

Over-the-counter birth control: background on progestin-only pills

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is committed to making the birth control pill available OTC to reduce disparities in reproductive health care access and outcomes, and to increase opportunities to access safe, effective contraception, free of barriers created by the need for a prescription, as part of a healthy sexual and reproductive life. Since 2004, our coalition has grown to comprise a diverse group of reproductive health, rights, and justice organizations, nonprofit research and advocacy groups, university-based researchers, and clinicians.

Based on collaborative review of the data along with scientific experts, the OCs OTC Working Group has reached broad consensus that a progestin-only pill (POP) is the best option for the first OTC OC in the United States because it presents the fewest barriers to the broadest population.

All OCs, including POPs and combined OCs (COCs, which contain both progestin and estrogen), are highly effective at preventing pregnancy, and this document provides more information on why the working group has decided to pursue a POP switch.

POPs are the safest OC option for the broadest population.

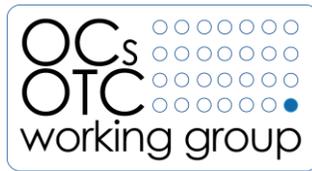
- There are very few contraindications to POPs (conditions that might make using an OC unsafe or make the pill less effective).
- These few contraindications to POPs are very rare. Less than 2% of women of reproductive age have a contraindication to POPs.
- All contraindications to POPs can be easily identified by people on their own, meaning the diagnosis of such a condition requires no medical tests or consultation with a clinician. Therefore, people can easily identify whether they have any health conditions that might make taking POPs riskier or reduce the pill's efficacy.

FDA approval of an OTC POP will likely be faster and more direct.

- The FDA has already approved progestin-only emergency contraception for OTC sale.
- COC products have a “black box” warning in the labeling related to smoking and cardiovascular side effects that may make the pathway to OTC approval more challenging.

POPs are an effective contraceptive choice for people in the United States and across the globe.

- While COC pills are currently more commonly used than POPs in the United States, in Europe, POPs are one of the most popular contraceptive methods.
- While the working group is initially pursuing a POP, the pill type that presents the fewest barriers to the broadest population, we look forward to a day when both POPs and COCs are options in the US market as OTC products.



Questions and answers about progestin-only pills (POPs)

Question: What is a progestin-only pill?

Answer: A progestin-only pill (POP) is a type of birth control pill that does not contain estrogen. All birth control pills are very safe and effective. However, because POPs lack the estrogen in combined oral contraceptives (COCs), they do not have the rare risk of estrogen-related complications such as stroke, heart attack, or blood clots (pulmonary embolus or deep venous thrombosis). Breastfeeding mothers and trans-masculine individuals may also desire to use a POP to avoid additional estrogen. Like all methods, POPs have pros and cons, and people considering a POP need to know that many users experience bleeding changes that, although usually tolerable, may mean they are not the best choice for everyone. Just like COCs, you take one pill a day. However, with a POP, you need to take it at the same time every day—if you take it more than three hours late, you need to use a back-up birth control method (like condoms) every time you have sex for 48 hours according to the label.

Question: How does the safety of POPs compare to COCs?

Answer: Both POPs and COCs are very safe. However, POPs have fewer and rarer contraindications (i.e., health conditions that might make use harmful or might make the pill less effective) compared to COCs. Most of the contraindications to COCs are related to the estrogen they contain. In a study of women aged 18-49, fewer than 2% had a contraindication to POPs, whereas 39% had at least one contraindication to COCs. However, in another study, only 2% of women seeking COCs and other combined hormonal contraceptive methods, such as the patch or ring, had any contraindications.

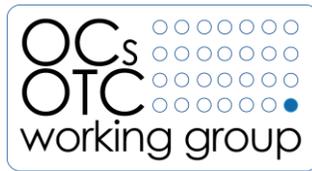
POPs present the fewest barriers to the broadest population. For example, certain communities, such as African-Americans, have a higher prevalence of hypertension, which is a contraindication to COCs and other products containing estrogen. But POPs are safe for people with hypertension. A POP is also the recommended OC option for smokers aged 35 or over, and those with cardiovascular disease or a history of blood clots (pulmonary embolus or deep venous thrombosis).

Question: How does the efficacy of POPs compare to COCs?

Answer: The pill—including POPs and COCs—is one of the most effective birth control methods available. There is insufficient evidence to compare efficacy between POPs and COCs, but both pill types are about 99% effective when used exactly as directed and 91% effective with typical use, meaning usually, but not always, used exactly as directed. In addition, an OTC POP or COC would be much more effective than other contraceptive options that are currently available OTC, such as condoms or spermicide.

Question: Can you tell me more about this three-hour window for POPs?

Answer: The labeling of most POPs requires taking the pill at the same time every day—if you take it more than three hours late, you need to use a back-up birth control method for 48 hours. There are pill reminder apps people can use on their computer or phone to remember to take the pill. More research is needed to understand if this three-hour window is really necessary, but for now, it's important to follow this recommendation.



Question: Most birth control pill users in the United States use COCs—would people be interested in a POP?

Answer: In the United States, POPs are much less common than COCs, accounting for only about 4% of all pill users. In Europe, however, they are one of the most popular methods that people use, and it is possible that, if more easily available, a POP could gain popularity in the US as well, particularly given its safety profile compared to COCs.

Question: Who most commonly uses POPs in the United States currently?

Answer: POPs are commonly used by people who are breastfeeding, since estrogen in COCs may reduce milk production. POPs are also sometimes used by people with health conditions like hypertension or older people who smoke, who are advised not to use COCs. Potential consumers will have to be educated about POPs and how they differ from the pill type they may be familiar with (COCs).

Question: Why are COCs more common than POPs in the United States?

Answer: We believe that the low use of POPs in the US is more related to a lack of familiarity and marketing, rather than something intrinsically unappealing about the formulation. Given that POPs have fewer contraindications compared to COCs and the potential for greater access through OTC availability, we are confident that they could gain widespread use in the US.

Question: What effects do POPs have on menstruation?

Answer: Breakthrough bleeding is more common with POPs; people considering POPs should get accurate information about potential side effects, just like people considering other progestin-only contraceptive methods, such as injectables, implants, and levonorgestrel-containing IUDs like Liletta, Mirena or Skyla. Additionally, POPs may result in lighter periods or stop a person's period altogether, which may be appealing to some people.