

Oral Contraceptive Pills

For over 50 years, American women have relied on oral contraceptive pills to prevent pregnancy. Oral contraceptives are now the most widely used form of contraception and are also commonly used to manage other health conditions. In the U.S., daily oral contraceptive pills have traditionally only been available with a prescription, but current legislative and advocacy efforts in some states have focused on broadening access to oral contraceptives by eliminating the requirement that women first have an in-person clinical visit. This factsheet provides an overview of oral contraception, discusses private insurance and Medicaid coverage, and reviews emerging strategies to promote and expand women’s access to oral contraceptives.

Background

In 1960, the Food and Drug Administration (FDA) approved the sale of Enovid for use as the first oral contraceptive. Controversial from its earliest days, in 1965, the Supreme Court ruling in *Griswold v Connecticut* upheld married women’s rights to contraception, followed in 1972 by the Supreme Court’s decision in *Eisenstadt v Baird* which extended the right to single, unmarried individuals.¹

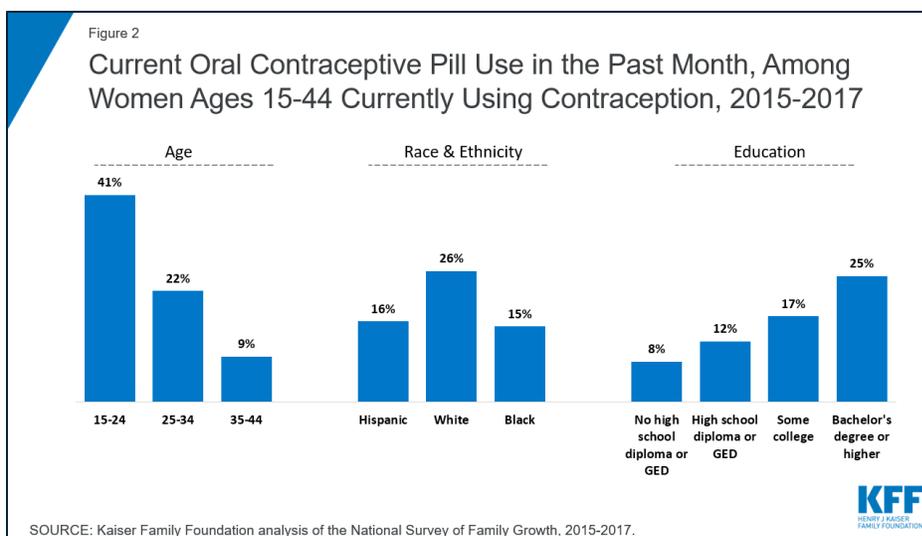
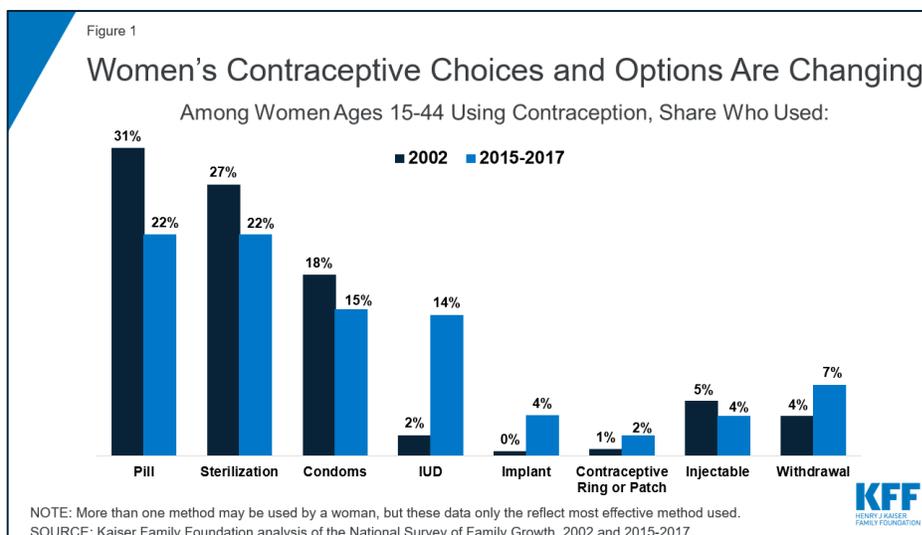
Oral contraceptive pills (OCP) consist of the hormones progestin and estrogen, or only progestin, and must be taken orally once per day in order to prevent pregnancy. Currently, there are three different types available on the market: the combination pill, the progestin-only pill, and the continuous use pill. The three formulations vary in their chemical hormonal composition as well as regimen for use (**Table 1**). Different brands further add to the diversity of OCP available by altering the type and/or dose of hormones. Emergency contraceptive pills are also a type of OCP, consisting of the progestin levonorgestrel, but are not intended for daily use. Rather, they are used to prevent pregnancy after unprotected sex.

