441—78.2(249A) Prescribed outpatient drugs. Payment will be made for "covered outpatient drugs" as defined in 42 U.S.C. Section 1396r-8(k)(2)-(4) as amended to July 1, 2026, subject to the conditions and limitations specified in this rule.

78.2(1) *Qualified prescriber.* All drugs are covered only if prescribed or ordered by an Iowa Medicaid-enrolled practitioner licensed or registered to prescribe as specified in Iowa Code section 155A.3(39).

78.2(2) *Prescription required.* As a condition of payment for all drugs, including "nonprescription" or "over-the-counter" drugs that may otherwise be dispensed without a prescription or drug order, a prescription or drug order shall be transmitted as specified in Iowa Code sections 124.308, 155A.3 and 155A.27 by the practitioner to the pharmacy. All prescriptions or drug orders shall be available for audit by the department.

78.2(3) *Qualified source.* All drugs are covered only if marketed by manufacturers that have signed a Medicaid rebate agreement with the Secretary of Health and Human Services in accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990 as amended to July 1, 2026).

78.2(4) *Prescription drugs.* Drugs that may be dispensed only upon a prescription are covered subject to the following limitations.

a. Prior authorization is required as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A.

(1) For any drug requiring prior authorization, reimbursement will be made for a 72-hour or three-day supply dispensed in an emergency when a prior authorization request cannot be submitted.

(2) Unless the manufacturer or labeler of a mental health prescription drug that has a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class enters into a contract to provide the state with a supplemental rebate, the drug may be placed on the preferred drug list as nonpreferred, with prior authorization required.

(3) For mental health prescription drugs requiring prior authorization that have a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class, reimbursement will be made for up to a seven-day supply pending prior authorization. A request for prior authorization shall be deemed approved if the prescriber:

1. Has on file with the department current contact information, including a current fax number, and a signed department Fax Confidentiality Certificate, and

2. Does not receive a notice of approval or disapproval within 48 hours of a request for prior authorization.

(4) Prior authorization for medication-assisted treatment will be governed pursuant to subrule 78.28(2).

b. Payment is not made for:

(1) Drugs whose prescribed use is not for a medically accepted indication as defined by Section 1927(k)(6) of the Social Security Act as amended to July 1, 2026.

(2) Drugs used for anorexia, weight gain, or weight loss.

(3) Drugs used for cosmetic purposes or hair growth.

(4) Reserved.

(5) Otherwise covered outpatient drugs if the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or the manufacturer's designee.

(6) Drugs described in Section 107(c)(3) of the Drug Amendments of 1962 as amended to July 1, 2026, and identical, similar, or related drugs (within the meaning of Section 310.6(b)(1) of Title 21 of the Code of Federal Regulations as amended to July 1, 2026 (drugs identified through the Drug Efficacy Study Implementation (DESI) review)).

(7) "Covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) as amended to July 1, 2026, for any "Part D eligible individual" as defined by 42 U.S.C. Section 1395w-101(a)(3)(A) as amended to July 1, 2026, including a member who is not enrolled in a Medicare Part D plan.

(8) Drugs prescribed for fertility purposes.

(9) Drugs used for the treatment of sexual or erectile dysfunction, except when used to treat a condition other than sexual or erectile dysfunction for which the drug has been approved by the U.S. Food and Drug Administration (FDA).

(10) Prescription drugs for which the prescription was executed in written (and nonelectronic) form unless the prescription was executed on a tamper-resistant pad, as required by Section 1903(i)(23) of the Social Security Act (42 U.S.C. Section 1396b(i)(23)).

(11) Drugs used for symptomatic relief of cough and colds, except for nonprescription drugs listed at subrule 78.2(5).

(12) Investigational drugs, including drugs that are the subject of an investigational new drug (IND) application allowed to proceed by the FDA but that do not meet the definition of a covered outpatient drug in 42 U.S.C. 1396r-8(k)(2)-(4) as amended to July 1, 2026.

78.2(5) *Nonprescription drugs.*

a. Nonprescription or over-the-counter (OTC) refers to a drug that may be lawfully sold without a prescription; however, Iowa Medicaid requires a prescription for covered OTC drugs. These drugs are subject to prior authorization requirements as specified in the preferred drug list (PDL) published by the department pursuant to Iowa Code section 249A.20A. The drugs are identified on the nonprescription (OTC) prescribed list by therapeutic category located on the PDL website (www.iowamedicaidpdl.com) under the PDL/PA tab.

b. Nonprescription drugs for use in a nursing facility, psychiatric medical institution for children (PMIC), or intermediate care facility for persons with an intellectual disability (ICF/ID) will be included in the per diem rate paid to the nursing facility, PMIC, or ICF/ID, with the exception of OTC insulin and pseudoephedrine.

78.2(6) *Quantity prescribed.*

a. Quantity prescribed. When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe not less than a one-month supply of covered prescription and nonprescription medication. Contraceptives may be prescribed in three-month quantities.

b. Prescription refills.

(1) Prescription refills shall be performed and recorded in a manner consistent with existent state and federal laws, rules and regulations.

(2) Automatic refills.

1. Automatic refills are allowed. Participation in an automatic refill program is voluntary and opt-in only, on a drug-by-drug basis.

2. The program must have:

- Easy-to-locate contact information through telephone, the program's website, or both;
- Easy-to-understand patient materials on how to select or unselect drug(s) for inclusion and how to disenroll;
- Confirmation that the member wants to continue in the automatic refill program at least annually;
- Confirmation of continued medical necessity provided by the Medicaid member or person acting as an authorized representative of the member, before the member receives the medication at the pharmacy or before the medication is mailed or delivered to the member, without which confirmation the drug(s) must be credited back to the Medicaid program; and
- Records of all consents, which must be in electronic or written format and must be available for review by auditors.

78.2(7) *Lowest cost item.* The pharmacist shall dispense the lowest cost item in stock that meets the requirements of the practitioner as shown on the prescription.

78.2(8) *Consultation.* In accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990) as amended to July 1, 2026, a pharmacist shall offer to discuss information regarding the use of the medication with each Medicaid member or the caregiver of a member presenting a prescription. The consultation is not required if the person refuses the consultation. Standards for the content of the consultation can be found in rules of the Iowa board of pharmacy.

[**ARC 0315D**, IAB 5/27/26, effective 7/1/26]