ADMINISTRACIÓN DE SEGUROS DE SALUD

ASES

GOBIERNO DE PUERTO RICO

Government Health Plan (GHP) – Plan Vital CLINICAL OPERATIONS AREA			
Non-Risk Arrangement Medication Management and Payment Policy			
Policy Number: **ASES-OC-2026/P005**	**Effective Date:** 9 / 1 /2026	**Revision Date:** / /2026	**Pages:** **13**
Approved by: Carlos Santiago Rosario, Esq., MHSA **Signature:** **Date:** 9 / 1 / 2026 Executive Director Diraida Maldonado, MHSA **Signature:** **Date:** 9 / 1 / 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 Non-Risk Arrangements Management and Payment Policy for medications covered under Plan Vital is to establish requirements and responsibilities and provide clear guidance to all parties involved in the administration, automated data entry, transferring, validation, and certification processes necessary for the execution of drug claims payments. This policy is established to ensure compliance with regulatory and operational standards in a formal and consistent manner among all the stakeholders in this policy.

This policy ensures that the Puerto Rico Health Insurance Administration (ASES) complies with all applicable state and federal regulations, while promoting accuracy, transparency, and accountability in the payment process.

II. SCOPE

This policy applies to all personnel and entities involved in the administration, processing, and payment of claims related to non-risk arrangements, including, but not limited to:

1. PBM (Pharmacy Benefit Manager)
2. Managed Care Organizations (MCOs)
3. Medicaid Program / MMIS,
4. ASES or
5. Any person, agency, or entity that participates directly or indirectly in the prior authorization and payment processes for the products or therapies subject to this policy.

III. LEGAL BASIS

In compliance with:

1. 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.
2. CMS Medicaid Managed Care regulations (42 CFR Part 438)
3. Medicaid Drug Rebate Program (42 U.S.C. §1396r-8) – Payment for Covered Outpatient Drug
4. Section 1115A of the Social Security Act – Prescription Drug Models
5. Puerto Rico Pharmacy Act (*Ley 247-2004*)
6. Patient Rights Act (*Ley 194-2011*)
7. Contract among ASES and the MCOs for the Plan Vital Program.

IV. DEFINITIONS

- **Claim:** A request submitted by a provider or pharmacy for payment of services rendered or medications dispensed to a beneficiary.
- **CGT (Cell and Gene Therapy)**: Advanced therapies based on cells or genetic modification.
- **DAW (Dispense as Written)**: An indicator used to specify that a medication must be dispensed exactly as prescribed, without generic substitution.
- **Duchesne Muscular Dystrophy (DMD)**: A severe, progressive genetic disorder that causes muscle weakness and wasting. It is caused by mutations in the gene responsible for making dystrophin, a protein essential for keeping muscle cells intact.
- **Hepatitis C (HCV):** A viral infection that causes liver inflammation. It spreads primarily through contact with infected blood. Left untreated, it can lead to severe, lifelong liver damage, including cirrhosis and liver cancer.
- **HIV (Human Immunodeficiency Virus):** A virus that targets the body's immune system, specifically CD4 T cells, which help fight infections and diseases.
- **Infusion Therapy:** A kind of therapy that involves delivering medications, nutrients, or fluids through a needle or catheter, most commonly intravenously (IV), but also subcutaneously, intramuscularly, or epidurally, depending on the treatment goals and medication type.
- **NDC (National Drug Code):** A unique code that identifies specific medications, including the manufacturer, product, and package size/form.
- **Non-Risk Arrangement (NRA):** An agreement where the managed care contractor is not financially liable for cost overruns or utilization changes. The contractor is typically reimbursed for incurred costs up to specified limits, rather than taking on full financial risk for patient care.
- **NPI (National Provider Identifier)**: A unique identifier assigned to healthcare providers in the United States.

- **Sickle Cell Disease (SCD)**: A hereditary hematologic condition associated with vaso-occlusive crises/events. Curative options like stem cell transplants and gene therapies offer long-term solutions for eligible patients.

- **Single Case Agreement (SCA):** A temporary contract between an insurance company and an out-of-network healthcare provider.

- **Spinal Muscular Atrophy (SMA)**: A rare genetic neuromuscular disease that causes the progressive loss of motor neurons in the spinal cord.

