis B surface antibody) AND has negative markers of hepatitis B (e.g., negative for hepatitis B core antibody)
        ii. Patient has previous HBV exposure (e.g., positive for hepatitis B core antibody or hepatitis B e antibody) AND negative for HBV DNA
    c. Hepatitis C virus (HCV), OR undetectable hepatitis C viral load if patient is positive for anti-hepatitis C antibody

Covered Doses:
The minimum recommended dose of Casgevy is 3 × 10^6 CD34+ cells/kg given by intravenous infusion

Casgevy is provided as a single dose for infusion containing a suspension of CD34+ cells in one or more vials.

Coverage Period:
One-time single-dose treatment

ICD-10:
D57.00, D57.01, D57.02, D57.40, D57.80

<u>Transfusion-dependent Beta-thalassemia (TDT)</u>
Meets medical necessity if all the following are met:

1. Transfusion dependence, defined as at least 10 transfusions of packed red blood cells (pRBC) in the past 2 years
2. Patient is 12 years of age or older
3. Patient is clinically stable and eligible to undergo myeloablative conditioning and hematopoietic stem cell transplantation
4. Patient does not have associated alpha-thalassemia, at least 1 alpha deletion, alpha multiplications, or sickle cell beta-thalassemia variant
5. Patient does not have a known 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic hematopoietic stem cell transplantation

6. Patient has not previously received allogeneic hematopoietic stem cell transplantation
7. Patient has not previously received gene therapy
8. Patient does not have advanced liver disease (e.g., liver cirrhosis, fibrosis, active hepatitis, liver iron concentration of ≥15 mg/g)
9. Patient does not have history of iron overload
10. White blood cell (WBC) count ≥3 x 10^9/L
11. Platelet count ≥50 x 10^9/L (unless related to hypersplenism)
12. Patient does not have any of the following viruses:
    a. HIV-1 or HIV-2
    b. Hepatitis B virus (HBV), unless one of the following:
        i. Patient has received previous vaccination against hepatitis B (e.g., positive for hepatitis B surface antibody) AND has negative markers of hepatitis B (e.g., negative for hepatitis B core antibody), or
        ii. Patient has previous HBV exposure (e.g., positive for hepatitis B core antibody or hepatitis B e antibody) AND negative for HBV DNA
    c. Hepatitis C virus (HCV), OR undetectable hepatitis C viral load if patient is positive for anti-hepatitis C antibody

Covered Doses:
The minimum recommended dose of Casgevy is 3 × 10^6 CD34+ cells/kg given by intravenous infusion

Casgevy is provided as a single dose for infusion containing a suspension of CD34+ cells in one or more vials.

Coverage Period:
One-time single-dose treatment

ICD-10:
D56.1

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Casgevy (exagamglogene autotemcel) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated;1/2024.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee