RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 23, 2020
TIME: 2:28 PM

WSR 21-02-004

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: The agency is amending 182-530-2000 to replace the list of covered generic products for the treatment of cough and cold. The new rules cover only those products with a preferred status on the Apple Health preferred drug list (AHPDL) on the date a prescription is dispensed. The agency is also amending WAC 182-530-2100 to correct references to 182-530-2000 that changed as part of this rule making.

Citation of rules affected by this order:

New:
Repealed:
Amended: 182-530-2000, 182-530-2100
Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 20-23-121 on November 18, 2020 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	____	Amended	____	Repealed	____

The number of sections adopted at the request of a nongovernmental entity:

	New	____	Amended	____	Repealed	____

The number of sections adopted on the agency's own initiative:

	New	____	Amended		Repealed	____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	____	Amended	2	Repealed	____

The number of sections adopted using:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	____	Amended	2	Repealed	____

Date Adopted: December 23, 2020	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

AMENDATORY SECTION (Amending WSR 19-22-016, filed 10/25/19, effective 11/25/19)

WAC 182-530-2000 Covered—Outpatient drugs, devices, and drug-related supplies. (1) The medicaid agency covers:

(a) Outpatient drugs, including over-the-counter (OTC) drugs, as defined in WAC 182-530-1050, subject to the limitations and requirements in this chapter, when:

(i) The drug is approved by the Food and Drug Administration (FDA);

(ii) The drug is for a medically accepted indication as defined in WAC 182-530-1050;

(iii) The drug is not excluded from coverage under WAC 182-530-2100;

(iv) The manufacturer has a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS). Exceptions to the drug rebate requirement are described in WAC 182-530-7500; and

(v) The drug is prescribed by a provider with prescriptive authority. Exceptions to the prescription requirement exist for family planning and emergency contraception in (b) of this subsection.

(b) Family planning drugs, devices, and drug-related supplies per chapter 182-532 WAC and as follows:

(i) OTC family planning drugs, devices, and drug-related supplies without a prescription when the agency determines it necessary for client access and safety;

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC 182-530-7500 on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, excluding emergency contraception, when dispensed in a one-year supply only, unless:

(A) A smaller supply is directed by the prescriber;

(B) A smaller supply is requested by the client;

(C) The pharmacy does not have adequate stock.

(c) Vitamins, minerals, and enzymes when prescribed for:

(i) Prenatal vitamins, when prescribed and dispensed to pregnant women;

(ii) A medical condition caused by a clinically documented deficiency;

(iii) A United States Preventive Services Task Force recommendation with an A or B rating;

(iv) Fluoride for clients under age twenty-one; or

(v) A clinically documented medical condition that causes vitamin, mineral, or enzyme deficiencies, and the deficiency cannot be treated through other dietary interventions.

(d) OTC drugs, vitamins, and minerals when determined by the agency to be the least costly therapeutic alternative for a medically accepted indication. All covered OTC products determined to be the least costly therapeutic alternatives for medically accepted indications will be included on the agency's published apple health preferred drug list. This subsection does not apply to products prescribed for the treatment of cough or cold symptoms. See this subsection (1)(h) of this section and WAC 182-530-2100 (1)(b)(v) for coverage of products prescribed for the treatment of cough and cold symptoms.

(e) Drug-related devices and drug-related supplies as an outpatient pharmacy benefit when:

(i) Prescribed by a provider with prescribing authority;

(ii) Essential for the administration of a covered drug;

(iii) Not excluded from coverage under WAC 182-530-2100; and

(iv) Determined by the agency that a product covered under chapter 182-543 WAC related to ((~~durable~~)) medical equipment and supplies should be available at retail pharmacies.

(f) Preservatives, flavoring, or coloring agents, only when used as a suspending agent in a compound.

(g) OTC and prescription drugs to promote tobacco/nicotine cessation.

(h) ((~~The following generic products~~)) For the treatment of cough and cold((~~:~~

~~(i) Dextromethorphan 15 mg/5 ml liquid or syrup;~~

~~(ii) Dextromethorphan/Guaifenesin 10 mg - 100/5 ml liquid or syrup, including sugar-free formulations;~~

~~(iii) Guaifenesin 100 mg/5 ml liquid or syrup;~~

~~(iv) Phenylephrine 10 mg tablets;~~

~~(v) Phenylephrine 2.5 mg/ml liquid or syrup;~~

~~(vi) Pseudoephedrine 30 mg and 60 mg tablets;~~

~~(vii) Pseudoephedrine 15 mg/5 ml liquid or syrup; and~~

~~(viii) Saline 0.65% nasal spray~~)), only those products included with a preferred status on the apple health preferred drug list (PDL), as described in WAC 182-530-4100, on the date a client's prescription is dispensed.

(2) The agency does not reimburse for any drug, device, or drug-related supply not meeting the coverage requirements under this section.

AMENDATORY SECTION (Amending WSR 19-22-016, filed 10/25/19, effective 11/25/19)

WAC 182-530-2100 Noncovered—Outpatient drugs and pharmaceutical supplies. (1) The medicaid agency does not cover:

(a) A drug that is:

(i) Not approved by the Food and Drug Administration (FDA); or

(ii) Prescribed for a nonmedically accepted indication, including diagnosis, dose, or dosage schedule that is not evidenced-based.

(b) A drug prescribed:

(i) For weight loss or gain;

(ii) For infertility, frigidity, impotency;

(iii) For sexual or erectile dysfunction;

(iv) For cosmetic purposes or hair growth; or

(v) For treatment of cough or cold symptoms, except as listed in WAC 182-530-2000 (1)((~~(i)~~)) (h).

(c) Drugs used to treat sexual or erectile dysfunction, in accordance with section 1927 (d)(2)(K) of the Social Security Act, unless such drugs are used to treat a condition other than sexual or erectile dysfunction, and these uses have been approved by the Food and Drug Administration.

(d) Drugs listed in the federal register as "less-than-effective" ("DESI" drugs) or which are identical, similar, or related to such drugs.

(e) Outpatient drugs for which the manufacturer requires as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or manufacturer's designee.

(f) A product:

(i) With an obsolete National Drug Code (NDC) for more than two years;

(ii) With a terminated NDC;

(iii) Whose shelf life has expired; or

(iv) Which does not have an eleven-digit NDC.

(g) Over-the-counter (OTC) drugs, vitamins, and minerals, except as allowed under WAC 182-530-2000 (1)((~~(i)~~)) (h).

(h) Any drug regularly supplied by other public agencies as an integral part of program activity (e.g., immunization vaccines for children).

(i) Free pharmaceutical samples.

(2) A noncovered drug can be requested through the exception to rule process as described in WAC 182-501-0160.

(3) If a noncovered drug is prescribed through the early and periodic screening, diagnosis, and treatment (EPSDT) process, an authorization request may be submitted indicating that the request is EPSDT related, and the request will be evaluated according to the process in WAC 182-501-0165. (See WAC 182-534-0100 for EPSDT rules.)