

REPORT



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Coverage of Contraceptive Services

A REVIEW OF HEALTH INSURANCE PLANS IN FIVE STATES

Prepared by:
Laurie Sobel, Alina Salganicoff and Nisha Kurani
Kaiser Family Foundation

and

Jennifer Wiens, Kimsung Hawks and Linda Shields
The Lewin Group

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Executive Summary

Insurance coverage of contraceptives has been the focus of legislative efforts at the state and federal level for many decades. With the passage of the Patient Protection and Affordable Care Act (ACA) came the requirement that most private plans provide coverage for women's preventive health care, including all prescribed FDA-approved contraceptive services and supplies, without cost-sharing. Federal guidance issued on preventive services coverage requirements states that plans are permitted to apply reasonable medical management techniques to "control cost and promote efficient delivery of care."¹ Since the provision became effective in August 2012, there have been ongoing anecdotal reports of some women experiencing difficulties in securing no-cost coverage from their plans.

To better understand how this provision is being implemented by health plans, Kaiser Family Foundation (KFF) staff, with the Lewin Group, reviewed the insurance plan coverage policies for 12 prescribed contraceptive methods (excluding oral contraceptives). Information was collected from 20 different insurance carriers in five states (California, Georgia, Michigan, New Jersey, and Texas) about how they are applying reasonable medical management (RMM) techniques in their coverage of women's contraceptive services. Interviews were conducted with plan officials for nine carriers and reviews of publicly available plan documents on contraceptive coverage policies were conducted for an additional 11 carriers. In total, the information collected from the interviews and document review represent well over 200 different lines of business across the nation.

Key findings include:

There is variation in how the contraceptive coverage provision is being interpreted and implemented by health plans. While most carriers are complying with the spirit of this requirement, there are exceptions. Because of these coverage differences some women may not have coverage without cost-sharing to the contraceptive method of their choice. Specifically, we found that a higher share of plans place limits on certain contraceptive methods:

- **Vaginal Ring:** While 12 carriers of the 20 we reviewed cover NuvaRing placing no RMM limitations or no cost-sharing requirements to policyholders, five plans only cover NuvaRing with cost-sharing and one plan does not cover it all. We found this to be the contraceptive method that is least likely to be covered by carriers (Table A). Some carriers report that they do not cover different contraceptive methods with the same chemical formulation. Because the carriers provide no-cost coverage of oral contraceptives, they may not cover or may charge cost-sharing for the NuvaRing or Patch, because it has the same chemical formulation that they are already covering with oral contraceptive pills.
- **Implants and Patch:** Some carriers place limitations in coverage of the contraceptive implants, with two carriers failing to offer coverage of any implant available, even with cost-sharing and with three carriers covering the contraceptive patch, but only with cost-sharing.
- **Intrauterine Devices:** Ten carriers cover all three FDA-approved IUDs with no RMM limitations and no cost-sharing. One carrier, however, does not cover ParaGard, which is the only non-hormonal IUD available to women.
- **Emergency Contraceptive Pills:** While most carriers covered the progestin-based Plan B emergency contraceptive (EC) pill or its generic equivalents, only 11 carriers cover the ella emergency contraceptive pill

without RMM limitations or cost-sharing. The ella EC pill is a different formulation and has a longer window of effectiveness and it may be preferable for women with a higher body mass index (BMI) than progestin-based EC pills, however, it does not have a generic equivalent. Two carriers do not cover ella at all.

Table A: Coverage of Female Contraceptive Methods Addressed in this Study

Method	Brand	Covered			Not Covered	Coverage or Limitations on Coverage Unknown
		With no RMM Limitations and No Cost-Sharing	With RMM Limitations and No Cost-Sharing	With Cost-Sharing with or without RMM limitations		
Ring	NuvaRing	12	1	5	1	1
Patch	OrthoEvra	7	1	5	5	2
Patch	Xulane (Generic)	14	-	3	1	2
Injection	Depo-Provera	6	1	3	8	2
Injection	Depo-Provera Generic	16	-	2	-	2
Injection	Depo-SubQ Provera 104	7	-	5	6	2
Implant	Implanon	11	1	-	4	4
Implant	Nexplanon	10	1	-	3	6
IUD –hormonal	Mirena	13	1	-	-	6
IUD – hormonal	Skyla	10	1	-	3	6
IUD – copper	ParaGard	14	-	-	1	5
Emergency Contraception	Ella	11	-	6	2	1
Emergency Contraception	Plan B*	5	-	5	10	1
Emergency Contraception	Generic Plan B	19	-	-	-	1
Female Sterilization	All procedures	10				10

Note: 20 carriers were reviewed.

*One carrier's coverage varies by product line and as result the responses to this item total 21.

While the law permits carriers to employ RMM limitations for contraceptive coverage, the FAQs issued by the Department of Labor specify that carriers should have a process in place for waiving coverage limitations for patients who have a medical need for contraceptives that are otherwise subject to cost-sharing or not covered.² None of the carriers we reviewed have established a formal process for beneficiaries to file a waiver contesting limitations on coverage for preventive services; carriers refer consumers to their usual appeal process. It is also not clear whether any carrier has an established expedited appeal process that would allow a woman timely access to emergency contraceptives that are not covered under the policy.

Ten carriers cover sterilizations without cost-sharing. However, it was difficult to ascertain coverage for sterilization from both the interviews and the plan document review for seven other carriers. In particular, there is uncertainty about the extent to which carriers cover the ancillary services associated with female sterilization, such as follow up visits and anesthesia.

Despite significant national attention to the availability of a religious accommodation to plans serving employers with a religious objection to some or all contraceptive methods, insurers reported that they have received very few notifications from employers qualifying for the accommodation. Carriers have not identified difficulties in implementing the accommodations that have been requested by employers.

Information about the contraceptive coverage policies used by health insurance carriers is not easily accessible. Many carriers we approached for this project were unwilling to participate in an interview; only nine out of 24 carriers invited agreed to be interviewed, and some of the individuals that participated in interviews (such as medical directors, pharmacy care managers, public policy executives, and attorneys) were not always able to address the full range of contraceptive topics included in the study. Furthermore, many of the publicly available documents do not clearly identify plan coverage decisions when it comes to how different contraceptive methods are covered and the limitations of the coverage. This makes it extremely difficult, if not impossible for policyholders to ascertain their current plan's contraceptive coverage policies.

