1700 Bent Creek Blvd.
Suite 200
Mechanicsburg, PA 17050

New and/or Updated Clinical Policies

11/24/2025

PA Health & Wellness (PHW) is adding and a new Clinical Policy that will provide guidance for the billing procedures for High Cost Drugs. This policy is to ensure that all MA enrolled, inpatient facilities, outpatient facilities, and pharmacies bill for high-cost drugs as required by Department of Human Services (DHS).

DHS requires PHW to comply with the Medicaid Drug Rebate Program requirements to facilitate drug rebate invoicing and collection on all Medicaid covered drugs as defined by CMS. This includes 837P, 837I, or NCPDP claims submitted by Inpatient facilities, Outpatient facilities, and Pharmacies. For Lyfgenia and Casgevy, the CMS Cell and Gene Therapy (CGT) Access Model for sickle cell disease applies. This policy specifies drug-specific billing procedures, claims submission, and payment expectations.

These billing procedures apply to High-cost Cellular and Gene Therapy Products as approved by the FDA (this list is updated regularly)

- https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products

For these High-cost Cellular and Gene Therapy Products inpatient facilities should:

- Submit the drug specific claim information separate from any other service.
- Other services may include the administration of the drug, which should be billed to the MCO on a separate claim from the drug
- The specific claim information must include the NDC dispensed and the NDC units dispensed for all drugs regardless of the type of drug dispensed.
- For Lyfgenia and Casgevy, these drugs fall under the CMS Cell and Gene Therapy (CGT) Access Model for sickle cell disease. The requirements for coverage under the CMS Cell and Gene Therapy (CGT) Access Model is outlined in this policy.

The effective date of this policy will be **1/1/2026**. This policy applies to the Community HealthChoices Line of Business (LOB).

Policy Number	Policy Name	Line of Business
PA.PHARM.21	High-Cost Drugs – Billing Procedures and Encounters	Medicaid (Community HealthChoices)

Questions or concerns? Please reach out to your Provider Representative or the PHW Pharmacy team at: PharmacyEscalationsPHW@Centene.com.

POLICY AND PROCEDURE

POLICY NAME: High-Cost Drugs – Billing Procedures and Encounters	**POLICY ID: PA.PHARM.21**
BUSINESS UNIT: PA Health & Wellness	**FUNCTIONAL AREA: Pharmacy Operations**
EFFECTIVE DATE: 11/06/2025	**PRODUCT(S): Medicaid**
REVIEWED/REVISED DATE:	
REGULATOR MOST RECENT APPROVAL DATE(S):	

POLICY STATEMENT:
This policy is to ensure that all MA enrolled, inpatient facilities, outpatient facilities, and pharmacies bill for high-cost drugs as required by Department of Human Services (DHS).

PURPOSE:
DHS requires PA Health & Wellness (PHW) to comply with the Medicaid Drug Rebate Program requirements to facilitate drug rebate invoicing and collection on all Medicaid covered drugs as defined by CMS. This includes 837P, 837I, or NCPDP claims submitted by Inpatient facilities, Outpatient facilities, and Pharmacies. For Lyfgenia and Casgevy, the CMS Cell and Gene Therapy (CGT) Access Model for sickle cell disease applies. This policy specifies drug-specific billing procedures, claims submission, and payment expectations.

SCOPE:
This policy applies to PA Health & Wellness Community HealthChoices (Medicaid) and contracted Inpatient facilities, Outpatient facilities, and Pharmacies.

POLICY:
If the claim type is an 837P or 837I, and PHW pays the billing provider for a drug based upon a HCPCS code such as a J-code or Q-code, the drug qualifies for a federal rebate. If the claim type is an 837P, 837I, or NCPDP and PHW pays the billing provider for a drug based upon the NDC, the drug qualifies for a federal rebate. Inpatient facilities, Outpatient facilities, and Pharmacies should follow the billing procedures below for High-cost Cellular and Gene Therapy Products. For Lyfgenia and Casgevy, the CMS Cell and Gene Therapy (CGT) Access Model for sickle cell disease applies.

PROCEDURE:
These billing procedures apply to High-cost Cellular and Gene Therapy Products outlined in this policy and as approved by the FDA (this list is updated regularly)

- https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products

For these High-cost Cellular and Gene Therapy Products inpatient facilities should:

- Submit the drug specific claim information separate from any other service.
- Other services may include the administration of the drug, which should be billed to the MCO on a separate claim from the drug
- The specific claim information must include the NDC dispensed and the NDC units dispensed for all drugs regardless of the type of drug dispensed.
- DHS has the responsibility of removing NDCs from the rebate invoicing process that are not rebate eligible (i.e. vaccines) or are billed by a 340B Covered Entity.

For Lyfgenia and Casgevy, these drugs fall under the CMS Cell and Gene Therapy (CGT) Access Model for sickle cell disease

- To be eligible for gene therapy to treat sickle cell disease as part of this model, a person must:
  - Have a documented medical diagnosis for sickle cell disease.
  - Be enrolled in Medicaid at time of therapy.
  - Have Medicaid as their primary payer.
  - Receive a gene therapy from a participating manufacturer.
  - Meet standardized prior authorization criteria established by DHS.
- PHW conditions payment for the administration of Lyfgenia (lovotibeglogene autotemcel) and Casgevy (exagamglogene autotemcel) to beneficiaries with a diagnosis of sickle cell disease (SCD) on provider membership in the CMS-designated patient registry for the model (the Center for International Blood & Marrow Transplant Research,

or CIBMTR) and participation in a CMS-specified study. CMS will communicate to the Department if any treatment center authorized by participating manufacturers to administer the model drug(s) fails to meet this requirement. Currently, all authorized treatment centers are eligible to participate in the model.