- **Synthroid (levothyroxine sodium):** A medicine that replaces the thyroid hormone when deficient.

- **Vaso-occlusive crisis (VOC) / Vaso-occlusive events (VOE)**: Also known as a pain crisis, the most common complication of Sickle Cell Disease (SCD).

V. RESPONSIBILITIES

ASES

1. Supervise the implementation and ongoing compliance with this policy.
2. Monitor payment timeliness metrics and ensure adherence to applicable federal and local requirements.
3. Coordinate continuous process improvements with all parties involved.
4. Execute contractual, corrective, or administrative measures when appropriate, based on performance, compliance findings, or audit outcomes.

MCOs

1. Maintain accurate and up-to-date eligibility information, including sharing this information with the PBM.
2. Adjust internal systems, workflows, and operational processes to comply with this policy **without exception**.
3. Guarantee payment to providers and PBMs within the established period according to contract requirements and CMS principles on timely payment.
4. Maintain complete and auditable compliance documentation for PA, billing, adjudication, reconciliation advance - payment process applicable to non-risk medication processes.
5. Coordinate and complete reconciliation processes with PBM and PRMMIS as required by ASES operational and financial oversight protocols.
6. Enhanced Requirements for the Administration of Designated Gene Therapies (SCD).

To ensure proper coordination, continuity of care, and compliance with federal and state oversight expectations, MCOs must adhere to the following requirements when administering designated gene therapy products (SCD):

- MCOs must condition payment for the administration of designated gene therapy products to eligible beneficiaries on the provider's enrollment in the CMS - designated patient registry (the Center for

International Blood & Marrow Transplant Research, CIBMTR) and participation in the required CMS study.

- MCOs must ensure continuity of care for beneficiaries receiving gene therapy for Sickle Cell Disease (SCD), including honoring prior authorizations when beneficiaries transition between fee-for-service (FFS) and managed care or switch between MCOs.
- MCOs must ensure that beneficiaries continue to have access to their established SCD gene therapy providers for at least one (1) year following the gene therapy infusion.
- MCOs must publish coverage criteria or utilization management policies for designated gene therapy products, establish primary and secondary provider points of contact, comply with required response timeframes, and either maintain an in - network treatment center qualified to administer each designated gene therapy or develop a template single - case agreement for SCD gene therapy services.
- Refer to Attachment A-Sickle Cell Payment Process

PBM

1. Submit invoices only after full completion of required pre - validations, including PA verification, NDC/HCPCS accuracy, cost validation, provider enrollment, and eligibility checks.
2. Provide technical and operational support during reconciliation processes, including error resolution, claim traceability, and data integrity verifications.
3. Management of rebate billing for all drugs under this policy.

PRMMIS

1. Process, match, and adjudicate claims according to all current federal, ASES, and MMIS operational rules.
2. Maintain integrity, security, and accuracy of the official Medicaid registration, eligibility, and claims system.
3. Implement system improvements that reduce variability in adjudication and payment release times, increase operational efficiency and reduce federal compliance risk.

VI. OPERATIONAL REQUIREMENTS

See Attachment A (Sickle Cell Payment Process) and Attachment B (Non at Risk Payment Process (Drugs through Medical Benefit)

1. Most drugs covered under non-risk arrangements are subject to prior authorization (PA) requirements before administration or dispensing. The PA must comply with CMS medical necessity standards and ASES clinical protocols.
2. Prior authorization for each drug must meet all clinical, administrative, and programmatic criteria as described. Requirements must follow **42 CFR §438.210**, which mandates objective, consistent, and non-discriminatory clinical criteria.
3. MCOs must follow and verify compliance with all applicable clinical protocols established by ASES when authorizing these drugs.

