Department of Medicaid

Clinical Coverage Policy

Sickle Cell Disease Cell and Gene Therapy (CGT) Access Policy

Policy Title: Sickle Cell Disease CGT Access Policy	Version No.: 1
Effective Date: January 1, 2026	Last Reviewed Date: 12/18/2025

Background

- The purpose of this access policy is to provide guidelines for the coverage of Casgevy (exagamglogene autotemcel) and Lyfgenia (lovotibeglogene autotemcel) through the Centers for Medicare and Medicaid Services Cell and Gene Therapy Access Model. The products in this access policy will be considered for coverage when the below criteria are met.
- Coverage is provided through the Ohio Medicaid Fee-For-Service medical benefit, regardless of managed care enrollment status (excluding dually eligible beneficiaries enrolled in the MyCare Ohio program).
- Providers are responsible for determining which CGT sickle cell disease medication is most appropriate for the member they are treating, based upon clinical criteria and FDA label indications as well as other individual circumstances.
- Providers must obtain prior authorization **through the Ohio Department of Medicaid** before initiating treatment with any products listed in this policy. Prior authorizations will not be issued with a retroactive approval date.

Criteria

All Products (Must meet ALL of the below; for applicable items, clinical documentation/chart notes must be submitted with the request)

- Beneficiary is currently enrolled in Ohio Medicaid Fee-For-Service or Managed Medicaid
- Beneficiary has a diagnosis of Sickle Cell Disease (SCD) confirmed by genetic testing
- Beneficiary is greater than or equal to twelve (12) years of age at the expected time of gene therapy administration
- Beneficiary is clinically stable and fit for transplantation
- Medication is prescribed by or in consultation with a board-certified hematologist with Sickle Cell Disease expertise
- Administration facility is listed as an Authorized/Qualified Treatment Center according to the product manufacturer
- Billing Provider is a member of the CMS-designated patient registry for the CGT Model (Center for International Blood & Marrow Transplant Research) and agrees to participate in the CMS-specified study

Product-Specific Criteria (Must meet ALL of the below for prescribed product)

Casgevy (exagamglogene autotemcel)

- Beneficiary has prior use and failure of, or intolerance to, hydroxyurea (per health care professional judgement)
- Beneficiary has experienced recurrent vaso-occlusive crises (VOCs) (defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation)

Lyfgenia (lovotibeglogene autotemcel)

- Beneficiary has prior use and failure of, or intolerance to, hydroxyurea (per health care professional judgement)
- Eligible Beneficiary's Treatment Center has a Sickle Cell Center
- Beneficiary meets either a or b (based on provider attestation):
    a. Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); or
    b. Experienced four (4) or more VOEs in previous twenty-four months, based on provider attestation

Length of Authorization: 12 months.

Approvals are for one (1) treatment course only.