Table 1: Types, Composition and Regimen for Daily Oral Contraceptive Pills	
Type and Composition	Regimen
Combined Pill: ² Consists of estrogen and progestin <i>Examples:</i> Yaz, Yasmin, Loestrin (iron-containing)	21-day packs: 1 pill per day for 21 days, followed by 7 days of nonuse for menstruation 28-day packs: 21 or 24 hormonal pills (brand dependent). The remaining pills either contain estrogen only or do not have hormones.
Progestin Only: Consists of progestin <i>Examples:</i> Norethindrone (Micronor), Norgestrel	28 day packs: all pills are active. Suggested to be taken daily at the same time within a three hour window.
Extended/Continuous Use: ³ Consists of estrogen and progestin <i>Examples:</i> Seasonale, Seasonique, Lybrel	91-day packs: 84 days of active hormone pills followed by 7 inactive pills, and/or low dose estrogen (results in 4 periods/year) 365 day pack: consist of 365 hormonal pills; no inactive pills.

Both the combined and progestin-only pills are highly effective with perfect use, with a failure rate (rate at which women become pregnant while using the contraceptive) less than 1%. However, the failure rate with “typical use” is 9%,⁴ which accounts for inconsistent or incorrect use.

The pill was the first FDA-approved contraceptive to be used in the U.S., and is still the most commonly used form of contraception. In 2015-2017, the most recent years for which there are national data, slightly less than a quarter (22%) of women age 15-44 who currently use contraception reported using the pill as their method of choice, a decline from 31% in 2002⁵ (Figure 1). At the same time, there has been a rise in use of intrauterine devices (IUDs), which have been promoted by several medical groups in recent years.

Among women who use any form of contraception, OCP use is higher among younger women, and decreases with age. White women are more likely to use OCP than Hispanic or Black women. OCP use increases with higher educational attainment (Figure 2).



OCPs are primarily used for pregnancy prevention, but they can also be used to address other health conditions, particularly menstrual-related disorders such as menstrual pain, irregular menstruation, fibroids, endometriosis-related pain, and menstrual-related migraines. Use of combined pills for acne has been formally approved by the FDA for specific brands.⁶ While most (86%) women who use OCP take them to prevent pregnancy, 14% use them solely for non-contraceptive reasons.⁷

Oral contraceptives are safe for most women.⁸ Possible side effects include headache, nausea, breast tenderness, and breakthrough bleeding. The combined hormonal pills may be associated with a small increased risk of deep vein thrombosis, heart attack and stroke for some women.⁹ Findings from one

study suggest small increases in the likelihood of first depression diagnosis with the use of hormonal contraception, including both oral combined and progestin-only pills.¹⁰