4. Payments for drugs and therapies under non-risk arrangements will be subject to requirements and validations within MMIS.
5. Claims must be submitted within 90 days from the date of service to be considered for payment in accordance with Law 138 of 2020.
6. Any claim that does not meet the established criteria will not be eligible for payment, and responsibility will fall on the corresponding MCO. The MCO is responsible for any errors related to authorization, billing, or documentation. ASES will conduct federal compliance recoveries when applicable.
7. Any alternative process or operational variation not contemplated in this policy must be submitted for evaluation, validation, and formal approval or denial. CMS requires that any deviation in standard processes be approved by the Medicaid Program.
8. Any errors, discrepancies, damages, or malfunctions identified in related processes or systems must be reported **immediately** following ASES incident reporting protocols.
9. ASES is responsible for supervising and ensuring full compliance with this policy.
10. PBM, MCO, and Medicaid operational units must strictly comply with the established guidelines to avoid delays, errors, or payment defaults.
11. All parties involved must guarantee the accuracy, completeness, and timeliness of all information submitted. This requirement is aligned with **42 CFR §438.210**, **42 CFR §455. Program Integrity**, and federal requirements for PA administration.
    Errors in these areas may result in:
    a. financial recoveries through audits,
    b. denial of federal matching funds,
    c. findings during CMS compliance reviews.
12. Clinical protocols for medications are published on the ASES webpage as reference for all participating entities.

VII. PAYMENT REQUIREMENTS AND PRMMIS VALIDATION CRITERIA FOR NON-RISK ARRANGEMENT MEDICATIONS

- Hospital Setting Considerations (See attachment A & B)

Beginning January 1, 2026, ASES implemented the APR-DRG inpatient payment model for inpatient hospital services. Drugs and therapies under this **Non at Risk Arrangements Medication Management and Payment Policy** are excluded from APR-DRG calculations and are under ASES risk.

This means for non-risk drugs administered on an inpatient basis:

1. Ancillary services under a hospital that are supportive medical services when diagnosed and treat a patient receiving these therapies as well as any other medication (out of those non at risk) are at risk of the MCOs.
2. Hospitals must bill the administration of these therapies as well as the ancillary services or any other treatment through the APR-DRG Model.
3. MCOs must reimburse hospitals for administration and ancillary services and other drugs under APR-DRG Model.
4. The ingredient cost of non - risk drugs follow the process established in this policy, involving MCOs (for those drugs process through medical benefit) and PRMMIS validations.
5. PRMMIS requires evidence of administration for payment reconciliation and data integrity.

- MCOs and Specialty Pharmacy Consideration

The following therapies:

Must be preauthorized (PA) and will be processed through the MCOs (Medical Benefit-Inpatient setting); **These drugs should be billed by the specialty pharmacy to the MCOs.**

1. Duchesne Muscular Dystrophy (DMD): (see attachment B)
   - Elevidys (requires PA)

2. Spinal Muscular Atrophy (SMA): (see attachment B)
   - Zolgensma (requires PA)
   - Spinraza (requires PA)

3. Sickle Cell Disease (SCD): (see attachment A)
   - Casgevy® (requires PA)
   - Lyfgenia® (requires PA)

The following drugs must be Preauthorized (PA) by the MCO but are process through the PBM (Pharmacy Benefit-Outpatient):

- Evrisdy (oral via (PO) - for SMA / requires PA)
- Hepatitis C treatments (requires PA first dispense)
- Synthroid
- HIV profilaxis and treatments (some require PA)

Prior Authorization Requirements (when applicable)

A. Plan Vital Managed Care Organizations (MCOs) are responsible for conducting administrative and clinical prior authorization (PA) evaluations and approving the therapy for those drugs to which it applies.
B. MCOs must retain complete PA documentation, including clinical notes and approvals, for audit, CMS compliance, and ASES oversight.PA evaluations must comply with 42 CFR §438.210 ensuring objective, non - discriminatory medical necessity criteria.
C. Within the non-risk arrangements there are various therapies and medications with specific billing and processing rules.

Non at Risk Arrangements Medication Management and Payment Policy General Process

