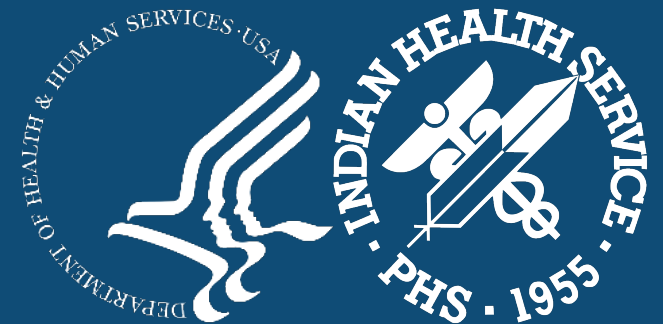


Implementation of Opill[®] - The First OTC Oral Contraceptive

July 23, 2024

Indian Health Service

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Opill® Approval & Launch



- Opill® (norgestrel 0.075mg) is the **first ever** over-the-counter (OTC) oral contraceptive or “birth control pill”
- Opill® is reshaping access to oral contraception **without barriers**
 - It can be found at retail locations across the U.S. (grocery stores, drug stores, pharmacies, online) with purchase (~\$20 for a 1 month supply)
 - Through pharmaceutical distributors for health care systems at no cost at IHS facilities
- Opill® has been used for over 50 years, with a proven safety record
- It is 91-98% effective (typical use vs perfect use) and starts working within 48 hours
- It is estrogen-free and safe to use post-partum, while breastfeeding/chestfeeding, and in individuals who have migraine headaches, high blood pressure, or other contraindications to estrogen-containing contraceptives

Opill[®] Approval & Launch



Norgestrel is approved by the FDA as a daily contraceptive pill

Journey from prescription to OTC started

OTC application for Opill[®] submitted to the FDA

FDA approves Opill[®] as the first daily oral contraceptive in July 2023

Opill[®] becomes commercially available late March / early April 2024

- Opill[®] was added to the IHS National Core Formulary in August 2023
- Dr. Christensen, IHS Chief Medical Officer, announced the availability of Opill[®] through usual pharmaceutical distributors in the IHS on April 8, 2024

Opill® Launch in the IHS

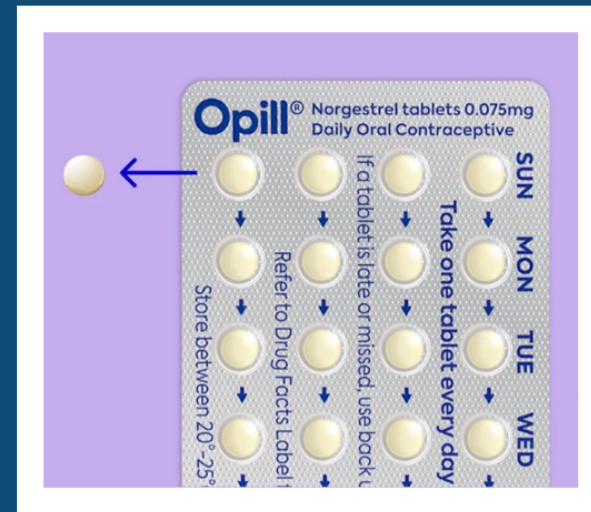


- Opill® was added to the IHS National Core Formulary in August 2023
 - This requires that this Opill® be available at all IHS federal facilities (once commercially available)
 - Tribal and Urban facilities are highly encouraged to provide access to Opill®
- Opill® is available **upon request with as few barriers as possible**, similar to OTC emergency contraception dispensing practices
 - IHS encouraged Opill® incorporation into current local policies, practices, and workflows in a way that works best for the local site and meets patient needs
 - Opill® should be offered as part of a comprehensive family planning portfolio with a wide variety of contraceptive options at the local facility
- Supply vs demand was a challenge in the first few weeks of the launch

Implementation Considerations



- IHS wanted to ensure Opill® access was expedited across the agency
 - New policies, new collaborative practice agreements, standing orders, protocols, and new workflow processes can take time to implement
- In anticipation of the needed resources at the local level, EXAMPLE resources were created.
 - Launch of the EXAMPLE resources coincided with commercial product availability
- IHS facilities determined the best way to implement Opill®
 - OTC processes vary from facility to facility
 - Pharmacy protocols vs other methods
 - No out-of-pocket cost for patients
 - Variable days supply available (1, 3, 6 month packs available)