Insurance Coverage and Financing of Oral Contraceptives

While OCP have been available since the mid 1960's, they were not always covered by insurance plans in the same way as other prescription drugs. In the early 1990's this became the focus of legislative action, first at the state and then the federal level. State legislatures began passing "[contraceptive equity laws](#)" which typically required that plans offering prescription drug coverage also cover contraceptives on the same terms as other prescriptions. Some state laws went further to require that plans cover all FDA-approved contraceptives. However, these state laws only applied to plans that were regulated by the state, but not self-funded or self-insured plans, which cover most workers with employer-sponsored insurance and are federally regulated through ERISA.¹¹ Furthermore, these laws did not address cost sharing, and one study found that between 1996 and 2006, women paid 56% of the cost of OCP under their private insurance plan.¹² Minimum coverage standards for employer-sponsored plans were established in 2000, when a federal ruling from the [Employment Equal Opportunity Commission](#) found it unlawful under the Civil Rights Act for plans to deny coverage for contraceptives if they covered other preventive prescription drugs and services.¹³ By 2010, 28 states required insurers that cover prescription drugs to provide coverage for the full range of FDA-approved contraceptives.¹⁴

Private Insurance and the ACA

In 2010, the Affordable Care Act (ACA) took state laws further by requiring most private plans (including self-funded, small and large group, and individual plans) to cover a wide range of recommended preventive services, without cost to policyholders. In 2011, Health Resources and Services Administration (HRSA), following recommendations issued by the Institute of Medicine, added that all FDA-approved contraceptive methods and patient counseling for women with reproductive capacity, as prescribed by a health care provider, be included as a preventive service.¹⁵

The policy requires that most private health insurance plans cover at least one form of each of the 18 FDA-approved contraceptive methods for women as prescribed without cost sharing.¹⁶ This means that plans must cover at least one of each of the three different types of oral contraceptives – the combined pill, the progestin-only pill and the continuous use pill – though it is up to an insurer's discretion using reasonable medical management practices whether to cover a brand name or generic contraceptive if both are available.¹⁷ Insurers are required to cover other contraceptives if medically necessary, and must provide a process for policyholders to request coverage of a contraceptive that is not already covered without cost sharing by the plan.

Additionally, 14 states ([CA](#), [CT](#), [DE](#), [IL](#), [ME](#), [MD](#), [MA](#), [NV](#), [NH](#), [NM](#), [NY](#), [OR](#), [VT](#), and [WA](#)) and [DC](#) have passed laws that build on the federal requirement for no cost sharing for FDA-approved contraceptive

methods for women (**Table 2**). Some of these states have gone beyond the ACA requirements, mandating coverage of vasectomies and/or over-the-counter contraceptives.

Table 2: Policies Expanding Contraceptive Coverage and Availability				
State	Expansion of pharmacists' prescribing authority (oral contraceptives) ¹	Insurers must cover FDA-approved contraception without cost sharing ²	Insurers must cover 12-month supply ³	Insurers must apply same cost-sharing rules to over-the-counter and prescription contraception
California	X	X	X	
Colorado	X		X ⁴	
Connecticut		X	X	
Delaware		X	X	
District of Columbia	X	X	X	
Hawaii	X		X ⁴	
Idaho	X			
Illinois		X	X	X
Maine		X	X	
Maryland	X	X	X ⁵	X
Massachusetts		X	X	
Nevada		X	X	
New Hampshire		X	X	
New Mexico	X	X ⁵		X
New York		X	X	X ⁵
Oregon	X	X	X	X
Rhode Island			X ⁴	
Tennessee	X			
Vermont		X	X	
Virginia			X ⁴	
Washington	X	X	X	X
TOTALS	10	15	18	6

SOURCE: Kaiser Family Foundation analysis of state laws. As of May 23, 2019.

¹ Some states require pharmacists to have a collaborative partnership with a physician or advanced practice clinician. States that have given pharmacists only expanded dispensing authority are not included here. NH, OH, UT, and WV permit pharmacists

to *dispense* certain self-administered hormonal contraceptives under a standing prescription drug order or consult agreement with a licensed physician, but not to *prescribe* them.

