MetroPlus Health

Policy and Procedure

Title: Casgevy	**Division: Medical Management** **Department: Pharmacy**
Approval Date: 2/17/2026	**LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare, Medicare, Ultracare**
Effective Date: 2/17/2026	**Policy Number: UM-MP354**
Review Date: 2/17/2026	**Cross Reference Number:**
Retired Date:	**Page 1 of 11**

I. POLICY DESCRIPTION:

Gene Therapy – Casgevy (exagamgluogene autotemcel)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Casgevy is a autologous hematopoietic stem cell (HSC)-based gene therapy indicated for sickle cell disease with recurrent vaso-occlusive crises (VOC). Casgevy edits CD34+ hematopoietic stem cells with CRISPR/Cas9 technology to reduce *BCL11A* expression that allows for increased γ-globin expression and fetal hemoglobin (HbF) production in erythroid cells. HbF production reduces hemoglobin S concentration and prevents red blood cells (RBC) from sickling.

Exagamglogene autotemcel is a cellular gene therapy consisting of autologous CD34+ hematopoietic cells edited by CRISPR/Cas9 technology to create a DNA double-strand break at a critical transcription binding site of the erythroid-specific enhancer region of the *BCL11A* gene. This modification reduces *BCL11A* expression in the erythroid lineage, allowing for increased γ-globin expression and fetal hemoglobin (HbF) production in erythroid cells. After exagamglogene autotemcel infusion, the edited CD34+ cells engraft in the bone marrow and differentiate to erythroid lineage cells with reduced *BCL11A* expression. In patients with severe sickle cell disease, HbF expression reduces intracellular hemoglobin S concentration, preventing the RBCs from sickling and addressing the underlying cause of disease, thereby eliminating vaso-occlusive crises. In transfusion-dependent beta-thalassemia, γ-globin production improves the imbalance in α-globin to non-α-globin, leading to improved erythropoiesis and increasing total Hb levels.

IV. POLICY:

Casgevy will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:
For Medicaid, SNP, HARP Plan members, follow the criteria below. The Plan will follow the instructions outlined by NYRx and use the Cell and Gene Therapy Form to submit information to NYRx. Casgevy is reimbursed by the Medicaid fee-for-service pharmacy program.

1. **Transfusion-Dependent β-Thalassemia (TDT)**
   A. Member must be ≥ 12 years of age;
   AND
   B. Member must have transfusion-dependent β-thalassemia.

2. **Sickle Cell Disease (SCD)**
   A. Member is ≥ 12 years of age;
   AND
   B. Member must have diagnosed with sickle cell disease (SCD);
   AND
   C. Member must have recurrent vaso-occulusive crises (VOCs).

Additionally, New York State (NYS) Department of Health's memo released on 1/12/2026 requires NYS managed care plan should ensure:

- The gene therapy is administered at an in-network qualified treatment center or have a single case agreement.
- Providers who submit a claim must be a member of the CMS-designated patient registry (i.e., the Center for International Blood & Marrow Transplant Research - CIBMTR) and participate in a CMS-specified study. A list of participating centers is available on the CIBMTR website.
- Continuity of care for beneficiaries that may transition between fee-for-service and managed care, or among Managed Care Plans.
- Beneficiaries continue to have access to their Sickle Cell Disease gene therapy providers for at least one year after receiving gene therapy.
- Providers have access to a primary and secondary Managed Care Plan representative.
- A Managed Care Plan representative is aware of the coverage policy guidance in the October 2025 Medicaid Update.

For All non-Medicaid LoBs:

INITIAL REQUEST:

1. **Beta-thalassemia, transfusion dependent (TDT):**

A. Member is ≥ 12 years of age and ≤ 35 years of age;
AND
B. Prescribed by or in consultation with a board-certified hematologist;
AND
C. Member has ONE of the following genotypes confirmed by DNA analysis:
i. Non-β^0/β^0 genotypes;
OR
ii. β^0/β^0 genotypes;
AND
D. Transfusion-depended β-thalassemia is defined as a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the two (2) years preceding administration of casgevy
AND
E. Member has not received a prior hematopoietic stem cell transplant;
AND
F. ALL of the following:
i. Member is a candidate to undergo hematopoietic stem cell transplantation (HSCT);
AND
ii. Member is ineligible for allogenic hematopoietic stem cell transplantation due to the absence willingness of a suitable, fully matched sibling donor*; [Note: if member declines HSCT, they are ineligible for Casgevy];*
AND
G. Member does not have ANY of the following:
i. More than two α-globin gene deletions;
OR
ii. Active infections (e.g., human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), Human T-lymphotrophic virus-1 and -2, bacterial, viral, fungal, parasitic infection);
OR
iii. Active liver disease (i.e. alanine transaminase (ALT) > 3 times upper limit of normal; direct bilirubin value > 2.5 times upper limit of normal; baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal; cirrhosis; bridging fibrosis; or active hepatitis);
OR
iv. Contraindications to any product or procedure required for treatment (i.e., red blood cell transfusions, use plerixafor and busulfan);

