Mass General Brigham
Health Plan

Casgevy
(exagamglogene autotemcel)

Policy Number: 075

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			

Casgevy (exagamglogene autotemcel) is an autologous hematopoietic stem cell-based gene therapy for sickle-cell disease (SCD) and for transfusion-dependent beta thalassemia (TBT). In this therapy, autologous CD34+ hematopoietic stem cells are edited with CRISPR/Cas9 technology at the erythroid specific enhancer region of *BCL11A* to reduce BCL11A expression in erythroid lineage cells, leading to increased expression of fetal hemoglobin (HbF).

FDA-approved indications
For the treatment of patients aged 12 and older with SCD with recurrent vaso-occlusive crises/events (VOC/VOE) or with TBT.

Coverage guidelines
Mass General Brigham Health Plan covers Casgevy when all of the following have been met:

1. Member is ≥12 years of age; and
2. Genetic test confirms SCD; and
3. At least 4 VOC/VOE in the past 24 months, including but not limited to:
    a. Acute pain event requiring a visit to a medical facility for pain medication(s) or red blood cell (RBC) transfusions;
    b. Acute chest syndrome;
    c. Acute splenic and/or hepatic sequestration;
    d. Priapism lasting longer than 2 hours and requiring a visit to a medical facility; and
4. Lab evaluation without evidence of advanced liver disease; and
5. No active/uncontrolled infections, including HIV, HBV and HCV; and
6. One of the following:
    a. Inadequate response to treatment with hydroxyurea for at least 3 months, with good adherence to therapy based on pharmacy claims or provider documentation, or
    b. Adverse reaction or contraindication to the use of hydroxyurea, or
    c. Chronic transfusion therapy without hydroxyurea for primary or secondary stroke prevention; and
7. Treatment will be administered in a qualified treatment facility as per product website.

Mass General Brigham Health Plan considers Casgevy to be experimental/investigational when used for TBT due to lack of published evidence of safety and efficacy for that condition.

Mass General Brigham Health Plan considers Casgevy to be experimental/investigational for all other indications.

Exclusions

1. History of HSCT
2. History of gene therapy for SCD

Medicaid variation

Mass General Brigham Health Plan uses the MassHealth Drug List for coverage determinations for members of the MGB ACO. Criteria for Casgevy are found in Table 45: Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents.

Medicare variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had no NCD or LCD for Casgevy (exagamglogene autotemcel).**

Codes

The following codes are included for informational purposes only; inclusion of a code does not constitute or imply coverage.

The list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
J3590	Unclassified biologics

Effective

September 2024: Ad hoc review. Updated medical necessity criteria.
April 2024: Effective date.

References

Casgevy (exagamglogene autotemcel), suspension for intravenous infusion [prescribing information]. Boston, MA: Vertex, 2023.

Frangoul H, Altshuler D, Cappellini MD, et al. CRISPR-Cas9 gene editing for sickle cell disease and β-thalassemia. *NEJM* 2021;384:252-60.

Sharma A, Boelens JJ, Cancio M, et al. CRISPR-Cas9 editing of the *HGB1* and *HGB2* promoters to treat sickle cell disease. *NEJM* 2023;389:820-32.