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) 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(38).

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, subject to the provisions of Iowa Code section 155A.29 regarding refills. 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).

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. However, prior authorization shall not be required for such a drug for a member whose regimen on the drug was established before January 1, 2011, as verified by documented pharmacy claims.

(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 Form 470-4914, 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 shall 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.

(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 and identical, similar, or related drugs (within the meaning of Section 310.6(b)(1) of Title 21 of the Code of Federal Regulations (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) for any "Part D eligible individual" as defined by 42 U.S.C. Section 1395w-101(a)(3)(A), 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.

(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 U.S. Food and Drug Administration (FDA) but that do not meet the definition of a covered outpatient drug in 42 U.S.C. 1396r-8(k)(2)-(4).

78.2(5) *Nonprescription drugs.*

a. The following drugs that may otherwise be dispensed without a prescription are covered subject to the prior authorization requirements stated below and as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A:

Acetaminophen tablets 325 mg, 500 mg
Acetaminophen elixir 160 mg/5 ml
Acetaminophen solution 100 mg/ml
Acetaminophen suppositories 120 mg
Artificial tears ophthalmic solution
Artificial tears ophthalmic ointment
Aspirin tablets 81 mg, chewable
Aspirin tablets 81 mg, 325 mg, and 650 mg oral
Aspirin tablets, enteric coated 325 mg, 650 mg, 81 mg
Aspirin tablets, buffered 325 mg
Bacitracin ointment 500 units/gm
Benzoyl peroxide 5%, gel, lotion
Benzoyl peroxide 10%, gel, lotion
Cetirizine hydrochloride liquid 1 mg/ml
Cetirizine hydrochloride tablets 5 mg
Cetirizine hydrochloride tablets 10 mg
Chlorpheniramine maleate tablets 4 mg
Clotrimazole vaginal cream 1%
Diphenhydramine hydrochloride capsules 25 mg
Diphenhydramine hydrochloride elixir, liquid, and syrup 12.5 mg/5 ml
Epinephrine racemic solution 2.25%
Ferrous sulfate solution 75 mg/0.6 ml (15 mg/0.6 ml elemental iron)
Ferrous sulfate tablets 325 mg
Ferrous sulfate elixir 220 mg/5 ml
Ferrous sulfate drops 75 mg/0.6 ml
Ferrous gluconate tablets 325 mg
Ferrous fumarate tablets 325 mg
Guaifenesin 100 mg/5 ml with dextromethorphan 10 mg/5 ml liquid
Ibuprofen suspension 100 mg/5 ml
Ibuprofen tablets 200 mg
Insulin
Lactic acid (ammonium lactate) lotion 12%
Levonorgestrel 1.5 mg
Loperamide hydrochloride liquid 1 mg/5 ml
Loperamide hydrochloride liquid 1 mg/7.5 ml
Loperamide hydrochloride tablets 2 mg
Loratadine syrup 5 mg/5 ml

Loratadine tablets 10 mg
Magnesium hydroxide suspension 400 mg/5 ml
Meclizine hydrochloride tablets 12.5 mg, 25 mg oral and chewable
Miconazole nitrate cream 2% topical and vaginal
Miconazole nitrate vaginal suppositories, 100 mg
Mineral products with prior authorization
Neomycin-bacitracin-polymyxin ointment
Nicotine gum 2 mg, 4 mg
Nicotine lozenge 2 mg, 4 mg
Nicotine patch 7 mg/day, 14 mg/day and 21 mg/day
Pediatric oral electrolyte solutions
Permethrin lotion 1%
Polyethylene glycol 3350 powder
Pseudoephedrine hydrochloride tablets 30 mg, 60 mg
Pseudoephedrine hydrochloride liquid 30 mg/5 ml
Pyrethrins-piperonyl butoxide liquid 0.33-4%
Pyrethrins-piperonyl butoxide shampoo 0.3-3%
Pyrethrins-piperonyl butoxide shampoo 0.33-4%
Salicylic acid liquid 17%
Senna tablets 187 mg
Sennosides-docusate sodium tablets 8.6 mg-50 mg
Sennosides syrup 8.8 mg/5 ml
Sennosides tablets 8.6 mg
Sodium bicarbonate tablets 325 mg
Sodium bicarbonate tablets 650 mg
Sodium chloride hypertonic ophthalmic ointment 5%
Sodium chloride hypertonic ophthalmic solution 5%
Tolnaftate 1% cream, solution, powder
Vitamins, single and multiple with prior authorization

Other nonprescription drugs listed as preferred in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A.

b. Nonprescription drugs for use in a nursing facility, PMIC, or ICF/ID shall be included in the per diem rate paid to the nursing facility, PMIC, or ICF/ID.

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), 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 shall be found in rules of the Iowa board of pharmacy.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8097B**, IAB 9/9/09, effective 11/1/09; **ARC 9175B**, IAB 11/3/10, effective 1/1/11; **ARC 9699B**, IAB 9/7/11, effective 9/1/11; **ARC 9834B**, IAB 11/2/11, effective 11/1/11; **ARC 9882B**, IAB 11/30/11, effective 1/4/12; **ARC 9981B**, IAB 2/8/12, effective 3/14/12; **ARC 0305C**, IAB 9/5/12, effective 11/1/12; **ARC 0580C**, IAB 2/6/13, effective 4/1/13; **ARC 2361C**, IAB 1/6/16, effective 1/1/16; **ARC 2930C**, IAB 2/1/17, effective 4/1/17; **ARC 4899C**, IAB 2/12/20, effective 3/18/20; see Delay note at end of chapter; **ARC 5175C**, IAB 9/9/20, effective 6/1/21; **ARC 5364C**, IAB 12/30/20, effective 3/1/21]