OR

v. History of severe cerebral vasculopathy, prior or current malignancy or immunodeficiency disorder;

vi. Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction [LVEF] < 45% by echocardiogram);

AND

H. Per provider, ALL of the following medications will be discontinued for the duration specified prior to mobilization if member is currently on them:

i. Iron chelation therapy for at least 7 days prior to mobilization and 2 days prior to conditioning (e.g., deferoxamine injection, deferiprone tablets or solution, and deferasirox tablet);

AND

ii. Anti-retrovirals for at least 1 month prior to mobilization and until all cycles of apheresis are completed *(Note: long-acting anti-retrovirals (e.g. Cabenuva, Sunlenca, Trogarzo, Edurant) may require a longer duration of discontinuation for elimination of medication)*;

AND

I. ONE of the following:

a. If member is biologically female of childbearing age, member meets ALL of the following:

i. Member has a negative serum pregnancy test before mobilization cycle and re-confirmed prior to myeloablative conditioning and right before administration of Casgevy;

AND

ii. Member will use an effective method of contraception from the start of mobilization through at least 6 months after Casgevy administration;

OR

b. If member is biologically male, member will use an effective method of contraception from the start of mobilization through at least 6 months after Casgevy administration;

AND

J. Member has not received prior treatment with other gene therapies (e.g., Zyntgelo (betibeglogene autotemcel)

2. Sickle Cell Disease (SCD) with Vaso-Occlusive Crises

A. Member is ≥ 12 years of age and ≤ 35 years of age;

AND

B. Prescribed by or in consultation with a board-certified hematologist;
AND

C. Member has a diagnosis of SCD with one of the following genotypes:
- **i.** β^s / β^s;
- **OR**
- **ii.** β^s / β^+;
- **OR**
- **iii.** β^s / β^0;

AND

D. Member has experienced four or more severe VOEs crises over the past 2 years as defined by ONE of the following:
- **i.** An episode of acute pain that resulted in a visit to a medical facility which required administration of at least ONE of the following:
  - **i.** Intravenous opioid;
  - **OR**
  - **ii.** Intravenous nonsteroidal anti-inflammatory drug;

OR

- **ii.** Acute chest syndrome (i.e., presence of a new pulmonary infiltrate associated with pneumonia-like symptoms (e.g., chest pain, fever [> 38.5°C/101.3°F], tachypnea, wheezing or cough, or findings upon lung auscultation, presence of a new pulmonary infiltrate consistent with Acute chest syndrome (ACS) that requires oxygen treatment and/or blood transfusion);

OR

- **iii.** Acute hepatic sequestration (i.e., sudden increase in liver size associated with pain in the right upper quadrant, abnormal results of liver function test not due to biliary tract disease, and the reduction of hemoglobin concentration by ≥ 2 g/dL below the baseline value);

OR

- **iv.** Acute splenic sequestration (i.e., enlarged spleen, left upper quadrant pain, and an acute decrease in hemoglobin concentration of ≥ 2 g/dL below the baseline value);

OR

- **v.** Acute priapism lasting > 2 hours and requiring a visit to a medical facility (i.e., sustained, unwanted painful erection lasting more than 2 hours and requiring care at a medical facility (with or without hospitalization)

E. Member's Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥60 (<16 years of age);
AND

F. Member has adequate bone marrow function as confirmed by ONE of the following:
- **i.** Absolute neutrophil count > 1,000/µL;

OR
- **ii.** Absolute neutrophil count > 500/µL for members taking hydroxyurea;

OR
- **iii.** Platelet count > 100,000/µL;

AND

G. Member has tried and failed ALL of the following for at least 6 months unless member has had a contraindication:
- **i.** Hydroxyurea as monotherapy;

