



Puerto Rico Health Insurance Administration (ASES) Clinical Operations Office			
Policy: Coverage of the Gene Therapy LYFGENIA® (lovotibeglogene autotemcel) for Sickle Cell Disease (SCD)			
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Approved by:			
Carlos Santiago Rosario, Esq., MHSA Executive Director		Signature: 	Date: 9 / 7 / 2026
Diraida Maldonado, MHSA Clinical Operations Director		Signature: 	Date: 9 / 7 / 2026 July 9, 2026
Reference: Section 1927 of the Social Security Act, 42 C.F.R. §447 Subpart I, and applicable CMS and FDA guidance related to cellular and gene therapies			

I. PURPOSE

The purpose of this policy is to establish the clinical criteria, operational requirements, and responsibilities applicable to the access and coverage of Cell and Gene Therapies (CGT) for the treatment of Sickle Cell Disease (SCD) under the Government Health Plan (Plan Vital).

This policy incorporates the clinical and operational criteria applicable to the gene therapy **LYFGENIA® (lovotibeglogene autotemcel)** in accordance with its FDA-approved indications and regulatory guidance.

II. SCOPE

 This policy applies to the PBM/RA, Managed Care Organizations (MCOs), the Puerto Rico Medicaid Program (PRMP), and any entity or subcontractor involved in administering the pharmacy benefit under Plan Vital.

III. LEGAL BASIS

This policy is established in compliance with Section 1927 of the Social Security Act, 42 C.F.R. § 447 Subpart I, and applicable CMS and FDA guidance related to cellular and gene therapies.

IV. DEFINITIONS

- **CGT (Cell and Gene Therapy):** Advanced therapies based on cells or genetic modification.
- **Confirmatory Genetic Testing:** Clinical requirement to confirm eligibility for gene therapy.
- **Sickle Cell Disease (SCD):** Hereditary hematologic condition associated with vaso-occlusive crises.
- **Vaso-Occlusive Events (VOEs):** Pain crises or complications related to obstructed blood flow.
- **ASES Special Coverage:** A component of Covered Services provided by the MCO. Services under this coverage are more extensive than the Basic Coverage services, and for which Enrollees are eligible only by "registering." Registration for Special Coverage is based on intensive medical needs occasioned by serious illness. Conditions under this coverage are established by ASES.

V. POLICY

ASES requires that the therapy LYFGENIA® obtain prior authorization and meet all clinical, administrative, and programmatic criteria described herein.

VI. COVERAGE CRITERIA

LYFGENIA® (lovotibeglogene autotemcel) must meet **ALL** the following:

1. Confirmatory genetic testing; AND
2. Documented failure or intolerance to hydroxyurea (including clinical judgment indicating inability to take hydroxyurea) at any time in the past; AND
3. Age $\geq$ twelve (12) years at the anticipated time of gene therapy administration; AND
4. Clinically stable and fit for transplantation; AND
5. Prescribed by, or in consultation with, a board-certified hematologist with expertise in SCD; AND
6. Treatment center must be a certified Sickle Cell Center or Qualified Treatment Center; AND
7. Beneficiary has not received a prior hematopoietic stem cell transplant; AND
8. Beneficiary has not received LYFGENIA® or any other gene therapy for this condition previously; AND
9. Meets one of the following (per provider attestation):
 - a. Currently receiving chronic transfusion therapy for recurrent VOEs; OR
 - b. Has experienced four (4) or more VOEs in the prior twenty-four (24) months as determined by the treating clinician.

VII. ELEGIBLE BENEFICIARY

A beneficiary is eligible when **all** the following requirements are met:

1. Documented medical diagnosis of Sickle Cell Disease (SCD); AND
2. LYFGENIA® has been prescribed in accordance with the FDA-approved label; AND
3. Beneficiary has Medicaid or Title XXI-funded Medicaid Expansion (CHIP) as the primary payer for the therapy; AND/OR
4. Beneficiary is enrolled in the Medicaid Program of a Model Participating State on the anticipated infusion date; AND
5. Beneficiary is enrolled in a Plan Vital managed care organization (MCO) on the infusion date.

VIII. CLINICAL CLARIFICATION

These clinical criteria pertain solely to eligibility for the use and administration of the medication and do not necessarily determine eligibility for registry in Special Coverage for Sickle Cell Disease.

IX. PROCEDURE AND RESPONSIBILITIES

The MCOs will start the process through a preauthorization (PA) request from a provider and adjudicate requests according to applicable criteria; MCOs will verify clinical and documentation requirements; ASES will evaluate out-of-criteria cases.

The request for the product to a specialty pharmacy will be done by the MCOs after preauthorizing the case to the pharmacies contracted by ASES to provide the medication to the institution with whom the MCOS has agreement to treat the patient with Sickle cell.

Prior authorization approval duration: 12 months

X. COMPLIANCE

Noncompliance may result in corrective actions, financial accountability, or regulatory review.

XI. EXCEPTIONS

ASES reserves the right to grant exceptions when justified and approved by the Executive Director or authorized representative.

XII. REVIEWS AND APPROVALS

Date	Section Review	Modification and Reason
July 2, 2026	Policy Creation	