REIMBURSEMENT POLICY STATEMENT
OHIO MEDICAID

Policy Name	Policy Number	Effective Date
340B Drug Pricing	PY-PHARM-0087	10-1-2022

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.

Table of Contents

Reimbursement Policy Statement 1
A. Subject 2
B. Background 2
C. Definitions 2
D. Policy 3
E. Conditions of Coverage 4
F. Related Policies/Rules 4
G. Review/Revision History 4
H. References 5

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.
- 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 Ohio Department of Medicaid to coordinate services for Medicaid members.
- Contract Pharmacy – A pharmacy contracted with a Covered Entity to dispense 340B medications purchased by the 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 Ohio 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 responsible for administering the 340B program.
- National Council for Prescription Drug Programs (NCPDP) – the standards organization that creates the standard format through which pharmacy claims are submitted to a Pharmacy Benefit Manager (PBM).
- 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.
- Pharmacy Benefit Manager (PBM) – The entity that processes retail pharmacy or PBM benefit claims for CareSource.
- Provider Administered Drugs – Drugs administered directly by a health care provider to a patient.

D. Policy

I. Pharmacies Allowed to Bill 340B Claims

A. Only Covered Entities that elected to dispense 340B medications to Medicaid members on the HRSA Medicaid Exclusion File may bill 340B claims.

B. Contract pharmacies are not allowed to bill for 340B purchased drugs.

II. Retail Pharmacy (Point-of-Sale) 340B Claims

A. In addition to the NDC and other fields consistently submitted to the PBM for payment, all 340B Covered Entities must identify 340B claims using either of the two below NCPDP Telecommunication Standard D.0 fields:

- Submission Clarification Code (SCC - Field 420-DK) of 20 and/or:
- Basis of Cost Determination - (Field 423-DN) of 08 plus their 340B acquisition cost in the Ingredient Cost Submitted (Field 4Ø9-D9)

B. When submitting 340B claims, providers are permitted, but not required to, submit Basis of Cost Determination Code 08. Providers electing to identify 340B claims using this field must also submit their 340B acquisition code in the Submitted Ingredient Cost field 409-D9.

C. For drugs not purchased at 340B rates, do not include either of the 340B identifiers listed above.

III. Provider Administered 340B Drug Claims

A. In addition to the HCPCS/CPT code, NDC, and other fields consistently submitted for claims payment, 340B Covered Entities should submit the claim on a CMS 1500 or UB-04 claim form with the either of the following modifiers:

- SE – Drug or biological acquired through the 340B drug pricing program discount

IV. Auditing and Monitoring

A. To ensure compliance with 340B billing requirements, CareSource will monitor both 340B and non-340B claim submissions to identify potential 340B claims. Should we identify a claim we believe is 340B, we will inform the provider of the potential billing error and ask for validation, as well as correction.

E. Conditions of Coverage

Reimbursement is dependent on, but not limited to, submitting the appropriate and applicable drug-related codes (HCPCS, CPT, NDC) along with appropriate 340B claim fields, if applicable.

F. Related Policies/Rules

ORC 5167.123 requires the following regarding managed care organization contracts with 340B providers:

A) No contract between a medicaid managed care organization, including a third-party administrator, and a 340B covered entity shall contain any of the following provisions:

(1) A payment rate for a prescribed drug that is less than the national average drug acquisition cost rate for that drug as determined by the United States centers for medicare and medicaid services, measured at the time the drug is administered or dispensed, or, if no such rate is available at that time, a reimbursement rate that is less than the wholesale acquisition cost of the drug, as defined in 42 U.S.C. 1395w-3a(c)(6)(B);

(2) A fee that is not imposed on a health care provider that is not a 340B covered entity;

(3) A fee amount that exceeds the amount for a health care provider that is not a 340B covered entity.

(B) The organization, or its contracted third-party administrators, shall not discriminate against a 340B covered entity in a manner that prevents or interferes with a medicaid recipient's choice to receive a prescription drug from a 340B covered entity or its contracted pharmacies.

(C) Any provision of a contract entered into between the organization and a 340B covered entity that is contrary to division (A) of this section is unenforceable and shall be replaced with the dispensing fee or payment rate that applies for health care providers that are not 340B covered entities.

G. Review/Revision History

	DATE	ACTION
Date Issued	08/26/2021	
Date Revised	08/25/2022	
Date Effective	10/01/2022	
Date Archived		

H. References

1. Frequently Asked Questions: 340B Drug Pricing Program. Available from: https://pharmacy.medicaid.ohio.gov/sites/default/files/2018-6-4%20340B%20FAQ.pdf. Revised June 2018
2. Section 5167.123 Medicaid MCO contracts with 340B program participants. Ohio Revised Code, Tital 51 Public Welfare, Chapter 5157 Medicaid Managed Care. Available from: https://codes.ohio.gov/ohio-revised-code/section-5167.123. Effective April 12, 2021
3. Modifiers Recognized by Ohio Medicaid. Revised January 28, 2022. https://medicaid.ohio.gov/static/Providers/Billing/BillingInstructions/ModifiersODM.pdf

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