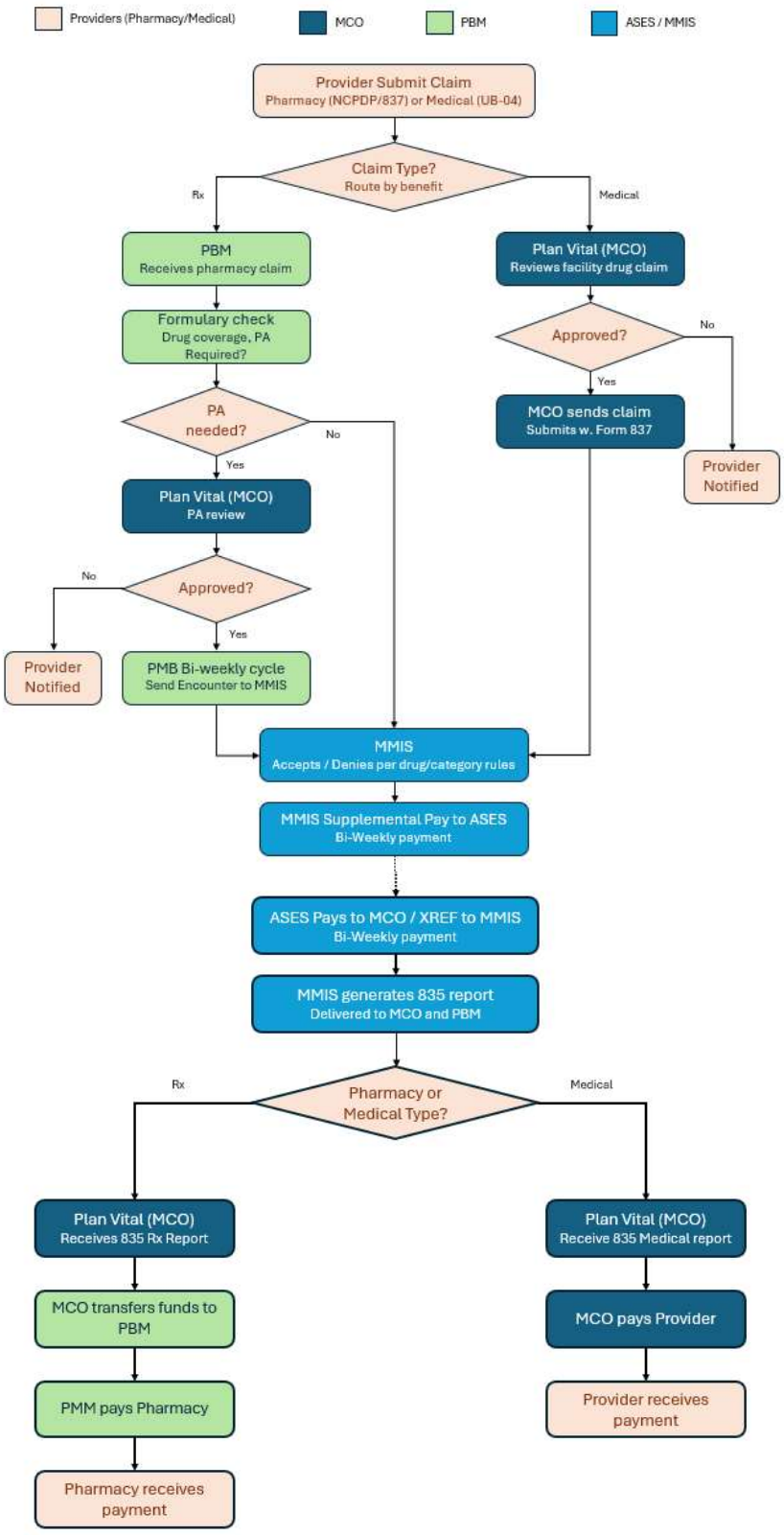
This process describes the validation, adjudication, payment of pharmacy and medical claims, involving providers, Plan Vital (MCO), PBM, PRMMIS and ASES.

1. **The provider submits a claim**
   - The claim type can be through **pharmacy benefit (Rx)** or **medical benefit/services**.
   - The provider uses the applicable forms (NCPDP/837 for pharmacy or UB-04 for medical services).

