ADMINISTRACIÓN DE SEGUROS DE SALUD

ASES

GOBIERNO DE PUERTO RICO

Puerto Rico Health Insurance Administration (ASES) Clinical Operations Office			
Policy: Coverage of the Gene Therapy CASGEVY® (exagamglogene autotemcel) for Sickle Cell Disease (SCD)			
Policy Number: **ASES-OC-2026/P002**	**Effective Date:** 7/31/2026	**Revision Date:**	**Pages:** **03**
Approved by: Carlos Santiago Rosario, Esq., MHSA **Signature:** **Date:** 9 / 7 / 2026 Executive Director Diraida Maldonado, MHSA **Signature:** **Date:** 9 / 7 / 2026 Clinical Operations Director			
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 **CASGEVY (exagamglogene 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 Crisis (VOCs)**: Pain crises or complications related to obstructed blood flow.

V. POLICY

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

VI. COVERAGE CRITERIA

CASGEVY® (exagamglogene 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. The product should be prescribed consistently with the FDA approved indications or label; 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; AND
7. Beneficiary has not received a prior hematopoietic stem cell transplant; AND
8. Beneficiary has not received CASGEVY® 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 VOCs; OR
   b. Has experienced four (4) or more VOCs 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. CASGEVY® 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 with an effective Supplemental Rebate Agreement (SRA) on the anticipated infusion date; AND
5. Beneficiary is enrolled in a Plan Vital managed care organization (MCO) on the infusion date and is included in the population covered under the SRA.

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.

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	