



Date: March 18, 2024

To: Pharmacies licensed in Wisconsin

From: Wisconsin Department of Health Services (DHS)

**Standing Order for OTC Norgestrel (Opill) Pills for Members of Wisconsin's  
Medicaid Programs**

**Definition**

A standing order is defined in Wis. Stat. § 450.01(21p) as an order transmitted electronically or in writing by a practitioner for a drug or device for multiple patients or for one or more groups of patients. A centralized standing order for pharmacists outlines predetermined conditions and criteria that, when met, enable pharmacists across Wisconsin to dispense over-the-counter hormonal contraception in the form of norgestrel (Opill) for Medicaid members, without a patient-specific prescription order. A licensed physician in Wisconsin and chief medical officer within the Department of Health Services (DHS) may issue a standing order that delegates authority to pharmacists practicing and licensed in Wisconsin to dispense over-the-counter hormonal contraception pills to those Medicaid member patients specified in the standing order.

**Subject**

Statewide Standing Order for Pharmacies – Over-the-counter norgestrel (Opill) hormonal contraception for Medicaid members

**Effective date**

March 18, 2024

**Expiration of standing order**

This order is effective as of the date signed and shall remain effective until withdrawn by Dr. Huebner, the secretary of DHS, or either's designee. Dr. Huebner retains the right to modify or supplement this order as needed.

**Approved for use as a population-based standing order by**

Wisconsin Department of Health Services

## **Purpose**

This standing order for Medicaid members delegates authority to pharmacists and outlines the policies and procedures necessary for dispensing over-the-counter hormonal contraception in the form of norgestrel (Opill) without a patient-specific prescription to authorized individuals. While many over-the-counter medications are covered for Medicaid members, federal rules require that members have a prescription from a health care provider in order for the drug(s) to be obtained through their coverage. This standing order is written to facilitate the administrative function of over-the-counter hormonal contraception medication coverage, in order to improve access for Medicaid members.

## **Policy**

This standing order authorizes pharmacists, located and licensed in Wisconsin, to maintain supplies of hormonal contraception pills for the purposes stated herein and does not prevent the use of patient-specific or third-party prescriptions for hormonal contraception pills written by prescribers.

## **Authority**

This standing order is issued pursuant to Wis. Stat. § 49.45(1), which permits the department to administer the medical assistance program, provide appropriate health care for eligible persons, and obtain the most benefits available under Title XIX of the federal Social Security Act.

## **Procedures**

This standing order authorizes pharmacists to dispense OTC hormonal contraception pills in the form of norgestrel (Opill) to members with coverage by Medicaid pursuant to the following procedures outlined herein:

### **Indication**

Norgestrel (Opill) tablets are indicated for use by members of reproductive potential and age to prevent pregnancy.

Because the efficacy of hormonal contraception is based on timely administration, an advance supply of contraception may be provided with instructions for future use.

### **Contraindications**

Known or suspected pregnancy. Norgestrel (Opill) tablets are NOT for use as emergency contraception.

Known or suspected breast cancer, or other progestin-sensitive cancer, now or in the past.

Undiagnosed abnormal uterine bleeding.

Hypersensitivity/allergy to any component of this product.

Benign or malignant liver tumors.

Acute liver disease.

### **Warnings/Precautions**

**Ectopic pregnancy:** Health care providers should be alert to the possibility of an ectopic pregnancy in patients who become pregnant or complain of lower abdominal pain while on norgestrel (Opill) tablets, and promptly refer such patients to their health care provider.

**Delayed follicular/ovarian cysts:** These may occur during hormonal contraception use. They often are asymptomatic and resolve spontaneously. In some cases, they are associated with abdominal pain and need surgery, and patients should be promptly referred to their health care provider.

**Abnormal bleeding patterns:** Irregular menstrual patterns are common among patients using norgestrel (Opill) tablets. Undiagnosed abnormal uterine bleeding should be evaluated before norgestrel (Opill) is prescribed (see contraindications).

**Liver disease:** Discontinue norgestrel (Opill) tablet use if jaundice or acute disturbances of liver function develop (see contraindications).

**Headache/Migraine:** The onset or exacerbation of migraine, or development of headache with a new pattern that is recurrent, persistent, or severe requires evaluation of the cause because patients with migraine may be at increased risk of stroke.

**Drug interactions:** The effectiveness of progestin-only pills is reduced by hepatic enzyme-inducing drugs such as phenytoin, carbamazepine, barbiturates, rifampin, efavirenz, bosentan and herbal preparations containing St. John's Wort (*hypericum perforatum*). This could result in unintended pregnancy or breakthrough bleeding. During concomitant use of norgestrel (Opill) and substances that may affect its efficacy, it is recommended that a nonhormonal back-up method of contraception (such as condom) be used in addition to the regular intake of norgestrel (Opill) tablets. Use of a nonhormonal back-up method is recommended for 28 days after discontinuation of substances that have led to induction of hepatic microsomal enzymes. For patients receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be considered.