2. **If it is a pharmacy (Rx) claim:**
    - The claim is received by **PBM**.
    - PBM verifies the **formulary and drug coverage**, including whether **prior authorization (PA)** is required.
    - If PA is required, **Plan Vital (MCO)** performs the review.
        - If approved, PBM continues processing the claim.
        - If denied, the provider is notified.
    - If PA is not required, the claim proceeds directly to the next step.
    - PBM sends the encounters to **PRMMIS** through its bi-weekly cycle.
3. **If it is a medical claim:**
    - **Plan Vital (MCO)** receives and reviews the claim.
    - If approved, the MCO submits the claim to PR**MMIS** using the **837 form**.
    - If denied, the provider is notified.
4. **Processing by PRMMIS and ASES**
    - **PRMMIS** receives the claims and applies the applicable rules to accept or deny the drug or service category.
    - **PRMMIS** then processes the **supplemental payment to ASES** through a bi-weekly payment cycle.
    - **ASES pays the MCO and/or refer to PRMMIS**, also through bi-weekly payments.
    - **PRMMIS** generates 835 reports, which are delivered to the MCO and PBM.
5. **Payment distribution based on the type of service**
    - **Specialty Pharmacy:**
      The MCO receives the 835 reports → transfers the funds to **PBM** → PBM pays the pharmacy → **the pharmacy receives payment**.
    - **Medical services:**
      The MCO receives the medical 835 report → **the MCO pays the provider directly** (Specialty Pharmacy)→ **the provider receives payment**.

The main difference is that pharmacy claims go through PBM, while medical claims are handled directly by the MCO.

DRUG RELATED CLAIMS FLOWCHART



Drug Category Requirements and PRMMIS Validation Criteria

Below are the validation requirements that PRMMIS must follow for each drug category under non-risk arrangement.

1. **Spinal Muscular Atrophy (SMA)**

SMA entered non-risk arrangement on January 1, 2023. Two medications fall under the medical benefit (Spinraza, Zolgensma) and one under pharmacy (Evrysdi).

Zolgensma & Spinraza (Medical Benefit) – Validation Criteria

- NPI provider match
- Age restriction of 730 days /2 years.
- Member enrolled in MCO
- Diagnosis codes: G12.0, G12.1, G12.8, G12.9
- Applicable NDCs from the official list
- Provider Type/Specialty: 25/022, 25/057, 25/100, 25/041
- Revenue codes: 230–231, 260, 261, 262,263, and 269, 490, 499
- HCPCS: J3399 (Zolgensma) and J2326 (Spinraza)
- Administration date must be within 14 days of the dispensing date.

Evrysdi (Pharmacy Benefit) – Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member Plan: Vital
- Claim is paid
- Valid NDC for Supplemental Payment
- Member age > 60 days
- Pharmacy enrollment in Medicaid

2. **Duchenne Muscular Dystrophy (DMD)**

Elevidys – Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member plan: TXIX, CHIP, Commonwealth
- Claim status: Paid
- Diagnosis code: G71.01
- Valid NDC
- HCPCS: J1413
- Administration date must be within 14 days of the dispensing date

3. Sickle Cell Disease

Casgevy & Lyfgenia – Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member Plan: TXIX, CHIP, Commonwealth
- Claim Status: Paid
- Diagnosis code: D57.0–D57.8
- Drug name match
- HCPCS codes: J3392 (Casgevy), J3394 (Lyfgenia)
- Valid corresponding NDC
- Administration date must be within 14 days of the dispensing date

4. HIV- Advance Payment Process

As of July 1, 2024, they became part of the ASES non-risk arrangement under Normative Letter 24-0621, Normative letter 24-0830-3 and ASES-CN-2026-0005-OC. New HIV drugs may be added by ASES as needed.

For these HIV drugs, the following process for payment applies:

a. Receipt of Invoices
1) The PBM shall submit invoices according to the bi-weekly schedule to MCOs.
2) The MCOs will verify basic integrity without delays.

b. Issuance of Payments
1) The MCOs will process and release payment as soon as the invoice is received, or no later than the following Monday after receipt.
2) Minimal operational validation will be allowed.
3) The Supplemental 835 file shall not be required to process this payment.

c. Reconciliation with PRMMIS
1) PRMMIS will process encounters per current rules.
2) Identified adjustments will be handled by contractual rules, including reversals and offsets.

d. Handling Discrepancies
1) MCOs and PBM shall begin reconciliation within 15 days of identifying a discrepancy once supplemental 835 is received by both.
2) MCOs and PBMs must carry out formal reconciliation processes using Supplemental 835.
3) Claims not reflected in supplemental 835 within the specified period must be deducted from the MCOs' payments to the PBM in the next advance payment. Continuous monitoring and documentation of findings are required.

Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member Plan: TXIX, CHIP or Commonwealth
- Claim is paid

- PBM: MC-Rx (before 07/01/2024) or Abarca (after 07/01/2024)
- Medicaid-enrolled pharmacy
- NDC valid for HIV Supplemental Payment (Group 106)

5. Synthroid

Synthroid has been in non-risk arrangement since 2017.