EXAMPLE
resources were
shared widely
across the IHS

Example Opill[®] Resources

- EXAMPLE resources were distributed to assist with rapid uptake and implementation
- EXAMPLE resources could be adopted or adapted to meet the facility's needs and expedite the incorporation of this OTC family planning option into local practices
- EXAMPLE resources distributed:
 - Navigating Opill[®] - Considerations for Policies and Documentation
 - Example Opill[®] Pharmacy Policy
 - Example Opill[®] Patient FAQ Handout
 - Example Opill[®] Provider Handout
 - Example Opill[®] Only Screening Form
 - Example Opill[®] + Emergency Contraception Screening Form
- The EXAMPLE resources were distributed through IHS listservs and the Maternal and Child Health communication network

Example Opill® Resources

Opill® (Norgestrel 0.075mg) Over the Counter (OTC) Oral Contraception Example Pharmacy Policy

TJC Reference: ()

Purpose:

Offer comprehensive family planning options for contraceptive care, including providing access to the-counter birth control pills, Opill® (norgestrel 0.075mg), at (insert location here) without requiring a medical visit. This policy defines processes for patients to request Opill® (norgestrel 0.075mg) and outlines the procedures for patients who opt to receive education and counseling.

Definitions:

Opill® (norgestrel 0.075 mg) is an oral progestin-only contraception pill that is now available over the counter upon request without a provider visit. There is no age restriction. Opill® (norgestrel 0.075mg) can be used to prevent pregnancy in people who can become pregnant.

Policy:

(insert location here) shall make OTC Opill® (norgestrel 0.075mg) oral contraception available upon request to all people who may become pregnant who are eligible for care at (insert location here) for the purpose of pregnancy prevention.

The service unit will ensure the distribution of Opill® (norgestrel 0.075mg) does not require any of the following:

- A prescription
- A pregnancy test
- Age verification
- A medical visit

Contraception will be provided with the package insert. Supplemental educational materials may be provided.

Patients who may become pregnant of any age may present to (insert location here) to request Opill® (norgestrel 0.075mg) from the pharmacy without a prescription to reduce the risk of pregnancy. Pharmacists may order and dispense Opill® (norgestrel 0.075mg). Any counseling provided and acceptance of the counseling should be documented, as well as documentation of educational materials provided, additional information about Sexually Transmitted Infection (STI) screening or other contraceptive options, and referrals to other medical care providers.

Navigating Opill® (Norgestrel 0.075mg) Considerations for Policies and Documentation

Opill® (norgestrel 0.075mg) is available OTC, so patients may purchase it at any retail store in the family planning aisle, at a retail pharmacy, or they may order it online. Opill® (norgestrel 0.075mg) comes in a single pack for a 28-day supply or multi-month packs. Opill® (norgestrel 0.075mg) is now available through the IHS Pharmaceutical Prime Vendor, McKesson, and other pharmaceutical distributors.

Here are some FAQs for determining how your site may consider integrating Opill® (norgestrel 0.075mg) into existing services:

Is a policy necessary for my pharmacy or clinic to dispense Opill® (norgestrel 0.075mg)?

Even though Opill® is OTC, it would be ideal to define precisely who will dispense Opill® (norgestrel 0.075mg) and how it will be dispensed. Some sites may already have existing policies for OTC birth control pills. Opill® (norgestrel 0.075mg) can be used to prevent pregnancy in people who can become pregnant. Patients may request Opill® (norgestrel 0.075mg) without a prescription. Documentation of counseling and acceptance of the counseling should be documented.

Take Control Of Your Choices, Your Birth Control and Your Future with Opill®



First-ever Over-the-Counter Birth Control Pill
No Prescription Needed
No Insurance Needed



Site Name

Opill® (norgestrel 0.075mg):

- Is FDA approved
- Has been used for over 50 years
- Begins working in 48 hours
 - Use back-up contraception for the first 48 hours (such as condoms)
- Is time sensitive!
 - It MUST be taken every day within a 3-hour window
- Is safe after having a baby and while breast/chestfeeding
- Is 91-98% effective when taken daily and a backup method of contraception is used for 48 hours after late/missed doses
- May cause irregular bleeding or no bleeding

Details here about how to access Opill® (norgestrel 0.075mg) at your site.

