Effective Date: 02/24/2025

Nevada Health Solutions LLC

NHS MEDICAL POLICY

Medication 2025-001
Gene Therapy for treatment of Sickle Cell Disease
(Exagamglogene autoemcel [Casgevy]
Lovotibeglogene autotemcel [Lyfgenia])

A. May be considered medically necessary as a one-time infusion when ALL the following are:

1	Age 12 or older with a diagnosis of Sickle Cell Disease with one of the following genotypes confirmed by molecular or genetic testing • Bs/Bs • Bs/Bo • Bs/B+
2	Documentation of a minimum of 4 vascular occlusive events (VOE) within the prior 24 months. A VOE is defined as at least one of the following: • An episode of acute pain with o medically determined cause other than vaso-occlusion, lasting more than two hours • Acute chest syndrome • Acute hepatic sequestration • Acute splenic sequestration • VOE requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hour and receiving IV medications at each visit • Priapism requiring any level of medical
3	Patient does not have more than two a-globin gene deletions
4	Documentation of confirmative screening showing the patient does not have any of the following infectious diseases: • HIV-1 • HIV-2 • HBV • HCV
5	Patient is able to provide an adequate number of cells to meet minimum recommended dose of 3 X 10^6 CD34+ cells/kg

6	Treatment plan includes documentation of intent to transfuse patient to a target of 8-10 g/dl, not to exceed 12 g/dl, and HbS of <30% to reduce SCD-related complications
7	Documentation that the patient is a candidate for an allogenetic HSCT, but ineligible due to absence of an appropriate donor
8	Documentation of compliance with hydroxyurea or another prescribed treatment regimen.
9	Patient has not previously received gene therapy for the requested diagnosis.
10	Patient has not received a prior hematopoietic stem cell transplant (HSCT)
11	Patient meets on of the following: • Has experienced, at any time in the past, an inadequate response or tolerance to a trial of hydroxyurea or • Has a contraindication to hydrourea
12	Patient will receive both of the following: • Full myeloablative conditioning with busulfan prior to treatment • Anti-seizure prophylaxis with agents other than phenytoin prior to initiating busulfan conditioning
13	Prescriber attests that patient will discontinue disease modifying therapies for sickle cell disease (e.g., hydroxyurea, crizanlizumab, voxelotor) 8 weeks before planned start of mobilization and conditioning.
14	Prescribed by a provider at a SCD treatment center with expertise in gene therapy
15	Prescribed by one of the following: • Hematologist/oncologist • Specialist with expertise in the diagnosis and management of sickle cell disease

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

SOURCES

Lovo-cel gene therapy for sickle cell disease: Treatment process evolution and outcomes in the initial groups of HGB-26 study. Kanter,Julie; Thompson, Alex; Pierciey, Francis Jr.; Hsieh, Matthew; Uchida, Naoy et al Am J Hematol 2023 Jan;98 (1) 11-22. Doi 10.1002/ajh.26741. Epub 22 Oct 10

Lyfgenia Clinical Trial Data hhttps://www.lyfgeniahcp.com.>clinical>study

Optum Rx Prior Authorization Guideline Effective Date: 2/16/2024 P&T approval Date: 2/15/2024

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description