- MCO bears the cost of the **generic** medication.
- ASES covers the difference between **generic cost and brand cost**.

Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member Plan: Vital
- Claim is paid
- DAW = 1, 2, or 8
- Valid Synthroid NDC
- Configurated payment formula in PRMMIS is Ingredient Cost Paid (Average Generic Unit Price * Quantity Dispensed)
  - Ingredient Cost Amount > 0 (position 2109)
  - Generic Unit Price > 0 (position (2250).
  - Quantity Dispense > 0 (position 1548).

6. Hepatitis C

Per **Normative Letter 24-0206**, the following drugs are part of non-risk arrangements:

Mavyret, Epclusa, Ribavirin and others approved through MCO following the exception processes (Vosevi and Harvoni).

Validation Criteria

- NPI provider match
- Member enrolled in MCO
- Member Plan: Vital
- Claim is paid
- Valid NDC for HCV Supplemental Payment

VIII. PRMMIS Requirements

- **PRMMIS as Official System of Record**

PRMMIS remains the official source for reconciliation, adjudication validation, and adjustments.

- **No Delays Allowed**

  No delay in PRMMIS or supplemental 835- file processes may justify delays in payment to facilities and/or pharmacies.

This policy prevails over any internal process that results in non-compliance with the prompt payment requirements of the Medicaid Program or the contract with the MCOs.

IX. MCO Requirements for Reimbursement Under Non-Risk Arrangements processed through the MCOs (Medical Benefit)

To receive reimbursement for the ingredient cost under non-risk arrangements, the MCO must:

1. Conduct prior authorization following its internal clinical and administrative criteria.
2. When the provider is not enrolled due to unique specialty circumstances, the MCO must certify applicability of "out-of-network / off-island" payment rules. But the provider still must enroll in Medicaid via PEP and the MCOs must require the provider to register in PEP.
3. Claims must include NDC and/or HCPCS codes and units dispensed.
4. Billed amount must represent **actual acquisition cost**, net of discounts, rebates, chargebacks, or adjustments.
5. Administration charges may be included in 837 or billed separately; the administration date must be within 14 days of the dispensing date.
6. Confirm referring/ordering provider type prior to dispensing.
7. Confirm all clinical criteria (diagnosis, age, prior therapy) before dispensing.
8. Validate evidence of administration as part of the reimbursement process.
9. Ensure billing providers submit claims in 837.
10. PRMMIS will identify non-risk drugs semi-monthly using 837 (MCO)
11. PRMMIS will confirm validated non-risk claims to ASES Finance for reimbursement.

Prompt payment ensures continuity of care and protects facility. Instructions are not intended to serve as a full billing manual. ASES may update requirements if new payment models (e.g., value-based contracts or Buy & Bill) are implemented, which may include agreements with manufacturers. ASES reserves the right to audit submissions and request drug invoices to validate actual acquisition cost.

Reconciliation with PRMMIS

- PRMMIS will match claims per business rules.
- Adjustments will follow contract requirements (reversals, refunds, offsets).
- MCO and Abarca must begin reconciliation within 15 days of discrepancy identification once supplemental 835 is received by both.
- ASES will intervene if deadlines or correction requirements are not met.

X. COMPLIANCE

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

XI. EXCEPTIONS

ASES may grant exceptions when justified and approved by the Executive Director or authorized representative.

XII. REVIEWS AND APPROVALS

Date	Section Review	Modification and Reason
8/14/2026	Policy Creation	

Attachment A – Sickle Cell Payment Process

The Puerto Rico Health Insurance Administration (ASES) has been accepted to participate in the **Cell and Gene Therapy (CGT) Access Model**. These CGT drugs are part of a CMS-special initiative under the Medicaid Drug Rebate Program (MDRP). As part of this model, the medications **Casgevy®** and **Lyfgenia®** will be incorporated into the **Plan Vital formulary**, effective **July 31, 2026**, and **are covered under ASES's risk**.