Phone: (000) 000-0000
Hours of Operation

Example Opill® Resources

Opill® (Norgestrel 0.075mg) Progestin-only OTC Oral Contraceptive Provider Information

What is Opill® (norgestrel 0.075mg) and what are the recent changes?

Opill® (norgestrel 0.075mg) was approved by the FDA in July, 2023, but it was not commercially available until late March/early April 2024. Opill® (norgestrel 0.075mg) is the first and only daily oral contraceptive for over-the-counter (OTC) use. Being available OTC will increase wide-spread availability and reduce barriers to accessing oral birth control options without healthcare provider evaluation.

Where will patients be able to access it?

Once Opill® (norgestrel 0.075mg) is commercially available, it can be purchased OTC at drug stores, convenience stores, pharmacies and online. IHS sites are highly encouraged to order and dispense their usual pharmaceutical distributors. Many IHS pharmacies will incorporate Opill® (norgestrel 0.075mg) into their current contraception or OTC policies. Opill® (norgestrel 0.075mg) should be offered as part of a comprehensive family planning portfolio with a wide variety of contraceptive options for people of all ages and childbearing age.

What is the anticipated cost of OTC Opill® (norgestrel 0.075mg)?

The manufacturer's suggested retail price is anticipated to be approximately \$20 for a 28-day supply of medication, and approximately \$50 for a 84-day supply of medication.¹ Check with your pharmacy or pharmaceutical distributor for acquisition pricing for your site.

Will Opill® (norgestrel 0.075mg) be covered by health insurance plans?

Existing language in some private and state Medicaid plans may allow for coverage of OTC birth control as Opill® (norgestrel 0.075mg), however coverage will be determined in real-time in the coming months.

Is Opill® (norgestrel 0.075mg) safe and effective?

When used as directed, Opill® (norgestrel 0.075mg) is safe and effective. With perfect use, Opill® (norgestrel 0.075mg) is approximately 98% effective in the first year of use. Typical use effectiveness is lower, at approximately 91% in one year of use.² Typical use effectiveness accounts for human errors, such as missed pills, late pills, or using backup methods when a person misses a pill.

Opill® (norgestrel 0.075mg) is generally safe for most people who could get pregnant. It is also safe for individuals that have contraindications to estrogen-containing contraceptive pills, including smokers, individuals who are breastfeeding/chestfeeding, and individuals who have a history of migraines without aura.³

Opill® (Norgestrel 0.075mg) Oral Over-The-Counter Birth Control Pills Frequently Asked Questions for Patients

What is Opill®?

Opill® is a daily oral birth control pill that is now available without a prescription. Opill® can be used to prevent pregnancy in people who can become pregnant.

Does Opill® contain estrogen?

No, Opill® is a progestin-only birth control pill, with no estrogen in it. Progestin is similar to a hormone in our bodies that plays a role in the menstrual cycle and pregnancy. Unlike birth control pills that contain estrogen, progestin-only pills do not increase the risk of blood clots, high blood pressure or heart disease.

Can I use Opill® while breastfeeding?

Yes, progestin-only pills may be used while breastfeeding/chestfeeding. Opill® can also be used immediately after childbirth to prevent pregnancy.

When and where can I get Opill®?

Opill® is available across the U.S. as of early April 2024. Check with your local IHS facility or IHS pharmacy to determine availability near you. Opill® will also be available over the counter and may be purchased at retail stores, pharmacies, and online.

How do I take Opill® for it to be most effective?

Opill® must be taken daily at the same time every day to prevent pregnancy. Opill® is very time-sensitive and must be taken within a 3-hour window of the time when you usually take your daily dose. Once you start taking the medication daily, Opill® will be effective after 48 hours. A backup method for pregnancy, such as condoms, should be used for the first 48 hours. When you finish one pack of 28 daily tablets, you should immediately start a new pack the next day at your usual dose time.

What if I miss a dose or take my pill late?

If you miss a dose of Opill® or take it 3 hours or more after your usual time, you should take your dose immediately and use a backup method of contraception, such as condoms, for 48 hours.

Example Opill® Resources

Contraceptive Care Screening

All information is OPTIONAL to determine appropriateness and the ideal use of OTC emergency contraception and/or OTC oral birth control. Detailed information is needed for Ulipristal 30mg, which is prescription only.

