

REIMBURSEMENT POLICY STATEMENT MICHIGAN HEALTH LINK

| WIICHIGAN HEALTH LINK | | | | | |
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| Policy Name | | Policy Number | Effective Date | | |
| 340B Drug Pricing | | PY-PHARM-0136 | 08/01/2025 | | |
| Policy Type | | | | | |
| Medical | Administrative | Pharmacy | REIMBURSEMENT | | |

Reimbursement Policy Statement: Reimbursement Policies prepared by HAP 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.

HAP 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 HAP 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 manufacturers 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 HAP CareSource, contracted by the Michigan Department of Health and Human Services 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 Michigan Medicaid for prescriptions and physician administered drugs provided to FFS members.



- Healthcare Common Procedure Coding System (HCPCS) A standardized set of medical codes maintained by the Centers for Medicare and Medicaid Services used to describe healthcare services, items, and procedures.
- **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 HAP 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 that are in the HAP CareSource pharmacy network are permitted 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 by entering the Submission Clarification Code (SCC) 20 in the NCPDP Telecommunication Standard D.0 field 420-DK.
 - 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 in the appropriate field in the electronic format using the Michigan Department of Health and Human Services modifier U6 and CMS modifiers for Outpatient Prospective



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Payment System (OPPS) 340B acquired drugs. Additionally, providers are required to submit the price paid (actual acquisition cost) for 340B purchased stock.

IV. Auditing and Monitoring

A. To ensure compliance with 340B billing requirements, HAP 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

None applicable

G. Review/Revision History

| Date Issued | | |
|----------------|------------|--|
| Date Revised | | |
| Date Effective | 08/01/2025 | |
| Date Archived | | |

H. References

- Michigan Department of Health and Human Services Medicaid Provider Manual https:// https://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf
- Michigan Department of Health and Human Services Medical Services
 Administration (MSA), Bulletin Number: MSA 17-07, Enhanced 340B Reporting
 Requirements. https://www.michigan.gov/-/media/Project/Websites/mdhhs/Folder2/Folder31/Folder1/Folder131/MSA 17-07.pdf

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