For many women, the ACA's contraceptive coverage provision has reduced their out-of-pocket health care costs and given them the opportunity to use more effective, but more costly, methods of contraception that had been unaffordable to them in the past. This report finds that there is variation in how insurance carriers are interpreting the guidelines for contraceptive coverage issued by HHS, and that not all methods may be covered without cost-sharing to women policyholders. The CDC and the Office of Population Affairs have clearly stated that offering women the full range of FDA-approved contraceptive methods is an element of high quality family planning services and emphasizes the importance of contraceptive choice in reducing a woman's risk of unintended pregnancy. For many women with private insurance coverage, access to this range of options is now a reality; for some however, their choice of plan may still result in limitations of their contraceptive options.

Introduction

Insurance coverage of contraceptives has been the focus of legislative efforts at the state and federal level for many decades. In the years immediately prior to the passage of the ACA, coverage for prescription contraceptives in private plans was widespread, but not universal. Between 1998 and 2003, more than half of states (28 states) had enacted contraceptive coverage mandates, and around the same time, discussions were occurring at the federal level surrounding contraceptive parity legislation. The state mandates typically required contraceptive parity in the small group and individual insurance markets but did not require the coverage be offered without cost-sharing. State laws, however, fell short of universal coverage as they only applied to state regulated plans, but not self-funded plans where 61% of covered workers are insured.³ In 2000, The Equal Employment Opportunity Commission ruled that employers with more than 15 employees must cover contraceptives for women if they offer health plans that cover preventive services and prescription drugs.

The Patient Protection and 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 clinical services without cost to policy holders. For adults, this far-reaching requirement includes all of the services that received highly rated recommendations from the independent United States Preventive Services Task Force (USPSTF), and immunizations recommended by the Centers' for Disease Control and Prevention (CDC) Advisory Committee for Immunization Practices (ACIP). The law also specifies that plans cover preventive services for women that are recommended by the Health Resources and Services Administration (HRSA).

To inform the development of these guidelines, HRSA commissioned the Institute of Medicine (IOM) to review existing evidence and make recommendations to fill in the gaps in the services for women identified by the USPSTF. In its report, the IOM identified eight new services, including contraceptive services and supplies.⁴ The IOM recommendations also specified that the most appropriate method of contraception varies according to each woman's needs and medical history, and therefore, the full range of contraceptive methods is necessary to ensure that women have "options depending upon their life stage, sexual practices, and health status."⁵ HRSA adopted the IOM's eight recommendations, including the requirement that plans provide no-cost coverage of all FDA-approved contraceptive methods as prescribed.⁶ The women's health provision became effective on August 1, 2012 and affected most women with private health insurance coverage starting in January 2013.

The HRSA Guidelines include a recommendation for all Food and Drug Administration (FDA) approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider.

While most health plans are now required to provide contraceptive methods and counseling to women with reproductive capacity with no out-of-pocket costs to beneficiaries, there are certain conditions that must be met. Women must be enrolled in a [non-grandfathered plan](#)⁷ and they must get services from an in-network provider. In addition, the federal regulations implementing the preventive services coverage requirement explicitly permit plans and issuers to use reasonable medical management to control cost and promote efficient delivery of care.⁸ This applies to coverage of all preventive services, not just contraceptive care. Neither the

Women's Preventive Service Guidelines nor the PHS Act, however, offers a specific definition or parameters for reasonable medical management, how it should be applied, or identification of all the FDA-approved contraceptive methods.

In an attempt to provide additional clarification on the implementation of the preventive services provisions of the ACA, the US Department of Labor's Employee Benefits Security Administration addressed the issue through a response to a series of Frequently Asked Questions (FAQs).⁹ The clarification states that a plan may limit the frequency, method, treatment or setting for the provision of a recommended preventive health service based on relevant evidence,¹⁰ but still does not provide a specific definition for reasonable medical management.

Since the provisions became effective, there have been multiple media reports of women experiencing difficulties in accessing no-cost coverage for the full range of FDA-approved methods of contraception. These anecdotal reports include women experiencing difficulty in securing coverage for brand named contraceptives as well as certain types of contraceptive methods.¹¹

To better understand how this policy is being implemented by plans, the Kaiser Family Foundation undertook a study to examine how the contraceptive coverage provision and the reasonable medical management rules are being interpreted by plans and how the interpretation could affect the availability of the full range of contraceptive services and supplies to which women are entitled under the law. Kaiser Family Foundation (KFF) staff with the Lewin Group reviewed the contraceptive coverage policies used by health plans in five states, and conducted interviews to collect more detailed information about how plans are applying reasonable medical management (RMM) in their coverage of women's contraceptive services. The specific methodology is described in the following section.

Methodology

The selection of the health insurance carriers included in this study was established through a multi-step process. Five states were selected as areas of focus: California¹², Georgia, Michigan, New Jersey, and Texas. These states were chosen because they reflect geographic and political diversity and include a representation of a mix of federal, partnership and state-based Marketplaces. Some of the selected states had contraceptive coverage mandates in place prior to the ACA and expanded Medicaid coverage under the ACA, and others did not. We then compiled a master list of health insurance carriers operating in each state based on public filings with state insurance agencies and other sources. Six carriers per state were selected for inclusion in the study from that list to cover the largest market share across lines of business (large group and Marketplace plans). If a carrier declined to participate in the study, an additional carrier was selected from the state.

In total, 24 insurance carriers, many of which operate in multiple states, were invited to participate in the study. The findings presented represent interviews and/or plan document reviews for 20 different carriers and were conducted between August and October of 2014. If a national carrier operates in more than one state in the study, but the coverage is the same in multiple states, their coverage is counted once. We were able to interview plan officials including medical directors, pharmacy care managers, public policy executives, attorneys and others for nine unique carriers. We then reviewed publically available carrier documents for an additional 11 carriers. In total, the interviews and document review represent well over 200 different lines of business across the nation, including many of the largest carriers in the nation. Carriers were assured that their responses would remain anonymous. Most of the national carriers we reviewed have standard coverage policies that apply to all (non-Medicaid) lines of business and states in which the carrier operates. We found little variation in the application of RMM limitations by plan type (large employer, Individual/Family and Small Employer Plans on and off the ACA Marketplaces). Because Medicaid coverage rules are established by state policies, the findings presented do not apply to plans that are serving Medicaid beneficiaries.

This study focuses on 12 contraceptive methods (Table 1). Some of these contraceptives are covered under plans' pharmacy benefit and others are covered under the medical benefit. The ACA contraceptive requirement does not specify the exact types of contraceptives that should be covered, only that all plans must cover FDA-approved contraceptives "as prescribed" without cost-sharing. This has been interpreted by some to mean that they should cover contraceptive methods that are available over-the-counter (OTC) when the consumer has a prescription from a provider.