These instructions are not intended to serve as a full billing manual. To ensure a uniform billing and reimbursement process for these therapies, the following requirements apply:

1. **Prior Authorization Requirements**

   A. Plan Vital Managed Care Organizations (MCOs) are responsible for conducting administrative and clinical prior authorization (PA) evaluations and approving the therapy when appropriate.
   B. MCOs must retain complete PA documentation, including clinical notes and approvals, for audit, CMS compliance, and ASES oversight.
   C. PA evaluations must comply with 42 CFR §438.210 ensuring objective, non-discriminatory medical necessity criteria.

2. **Billing and Operational Process**

   Only **one billing provider** (specialty pharmacy) may bill for the CGT medication per treatment.

   A. Specialty Pharmacy Responsibilities

      i. Providers must correctly assign all billing codes corresponding to services rendered.
      ii. Hospitals must acquire the drug through a **Specialty Pharmacy**.
      iii. The Specialty Pharmacy will bill the **drug ingredient cost** to the MCO.
      iv. The MCO must pay the Specialty Pharmacy **as soon as the drug is delivered and administration is confirmed**, consistent with CMS prompt payment principles.
      v. The specialty pharmacy must ensure that the service date reflects the drug dispensing date.

   B. Hospital Administration Billing

      i. When a specialty pharmacy dispenses the drug, the hospital must submit a **separate administration claim within 14 days of the dispensing date.**

ii. MCO must validate the **evidence of administration**, as required under PRMMIS processing and CMS drug oversight rules.
iii. The claim for Casgevy or Lyfgenia must be submitted **separately from all other hospital services**, using an independent **UB-04** with the corresponding NDC and HCPCS code.

C. Billing Methodology

i. CGT drugs **must not** be included in the APR-DRG inpatient payment calculation or bundled into institutional reimbursement.
ii. Billed amount must reflect the **Actual Acquisition Cost (AAC)**, net of all rebates, chargebacks, discounts, and invoice adjustments.
iii. Administration services and related preparatory/post-procedures may be billed in the 837 format or separately; these services are **at MCO risk**.
iv. Administration date must be within 14 days of the dispensing date.

D. PRMMIS

i. On a semi-monthly basis, PRMMIS will identify CGT claims submitted via the 837 (MCO).
ii. PRMMIS will validate non-risk CGT drug claims and transmit the report to ASES Finance for reimbursement.

ASES does not prefer one CGT drug over the other. Therapy choice is a clinical decision of the treating physician. Prompt and rapid payment protects pharmacy and hospital cash flow and ensures continuity of care.

3. Billing Requirements

A. Each claim must clearly include:

- NPI provider match
- Member enrolled in MCO
- Member Plan: TXIX, CHIP, Commonwealth
- Claim Status: Paid
- Diagnosis code: D57.0–D57.8
- Drug name match
- HCPCS codes: J3392 (Casgevy), J3394 (Lyfgenia)
- Valid corresponding NDC
- Administration date must be within 14 days of the dispensing date.

4. Reimbursement Requirements

A. HCPCS codes J3392 and J3394 are separately reimbursable and excluded from APR-DRG payment methodologies.
B. Reimbursement for Casgevy and Lyfgenia will occur through a Single Case Agreement (SCA) or an agreement between the MCO, the specialty pharmacy and the hospital. Payment must be no less than the Actual Acquisition Cost (AAC).
C. Supporting documentation such as purchase invoices must be submitted to validate. Claims lacking documentation will be denied.

5. 340B Program Restriction

Hospitals and providers may not collect 340B Drug Pricing Program discounts for Model Drugs for beneficiaries covered under the CGT Access Model.

6. HCPCS Codes

A. J3392 – Injection, exagamglogene autotemcel
1 billable unit = 1 treatment
B. J3394 – Injection, lovotibeglogene autotemcel
1 billable unit = 1 treatment

7. CMS & ASES Compliance

This attachment is compliant with:

- 42 CFR §438.210 (Medical necessity and PA requirements)
- 42 CFR §447 (Pharmacy reimbursement and AAC rules)
- 42 CFR §455 (Program Integrity)
- CMS CGT Access Model operational guidelines
- APR-DRG inpatient payment exclusion rules for carve-out drugs
- ASES Circular Letters 24-0621 and 24-0206
- Medicaid Drug Rebate Program rules for CGT drugs

Attachment B
Non at Risk Payment Process (Drugs through Medical Benefit)

The Puerto Rico Health Insurance Administration (ASES) informs that it has been accepted to cover some Cell and Gene Therapy (CGT) thought Non-Risk Arrangement Model (only the drugs). As part of this model, the following drugs are covered under the Government Health Plan, Plan Vital as previously indicated with the Normative Letter 25-1203 from December 3rd, 2025 and the Normative Letter ASES-CN-2026-0004-OC from July 15,2026.

