



REIMBURSEMENT POLICY STATEMENT GEORGIA MEDICAID

Policy Name		Policy Number	Effective Date
340B Drug Pricing		PY-PHARM-0086	01/01/2023
Policy Type			
Medical	Administrative	Pharmacy	REIMBURSEMENT

Reimbursement Policy Statement: Reimbursement Policies prepared by CareSource and its affiliates are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CareSource and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

340B Drug Pricing

B. Background

Reimbursement policies are designed to assist you when submitting claims to CareSource. They are routinely updated to promote accurate coding and policy clarification. These proprietary policies are not a guarantee of payment. Reimbursement for claims may be subject to limitations and/or qualifications. Reimbursement will be established based upon a review of the actual services provided to a member and will be determined when the claim is received for processing. Health care providers and their office staff are encouraged to use self-service channels to verify member's eligibility.

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS/ICD-10 code(s) for the product or service that is being provided. The inclusion of a code in this policy does not imply any right to reimbursement or guarantee claims payment.

The 340B Drug Pricing Program is a federal program, which limits the cost of covered outpatient drugs to eligible health care organizations and covered entities. The purpose of the program was to enable covered entities "to stretch scarce federal resources as far as possible, reach more eligible patients and provide more comprehensive services." This policy describes the claim submission requirements for outpatient pharmacy and provider administered drugs.

C. Definitions

- **340B Covered Entity (CE)** – A facility that is eligible to purchase drugs through the 340B Program and appears on the HRSA Office of Pharmacy Affairs Information System (OPAIS).
- **340B Drug Discount Program (340B)** – Section 340B of the Public Health Service (PHS) Act (1992) that requires drug manufactures participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.
- **340B Medicaid Exclusion File (MEF)** – A file established by HRSA to assist 340B covered entities and States in the prevention of duplicate discounts for drugs subject to Medicaid rebates.
- **Actual Acquisition Cost** – The actual prices paid to acquire drug products sold by a specific manufacturer.
- **Care Management Organization (CMO)** – Organizations, such as CareSource, contracted by the Georgia Department of Community Health to coordinate services for Medicaid members.
- **Contract Pharmacy** – A pharmacy under contract with a Covered Entity.
- **Current Procedural Terminology (CPT)** – A medical code set maintained by the American Medical Association to describe and bill for medical, surgical, and diagnostic services.



- **Fee-for-Service (FFS)** - Claims billed directly to Georgia Medicaid for prescriptions and physician administered drugs provided to FFS members
- **Healthcare Common Procedure Coding System (HCPCS)** – A set of health care procedure codes based on CPT.
- **Health Resources and Services Administration (HRSA)** – The primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable.
- **National Drug Code (NDC)** – A drug product that is identified and reported using a unique, three-segment number, which serves as a universal product identifier for the specific drug.
- **Covered Outpatient Drug (COD)** - A drug which may be dispensed only upon a prescription and is “treated as a prescribed drug for the purposes of section 1905(12)” of the Social Security Act, (with the exception of those defined as not meeting the definition) in paragraphs II and III, Section E. [Conditions of Coverage] in the Medicaid Drug Rebate Program (MDRP) Coverage Rules - AC Reject) policy.
- **Provider Administered Drugs** – Drugs administered directly by a health care provider to a patient.

D. Policy

- I. Outpatient Pharmacy (Point-of-Sale) 340B Claims
 - A. Effective April 1, 2017, all 340B Covered Entities are required to use a submission clarification code when billing the Georgia Medicaid Division on Fee-for-Service (FFS) and Care Management Organization (CMO) outpatient pharmacy claims per Part II Policies and Procedures for Pharmacy Services Manual as published by the Georgia Department of Community Health.
 - B. The Covered Entity must submit claims through their pharmacy claims platform through our pharmacy benefits manager, Express Scripts, and the claim must include:
 1. A value of “08” in the Basis of Cost Determination field, 423-DN
 2. A value of “20” in the submission clarification code field 420-DK
 3. National Drug Code (NDC) of the drug dispensed
 4. Actual Acquisition Cost (AAC)
 - C. Express Scripts will indicate on the encounter file any 340B submitted claims to Georgia Medicaid in order to ensure rebates are not collected on these drugs. It is the responsibility of Express Scripts to review the updated Health Resource and Service Administration (HRSA) 340B discount drug program file quarterly. The pharmacy should bill appropriately and their transactions are subject to audit. Please visit the Express Scripts Pharmacist Resource Center for additional information.
 - D. If the product is not purchased at 340B pricing, do not include the basis of cost determination value or the submission clarification code values and bill at the regular Medicaid (FFS or managed care) rate.
 - E. Contract pharmacies are not allowed to bill for 340B purchased drugs. All 340B acquired drugs identified and discounted at the claim level must be carved-out for Medicaid (FFS or managed care).



II. Provider Administered 340B Drug Claims

A. For Provider Administered Drugs, the 340B Covered Entity must submit the claim on a CMS 1500 or UB-04 and the claim must include:

1. The HCPCS/CPT code
2. National Drug Code (NDC)
3. Actual Acquisition Cost – If the drug is not purchased at 340B pricing, bill at the regular Medicaid (FFS or Managed care) rate

B. The Health Resources and Services Administration (HRSA) Medicaid Exclusion File (MEF) will be used as the sole means to identify 340B drug claims on the encounter file submission to Georgia Medicaid.

E. Conditions of Coverage

Reimbursement is dependent on, but not limited to, submitting approved HCPCS and CPT codes along with appropriate modifiers, if applicable. Please refer to the individual fee schedule for appropriate codes.

F. Related Policies/Rules

PAD-0099-GA-MCD Medicaid Drug Rebate Program (MDRP) Coverage Rules - AC Reject

G. Review/Revision History

	DATE	ACTION
Date Issued	05/13/2021	
Date Revised	12/07/2022	Updated section (D) to align with DCH policy and procedures
Date Effective	01/01/2023	
Date Archived		

H. References

1. Georgia Department of Community Health Division of Medicaid. Part II Policies and Procedures for Pharmacy Services. Revised November 2022.
[part ii policies and procedures manual for pharmacy services oct 2022 20221128161317.pdf \(georgia.gov\)](#)

The Reimbursement Policy Statement detailed above has received due consideration as defined in the Reimbursement Policy Statement Policy and is approved.