This study did not review the medical management approaches used by plans to limit the coverage of oral contraceptives because of the vast number of different formulations, brands and generics that are available.

Table 1: Female Contraceptive Methods Addressed in this Study						
Method	Benefit Category	Brand	Generic	Cost	Duration	Typical Use Failure Rate*
Ring	Pharmacy	NuvaRing	Not available	\$15-80	3 weeks	9%
Patch	Pharmacy	OrthoEvra	Xulane, norelgestromin/ethinyl estradiol	\$15-80	1/ week for 3 weeks	9%
Emergency Pill	Pharmacy	ella	Not available	\$45-70	1 time use	n/a
Emergency Pill	Pharmacy and OTC	Plan B, Plan B One Step	Levonorgestrel	\$35-60	1 time use	n/a
Injection	Medical and Pharmacy	Depo-Provera	Medroxyprogesterone acetate injection	\$35-100	3 months	6%
Injection	Medical and Pharmacy	Depo-SubQ Provera 104	Not available	\$35-160	3 months	6%
Implant	Medical and Pharmacy	Implanon	Not available	\$400-800	3 years	.05%
Implant	Medical and Pharmacy	Nexplanon	Not available	\$400-800	3 years	.05%
IUD – hormonal	Medical and Pharmacy	Mirena	Not available	\$500-1000	5 years	.2%
IUD - hormonal	Medical and Pharmacy	Skyla	Not available	\$500-1000	3 years	.9%
IUD – copper	Medical and Pharmacy	ParaGard	Not available	\$500-1000	10 years	.8%
Sterilization	Medical	n/a	n/a		Permanent	.5%

Note: *Failure rate is defined as the percent of women who experience an unintended pregnancy within the first year of typical use.

Source: CDC, Reproductive Health, [Contraception](#), accessed April 1, 2015; Trussell J. [Contraceptive failure in the United States](#).

Contraception; ARHP, Facts About Intrauterine Contraception.

Defining “Reasonable” Medical Management

Prior to the passage of the ACA, “medical management” had been broadly understood to encompass tactics and practices used by insurance carriers’ to “modify consumer and provider behavior to improve the quality and outcome of healthcare delivery.”¹³ Health insurance carriers have traditionally used medical management techniques to determine a plan’s pharmacy and medical benefits coverage, including but not limited to prescription drugs and medical procedure costs, availability, and mode of delivery.

Medical management techniques are typically presented as practices which promote the most cost-efficient and effective drug and procedure options while simultaneously allowing the insurer to control expenditures and utilization of comparable drug brands. Examples of medical management tactics include, but are not limited to, categorizing brand and generic drugs and devices in tiers based on either cost, type and or mode of delivery; steering consumers to generic equivalent drug options; requiring provider authorization to acquire a preferred brand drug; and limiting quantity and or supply. Health insurance carriers typically limit coverage of medical services to providers within their contracted provider network. For medical benefits discussed in this report, references to covered benefits imply that they are provided by an in-network provider. The plans are not required to provide no-cost contraceptive services and supplies to policyholders using out-of-network providers unless there are no available in-network providers able to provide the medical treatment.

In making coverage determinations for contraceptives, health insurance carriers customarily cover a specific list of prescription drugs or supplies on a formulary. This list may or may not include medical drugs, which are medications that are administered in a physician’s office or healthcare facility and are typically supplied by a healthcare provider. Drugs on a formulary are typically grouped into tiers. The tier that a medication or a contraceptive is assigned to can determine the consumer’s portion of the drug cost or even if the plan will cover it at all. A typical drug benefit includes three or four tiers.

In some cases, a carrier will require a member to first try a lower tier formulary drug or therapy to treat a medical condition before they will pay for an alternative drug or therapy for that condition. This process is known as step therapy or “fail first.” For example, if Drug A and Drug B both treat a medical condition, a carrier may not cover Drug B unless the member tries Drug A first. Only if Drug A does not work for the member, will they then cover Drug B. Another type of medical management is prior authorization, which requires providers to first obtain approval from a health insurance carrier to prescribe the service or medication before it can be covered.

While these approaches are broadly applied to many medical treatments and interventions, contraceptive choice is a central element of high quality family planning services. The CDC and the federal Office of Population Affairs recently issued a report to provide guidance to health care providers about the core elements of high quality family planning services.¹⁴ The report specifically states that “Contraceptive services should include consideration of a full range of FDA-approved contraceptive methods, a brief assessment to identify the contraceptive methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary.” The CDC report emphasizes the importance of contraceptive choice in reducing women’s risk of unintended pregnancy, but does not specifically address how medical management should be addressed or applied in the context of insurance coverage of contraceptive services and supplies.

Coverage of Select Contraceptive Methods

VAGINAL RING

The vaginal ring is a hormonal contraceptive method in the form of a small, flexible ring that is inserted vaginally by a woman once every three weeks, and then removed and discarded for the remaining week each month. Currently, the NuvaRing is the only FDA-approved vaginal ring. The NuvaRing functions by releasing estrogen and progestin, the same hormones in the combination birth control pill. The NuvaRing is effective for three weeks, and has a typical use failure rate of 9%, meaning the percentage of women who experience an unintended pregnancy within the first year of using the contraceptive method. One NuvaRing (which lasts for 30-days) costs between \$15 to \$80 per month.



Findings

- Twelve carriers of the 20 we reviewed cover NuvaRing, placing no RMM limitations or no cost-sharing requirements to policyholders (Table 2). One additional carrier does not require cost-sharing, but applies step therapy; the member must have tried or experienced intolerance to at least two generic oral contraceptives in the previous 180 days and provide documentation for why an oral contraceptive cannot be used.
- Three carriers cover NuvaRing, but charge cost-sharing. One of these carriers specified the rationale for the decision was that they have determined that contraceptives with the same progestin are equivalent to each other without regard to the delivery method. The carrier covers a birth control pill with no cost-sharing, and therefore charges cost-sharing for the NuvaRing, which has the same chemical composition as some birth control pills. One additional carrier requires both cost-sharing and prior authorization to show medical necessity on why formulary oral contraceptives are not suitable before they will cover the NuvaRing. One carrier does not cover NuvaRing at all.

