

The evidence supports over-the-counter access to progestin-only pills: A research summary

The FDA is currently reviewing an application for an over-the-counter (OTC) progestin-only birth control pill (POP). If approved, it would be the first OTC birth control pill available in the United States. This research summary highlights key evidence in support of OTC access to POPs.

Challenges and barriers to accessing birth control

<u>Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill</u> use among Black, Indigenous, and people of color. *Contraception*, January 2023.

 In a study with Black, Indigenous, and people of color between May 2021-March 2022, 45% of participants reported facing at least one challenge accessing birth control in the past year.

<u>Prescription birth control access among U.S. women at risk of unintended pregnancy.</u> *Journal of Women's Health*, December 2015.

• Nearly one-third (29%) of adult women* who have ever tried to obtain or refill a prescription for birth control faced access barriers.

Experiences and interest in using POPs

<u>Interest in continued use after participation in a study of over-the-counter progestin-only pills</u> in the United States. *Women's Health Reports*, November 2022.

- 83% of adults and teens who had used an OTC POP in a trial reported likely future OTC POP use if available, with a greater likelihood among Hispanic/Latinx and Black participants and adults with public insurance, prior pregnancies, and some college.
- Adults and teens were willing to pay up to \$20 per month out of pocket, on average.

<u>Experiences using a progestin-only pill in an over-the-counter environment in the United States:</u> <u>A cross-sectional survey.</u> *BMJ Sexual and Reproductive Health*, October 2022.

- 77% of participants who had used an OTC POP in a trial and had used contraception in the month prior to the study said their overall OTC POP experience was similar or better than their previous method.
- Top benefits compared with prior methods included less worry about pregnancy, ease of access, fewer side effects, and greater decision-making power.

<u>Interest in over-the-counter access to a progestin-only pill among women in the United States</u>. *Women's Health Issues*, Mar-Apr 2018.

- In a nationally representative survey, 39% of adults at risk of unintended pregnancy and 29% of teens reported likely OTC POP use.
- Adults were willing to pay up to \$15 per month and teens up to \$10 per month on average.

^{*} The term 'women' is used in reference to research studies that identified the gender of participants as 'women'. We acknowledge that using 'women' may be inaccurate if participants were not asked or allowed to provide their gender and that these data limitations may exclude the experiences of some people seeking contraception who do not identify as 'women', such as non-binary or transgender individuals.

<u>Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color.</u> *Contraception*, January 2023.

- In a study with Black, Indigenous, and people of color, 67% of participants said they were likely to use an OTC birth control pill.
- 71% of participants who weren't currently using any contraceptive method reported they were likely to use an OTC birth control pill.

<u>Experiences of progestin-only pill users in the United States and attitudes toward over-the-counter access</u>. *Perspectives on Sexual and Reproductive Health*. June 2023.

- Data collected from focus group discussions with 36 POP users between July and November 2020 show that three quarters of participants described their overall POP experience as positive, mostly because they experienced minor or no side effects and thought the pill was effective.
- Participants overwhelmingly supported OTC availability of POPs and expressed interest in purchasing an OTC POP.

Safety and efficacy of POPs

<u>Effectiveness and efficacy rates of progestin-only pills: A comprehensive literature review.</u> *Contraception,* March 2023.

- Findings suggest POPs may be more effective with typical use than currently believed.
- The review estimates that two pregnancies will occur during typical use if 100 people took the pill for a year, which is lower than the current estimation of seven pregnancies.

The effect of deliberate non-adherence to a norgestrel progestin-only pill: A randomized, crossover study. Contraception, September 2022.

- The current guidance for POPs calls for them to be taken at the same time each day, with a three-hour window. While more research is needed, this study shows that there is likely a wider window of time for maintaining efficacy if a pill is missed or delayed.
- The data showed that taking a POP containing norgestrel six hours late or missing one pill entirely appears to have little impact on contraceptive efficacy (i.e., cervical mucus thickening and disruption of ovarian activity).

A review of the effectiveness of a progestogen-only pill containing norgestrel 75 μg/day. Contraception, January 2022.

Results reveal that overall failure rates for norgestrel ranged from 0 to 2.4 pregnancies
that would occur during typical use if 100 people took the pill for a year, showing that
this POP is highly effective and a good option for making available OTC.

Efficacy, safety, and personal considerations. Contraceptive Technology, 2018.

- With perfect use (if someone never forgets to take a pill and takes them at the same time every day), it is currently estimated that POPs are about 99% effective.
- With typical use, it is currently estimated that POPs are about 93% effective.

<u>Contraindications to progestin-only oral contraceptive pills among reproductive-aged women.</u> *Contraception,* September 2012.

- Data were collected from two studies, one with a sample of reproductive-aged women*
 in El Paso, Texas and the other with a sample of current oral contraceptive (OC) users.
 Very few women* in both samples (1.6% and 0.6%, respectively) had contraindications
 to POPs.
- Women* were able to accurately self-screen for contraindications to POPs using a checklist.
- The low prevalence of contraindications for POPs shows they are a good choice for being available OTC.

About Free the Pill

Free the Pill, operated by <u>Ibis Reproductive Health</u>, is a campaign to educate and engage in support of over-the-counter (OTC) birth control pills in the United States that are affordable, fully covered by insurance, and available to people of all ages. Campaign activities are driven by a coalition of more than 200 reproductive health, rights, and justice organizations, research and advocacy groups, youth activists, health care providers, medical and health professional associations, and other professionals, who have been working since 2004 to build the evidence in support of OTC birth control pills in the United States.