² Insurers may apply cost sharing for drugs or devices that are therapeutically equivalent to another contraceptive drug or device that is already covered under the same policy. Some states require that all contraceptive drugs, devices, and other products be covered, while others require that at least one be covered. Also, some states require the method be prescribed. [Many states](#) permit exemptions for employers with religious and/or moral objections to contraception.

³ Effective in 2020, NM will require insurers to cover a 6-month supply of contraceptives.

⁴ State law does not prohibit cost sharing.

⁵ Effective in 2020.

Since the implementation of the ACA's contraceptive coverage provision, fewer women are paying out of pocket for contraceptives.¹⁸ According to a 2019 Kaiser Family Foundation unpublished analysis of the Truven Health Analytics MarketScan Commercial Claims and Encounters Database, among women with health insurance from a large employer who use OCP, the share experiencing out-of-pocket spending on OCP declined from 94% in 2012 to 11% in 2017.¹⁹

Controversial since its inception, the provision has sparked litigation and new regulations in response to lawsuits that have reached the Supreme Court. Although the Obama administration allowed certain religious employers with an objection to contraception to request an exemption from the requirement, the Trump administration recently expanded eligibility to almost all employers that have a religious or moral objection. Female employees, dependents, and students of these exempt employers would no longer be entitled to coverage for the full range of FDA-approved contraceptives at no cost.²⁰ These regulations were set to go into effect January 14, 2019, but the Federal District Court for Eastern Pennsylvania issued a national stay in January 2019, blocking the implementation of the regulations while the litigation brought by states proceeds through the courts.²¹

Public Programs

Federal law has long required state Medicaid programs to cover family planning services and supplies without cost sharing and provides states with an enhanced federal match for providing these services. States that expanded Medicaid under the ACA must follow the ACA requirements for private plans and are required to cover all 18 FDA-approved contraceptive methods for women. There is no similar requirement for populations that were traditionally eligible for full-scope Medicaid or through a Medicaid family planning expansion program, and there is variation between states on the specific services that are covered.²²

Since the passage of the ACA, some states have strengthened their contraceptive coverage requirements. For example, in 2014, California passed the [Contraceptive Coverage Equity Act of 2014](#) which extends the ACA's coverage policy beyond private plan beneficiaries to all Medicaid managed care enrollees, regardless of whether they qualify as a result of the ACA expansion or through traditional pathways. [MA](#), [NV](#), and [VT](#) have since enacted similar laws.

Coverage for oral contraceptives is also required in the Indian Health Service, the federal program that provides care on or near Indian reservations as well as in the Tricare program for active military personnel and their dependents.

Medicare, the federal program for seniors 65 and older as well as younger adults with permanent disabilities, does not require coverage for oral contraceptives. In 2016, an estimated 1.35 million women under age 50 were enrolled in Medicare.²³ Medicare beneficiaries that have enrolled in private Medicare Advantage plans or who have opted in to the Medicare Part D prescription drug benefit *may* have coverage for oral contraceptives, but the scope of coverage varies between plans. There were an estimated 956,000 women of reproductive age that were dually eligible for Medicaid and Medicare.²⁴

Expanding Access to Contraception

In 2011, one third of women at risk for unintended pregnancy who tried to obtain a prescription for contraception reported having trouble doing so.²⁵ Furthermore, it is estimated that more than 19 million women of reproductive age live in an area considered to be a 'contraceptive desert', meaning there is limited access to a publicly-funded provider who offers contraception.²⁶ Research also points to the effects of state policies on the shrinking number of family planning providers that offer the full scope of contraceptive methods in some communities.²⁷

In recent years, there has been public debate and emerging state policy action to mitigate some of these access barriers by expanding the availability of daily oral contraceptive pills through different mechanisms. Approaches that are being considered include: making OCP available over-the-counter without a prescription; expanding the ability of pharmacists to furnish OCP without the need for a clinical visit; extending the supply amount that is dispensed at one time; and using mail-based online services or smartphone applications.