Table 2: Carriers Covering NuvaRing by Cost-Sharing Requirement and RMM Limitations	
NuvaRing Coverage	NuvaRing
Covered with no RMM limitations and no cost-sharing	12
Covered with prior authorization and no cost-sharing	-
Covered with step therapy and no cost-sharing	1
Covered with cost-sharing but no RMM limitations	3
Covered cost-sharing unknown	1
Covered with prior authorization/step therapy and cost-sharing	2
Not covered	1

Note: 20 carriers were reviewed.

CONTRACEPTIVE PATCHES

Birth control patches are applied topically and stick directly on the skin, releasing estrogen and progestin into the bloodstream. A new patch is applied once a week for three weeks, followed by one patch-free week. The patch may be less effective for overweight women, and though the typical use failure rate is 9%, it may be higher for women whose weight is at or over 198 pounds.¹⁵



Three patches (a 30-day supply) costs about \$15 to \$80. Until recently, OrthoEvra was the only patch available. The generic patch, Xulane, became available in April, 2014. Since we started this study, Janssen Pharmaceuticals, the manufacturer of the OrthoEvra patch has discontinued production of the patch. Going forward, the generic alternative will be the only patch available.

Findings

We found that birth control patches are not covered by some carriers who use the rationale that it is the same chemical composition also available in generic birth control pills that are less expensive; some carriers use the same rationale to limit coverage of the NuvaRing.

- OrthoEvra: Seven carriers cover the OrthoEvra patch with no RMM limitations and no cost-sharing (Table 3). Another carrier covers the OrthoEvra patch with no cost-sharing and requires prior authorization. Five carriers cover OrthoEvra with no RMM limitations but require cost-sharing. Five carriers do not cover OrthoEvra.
- Generic patch (Xulane): We found that 14 carriers cover the generic patch with no RMM limitations and no cost-sharing. Three carriers cover the generic patch with no RMM limitations but require cost-sharing. One carrier does not cover the generic patch.
- Six carriers cover both the generic and brand patches with no cost-sharing and no RMM limitations. Nine carriers cover either the generic or brand patch with no cost-sharing and no RMM limitations. In total, 15 carriers cover at least one type of patch without cost-sharing or RMM limitations.

Table 3: Carriers Covering Patches by Type, Cost-Sharing Requirement and RMM Limitations

Patch Coverage	Xulane (Generic)	OrthoEvra
Covered with no RMM limitations and no cost-sharing	14	7
Covered with prior authorization and no cost-sharing	-	1
Covered with step therapy and no cost-sharing	-	-
Covered with cost-sharing and no RMM limitations	3	5
Covered cost-sharing unknown	1	1
Covered with prior authorization/step therapy and cost-sharing	-	-
Not covered	1	5
Unknown*	1	1

Note: 20 carriers were reviewed. *Individuals participating in interviews were unable to respond or information was not included in plan documents.

INJECTIONS

The birth control injection is a shot administered typically in the arm by a clinician in a clinic or out-patient setting once every three months. The shot releases the hormone DMPA, a progestin, to prevent pregnancy. The typical use failure rate for the injection is 6%. The brand-name Depo-Provera is an intramuscular injection, while Depo-subQ Provera 104 is a newer, brand-name subcutaneous injection. The formulation for the Depo subQ Provera 104 injection provides slower and more sustained absorption of the progestin than intramuscular Depo-Provera. This enables a lower dose of progestin (104 mg versus 400 mg) and reduces peak blood levels by half, but with the same duration of effect as conventional intramuscular Depo-Provera. In addition to the lower dose, subcutaneous administration can be less painful than intramuscular injection. There is a generic equivalent for Depo-Provera, but not Depo-subQ Provera 104. One injection lasts for three months and costs \$35 to \$100 (excluding office exam fees).



Findings

- Depo-Provera: Six carriers cover brand Depo-Provera with no RMM limitations and no cost-sharing (Table 4). One additional carrier requires a prior authorization. Three carriers cover Depo-Provera with cost-sharing and no RMM limitations. Eight carriers do not cover Depo-Provera. Three of the carriers that do not cover Depo-Provera, or cover it with cost-sharing, indicated that the generic is covered with no cost-sharing.
- Generic for Depo-Provera: Sixteen carriers cover the generic Depo-Provera without cost-sharing. One carrier covers the generic Depo-Provera with cost-sharing and without RMM limitations, while another carrier covers it but requires cost-sharing as well as prior authorization.
- Eighteen carriers cover either Depo-Provera or its generic, without cost-sharing or RMM limitations.
- Depo-subQ Provera 104: Seven carriers cover Depo-subQ Provera 104 with no RMM limitations and cost-sharing. Five carriers cover it with cost-sharing. Another six carriers do not cover Depo-subQ Provera .
- Overall, three carriers cover all three injections and six carriers cover the brand-name or generic Depo-Provera, as well as Depo-subQ Provera 104.

Table 4: Carriers Covering Injections by Type, Cost-Sharing Requirement, and RMM Limitations

Injection Coverage	Generic Depo-Provera	Depo-Provera	Depo-subQ Provera 104
Covered with no RMM limitations and no cost-sharing	16	6	7
Covered with prior authorization and no cost-sharing	-	1	-
Covered with step therapy and no cost-sharing	-	-	-
Covered with cost-sharing and no RMM limitations	1	3	5
Covered cost-sharing unknown	2	1	1
Covered with prior authorization/step therapy and cost-sharing	1	-	-
Not covered	-	8	6
Unknown*	-	1	1

Note: 20 carriers were reviewed. *Individuals participating in interviews were unable to respond or information was not included in plan documents.

IMPLANTS

A contraceptive implant is a thin, plastic hormone-releasing rod that is inserted under the skin of a woman's arm by a health care provider. Implanon and Nexplanon, the brand name implants, are each effective for three years and work by releasing progestin into the body. Nexplanon is newer than Implanon and is designed to be visible through x-ray, CT scan, ultrasound scans, or MRI, and has a different applicator. Both implants are long-acting reversible contraceptives and have the lowest typical use failure rate of all FDA-approved contraceptives at .05%. After use, implants must be removed by a provider in a clinic or outpatient setting. Implants cost \$400 to \$800 (excluding exam fees).



Findings

- Eleven carriers cover Implanon and 10 cover Nexplanon with no RMM limitations and no cost-sharing (Table 5). One additional carrier requires prior authorization for both Implanon and Nexplanon. Four carriers do not cover Implanon and three carriers do not cover Nexplanon.
- Ten carriers cover both implants with no cost-sharing and no RMM limitations. One carrier covers only one implant with no cost-sharing and no RMM limitations. In total, 11 carriers cover at least one implant. Two carriers do not cover either Implanon or Nexplanon even with cost-sharing. For four carriers, we were unable to ascertain coverage for either implant.

