



## Coverage of Over-the-Counter Drugs in Medicaid

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Drug coverage is an important facet of the Medicaid program. Although it is an optional benefit, all states cover outpatient prescription drugs in their Medicaid programs.<sup>1</sup> States have significantly more leeway, however, in whether they cover over-the-counter (OTC) drugs. In the last twenty years, more drugs that were once only available through a prescription, including many allergy medications and medication to treat reflux, have become available OTC.<sup>2</sup> Thus it is particularly important for advocates to understand the circumstances in which Medicaid programs cover OTC drugs. This Fact Sheet provides an overview of Medicaid rules for OTC drug coverage and discusses a variety of state examples for Medicaid program coverage of OTC drugs.

### What is an OTC drug?

OTC or nonprescription drugs are medications that can be sold directly to a consumer without a prescription from a health care professional. Some drugs may be legally classified as over-the-counter (*i.e.*, no prescription is required), but may only be dispensed by a pharmacist after an assessment of the patient's needs or the provision of patient education. Many OTC drugs are available for purchase outside of a pharmacy, in locations such as convenience stores, supermarkets, and gas stations.

### ***Federal Law requirements on OTC coverage in Medicaid***

In general, states need not cover OTC drugs in their Medicaid programs, even when they cover outpatient prescription drugs.<sup>3</sup> State Medicaid programs must, however, cover

<sup>1</sup> Prescription Drugs, Medicaid.gov, <https://www.medicaid.gov/medicaid/prescription-drugs/index.html> (last visited November 18, 2019).

<sup>2</sup> See Eve Tahmincioglu, *Over the Counter, Yes, but Out of the Insurance Plan*, N.Y. TIMES, Jul. 4, 2004, <https://www.nytimes.com/2004/07/04/business/sunday-money-spending-over-the-counter-yes-but-out-of-the-insurance-plan.html>.

<sup>3</sup> 42 U.S.C. §§ 1396r-8(d)(2)(F), (k)(4).

nonprescription prenatal vitamins and fluoride preparations for pregnant people, and certain nonprescription tobacco cessation products.<sup>4</sup> In addition, under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) provisions of the Medicaid Act, state Medicaid programs should cover nonprescription medications necessary to correct or ameliorate an illness or condition of a beneficiary who is under age 21.<sup>5</sup>

OTC drugs – whether mandatory OTC drugs required by statute or additional OTC drugs covered at state option – are only included under the federal Medicaid program when are prescribed by an authorized prescriber.<sup>6</sup> In other words, despite the fact that, by definition, a prescription is not required to purchase these medications, states can only obtain federal Medicaid dollars for OTC drugs if they are prescribed.<sup>7</sup> States may also provide OTC drugs that are not prescribed to their Medicaid beneficiaries with state funds. OTCs that are prescribed by an authorized prescriber fall into two categories.

First, some OTC drugs are considered “covered outpatient drugs” under the Medicaid Act. When an OTC drug is prescribed and meets criteria to be considered a “covered outpatient drug” under the Medicaid Act, it is treated as a “covered outpatient drug,” and the other statutory conditions that apply to such drugs apply.<sup>8</sup> CMS has established the following criteria for covered outpatient drugs:

1. It is an FDA-approved prescription drug, biological product, or insulin as defined by statute with an FDA-assigned National Drug Code (NDC);
2. It is not dispensed as part of inpatient hospital services, hospice services, dental services (with limited exceptions), physicians’ services, outpatient hospital services, nursing facility services and services provided by an intermediate care facility, other laboratory and x-ray services, or renal dialysis;
3. It is prescribed for a medically accepted indication, as defined by statute; and
4. The manufacturer has entered a rebate agreement with CMS.<sup>9</sup>

<sup>4</sup> 42 U.S.C. §§ 1396r-8(d)(2)(E), (d)(7)(A).

<sup>5</sup> *Id.* § 1396d(r)(5).