Effectiveness of progestin-containing hormonal contraceptives and emergency contraceptive ulipristal acetate (Ella) may be decreased if progestin-containing hormonal contraceptives are used within five days after ulipristal acetate dosing. If a patient wishes to use norgestrel (Opill) tablets after using ulipristal acetate, they should do so no sooner

than 5 days after the intake of ulipristal acetate and they should use a reliable barrier method for subsequent acts of intercourse until their next menstrual period.

Consult the product information of concomitant medications/substances to identify potential interactions.

**Gastrointestinal:** Diarrhea and/or vomiting within 4 hours after taking a pill may reduce hormone absorption. Patients should use a nonhormonal back-up method of birth control (such as a condom or spermicide) during the next 48 hours.

**Pregnancy:** Norgestrel (Opill) tablets are contraindicated for use in pregnant patients because there is no need for pregnancy prevention in someone who is already pregnant (see contraindications). Published studies report no harmful effects on fetal development associated with long-term use of contraceptive doses of oral progestins in pregnant patients. Discontinue norgestrel (Opill) tablets if pregnancy is confirmed.

**Nursing:** Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma. No adverse effects have been reported on breastfeeding performance or infant health.

**Fertility following discontinuation of hormonal contraception:** The limited available data do not indicate a significant delay in the return of normal ovulation and fertility following discontinuation of progestin-only oral contraceptives.

**Pediatric use:** Safety and efficacy of norgestrel (Opill) tablets have been established in patients of reproductive age, including adolescents as young as 15 years of age, and almost 30% of subjects in the clinical trials were under 20 years of age. Use of this product before menarche is not indicated.

**Overdosage:** Symptoms of oral contraceptive overdosage may include nausea, vomiting, breast tenderness, dizziness, somnolence (drowsiness/fatigue), and withdrawal bleeding. There is no specific antidote and further treatment of overdose, if necessary, is directed to the symptoms.

### **Administration/Use**

Norgestrel (Opill) is a progestin-only form of hormonal contraception. In order to achieve maximum contraceptive effectiveness, norgestrel (Opill) tablets must be taken exactly as directed. The patient should take one tablet every day, at the same time. Administration is continuous, with no interruption between pill packs.

### **Side Effects**

Like any medication, norgestrel can have side effects. The most common side effects may include irregular vaginal bleeding, nausea, breast tenderness, and headaches. These

side effects are generally mild and often resolve on their own, but it is important to seek medical advice if they are persistent or severe. An increased risk of the following adverse reactions has been reported with the use of progestin-only oral contraceptives (see WARNINGS section for additional information):

- Delayed follicular atresia/ovarian cysts.
- Menstrual irregularity, changes in menstrual flow; breakthrough bleeding/spotting; amenorrhea; prolonged bleeding.
- Headache
- Dizziness
- Nausea
- Increased appetite
- Abdominal pain, cramps, and bloating
- Fatigue
- Vaginal discharge
- Dysmenorrhea
- Nervousness
- Backache
- Breast discomfort
- Acne

### **Hormonal Contraception consultation with patient**

1. Confirm patient indication for hormonal contraception with Norgestrel (Opill) as noted above and confirm selected OTC product is covered by Medicaid.
2. Screen for contraindications and drug-drug interactions as noted above.
3. Review proper use/administration.
4. Discuss possible side effects.
5. Provide FDA-approved written patient instructions to read about proper use of norgestrel (Opill).
6. Encourage patient to pursue consultation with their health care provider, to consider their best options for longer term contraception use.

**Dispense Contraception: OTC norgestrel (Opill) 0.075 mg: Take one tablet by mouth once daily at the same time. Quantity supplied: May dispense up to 84 tablets, with PRN refills to allow for up to a one year's supply.**

## **Patient Instructions**

Take one tablet by mouth daily, at the same time every day.

Norgestrel (Opill) tablets should be taken at the same time every day, including throughout all bleeding episodes. Patient should use a nonhormonal back-up method of contraception (such as condoms or spermicides) for the next 48 hours whenever norgestrel (Opill) tablets are taken 3 or more hours late, or if they have vomiting or diarrhea within 4 hours after taking the pill.

Use of norgestrel (Opill) tablets may be associated with changes in their normal menstrual bleeding pattern. However, patients who miss two periods (or have missed a single period but have missed doses of norgestrel [Opill]) or suspect they may be pregnant should take a pregnancy test.

Patients should inform their health care provider if they develop repeated vaginal postcoital bleeding, prolonged episodes of bleeding, amenorrhea, or development of severe abdominal pain. The patient is encouraged to contact their primary care professional, reproductive health provider, or family planning clinic for follow-up, especially if they have symptoms of concern, concerns for STIs, or need additional contraceptive counseling.

Hormonal contraception such as norgestrel (Opill) does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs). The patient should be seen by a health care provider for evaluation if they have concerns about possible STI risk or transmission.

### **Hormonal Contraception Norgestrel (Opill) Pills for Wisconsin Medicaid members Standing Order Signature:**



Signature

March 18, 2024

Date

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