OR
- **ii.** Hydroxyurea in combination with other disease-modifying agents (e.g., Endari (L-glutamine), Adakveo (crizanlizumab));

AND

H. Member has not received a prior hematopoietic stem cell transplant;
AND

I. ALL of the following:
- **i.** Member is a candidate to undergo hematopoietic stem cell transplantation (HSCT); suitable fully matched donor OR suitable matched sibling donor

AND
- **ii.** Member is ineligible for allogenic hematopoietic stem cell transplantation due to the absence of a suitable donor *[Note: if member declines HSCT, they are ineligible for Casgevy];*

AND

J. Member does not have ANY of the following:
- **i.** More than two α-globin gene deletions;

OR
- **ii.** Active infections (e.g., human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), Human T-lymphotrophic virus-1 and -2, bacterial, viral, fungal, parasitic infection);

OR
- **iii.** Active liver disease (i.e. alanine transaminase (ALT) > 3 times upper limit of normal; direct bilirubin value > 2.5 times upper limit of normal; baseline prothrombin time (international normalized ratio

[INR]) > 1.5 times upper limit of normal; cirrhosis; bridging fibrosis; or active hepatitis);

OR

iv. Contraindications to any product or procedure required for treatment (i.e., red blood cell transfusions, use plerixafor and busulfan);

OR

v. History of severe cerebral vasculopathy, prior or current malignancy or immunodeficiency disorder, allogeneic transplant, considered for other HSCT and other gene therapy for SCD;

AND

K. Per provider, ALL of the following medications will be discontinued for the duration specified prior to mobilization if member is currently on them:

i. Disease-modifying therapies for sickle cell disease for at least 2 months prior to mobilization and 2 days prior to conditioning (e.g., hydroxyurea, Endari (L-glutamine), Adakveo (crizanlizumab));

AND

ii. Erythropoietin for at least 2 months prior to mobilization;

AND

iii. Iron chelation therapy for at least 7 days prior to mobilization and 2 days prior to conditioning (e.g., deferoxamine injection, deferiprone tablets or solution, and deferasirox tablet);

AND

iv. Granlocyte-colony stimulating factor (G-CSF) not to be administered prior to or with mobilization agents;

AND

v. Anti-retrovirals for at least 1 month prior to mobilization and until all cycles of apheresis are completed *(Note: long-acting anti-retrovirals (e.g. Cabenuva, Sunlenca, Trogarzo, Edurant) may require a longer duration of discontinuation for elimination of medication)*;

AND

L. ONE of the following:

i. If member is biologically female of childbearing age, member meets ALL of the following:

i. Member has a negative serum pregnancy test before mobilization cycle and re-confirmed prior to myeloablative conditioning and right before administration of Casgevy;

AND

ii. Member will use an effective method of contraception from the start of mobilization through at least 6 months after Casgevy administration;

OR

ii. If member is biologically male, member will use an effective method of contraception from the start of mobilization through at least 6 months after Casgevy administration;

AND

M. Member has not received Casgevy or any other gene therapy previously;

AND

N. Member is not currently enrolled in a TDT clinical trial or is ineligible for clinical trial enrollment

Initial Duration of Approval: *One time infusion per lifetime*

RENEWAL REQUEST:
Casgevy will not be renewed for additional requests as this is a one-time therapy.

Renewal Duration of Approval: *Not Applicable*

V. LIMITATIONS/ EXCLUSIONS:

Casgevy be considered experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy.

Casgevy is only available at Qualified Treatment Centers.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J3392	Injection, exagamglogene autotemcel, per treatment

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
D56.1	Beta Thalassemia
D56.3	Thalassemia minor
D56.5	Hemoglobin E-beta thalassemia
D57.00	Hb-Ss Disease With Crisis, Unspecified
D57.01	Hb-Ss Disease With Acute Chest Syndrome