<sup>6</sup> *Id.* §§ 1396r-8(k)(4); DMDL, Defining a “Prescribed Drug” and a “Covered Outpatient Drug” 4 (Oct. 5, 2016) (No. 178) [hereinafter DMDL No. 178], <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-178.pdf>

<sup>7</sup> Defining a “Prescribed Drug” and a “Covered Outpatient Drug” 4 (Oct. 5, 2016) (No. 178)), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-178.pdf>

<sup>8</sup> 42 U.S.C. §§ 1396r-8(k)(4); see Michelle Lilienfeld, Nat’l Health Law Prog., *Medicaid Outpatient Prescription Drugs* (2016) (describing the requirements for drug coverage in Medicaid broadly), <https://healthlaw.org/resource/fact-sheet-medicaid-outpatient-prescription-drugs>.

<sup>9</sup> 42 C.F.R. 447.502; see also DMDL No. 178, *supra* note 6, at 4.

Federal regulations therefore explicitly exclude “[a]ny drug product prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA; [and o]ver-the-counter products that are not drugs” from the definition of covered outpatient drugs.<sup>10</sup>

Second, other OTC drugs may be covered in Medicaid when as “prescribed drugs.” Such drugs need not meet the above criteria for “covered outpatient drugs.” Prescribed drugs may include OTC drugs whose manufacturer has not entered a rebate agreement with CMS or that do not have an NDC number provided by the FDA. In guidance, CMS has described “prescribed drugs” as the larger category of drugs for which federal Medicaid funds are available, which includes, but is not limited to, “covered outpatient drugs,” stating that: “‘covered outpatient drugs’ are a subset of prescribed drugs.”<sup>11</sup> The concept of a prescribed drug is defined in regulation as:

[S]imple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are - (1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of th[eir] professional practice as defined and limited by Federal and State law; (2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and (3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.<sup>12</sup>

CMS has also clarified that “a product [that] meets the regulatory definition of ‘prescribed drug’ . . . may be covered by a state, and is eligible for [federal Medicaid funds]. . . . even if it is not a ‘covered outpatient drug.’”<sup>13</sup> Thus, states may, but are not required to, cover a broad range of OTC medications in their Medicaid programs as long as they meet the regulatory criteria.

## State Examples

While most coverage of OTC drugs is optional for states, the majority (42 jurisdictions in 2018) take up the option.<sup>14</sup> Several states (18 jurisdictions) limit which OTC medications are covered in their Medicaid programs, and many (18) also impose other limitations such as prior authorization, quantity limits, or step therapy requirements.<sup>15</sup> In order to obtain federal Medicaid funds, states must limit coverage of OTC drugs to those prescribed by an authorized

<sup>10</sup> 42 C.F.R. § 440.502(3).

<sup>11</sup> DMDL No. 178, *supra* note 6, at 4.

<sup>12</sup> 42 C.F.R. § 440.120(a).

<sup>13</sup> DMDL No. 178, *supra* note 6, at 4.

<sup>14</sup> See Kaiser Fam. Found., Medicaid Benefits: Over-the-Counter Products, <https://www.kff.org/other/state-indicator/medicaid-benefits-over-the-counter-products> (last visited Nov. 22, 2019).

<sup>15</sup> See *id.*

provider, which can serve as a barrier to care as consumers must take the additional step of consulting a prescriber before obtaining the medication they need. Nonetheless, multiple models for access have emerged and continue to evolve as advocates push for a delivery system that best serves low-income enrollees.

### **Access to OTC contraception**

Federal Medicaid law requires states to cover “family planning services and supplies” without cost-sharing.<sup>16</sup> As with most other Medicaid services, states have some discretion to determine what family planning services and supplies to cover in their programs, as long the coverage is “sufficient in amount, duration, and scope to reasonably achieve its purpose.”<sup>17</sup> There are currently five FDA-approved contraceptive methods available OTC: male/external condom, female/internal condom, spermicide, sponge with spermicide, and levonorgestrel emergency contraception (EC). Notably, federal Medicaid law does not explicitly require coverage of OTC contraceptives and coverage varies widely by state and eligibility pathway.