Over the Counter (OTC)

Research suggests that OTC access would increase the use of contraception and facilitate continuity of use.²⁸ It could also allow women to save time spent on travel, at doctor's office, and off work. **Leading medical groups** including the American Medical Association, American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists have endorsed the principle of making some oral contraceptives available OTC and the issue has garnered broad public support. In a national survey, 74% of women reported that they supported OTC access of OCP.²⁹

The switch from prescription-only to OTC availability requires FDA review and approval. This action is typically triggered by the manufacturer's petition for an FDA review, can take upwards of three or four years, and a separate review is required for each product. In order for the FDA to approve the conversion to OTC status a drug must meet certain criteria:³⁰ users can easily diagnose need for the drug and monitor use without clinician screening; the drug must have low toxicity and low potential for abuse or

interactions with other drugs; the drug cannot have significant toxicity if overdosed; and the drug must not have properties that make it impractical for OTC use.

Research shows that OTC oral contraception generally meets these requirements,³¹ and women can effectively use checklists to identify contraindications.³² One study found 96% of cases demonstrated agreement between women's assessment of contraindications using the checklist and a clinician's independent evaluation.³³ Currently, Plan B emergency contraception and its generic equivalents, which contain a higher dose of progestin only (found in OCP), is available OTC.³⁴ In December 2016, HRA Pharma and Ibis Reproductive Health announced that they were in partnership to submit an application to make a progestin-only pill available for OTC use in the U.S. The progestin-only pills have fewer and rarer contraindications than combined pills, making them a better candidate for FDA approval for OTC use.

The ACA currently requires no-cost coverage for contraceptives, but only when the method is prescribed. Legislation at the federal or state level, or administrative changes to the ACA's preventive services policy would be needed to define coverage to include non-prescribed contraceptives. At the state level, [Maryland](#) became the first state to enact such a [law](#), effective January 2018, requiring insurers to cover OTC contraceptives without a prescription with the same cost-sharing rules that apply to prescription contraceptives. [IL](#), [NM](#), [NY](#), [OR](#), and [WA](#) have passed similar laws since then.

Pharmacy Access

Another avenue that is gaining support in some states allows pharmacists to furnish or dispense OCP without first requiring an in-person medical visit to a physician. As of February 2019, nine states ([CA](#), [CO](#), [HI](#), [ID](#), [MD](#), [NM](#), [OR](#), [TN](#), and [WA](#)) and [DC](#) allow pharmacists to prescribe OCP to women (**Table 2**). All of these states allow pharmacists to prescribe at least oral contraceptives, but states vary in other details, such as prescriptive authority (e.g., collaborative practice agreements and statewide protocols),³⁵ minimum age requirements, other types of contraceptives that pharmacists can prescribe, the length of the supply, and whether the patient needs a prior prescription from a physician.

Some states, including [NH](#), [OH](#), [UT](#), and [WV](#), permit pharmacists to *dispense* certain self-administered hormonal contraceptives under a standing prescription drug order or consult agreement with a licensed physician, but not to *prescribe* them.

Although pharmacy access can remove some barriers to obtaining contraceptives, some challenges still remain for women seeking a contraception prescription from a pharmacist. For example, pharmacies typically charge consultation fees, which some reports suggest can be as high as \$50 in certain areas.³⁶ Although insurers are generally required to cover contraceptives without cost sharing, they are not obligated to cover this fee. Also, pharmacies can choose not to participate or may not have any trained pharmacists.³⁷

From the pharmacy perspective, pharmacists must elect to complete additional education requirements, which vary by state, and often include several hours of continuing education from an accredited training program.³⁸ Additionally, states may not have a reimbursement mechanism in place to pay pharmacists for providing this service. For example, while OR and HI require plans to reimburse the dispensing entities, CA's law does not require reimbursement for payers other than [Medicaid](#). In the absence of reimbursement, many pharmacies instead rely on the consultation fees mentioned above.