Cell and Gene Therapies (CGT) for the treatment of:

1. Duchesne Muscular Dystrophy (DMD):
   - Elevidys (requires PA)

2. Spinal Muscular Atrophy (SMA)
   -Zolgensma (requires PA)
   -Spinraza (requires PA)

3. Sickle Cell Therapies (See attachment A)

To ensure a uniform billing and reimbursement process for these therapies, the following requirements apply.

1. **Prior Authorization Requirements**

   A. Plan Vital Managed Care Organizations (MCOs) are responsible for conducting administrative and clinical prior authorization (PA) evaluations and approving the therapy when appropriate.
   B. MCOs must retain complete PA documentation, including clinical notes and approvals, for audit, CMS compliance, and ASES oversight.
   C. PA evaluations must comply with 42 CFR §438.210 ensuring objective, non-discriminatory medical necessity criteria.

2. **Billing and Operational Process**

   Only **one billing provider** (specialty pharmacy) may bill for the drugs medication for the treatment of DMD, SMA and SCD mention in this policy.

   A. Specialty Pharmacy Responsibilities

      i. Specialty Pharmacy must correctly assign all billing codes corresponding to services rendered.
      ii. Hospitals must acquire the drug through a **Specialty Pharmacy**.
      iii. The Specialty Pharmacy will bill the **drug ingredient cost** to the MCO.

iv. The MCO must pay the Specialty Pharmacy **as soon as the drug is delivered and administration is confirmed**, consistent with CMS prompt payment principles.
v. The specialty pharmacy must ensure that the service date reflects the drug dispensing date.
vi. The MCO must pay to the Pharmacy **as soon as the drug is delivered and administration is confirmed**, consistent with CMS prompt payment principles.

B. Hospital Administration Billing

i. When a specialty pharmacy dispenses the drug, the hospital must submit a **separate administration claim** within **14 days** of the dispensing date.
ii. MCO must validate the **evidence of administration**, as required under PRMMIS processing and CMS drug oversight rules.
iii. The claims for these drugs must be submitted **separately from all other hospital services**, using an independent **UB-04** with the corresponding NDC and HCPCS code.

C. Billing Methodology

i. These drugs **must not** be included in the APR-DRG inpatient payment calculation or bundled into institutional reimbursement.
ii. Billed amount must reflect no less the **Actual Acquisition Cost (AAC)**, net of all rebates, chargebacks, discounts, and invoice adjustments.
iii. Administration services related to preparatory or post-procedural steps, ancillary services, and medications or treatments may be billed using the UB-04 format or separately; these services are **at MCO risk**.
iv. Supporting documentation such as purchase invoices must be submitted to validate. Claims lacking documentation will be denied.
v. Administration date must be within 14 days of the dispensing date.

D. PRMMIS

i. On a semi-monthly basis, MMIS will identify CGT claims submitted via 837 (MCO).
ii. MMIS will validate non-risk CGT drug claims and transmit the report to ASES Finance for reimbursement.

3. **Therapy choice is a clinical decision of the treating physician. Prompt and rapid payment protects pharmacy and hospital cash flow and ensures continuity of care.**

4. **Billing Requirements (See Non-Risk Arrangement Medication Management and Payment Policy)**

5. 340B Program Restriction

Hospitals and providers may not collect 340B Drug Pricing Program discounts for Model Drugs for beneficiaries covered under the CGT Access Model.

6. CMS & ASES Compliance

This attachment is compliant with:

- 42 CFR §438.210 (Medical necessity and PA requirements)
- 42 CFR §447 (Pharmacy reimbursement and AAC rules)
- 42 CFR §455 (Program Integrity)
- CMS CGT Access Model operational guidelines
- APR-DRG inpatient payment exclusion rules for carve-out drugs
- ASES Circular Letters 24-0621 and 24-0206
- Medicaid Drug Rebate Program rules for CGT drugs