

# Free the Pill

## For Providers: Frequently Asked Questions about Opill

### What is Opill (norgestrel 0.075 mg)?

Opill is a progestin-only daily birth control pill (POP) that contains the progestin norgestrel 0.075mg. It was approved by the US Food and Drug Administration (FDA) in July 2023 as the first and only oral contraceptive available over the counter (OTC) in the US, and is now the most effective OTC contraceptive option available in the country. At a suggested retail price of \$19.99 per monthly pack, Opill is available for sale online and at major retailers across the country, and is available to people of all ages, with no age restriction. Two other types of POPs (norethindrone 0.35 mg and drospirenone 4 mg) are available in the US, but currently require a prescription. POPs containing other progestins, including desogestrel and levonorgestrel, are available in other countries.

### Do providers support over-the-counter access to oral contraceptives?

Major medical associations—including the [American Academy of Family Physicians](#), the [American College of Obstetricians and Gynecologists](#), the and the [American Medical Association](#)—support OTC access to oral contraceptives without age restrictions because they are safe and effective.<sup>[1]</sup>

### What are the contraindications to POPs?

POPs are safe for most people to take. Studies have shown a low prevalence of contraindications for POPs <sup>[2,3]</sup>, which include breast cancer, severe cirrhosis, liver tumors, systematic lupus, having had malabsorptive bariatric surgery, and taking certain anticonvulsants or antimicrobial treatments.<sup>[4]</sup> Contraindications to oral contraceptives are rarer among adolescents compared to adults.<sup>[5]</sup>

### Can people safely take POPs without a prescription?

Research demonstrates that people can safely take POPs without having to obtain a prescription from a provider and that they can accurately self-screen for contraindications. A self-screening study of over 1,200 women found that less than 1% incorrectly thought they were appropriate for a POP when they were not, or incorrectly thought that a POP was not safe for them.<sup>[2]</sup> Research also indicates that adolescents can understand the drug facts label <sup>[6]</sup> to determine if OTC oral contraceptives are right for them and that minors can self-screen for contraindications as well as or better than young adults.<sup>[7]</sup> As part of the application to the US FDA to make Opill available OTC, a study must be conducted to assess

whether people can determine whether Opill was appropriate for them after reading the drug facts label. Of the 1,172 adults and teens who participated in the study, 98% correctly decided whether Opill was appropriate for use or not.<sup>[8]</sup>

### **How effective are POPs and Opill in particular?**

With perfect use, POPs are 99% effective, and with typical use they are currently estimated to be 93% effective.<sup>[9]</sup> Findings from a recent review suggest that POPs may be closer to 98% effective with typical use and another review estimated a similar rate for norgestrel 0.075mg in particular.<sup>[10]</sup> Opill, when used as directed, is 98% effective.<sup>[11]</sup> While there is insufficient data from randomized controlled trials to compare the effectiveness of POPs with COCs, both types of birth control pills are much more effective than any other form of contraception currently available OTC in the US.<sup>[12]</sup>

### **Is there any new research on timing of intake for POPs and for Opill in particular?**

Current guidance recommends POPs be taken at the same time each day within a three-hour window.<sup>[13]</sup> However, recent research suggests that for some POP formulations, including Opill, there is likely a wider window of time for maintaining efficacy if a pill is missed or delayed.<sup>[14–16]</sup> There is very little clinical data supporting this strict 3-hour timing for intake.<sup>[17]</sup>

### **How do users of Opill feel about bleeding changes?**

Bleeding changes are a common side effect of using progestin-only contraceptives<sup>[13,18]</sup> and research has shown that these changes can be viewed as positive or negative.<sup>[19]</sup> Of the 2,575 people who used Opill in clinical trials, about half experienced bleeding changes, including 49% experiencing breakthrough bleeding, 47% experiencing spotting, and 29% experiencing amenorrhea.<sup>[20]</sup> A follow-up study of 550 adults and 115 teens who participated in a trial evaluating OTC use of Opill found that 80% felt the menstrual bleeding they experienced was acceptable or they were neutral about it.<sup>[21]</sup>

### **How can health care professionals support patients using OTC contraceptive methods?**

Health care professionals can be a trusted source of information for many people, especially adolescents, when making decisions about their reproductive health. Research has shown that many young people prefer to get answers to questions about an OTC POP by asking a pharmacist or other health care provider.<sup>[21]</sup> As Opill may be the first contraceptive method used by some people, it is essential for health

care professionals to have accurate information about Opill when providing contraceptive counseling and when answering questions asked by Opill users. It is also important for health care professionals to be supportive, non-judgmental, and informative about confidentiality and disclosure policies—especially when interacting with adolescents and young adult patients.

#### Other resources for health care professionals:

- [opillhcp.com](https://opillhcp.com) – Opill’s website for health care providers
- Opill’s [consumer information leaflet](#)
- JAMA Network’s [patient page on OTC POPs](#)
- Commentary: [A clinical perspective on Opill](#) in *Obstetrics & Gynecology* (February 2024)
- Free the Pill’s [research summary on safety and efficacy of OTC POPs](#)
- ACOG’s [Practice Advisory on Opill](#)
- Medscape’s [CME & Education module on Opill and OTC contraception](#)
- Free the Pill’s [Opill FAQ for the general public](#)

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