D57.02	Hb-Ss Disease With Splenic Sequestration
D57.03	Hb-Ss Disease With Cerebral Vascular Involvement
D57.04	Hb-Ss Disease With Dactylitis
D57.09	Hb-Ss Disease With Crisis With Other Specified Complication
D57.1	Sickle-Cell Disease Without Crisis
D57.20	Sickle-Cell/Hb-C Disease Without Crisis
D57.211	Sickle-Cell/Hb-C Disease With Acute Chest Syndrome
D57.212	Sickle-Cell/Hb-C Disease With Splenic Sequestration
D57.213	Sickle-Cell/Hb-C Disease With Cerebral Vascular Involvement
D57.214	Sickle-Cell/Hb-C Disease With Dactylitis
D57.218	Sickle-Cell/Hb-C Disease With Crisis With Other Specified Complication
D57.219	Sickle-Cell/Hb-C Disease With Crisis, Unspecified
D57.40	Sickle-Cell Thalassemia Without Crisis
D57.411	Sickle-Cell Thalassemia, Unspecified, With Acute Chest Syndrome
D57.412	Sickle-Cell Thalassemia, Unspecified, With Splenic Sequestration
D57.413	Sickle-Cell Thalassemia, Unspecified, With Cerebral Vascular Involvement
D57.414	Sickle-Cell Thalassemia, Unspecified, With Dactylitis
D57.418	Sickle-Cell Thalassemia, Unspecified, With Crisis With Other Specified Complication
D57.419	Sickle-Cell Thalassemia, Unspecified, With Crisis
D57.42	Sickle-Cell Thalassemia Beta Zero Without Crisis
D57.431	Sickle-Cell Thalassemia Beta Zero With Acute Chest Syndrome
D57.432	Sickle-Cell Thalassemia Beta Zero With Splenic Sequestration
D57.433	Sickle-Cell Thalassemia Beta Zero With Cerebral Vascular Involvement
D57.434	Sickle-Cell Thalassemia Beta Zero With Dactylitis
D57.438	Sickle-Cell Thalassemia Beta Zero With Crisis With Other Specified Complication
D57.439	Sickle-Cell Thalassemia Beta Zero With Crisis, Unspecified
D57.44	Sickle-Cell Thalassemia Beta Plus Without Crisis
D57.451	Sickle-Cell Thalassemia Beta Plus With Acute Chest Syndrome
D57.452	Sickle-Cell Thalassemia Beta Plus With Splenic Sequestration
D57.453	Sickle-Cell Thalassemia Beta Plus With Cerebral Vascular Involvement
D57.454	Sickle-Cell Thalassemia Beta Plus With Dactylitis
D57.458	Sickle-Cell Thalassemia Beta Plus With Crisis With Other Specified Complication
D57.459	Sickle-Cell Thalassemia Beta Plus With Crisis, Unspecified
D57.80	Other Sickle-Cell Disorders Without Crisis
D57.811	Other Sickle-Cell Disorders With Acute Chest Syndrome
D57.812	Other Sickle-Cell Disorders With Splenic Sequestration
D57.813	Other Sickle-Cell Disorders With Cerebral Vascular Involvement

D57.814	Other Sickle-Cell Disorders With Dactylitis
D57.818	Other Sickle-Cell Disorders With Crisis With Other Specified Complication
D57.819	Other Sickle-Cell Disorders With Crisis, Unspecified

VIII. REFERENCES:

1. U.S. Food and Drug Administration. Casgevy (exagamglogene autotemcel) prescribing information. Silver Spring, MD: US Food and Drug Administration; 2023. Accessed February 10, 2026. https://www.fda.gov/media/174615/download
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4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Beta Thalassemia. Version 2025. Plymouth Meeting, PA: NCCN; 2025. Accessed February 10, 2026.
5. 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(3):252-260. doi:10.1056/NEJMoa2031054
6. Vertex Pharmaceuticals Incorporated. Casgevy (exagamglogene autotemcel) clinical trial data: CLIMB-111 and CLIMB-121. Boston, MA: Vertex Pharmaceuticals Incorporated; 2023.
7. U.S. Food and Drug Administration. FDA approves first CRISPR-based gene editing therapy for sickle cell disease and beta thalassemia. FDA News Release. December 8, 2023. Accessed February 10, 2026. https://www.fda.gov/news-events

REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	JL	2/17/2026

Approved:	Date:	Approved:	Date:
David Ackman — Digitally signed by David Ackman Date: 2026.04.16 07:22:19 -04'00'		Sanjiv Shah MD — Digitally signed by Sanjiv Shah MD Date: 2026.04.17 10:13:46 -04'00'	
David Ackman, MD **VP of Medical Director**		**Sanjiv Shah, MD** **Chief Medical Officer**	

Title: Casgevy	**Division: Medical Management** **Department: Pharmacy**
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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication. MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.