Table 5: Carriers Covering Implants by Type, Cost-Sharing Requirement, and RMM Limitations

Implant Coverage	Implanon	Nexplanon
Covered with no RMM limitations and no cost-sharing	11	10
Covered with prior authorization and no cost-sharing	1	1
Covered with step therapy and no cost-sharing	-	-
Covered with cost-sharing and no RMM limitations	-	-
Covered cost-sharing unknown		2
Covered with prior authorization/step therapy and cost-sharing	-	-
Not covered	4	3
Unknown*	4	4

Note: 20 carriers were reviewed. *Individuals participating in interviews were unable to respond or information was not included in plan documents.

INTRAUTERINE DEVICES (IUD)

Along with implants, intrauterine devices (IUDs) fall under the category of long-acting reversible contraceptives (LARCs). IUDs are plastic T-shaped contraceptives that are inserted into the uterus by a health care provider. There are two types of IUDs available in the United States, hormonal and copper. Currently, there are two hormonal IUD's on the market – Mirena and Skyla – and a third hormonal IUD Liletta was approved by the FDA in February 2015. While both Mirena and Skyla release progestin, Mirena releases slightly more progestin per day into the body, is slightly larger, and is effective for up to five years compared to Skyla, which is effective for up to three years. The typical use failure rate for Mirena is .2%, and .9% for Skyla.



The copper IUD is non-hormonal and goes by the brand name ParaGard. It prevents pregnancy by preventing sperm from reaching and fertilizing the egg, and possibly by preventing the egg from attaching in the uterus. It is effective for up to 10 years, has a typical use failure rate of .8% and can be used as emergency contraception up to five days after unprotected sex or contraceptive failure. All IUD's must be removed by a health care provider in a clinic or outpatient setting. IUDs cost between \$500 and \$1,000 (excluding exam fees).

IUDs are typically inserted in a physician's office or other outpatient setting. One carrier noted that IUDs can be expensive for doctors to purchase and stock in their offices. Doctors who do not stock IUDs can obtain them "on demand" from a specialty pharmacy, but this may require that women come back to the provider for a second visit.

Findings

- Hormonal IUDs, Mirena and Skyla: Thirteen carriers cover Mirena with no RMM limitations and no cost-sharing (Table 6). One additional carrier requires prior authorization and no cost-sharing. Ten carriers cover Skyla with no RMM limitations and no cost-sharing. One additional carrier requires prior authorization and no cost-sharing. Three carriers do not cover Skyla. Ten carriers cover both hormonal IUDs, Mirena and Skyla, with no cost-sharing and no RMM limitations. Three carriers cover either Skyla or Mirena, but not both hormonal IUDs.
- Copper IUD, ParaGard: Fourteen carriers cover ParaGard with no RMM limitations and no cost-sharing. One carrier does not cover ParaGard, which is the only non-hormonal IUD available to women.
- Ten carriers cover all three IUDs and four carriers cover one IUD with no RMM limitations and no cost-sharing. In total, 14 carriers cover at least one IUD with no cost-sharing and no RMM limitations and we were unable to ascertain coverage from four carriers.

Table 6: Carriers Covering IUDs by Type, Cost-Sharing Requirement, and RMM Limitations

IUD Coverage	Mirena	Skyla	ParaGard
Covered with no RMM limitations and no cost-sharing	13	10	14
Covered with prior authorization and no cost-sharing	1	1	-
Covered with step therapy and no cost-sharing	-	-	-
Covered with cost-sharing and no RMM limitations			
Covered with cost-sharing unknown	2	2	1
Covered with prior authorization/step therapy and cost-sharing	-	-	-
Not covered	-	3	1
Unknown*	4	4	4

Note: 20 carriers were reviewed. *Individuals participating in interviews were unable to respond or information was not included in plan documents.

EMERGENCY CONTRACEPTIVE PILLS

Emergency contraception (EC) is used to prevent pregnancy after unprotected sex or contraceptive failure. There are several methods of EC that are available in the U.S. including progestin-based pills, ulipristal acetate, and copper IUDs. Unlike the copper IUD, EC pills are not intended for use as a regular contraceptive method.

The Plan B formulation (progestin-based) is also available in generic forms, known as Take Action, Next Choice One Dose, and My Way. Progestin-based EC pills are effective up to three days after unprotected sex. Take Action, Next Choice One Dose and My Way are approved for sale over the counter (OTC). There are other generic brands available, but the FDA has not approved their OTC availability and thus they remain “behind the counter” requiring the pharmacist to dispense the pills. The cost of OTC emergency contraceptive pills varies from \$30 to \$60.



Ulipristal acetate, marketed as ella, was approved by the FDA in 2010 for sale and use in the U.S. Ella is a single-dose pill that is effective in preventing pregnancy up to five days after unprotected intercourse, giving women a longer timeframe to prevent unintended pregnancy than Plan B. Unlike progestin-based EC, a prescription is required for ella.

Recent studies have raised questions about the effectiveness of EC pills in preventing unintended pregnancy in overweight and obese women. While these studies do not conclusively establish specific weight or body mass index (BMI) thresholds for progestin-based EC pills or ella, it is suggested that women with BMI thresholds greater than 25 take ella rather than a progestin-based formulation.¹⁶ However, the effectiveness of ella appears to diminish at BMI thresholds above 35.¹⁷

Findings

- ella: Eleven carriers cover ella with no RMM limitations and no cost-sharing. Six carriers cover ella, but charge cost-sharing, and two carriers do not cover ella at all

- **Plan B:** Five carriers cover Plan B with no RMM limitations and no cost-sharing. Ten carriers do not cover Plan B. One of the carriers' coverage of the Plan B varies by product line. For this carrier, Plan B is covered within the individual and Small Employer Plans available on the Marketplace with cost-sharing, but it is not covered in the large group product lines. In table 7, this carrier is included twice to indicate its separate coverage policies.
- **Generic EC pills:** Nineteen carriers cover generic progestin-based EC pills with no cost-sharing. We were not able to determine the cost-sharing from plan documents for one carrier, although it appears that they cover generic EC pills. At least one carrier covers OTC purchases from a network pharmacy when the policy holder has prescription. Another carrier makes reimbursement forms available at network pharmacies for policyholders purchasing EC pills OTC, that is, it is covered if they don't have a prescription from a clinician.