- Beneficiaries receiving SCD gene therapies included in the model must continue to have access to their same SCD gene therapy providers until at least one year after receiving their gene therapy infusion.
- Under the model, administration of gene therapy for SCD will be for individuals who are inpatient. The 340B program does not apply to drugs used for individuals who are inpatient.
- Please see PHW's policies for Lyfgenia and Casgevy for medical necessity requirements and additional information on the CMS Cell and Gene Therapy (CGT) Access Model.
    - PA.CP.PHAR.603 - Exagamglogene autotemcel (Casgevy)
    - PA.CP.PHAR.627 - Lovotibeglogene autotemcel (Lyfgenia)

For high-cost drug encounters:

- The CHC-MCO must report the necessary Drug Encounter Data in order for the Department to invoice drug manufacturers for rebates for all Covered Drugs. This includes physician-administered drugs, drugs dispensed by 340B covered entities or contract pharmacies, and drugs dispensed to Participants with private or public pharmacy coverage and CHC-MCO secondary coverage.
- The CHC-MCO must report all Drug information, including National Drug Codes (NDCs) and accurate NDC units for all drug claim types, NCPDP, 837 Professional, 837 Institutional, etc., as designated by the Department
- When PHW's paid amount on a drug claim (837P, 837I, or NCPDP) exceeds PROMISe™ field limitations, the encounter will need to be submitted with the maximum PROMISe™ allowable value, $999,999.99, in the MCO paid amount field.
- Then on the drug supplemental file, PHW will ensure that the high-cost drug ICN assigned by PROMISe™ is submitted with the actual MCO paid amount and NDC units. The Department, Mercer and other vendors will access the drug supplemental file to obtain the actual MCO paid amounts for these high-cost drug encounters.

Examples of FDA Approved Cellular and Gene Therapy Products
ABECMA (idecabtagene vicleucel)
ADSTILADRIN (nadofaragene firadenovec-vcng)
ALLOCORD (HPC, Cord Blood)
AMTAGVI (lifileucel)
AUCATZYL (obecabtagene autoleucel)
BEQVEZ (fidanacogene elaparvovec-dzkt)
BREYANZI (lisocabtagene maraleucel)
CARVYKTI (ciltacabtagene autoleucel)
CASGEVY (exagamglogene autotemcel [exa-cel])
CLEVECORD (HPC Cord Blood)
Ducord, HPC Cord Blood
ELEVIDYS (delandistrogene moxeparvovec-rokl)
ENCELTO (revakinagene taroretcel-lwey)
GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen)
HEMACORD (HPC, cord blood)
HEMGENIX (etranacogene dezaparvovec-drlb)
HPC, Cord Blood
HPC, Cord Blood - MD Anderson Cord Blood Bank
HPC, Cord Blood - LifeSouth
HPC, Cord Blood - Bloodworks
IMLYGIC (talimogene laherparepvec)

KEBILIDI (eladocagene exuparvovec-tneq)
KYMRIAH (tisagenlecleucel)
LANTIDRA (donislecel)
LAVIV (Azficel-T)
LENMELDY (atidarsagene autotemcel)
LUXTURNA (voretigene neparvovec-rzyl)
LYFGENIA (lovotibeglogene autotemcel [lovo-cel])
MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane)
OMISIRGE (omidubicel-onlv)
PAPZIMEOS (zopapogene imadenovec-drba)
PROVENGE (sipuleucel-T)
REGENECYTE (HPC, Cord Blood)
RETHYMIC (allogeneic processed thymus tissue – agdc)
ROCTAVIAN (valoctocogene roxaparvovec-rvox)
RYONCIL (remestemcel-L-rknd)
SYMVESS (acellular tissue engineered vessel-tyod)
SKYSONA (elivaldogene autotemcel)
STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat)
TECARTUS (brexucabtagene autoleucel)
TECELRA (afamitresgene autoleucel)
VYJUVEK (beremagene geperpavec-svdt)
YESCARTA (axicabtagene ciloleucel)
ZEVASKYN (prademagene zamikeracel)
ZYNTEGLO (betibeglogene autotemcel)
ZOLGENSMA (onasemnogene abeparvovec-xioi)

REFERENCES:
2026 Community HealthChoices Agreement
SYSTEMS NOTICE #SYS-2025-006 - Encounter Data - High-Cost Drug Encounters
Managed Care Operations Memorandum *General Operations* OPS # 10/2013-012
Managed Care Operations Memorandum MCO Drug Rebates 837I Outpatient Drug Claims
PA.CP.PHAR.603 - Exagamglogene autotemcel (Casgevy)
PA.CP.PHAR.627 - Lovotibeglogene autotemcel (Lyfgenia)

ATTACHMENTS:

ROLES & RESPONSIBILITIES: Policy Manager: Jason Skaria, Director Clinical Pharmacy Services

REGULATORY REPORTING REQUIREMENTS:
State Approval

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.