WALK-IN CONTRACEPTION REQUEST		
<input type="checkbox"/> Emergency Contraception + Condoms	<input type="checkbox"/> OTC Birth Control + Condoms	<input type="checkbox"/> Condoms

Levonorgestrel 1.5mg Screening **OTC** EMERGENCY CONTRACEPTION	Ulipristal 30mg Screening **PRESCRIPTION ONLY** EMERGENCY CONTRACEPTION
Timing of intercourse <input type="checkbox"/> 3 days (72 hrs) or less since unprotected intercourse or a failed contraceptive occurred	Timing of intercourse <input type="checkbox"/> 5 days (120 hrs) or less since unprotected intercourse or a failed contraceptive occurred
BMI Assessment <input type="checkbox"/> Patient BMI is under 25 kg/m ² (or under 165 lbs) • Ideal for maximum effectiveness <input type="checkbox"/> Patient BMI is <u>over</u> 25 kg/m ² (or over 165 lbs) • Levonorgestrel 1.5mg effectiveness may be lower, consider prescription-only ulipristal 30mg	BMI Assessment <input type="checkbox"/> Patient BMI is under 25 kg/m ² (or under 165 lbs) • Any BMI is acceptable for ulipristal 30mg <input type="checkbox"/> Patient BMI is <u>over</u> 25 kg/m ² (or over 165 lbs) • Ulipristal 30mg may be more effective than levonorgestrel 1.5mg in individuals with a BMI over 25 kg/m ²
Contraindications None	Contraindications <input type="checkbox"/> Use of ulipristal more than once per menstrual cycle • May take if a menstrual cycle occurred since previous dose <input type="checkbox"/> Current Breastfeeding/Chestfeeding

BODY MASS INDEX (BMI) – Weight and height may impact the effectiveness of Levonorgestrel 1.5mg!
 When possible, it is ideal to gather information to offer the most effective emergency contraception method.
 Weight: _____ kg/lbs (circle one) Height: _____ cm/inches (circle one) BMI: _____ kg/m² (see BMI chart)

Opill® (Norgestrel 0.075mg) Screening - **OTC** BIRTH CONTROL PILL	
CONSIDERATIONS/ CONTRAINDICATIONS – Opill® is not recommended with any "Yes" response in this section	
Is the patient currently pregnant or suspected to be pregnant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does the patient have a history of breast cancer or a current breast cancer diagnosis?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does the patient have an allergy to <u>norgestrel</u> or progestin-only contraceptives?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the patient ACTIVELY using other birth control including oral birth control pills, vaginal rings, patches, implants, injections, or an IUD (intra-uterine device)? • If yes, they may transition to Opill® after consideration and discussion around discontinuation of the current birth control method.	Yes <input type="checkbox"/> No <input type="checkbox"/>
POTENTIAL DRUG INTERACTIONS – A "Yes" response should prompt further discussion with a pharmacist or healthcare provider	
Has the patient used the emergency contraception medication ulipristal (Ella®) in the past 5 days? • If yes, Opill® start should be delayed by 5 days and a reliable contraceptive backup method (condoms) should be used until the next menses.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the patient taking liver enzyme inducer medications (e.g., phenytoin, carbamazepine, rifampin, barbiturates, efavirenz, <u>bosentan</u> , or St. John's Wort)? • If yes, Opill® effectiveness is reduced and may result in unintended pregnancy or breakthrough bleeding.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Contraceptive Care - Screening for Opill®

All information is OPTIONAL to determine appropriateness and the ideal use of OTC oral birth control.

Opill® (Norgestrel 0.075mg) Screening - **OTC** BIRTH CONTROL PILL	
CONSIDERATIONS/ CONTRAINDICATIONS – Opill® is not recommended with any "Yes" response in this section	
Is the patient currently pregnant or suspected to be pregnant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does the patient have a history of breast cancer or a current breast cancer diagnosis?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does the patient have an allergy to <u>norgestrel</u> or progestin-only contraceptives?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the patient ACTIVELY using other birth control including oral birth control pills, vaginal rings, patches, implants, injections, or an IUD (intra-uterine device)? • If yes, they may transition to Opill® after consideration and discussion around discontinuation of the current birth control method.	Yes <input type="checkbox"/> No <input type="checkbox"/>
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REFERRAL/INTEREST IN ALTERNATE CONTRACEPTION OPTIONS?	
Is the patient interested in other contraceptive options and would like to be referred to a provider for a medical or contraceptive visit?	Yes <input type="checkbox"/> No <input type="checkbox"/>



Thank You!

For example resources, contact:

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