Table 7: Carriers Covering Emergency Contraception by Type, Cost-Sharing Requirement, and RMM Limitations

Emergency Contraception Coverage	Ella	Generic Plan B	Plan B ^{1,2}
Covered with no RMM limitations and no cost-sharing	11	19	5
Covered with prior authorization/ step therapy and no cost-sharing	-	-	-
Covered with cost-sharing and no RMM limitations	6		5
Covered with cost-sharing unknown	1	1	1
Covered with prior authorization/step therapy and cost-sharing	-	-	-
Not covered	2	-	10

Note: 20 Carriers were reviewed.¹ One carrier's coverage varies by product line and as result the responses to this item total 21.² Two carriers cover the one pill dose (Plan B One-Step) and not the two pill dose of Plan B.

PERMANENT FORMS OF FEMALE STERILIZATION

Regardless of the setting in which it is performed, sterilization is performed by a clinician and requires ancillary services and follow-up care. There are different procedures to achieve sterilization. Surgical sterilization closes the fallopian tubes by being cut, tied, or sealed. This stops the eggs from going down to the uterus where they can be fertilized. The surgery can be done a number of ways: laparoscopic, hysteroscopic, and mini laparotomy. Essure is the first non-surgical method of sterilizing women. A thin tube is used to thread a tiny spring-like device through the vagina and uterus into each fallopian tube. The device works by causing scar tissue to form around the coil. This blocks the fallopian tubes and stops the egg and sperm from joining. Coverage of this sterilization was more complicated to ascertain than other methods.

Findings

- We were able to confirm that 10 carriers cover female sterilization with no RMM limitations and no cost-sharing. Three carriers cover female sterilization, but cost-sharing is unknown (Table 8).
- One carrier mentioned that cost-sharing may sometimes apply depending on how the physician bills and/or how system edits are applied. One carrier indicated that coverage is restricted to members at least 21 years of age.

- Seven carriers' coverage of female sterilization is unknown because the information was not included in plan documents. Sterilization is a medical benefit and the publically available plan documents related almost entirely to pharmacy benefits.
- Carriers were asked about three female sterilization procedures: laparoscopic, hysteroscopic, and mini laparotomy. The five carriers responding to these questions cover all three procedures with no cost-sharing. One reason cited for the lack of specificity about coverage of specific procedures is that the method selected is at the discretion of the physician, meaning that any procedure performed under the category of female sterilization is covered.
- Five carriers cover ancillary services, including anesthesia and supplies, and follow-up care with no cost-sharing. One carrier, however, does not cover these services. Of the remaining carriers, one indicates that only anesthesia and supplies require cost-sharing and another indicates that anesthesia and supplies are covered with no cost-sharing but notes that follow-up care is not a covered benefit.

Table 8: Female Sterilization Coverage by Cost-Sharing Requirement and RMM Limitations

Covered with no RMM limitations and no cost-sharing	10
Covered with no RMM limitations, cost-sharing unknown	3
Covered with step therapy and no cost-sharing	-
Covered with cost-sharing and no RMM limitations	-
Covered with prior authorization / step therapy and cost-sharing	-
Not covered	-
Unknown*	7

Note: 20 carriers were reviewed. * Individuals participating in interviews were unable to respond or information was not included in plan documents.

Related Coverage Issues

PROCESS FOR WAIVING COVERAGE LIMITATIONS

While carriers may employ reasonable medical management techniques, the FAQs issued by the DOL specify that carriers should have a “waiver” process for patients who have a medical need for contraceptives that are otherwise subject to cost-sharing or not covered.¹⁸ The Center for Consumer Information & Insurance Oversight published the following illustration of this requirement:

For example, plans may cover a generic drug without cost-sharing and impose cost-sharing for equivalent branded drugs. However, in these instances, a plan or issuer must accommodate any individual for whom the generic drug (or a brand name drug) would be medically inappropriate, as determined by the individual’s health care provider, by having a mechanism for waiving the otherwise applicable cost-sharing for the branded or non-preferred brand version.¹⁹

There was some confusion among the carriers interviewed about what was meant by a “waiver” of cost-sharing requirement. However, carriers identified two mechanisms by which a member can request a waiver of cost-sharing based on medical necessity. One way is for the member to request an “exception to the initial coverage decision.” This usually requires that patient’s provider submit a request demonstrating medical necessity for the contraceptive method or product that is normally not covered without cost-sharing.

The second way this is handled by carriers is through the appeals process required by the ACA. The interim final rules issued by HHS codify a member’s right to appeal a claim or coverage denial to the carrier and their right to external review. States may use the standards issued by the National Association of Insurance Commissioners (NAIC) in their external review process. Alternatively, they may utilize the HHS-administered federal external review process or contract with an accredited independent review organization to review external appeals on their behalf.²⁰ This timing, however, may be problematic and lead to delays which are not in the best interest of standards for quality contraceptive care. Regardless of the process, the carrier’s responses to the waiver request varies, and may not result in a woman obtaining the contraceptive method of her choice without cost-sharing. For example, one carrier will charge the member the difference in cost between the brand-name and generic contraceptive.

Of concern, none of the carriers interviewed had an expedited waiver or appeal processes for emergency contraceptives other than the expedited appeal process required for all other benefits, which may not be timely enough for women seeking emergency contraceptives.

RELIGIOUS EXEMPTIONS AND ACCOMMODATIONS

Certain religious employers have a religious objection to some all or contraceptive methods and may be “exempt” from the ACA contraceptive coverage mandate. Specifically “religious employers”, primarily churches and other institutions of worship, are exempt. An *exemption* means that the employer does not have to include contraceptive coverage for their workers and their dependents in their health plan.

There is also an *accommodation* available to nonprofit religiously-affiliated organizations that object to contraceptive coverage on religious grounds. Under the accommodation, a religiously affiliated nonprofit

employer does not have to contract, arrange, pay or refer their employees for contraceptive coverage. To obtain an accommodation, nonprofit employers with religious objections to contraceptives are required to provide a copy of its self-certification that it qualifies for the accommodation to its health insurance carrier or third party administrator, or notify HHS of their objection. However, the health carrier used by the nonprofit employer must provide coverage of contraceptives, at no cost, to the women and dependents covered by to the employer. The carrier is responsible for notifying the policy holders, and must provide coverage of the contraceptive methods separately. Very little is known, however, about the frequency of such requests to insurers and how insurers have responded to this requirement.

