

Administrative Policy Statement					
MICHIGAN MEDICAID					
Policy Name		Policy Number	Date Effective		
Medicaid Drug Rebate Program (MDRP) Coverage Rules - AC Reject		PAD-0099-MI-MCD	10/1/2024		
Policy Type					
Medical	ADMINISTRATIVE	Pharmacy	Reimbursement		

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy 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 Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Table of Contents

Adn	ninistrative Policy Statement	. 1
Α.	Subject	. 2
B.	Background	. 2
	Definitions	
D.	Policy	. 3
	Conditions of Coverage	
F.	Related Policies/Rules	. 5
G.	Review/Revision History	. 5
Н.	References	. 5

PAD-0099-MI-MCD Effective Date: 10/1/2024



Medicaid Drug Rebate Programs (MDRP) agreement requirements, covered outpatient drugs and the AC pharmacy claims reject code

B. Background

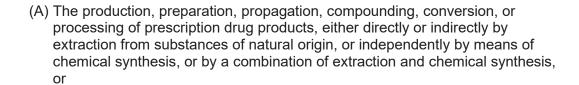
This policy serves as guidance for CareSource pharmacy staff on the Medicaid Drug Rebate Program as it relates to the definition of covered outpatient drugs and conditions for claims payment.

C. Definitions

- I. <u>Covered Outpatient Drug</u> (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 in paragraphs II and III, Section E. [Conditions of Coverage] below).
- II. <u>Medicaid Drug Rebate Program</u> (MDRP) A program that includes Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.
- III. <u>National Drug Rebate Agreement</u> (NDRA) An agreement entered into by a drug manufacturer with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.
- IV. <u>Section 340B Drug Pricing Program</u> A discount drug pricing program under Section 340B of the Public Health Service Act that "requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients".
- V. <u>Federal Supply Schedule</u> (FSS) Also known as General Services Administration Schedule (GSA), and Multiple Award Schedule (MAS), is a "long-term governmentwide contract with commercial companies that provides access to millions of commercial products and services at fair and reasonable prices to the government".
- VI. <u>National Council for Prescription Drug Programs (NCPDP) Reject Code</u> A type of reject error code received by a pharmacy upon processing a prescription.
- VII. Manufacturer Any entity that is "engaged in:-



Effective Date: 10/1/2024



(B) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a "wholesale distributor of drugs or a retail pharmacy licensed under State law."

D. Policy

- I. In order for a drug to be eligible for coverage by Medicaid under the Medicaid Drug Rebate Program (MDRP) it has to meet two requirements:
 - A. It has to meet the definition of a covered outpatient drug (COD) under Section 1927 of the Social Security Act which states the requirements for rebate agreements.
 - B. The **manufacturer must have** entered into and have in effect, on the date of service dispensed, **the following agreements**:
 - i. A National Drug Rebate Agreement (NDRA);
 - ii. A pricing agreement for the Section 340B Drug Pricing Program administered by the Health Resources and Services Administration: AND
 - iii. A master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule (FSS).

II. AC Reject Code

a. Pharmacy claims not eligible for reimbursement due to not meeting CMS MDRP requirements will reject at the pharmacy with the following Pharmacy NCPDP Reject Code and Reject Code Description:

AC - Product Not Covered Non-Participating Manufacturer;

Manufacturer is not participating in drug rebate on date of service dispensed.

Note: Michigan Medicaid Health Plans must cover certain products for Medicaid members (or specifically for Children's Special Health Care Services members) regardless of rebate, as required by the State.

E. Conditions of Coverage

- I. "A drug can only be considered a covered outpatient drug if it:
- A. Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;



Effective Date: 10/1/2024

B. Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the

meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that

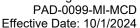
it is a "new drug" (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

C. Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw

approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

- D. Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or
- E. Is insulin certified under section 506 of the FFDCA.
- II. "A covered outpatient drug does not include:
 - A. Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;
 - B. Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph I, Section E. Conditions of Coverage above:
 - C. Any drug product or biological used for a medical indication which is not a medically accepted indication;
 - D. Over-the-counter products that are not drugs".
- III. "A covered outpatient drug <u>does not</u> include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):
 - A. Inpatient Services;
 - B. Hospice Services;







- C. Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- D. Physician services:
- E. Outpatient hospital services;
- F. Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;
- G. Other laboratory and x-ray services; or
- H. Renal dialysis."
- IV. In exchange for state Medicaid coverage of most of a manufacturer's drugs, "rebates are paid by these drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program".
- F. Related Policies/Rules
- G. Review/Revision History

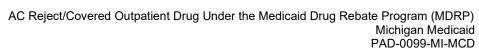
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H. References

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- 2. Social Security. Compilation of The Social Security Laws. Payment for Covered Outpatient Drugs. Retrieved June 7, 2022 from www.ssa.gov
- 3. Medicaid Drug Rebate Program (MDRP). Retrieved June 8, 2022 from www.medicaid.gov
- 4. American Hospital Association. Fact Sheet: The 340B Drug Pricing Program. Retrieved June 8, 2022 from www.aha.org
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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.





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