Additionally, the most common form of utilization control for OTC contraception in Medicaid is a prescription requirement.<sup>18</sup> As of 2016, of the 35 state Medicaid programs that cover levonorgestrel EC, 27 require a prescription.<sup>19</sup> The programs that reportedly allow coverage of this method without a prescription are Georgia (for enrollees under 17), Illinois (3 dose limit per visit), Maryland, Minnesota (maximum of 3 packs per dispensing), Nebraska, New York (up to 6 times per year), Oregon, and Washington.<sup>20</sup> Of the 30 programs that reported coverage of non-EC OTC contraception, 22 require a prescription in all situations.<sup>21</sup> The states reporting coverage without a prescription include Illinois, Indiana, Maryland, Minnesota, Mississippi (internal/female and external/male condoms for family planning waiver enrollees as a medical claim), Nebraska, Oregon, and Texas (external/male condoms and spermicide dispensed by family planning agencies).<sup>22</sup>

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<sup>16</sup> 42 U.S.C. §§ 1396d(a)(4)(C), (10); 42 C.F.R. § 447.56(a)(2)(ii) (prohibiting imposition of cost-sharing for family planning services and supplies). States do not have to cover family planning services and supplies for individuals who qualify for Medicaid due to their status as medically needy. See also 42 U.S.C. § 1396o(a)(2)(d).

<sup>17</sup> 42 C.F.R. § 440.230(b); CMS, STATE MEDICAID MANUAL § 4270.B.

<sup>18</sup> See Kaiser Fam. Found., Medicaid Coverage of Family Planning Benefits: Results from a State Survey, <http://files.kff.org/attachment/Report-Medicaid-Coverage-of-Family-Planning-Benefits-Results-from-a-State-Survey> (last visited Nov. 22, 2019).

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* See also Wash. State Health Care Auth., *Washington Apple Health (Medicaid): Prescription Drug Program Billing Guide* 31, 36, 47 (2019), <https://www.hca.wa.gov/assets/billers-and-providers/prescription-drug-bg-20191001.pdf>.

<sup>21</sup> See Kaiser Fam. Found., *supra* note 18.

<sup>22</sup> *Id.*

Medicaid benchmark benefits for the expansion population must incorporate Essential Health Benefits (EHBs).<sup>23</sup> Federal regulations require the EHB to include coverage of all preventive services required under the ACA, including at least one form of contraception in each of the 18 FDA-approved contraceptive method categories for women.<sup>24</sup> This means that at least one form of male/external condom, female/internal condom, spermicide, sponge with spermicide, and levonorgestrel emergency contraception, all of which are available OTC, must be covered in Medicaid alternative benefit plans, but a prescription may still be required.<sup>25</sup>

Some states have gone beyond federal coverage requirements by passing progressive Contraceptive Equity laws. The scope of coverage under Contraceptive Equity laws varies by state, but specifically apply to OTC contraceptives in the state Medicaid program in Delaware and Washington, DC. In Delaware, coverage of levonorgestrel EC *without a prescription* is required in Medicaid.<sup>26</sup> Alternatively in DC, coverage of all OTC contraceptives is required in Medicaid, but prescription requirements are not clear.<sup>27</sup>

### ***Pharmacist prescribing***

The media often refers to state pharmacist prescribing laws as creating OTC access.<sup>28</sup> However, OTC status is a *federal* FDA designation. Additionally, federal law requires all written Medicaid prescriptions for outpatient drugs, whether handwritten or computer-generated, to be tamper-resistant in order for them to be reimbursed, further complicating OTC access.<sup>29</sup> States, nonetheless, have the power to determine scope of practice, namely who can write a prescription and who can dispense medications. While state pharmacist prescribing laws do not create true OTC access, they do allow pharmacists to prescribe certain drugs that previously could only be accessed through a physician. For example, in California pharmacists can now prescribe self-administered hormonal birth control, naloxone, pre- and post-exposure prophylaxis, nicotine replacement products, flu shots, and travel medications in certain jurisdictions.<sup>30</sup> Pharmacists can also prescribe certain OTC contraceptives in some

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<sup>23</sup> 42 C.F.R. § 440.347.

<sup>24</sup> 45 C.F.R. § 156.115(a)(3).

<sup>25</sup> Dep'ts of Labor, Health & Human Servs., & Treasury, *FAQs About Affordable Care Act Implementation (Part XXVI)* (2015), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf>.

<sup>26</sup> DEL. CODE ANN. tit. 18, § 3342A.

<sup>27</sup> D.C. CODE § 31-3834.02.

<sup>28</sup> See, e.g., Leanne Shinkle, *Over-the-Counter Birth Control Coming to West Virginia*, WSAZ NEWSCHANNEL 3, June 10, 2019, <https://www.wsaz.com/content/news/Over-the-counter-birth-control-coming-to-West-Virginia--511094222.html>.

