

FDA Approves First Over-the-Counter Birth Control Pill

On July 13, the U.S. Food and Drug Administration (FDA) [approved](#) Opill, the first over-the-counter (OTC) birth control pill available in the United States. This approval comes six decades after daily birth control pills were first introduced in the country.

Manufactured by Perrigo, the OTC birth control pill will help make oral contraceptives easier to obtain, especially by teenagers and women who don't regularly see a health care provider. This decision joins the United States with about 100 other nations allowing the sale of OTC birth control pills.

“When used as directed, daily oral contraception is safe and is expected to be more effective than currently available nonprescription contraceptive methods in preventing unintended pregnancy.”

- Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research

Health experts and women's health groups have pushed for a nonprescription option due birth control pill's safety and efficacy. Today, most U.S. birth control pills contain a combination of the hormones progestin and estrogen. Opill is part of an older generation of contraceptives and only contains

progestin. Such formulations generally have few side effects and health risks but can be less effective if they're not taken around the same time daily.

The cost and insurance coverage of Opill remains in question, but the manufacturer says it would keep the drug affordable and offer financial assistance to those who qualify. Under the Affordable Care Act, group health plans and insurers must cover women's preventive services—including birth control—at no cost. However, that requirement only applies to prescription products since insurers typically don't cover OTC drugs.

What's Next?

The FDA's approval can potentially transform contraceptive access and reproductive health. The manufacturer expects Opill to be available over the counter in stores starting in January or February 2024. Additionally, Opill will not have an age restriction. The suggested retail price is expected to be announced this fall.

We will continue to monitor the availability, pricing and insurance implications of OTC birth control pills.