In general, the carriers we interviewed did not report difficulties in providing religious accommodation to the very few employers requesting it. All the carriers interviewed indicated that the number of employers requesting accommodation represented only a small fraction of their consumers and that they had “very few, if any” requests for the religious accommodation.

Carriers interviewed noted that they notify members of the employer’s accommodation in two primary ways. One method is to inform members, upon enrollment and in the standard annual notification of coverage, that payment for contraceptive services is provided by the carrier and excluded by their employer. Another method is to send a separate communication to members once the employer is flagged as “religiously affiliated” in the carrier’s system. One of the interviewed carriers issues a separate ID card for members to use to obtain contraceptive services.

HHS guidance suggests that the religious accommodation will be cost neutral to carriers and KFF asked carriers if they adjusted premiums as a result of the accommodation. Only one carrier indicated that they adjusted premiums for employers requesting the accommodation.

With respect to self-insured health plans, an employer can either provide a copy of its self-certification to its third party administrator (TPA) or notify HHS in writing. The TPA must then provide contraceptive services for the women in the health plan, at no cost to the women or employer. These costs can be offset by adjustments in Federally-Facilitated Marketplace user fees paid by a health insurance carrier with which the TPA has an arrangement. If the carrier does not offer exchange products, they may request that the funds are passed through a carrier that does offer exchange products. None of the interviewed carriers with self-funded products reported that they are pursuing adjustments at this time.

WELL WOMAN OFFICE VISITS AND COUNSELING

One of the women’s preventive services recommended by the Institute of Medicine and adopted by HRSA is the well woman visit. The [HRSA guidelines](#) specify that plans should cover an annual visit, “although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman’s health status, health needs, and other risk factors.” The [February 20, 2013 FAQs](#) further clarify that, “If the clinician determines that a patient requires additional well woman visits for this purpose, then the additional visits must be provided...without cost-sharing and subject to reasonable medical management.”²¹

Generally carriers that were reviewed did not place limits on the number of well woman visits with network providers and stated they will cover all visits for preventive care, without cost-sharing. For example, one carrier

indicated that claims with preventive care CPT4 codes are covered as preventive when received from in-network providers. This highlights the important role of provider billing in ensuring access to contraceptive services.

One carrier indicated that well woman visits with no cost-sharing are limited to one per year, “with consideration given for additional visits.” In the document review of another carrier it is specified that that one annual visit and one additional visit are covered without cost-sharing, but no mention of how it would be handled if women required additional preventive visits.

Interestingly, a different carrier indicated that medical visits for the purpose of obtaining a prescription for an emergency contraceptive are covered without cost-sharing. All of the carriers reviewed by this study cover medical visits for contraceptives, including counseling, and consider them preventive visits and cover them without cost-sharing. Additional preventive visits later in the year (after the annual well woman visit) are also covered without cost-sharing.

Conclusion

This analysis finds that there is variation in how the ACA's contraceptive coverage requirement is being interpreted and implemented by health plans. While most carriers are complying with the spirit of the contraceptive coverage requirement, there are some exceptions that appear to be attributable to the carriers' interpretations of the HHS regulations. In particular, some of the plans did not differentiate between similar hormonal formulations that had different delivery mechanisms, i.e., oral contraceptives, patches and vaginal rings. Because of this variation across plans, some women may not have coverage without cost-sharing to the contraceptive method of their choice. This practice does not support the current quality guidelines for family planning issued by the CDC and the federal HHS Office of Population Affairs.

The most commonly employed RMM limitation is offering preferred coverage of generics with no cost-sharing. Of the specific contraceptives studied for which a generic is available, the EC pill Plan B and the patch, carriers are less likely to also cover the brand version. Twice as many carriers cover the generic patch Xulane with no cost-sharing and no RMM limitations compared to the brand OrthoEvra patch. Xulane first became available in 2014, so it is possible that more plans will cover the generic in 2015 and, notably, in October 2014 the distribution of the OrthoEvra patch was discontinued. In addition, 16 carriers cover generic Depo-Provera injection with no cost-sharing and no RMM, but only 6 cover the brand Depo-Provera injection. While nearly all carriers (19 carriers) cover at least one generic progestin-based emergency contraceptive pill (equivalent to Plan B) with no cost-sharing, only five cover the brand Plan B.

When a generic alternative is not available, many carriers cover all the available alternatives, but some plans don't. For example, at the time the study was conducted there were only three brand-name IUDs approved by the FDA. Ten of the carriers in the study cover all three IUDs with no cost-sharing. One carrier does not cover ParaGard at all which is the only non-hormonal IUD available to women. Similarly, 10 carriers cover both of the brand implants Implanon and Nexplanon with no cost-sharing and no RMM limitations, but two carriers do not cover either brand of implant even with cost-sharing.

Notably, NuvaRing is not available as a generic and seven of the carriers interviewed apply RRM limitations and/or cost-sharing to the NuvaRing. Their rationale is that the chemical compounds are the same as other covered forms of contraception that are covered with no RMM limitations and no cost-sharing. Essentially, these carriers do not consider different delivery mechanisms that use the same active ingredients to constitute a separate and distinct form of FDA-approved contraceptive. This can also limit coverage without cost-sharing to implants and contraceptive patches.

The ella emergency contraceptive pill does not have a generic equivalent. Six carriers do not make ella available without cost-sharing and two carriers do not cover ella at all. We were not able to determine one carrier's cost-sharing for ella. This is of potential concern given recent findings that ella has a longer time window of effectiveness and may be a more preferable choice than Plan B or the generic equivalents to Plan B for women with higher BMIs.

All carriers interviewed reported that IUD and implant coverage includes the office visits necessary for insertion and removal with no cost-sharing. Likewise, carriers include the office visit for injections. However, this policy was not clearly reported or documented in all plan materials. In addition, there is considerable

uncertainty about the extent to which ancillary services associated with female sterilization, such as anesthesia or follow up care, would be covered with no cost-sharing.

Despite significant national attention to the availability of a religious accommodation, the carriers reported that very few employers using their plans elected the accommodation. Carriers did not identify difficulties in implementing the accommodation and none of the carriers with self-funded lines of business anticipate seeking reimbursement through a reduction in the fees they pay the Federally Facilitated Marketplace.

