

Lyfgenia (lovotibeglogene autotemcel)

Policy Number: 078

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

Lyfgenia (lovotibeglogene autotemcel) is an autologous hematopoietic stem cell-based gene therapy for sickle-cell disease (SCD). In this therapy, autologous CD34+ hematopoietic stem cells are collected from the patient and then transfected with lovotibeglogene autotemcel. Once the cells are ready, the patient undergoes a conditioning regimen to replace their hematopoietic stem cells with the gene therapy stem cells. The gene therapy stem cells settle in the patient's bone marrow where they grow and produce new blood cells containing the normal hemoglobin gene.

FDA-approved indications

For the treatment of patients aged 12 and older with SCD and a history of vaso-occlusive crises/episodes (VOC/VOE).

Coverage guidelines

Mass General Brigham Health Plan covers Lyfgenia 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, or 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.

Mass General Brigham Health Plan considers Lyfgenia to be experimental/investigation for all other indications.

Exclusions

1. History of allogenic HSCT

2. History of any gene therapy treatment
3. One or more α -globin gene deletions

Medicaid variation

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. When there is no guidance from MassHealth 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, MassHealth had no guidance for Lyfgenia (lovotibeglogene autotemcel).** Criteria for Lyfgenia 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.

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
J3394	Injection, lovotibeglogene autotemcel

Effective

August 2024: Code update, retroactive to 7/1/2024
 July 2024: Effective date.

References

Kanter J, Walters MC, Krishnamurti L, et al. Biologic and clinical efficacy of LentiGlobin for sickle cell disease. *NEJM* 2022;386:617-28.

Lyfgenia (lovotibeglogene autotemcel), suspension for intravenous infusion [prescribing information]. Somerville, MA: Bluebird Bio, 2023.