12-Month Supply

Another approach to facilitate access to oral contraceptives involves increasing the dispensing period of contraceptives to 12 months per prescription. Currently, dispensing patterns vary by insurer, with many plans limiting supply of pills to one-to-three month periods.³⁹ In fact, 70% of women receive a supply of 3 months or less, while only 15% receive a supply for more than 6 months.⁴⁰ Providing women with a longer lasting supply of pill packs may lead to more consistent contraceptive use.⁴¹ Women who receive a one-year supply have been found to be 30% less likely to have an unintended pregnancy compared to women receiving a one to three month supply.⁴²

In 2015, Oregon heralded the movement of extended supply and passed a [law](#) requiring insurers to provide coverage for a three-month supply of contraceptives when first prescribed, followed by a 12-month supply of contraceptives.⁴³ Laws requiring coverage for 12 months of oral contraceptives have since been enacted in 15 additional states plus [DC](#): [CA](#), [CO](#), [CT](#), [DE](#), [HI](#), [IL](#), [ME](#), [MA](#), [NV](#), [NH](#), [NY](#), [RI](#), [VT](#), [VA](#), and [WA](#); [MD's](#) law will take effect in 2020 (**Table 2**). Beginning in 2020, [NM](#) will require coverage for a 6 month supply. While most of these states have enacted policies that require no-cost contraceptive coverage similar to the ACA's contraceptive coverage provision, CO, HI, RI, and VA have not yet done so. This means that although insurers must cover a 12-month supply in these four states, state law does not prohibit cost sharing; however, most plans must abide by the federal requirement and not charge any cost sharing for prescribed, FDA-approved contraceptive methods.

Online Services and Smartphone Applications

A new intermediary telemedicine market has emerged between health care providers and the patient that may decrease barriers to obtaining the pill, particularly for women living in contraceptive deserts. A growing number of online services and smartphone applications offer options for patients to speak with providers by video or chat, get prescriptions, and order birth control pills through mail delivery. These services work by collaborating with physicians, pharmacies, and sometimes health insurers to prescribe and ship OCP to the patient's home or a local pharmacy.

Costs for these services vary between companies.⁴⁴ Most charge a fee for the prescription and/or consultation, which is typically not covered by insurance and ranges in price from free up to \$99. [Planned Parenthood Direct](#) and [PRJKT RUBY](#) do not charge a consultation/prescription fee. Some companies, like [Nurx](#), accept insurance, including Medicaid, to pay for the pills, while others do not. Without insurance, pills range in price from \$15 to \$20 per pack.

Most companies ship the OCP free of charge to the patient's home, while some require pick up from a local pharmacy. Prescriptions are often valid for 12 months and patients are sent either a one- or three-month supply of pills. Video/audio consultations are required by certain services, including [PlushCare](#), [HeyDoctor](#), and [Maven](#), before receiving the prescription. Services that do not require a consultation do require patients to complete a health assessment or questionnaire to determine eligibility and the appropriate pill.

People in every U.S. state have access to at least one of these services, but the minimum age to use the service varies by company and state law, although many require the person to be at least 18 years old. One service, only available to people in California, [Pandia Health](#), offers service to any age, per [state law](#).

Oral contraceptives are the most commonly used form of prescription contraception in the U.S. Most women with private insurance or Medicaid can receive no-cost coverage for OCPs. There has been interest and action to make OCP available over-the-counter nationally, but this has not yet been approved by the FDA, although a progestin-only pill is under FDA review for OTC provision. Several states have enacted policies to broaden OCP access, particularly through pharmacies and insurance coverage for longer lasting supplies, and many more states are considering them. The use of telemedicine to expand OCP access continues to evolve, with many women now able to obtain OCP using smartphone and web-based services.

Endnotes

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