One of the cross-cutting findings of this analysis was how difficult it is to ascertain the limits on contraceptive coverage used by different carriers. The contraceptive coverage policies used by health insurance carriers were not easily accessible. Many carriers we approached for this project were unwilling to participate in an interview; only 9 out of 24 carriers invited agreed to be interviewed. Furthermore, the individuals that did participate in interviews, such as medical directors, pharmacy care managers, public policy executives, attorneys and others, were sometimes unable to respond to the full range of contraceptive topics addressed in this study. This information is even more opaque in many of the plan materials available to policyholders. Many of the publicly available documents do not clearly identify plan coverage rules when it comes to how different contraceptive methods are covered and the limitations of the coverage. This makes it extremely difficult, if not impossible for women in some plans to ascertain their coverage options. This also makes it difficult for women to determine coverage while comparing plans during open enrollment.

The current regulations and FAQs subsequently issued by HHS do not specifically proscribe how plans should implement this coverage and allow plans to apply their own definitions of reasonable medical management. In response to concerns registered by women experiencing both coverage denials and cost-sharing for FDA-approved methods such as the contraceptive ring and patch, the California State Legislature passed the [Contraceptive Coverage Equity Act of 2014](#) that was signed by Governor Jerry Brown in October 2014. This new law requires plans to cover prescribed FDA-approved contraceptives without cost-sharing. The law specifies that a plan does not have to cover more than one therapeutic equivalent of a contraceptive drug, device, or product, as long as at least one is covered without cost-sharing. Contraceptives with the same chemical formulation and delivery mechanism are therapeutically equivalent. Starting in January 2016, plans in California will be required to cover the vaginal ring, patch and birth control pills even if they have the same chemical formulation, because these methods have different delivery mechanisms. While plans must cover alternative methods/products without cost sharing, when a contraceptive product that is covered by the plan is not available or is deemed medically inadvisable by the enrollee's provider, plans may apply utilization management (e.g. step therapy or prior authorization).

For many women, the ACA's contraceptive coverage provision has reduced their health care out-of-pocket costs and given them the opportunity to use more effective but more costly methods of contraception that had been unaffordable to them in the past. This report finds that there is variation in how insurance carriers are interpreting the guidelines for contraceptive coverage issued by HHS, and that not all FDA-approved methods may be covered without cost-sharing to women policyholders. The CDC and the Office of Population Affairs have clearly stated that offering women the full range of FDA-approved contraceptive methods is an element of high quality family planning services and emphasizes the importance of contraceptive choice in reducing women's risk of unintended pregnancy. For many women with private insurance, this range of options is now a reality, for some however, their choice of plan may still result in limitations of their contraceptive options.

Endnotes

- ¹ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part XII](#)” February 20, 2013.
- ² Affordable Care Act Implementation Frequently Asked Questions (FAQs) 12, Departments of Treasury, Labor, and Health and Human Services, February 20, 2013.
- ³ Kaiser Family Foundation and Health Research Educational Trust, [2014 Employer Health Benefits Survey](#).
- ⁴ Institute Of Medicine (“IOM”), [Clinical Preventive Services for Women: Closing the Gaps](#), page 105 (2011).
- ⁵ Institute Of Medicine (“IOM”), [Clinical Preventive Services for Women: Closing the Gaps](#), page 105 (2011).
- ⁶ U.S. Department of Health & Human Services, Women’s Preventive Services: [Required Health Plan Coverage Guidelines](#).
- ⁷ Grandfathered plans are those that were in existence on March 23, 2010 and have stayed basically the same. If you buy coverage on your own and you first purchased your policy prior to March 23, 2010, it may be a grandfathered plan. See Kaiser Family Foundation, Health Reform FAQs, “[What is a grandfathered plan? How do I know if I have one?](#)”
- ⁸ [45 CFR § 147.130\(a\)\(4\)](#).
- ⁹ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part XII](#)” February 20, 2013; US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part II](#)” May 13, 2010.
- ¹⁰ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part II](#)” May 13, 2010.
- ¹¹ Andrews, M. [Insurers Refuse to Cover some Contraceptives, Despite Health Law](#), NPR Shots Blog; Sonfield A. 2013. “[Implementing the Federal Contraceptive Coverage Guarantee: Progress and Prospects](#).” Guttmacher Policy Review. 16(4).
- ¹² In September 2014, California Governor Brown signed SB-1053 into law, requiring health insurance policies in California to cover all FDA-approved contraceptives drugs, devices, and products, as well as voluntary sterilization procedures, contraceptive education and counseling, and related follow-up services by 2016, with no cost-sharing. The California law limits the use of reasonable medical management, and goes beyond the Federal requirements by prohibiting non-grandfathered and Medi-Cal plans from imposing cost-sharing requirements or other restrictions or delays in provision of contraceptive benefits. This law was not effective at the time of this study.
- ¹³ Garner. IT Glossary- [Medical Management](#).
- ¹⁴ Gavin L et al., 2014. [Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs](#), Morbidity and Mortality Weekly Report. 63(RR04); 1-29.
- ¹⁵ CDC, Reproductive Health – Contraception; Ziemann M, Guillebaud J, Weisberg E, Shangold G, Fisher A, Creasy G. Contraceptive efficacy and cycle control with the Ortho Evra/Evra transdermal system: the analysis of pooled data. *Fertility and Sterility* 2002;77: S13–18.
- ¹⁶ Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, Gainer E, Ulmann A. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception*. 2011;84:363-7; Zhang, L., et al., Pregnancy Outcome After Levonorgestrel-only Emergency Contraception Failure: A Prospective Cohort Study, *Human Reproduction*, 2009; Food and Drug Administration, Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, Federal Registrar 1997; 62: 8610-2; Office of Population Research at Princeton University, Efficacy, May 2013.
- ¹⁷ Moreau C, Trussell J. Results from pooled Phase III studies of ulipristal acetate for emergency contraception. *Contraception*. 2012;86:673-680.
- ¹⁸ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part XII](#)” February 20, 2013.
- ¹⁹ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part XII](#)” February 20, 2013.
- ²⁰ Center for Consumer Information & Insurance Oversight Affordable Care Act: Working with States to Protect Consumers, May 22, 2014.
- ²¹ US Department of Labor: Employee Benefits Security Administration “[FAQs about Affordable Care Act Implementation Part XII](#)” February 20, 2013.



THE HENRY J. KAISER FAMILY FOUNDATION

Headquarters

2400 Sand Hill Road
Menlo Park, CA 94025
Phone 650-854-9400 Fax 650-854-4800

Washington Offices and Barbara Jordan Conference Center

1330 G Street, NW
Washington, DC 20005
Phone 202-347-5270 Fax 202-347-5274

www.kff.org

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