<sup>29</sup> 42 U.S.C. § 1396b(i)(23).

<sup>30</sup> CAL. BUS. & PROF. CODE §§ 4052(a)(10), 4052.01.

jurisdictions, namely levonorgestrel EC, which allows enrollees to use insurance coverage for this OTC product when purchased from a pharmacy counter.<sup>31</sup>

Pharmacist prescribing is a growing state trend, and payment for pharmacist services is critical to the success of this access model. CMS encourages states to consider using pharmacy access models to promote access.<sup>32</sup> Federal guidance makes clear that state Medicaid programs have the flexibility to expand the scope of services for which pharmacists can receive reimbursement, including dispensing drugs based on independently initiated prescriptions.<sup>33</sup> Yet only a handful of states require Medicaid coverage of pharmacist-prescribed drugs.

In California, legislation authorizes pharmacists to enroll as Medicaid providers and receive reimbursement for furnishing travel medications, naloxone hydrochloride, nicotine replacement therapy, and self-administered hormonal contraception, initiating and administering immunizations, and providing tobacco cessation counseling.<sup>34</sup> Despite the already low Medi-Cal reimbursement rates, the legislation requires the rate of reimbursement for pharmacist services to be at 85% of the fee schedule for physician services.<sup>35</sup>

Other states have narrowly expanded pharmacist prescribing, and consequently pharmacist counseling reimbursements in Medicaid, only for contraceptive services. In Oregon, Medicaid began directly reimbursing pharmacies for contraceptive claims in July 2017.<sup>36</sup> Since then, 10% of all new oral and transdermal contraceptive prescriptions were written by pharmacists, and nearly 74% of those patients had not used any form of prescribed birth control in the prior month.<sup>37</sup> In Maryland, both Medicaid and CHIP must provide coverage to pharmacists for contraceptive services.<sup>38</sup> Similarly in DC, Medicaid reimbursement to a pharmacist for self-administered hormonal contraception is determined by regulation.<sup>39</sup>

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<sup>31</sup> *Id.* § 4052(a)(10)(A)(1).

<sup>32</sup> CMCS, *State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols* (2017), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf>.

<sup>33</sup> *Id.*

<sup>34</sup> CAL. WELF. & INST. CODE § 14132.968(b)(1).

<sup>35</sup> *Id.* § 14132.968(a)(3).

<sup>36</sup> Ass'n of State & Territorial Health Officials, *Oregon Authorizes Pharmacists to Prescribe Hormonal Birth Control* (2017), <https://www.astho.org/Programs/Maternal-and-Child-Health/Documents/Oregon-Authorizes-Pharmacists-to-Prescribe-Hormonal-Birth-Control/>.

<sup>37</sup> Lorinda Anderson et al., *Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population*, 133 OBSTETRICS & GYNECOLOGY 1231 (June 2019).

<sup>38</sup> MD. CODE ANN., HEALTH-GEN. § 15-148(c).

<sup>39</sup> D.C. CODE § 3-1202.08(g-1)(3).

Finally, a small number of states have implemented Medicaid-covered pharmacist prescribing only for emergency contraception, due to the time-sensitive nature of the medication. In Massachusetts, Medicaid requires coverage of levonorgestrel EC without a prescription when dispensed by a pharmacist.<sup>40</sup> In New Mexico, Medicaid can pay for levonorgestrel EC as either a prescription or OTC drug, although the term OTC may be misleading in this context since both options require pharmacy claims.<sup>41</sup>

## **Conclusion**

This Fact Sheet has provided an overview of Medicaid OTC drug coverage rules, and examples of how states have provided access to OTC drugs in their Medicaid programs. For in-depth information, advocates should check federal transmittals and guidance documents, and state law. In addition, advocates should look at court decisions that address how the Medicaid requirements have been interpreted and state efforts to expand or restrict Medicaid OTC drug coverage and access. Please visit our website at [healthlaw.org](http://healthlaw.org) for further Medicaid OTC drug publications and updates.

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<sup>40</sup> MASS. GEN. LAWS ch. 118E, § 10K.

<sup>41</sup> N.M. Human Servs. Dep't, Med. Assistance Program Manual Supplement 09-05 (2009), <https://www.nmpharmacy.org/Resources/Documents/EC-OTC%20Medicaid%20Supplement.pdf>.