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**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 by a legally qualified practitioner (physician, dentist, podiatrist, optometrist, physician assistant, or advanced registered nurse practitioner). Pursuant to Public Law 111-148, Section 6401, any practitioner prescribing drugs must be enrolled with the Iowa Medicaid enterprise in order for such prescribed drugs to be eligible for payment.
- **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, a prescription shall be transmitted as specified in Iowa Code sections 124.308 and 155A.27, subject to the provisions of Iowa Code section 155A.29 regarding refills. All prescriptions 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 as amended by 2010 Iowa Acts, Senate File 2088, section 347.
- (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.
  - 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) Rescinded IAB 2/8/12, effective 3/14/12.
- (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, except when prescribed for a medically accepted indication other than infertility, as defined in subparagraph (1).

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(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 325 mg, 650 mg, 81 mg (chewable)

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

Calcium carbonate chewable tablets 500 mg, 750 mg, 1000 mg, 1250 mg

Calcium carbonate suspension 1250 mg/5 ml

Calcium carbonate tablets 600 mg

Calcium carbonate-vitamin D tablets 500 mg-200 units

Calcium carbonate-vitamin D tablets 600 mg-200 units

Calcium citrate tablets 950 mg (200 mg elemental calcium)

Calcium gluconate tablets 650 mg

Calcium lactate tablets 650 mg

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 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

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Lactic acid (ammonium lactate) lotion 12%

Loperamide hydrochloride liquid 1 mg/5 ml

Loperamide hydrochloride tablets 2 mg

Loratadine syrup 5 mg/5 ml

Loratadine tablets 10 mg

Magnesium hydroxide suspension 400 mg/5 ml

Magnesium oxide capsule 140 mg (85 mg elemental magnesium)

Magnesium oxide tablets 400 mg

Meclizine hydrochloride tablets 12.5 mg, 25 mg oral and chewable

Miconazole nitrate cream 2% topical and vaginal

Miconazole nitrate vaginal suppositories, 100 mg

Multiple vitamin and mineral products with prior authorization

Neomycin-bacitracin-polymyxin ointment

Niacin (nicotinic acid) tablets 50 mg, 100 mg, 250 mg, 500 mg

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

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 and dispensed.* 

- a. When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe a quantity of prescription medication sufficient for up to a 31-day supply. Oral contraceptives may be prescribed in 90-day quantities.
- b. Oral solid forms of covered nonprescription items shall be prescribed and dispensed in a minimum quantity of 100 units per prescription or the currently available consumer package size except when dispensed via a unit-dose system.
- **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

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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 249 A.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]