Intrauterine Devices and Implants: A Guide to Reimbursement

SECOND EDITION











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The American College of Obstetricians and Gynecologists (ACOG) is a membership organization dedicated to the advancement of women's health care through continuing medical education, practice, and research. The College's Long-Acting Reversible Contraception (LARC) Program works to reduce unintended pregnancy in the US by providing information and guidance on the most effective reversible contraceptive methods, the contraceptive implant and intrauterine devices (IUDs), and by increasing access to the full range of contraceptive methods. For more information about the ACOG LARC Program, visit acog.org/goto/LARC.

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The National Women's Law Center (NWLC) is a non-profit organization whose mission is to expand the possibilities for women and girls by working to remove barriers based on gender, open opportunities, and help women and their families lead economically secure, healthy, and fulfilled lives— especially low-income women and their families. For more information about NWLC, visit nwlc.org.

The University of California, San Francisco (UCSF) Bixby Center for Global Reproductive Health works to ensure that women, men, and adolescents have the power to manage their health, including access to safe and effective birth control, abortion, childbirth, and prevention and care for sexually transmitted infections. UCSF's rigorous research generates evidence that is translated into better health policies and clinical care. For more information about the UCSF Bixby Center, visit bixbycenter.ucsf.edu.

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SECTION 1: INTRODUCTION

Long-acting reversible contraceptive (LARC) methods such as intrauterine devices (IUDs) and contraceptive implants are safe and highly effective forms of contraception. Although these methods are cost-effective over time, the upfront prices of LARC methods are significantly higher than other contraceptives. Insurance coverage of LARC has improved in recent years, reducing or eliminating the out-of-pocket cost barriers for many women. However, the underlying pricing inequity continues to pose challenges that are particularly salient for safety-net family planning providers that offer these methods—or that would offer these methods but cannot afford to stock them. In turn, these obstacles create access barriers for women seeking LARC methods, especially low-income and uninsured women. Both patients and providers identify cost as the most significant barrier to accessing LARC methods. 3,4,5

This guide aims to explain the landscape of LARC public and commercial insurance coverage and serve as a resource for providers navigating stocking, reimbursement, and other scenarios that create barriers to the provision of these methods. The guide is intended to help alleviate financial challenges so that providers are better able to offer the full range of contraceptive methods and minimize out-of-pocket costs or delays in care for their patients. This guide is not intended to endorse LARC methods over other types of contraception, nor is it intended to endorse any one commercial product or program. Quality family planning care is patient-centered: respectful of and responsive to individual patient preferences, needs, and values. ⁶ Choosing the most appropriate method, or whether to use a method at all, is an individualized process influenced by women's preferences and concerns, reproductive goals, and medical histories.

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SECTION 2: COVERAGE ELIGIBILITY

The landscape of health care coverage is changing in the United States - and this is good news for women seeking affordable access to contraception, including LARC methods. The Affordable Care Act (ACA) is dramatically expanding the availability of both public and commercial insurance options that are required to cover all methods of contraception approved by the US Food and Drug Administration (FDA), without cost-sharing. The ACA defines cost-sharing as including "deductibles, coinsurance, copayments, or similar charges." In addition, longstanding Medicaid coverage rules continue to ensure broad access to LARC methods and other family planning services and supplies. However, in spite of these strong requirements, some women continue to encounter barriers to coverage that may be more prevalent in the context of LARC than other less expensive or self-administered methods. This section provides a basic overview of federal contraceptive coverage requirements for commercial plans, state Medicaid programs, and other types of insurance. Advocacy tips and resources are offered throughout for providers that encounter inappropriate coverage denials in their practices.

2.1: Commercial plans

Commercial plan coverage requirements for LARC methods

Most commercial insurance plans must cover LARC methods without cost-sharing. Under the ACA, all new insurance plans (both individual and employer-sponsored plans) are required to cover all FDA-approved methods of contraception, sterilization, and related education and counseling without cost-sharing. (Note: the ACA contraceptive coverage requirement described in this section also applies to Medicaid "Alternative Benefit Plans," explained in Section 2.2.) No cost-sharing means that patients should not have any out-of-pocket costs, including payment of deductibles, co-payments, co-insurance, fees, or other charges for coverage of contraceptive methods, including LARC. Patients cannot be asked to pay upfront and then be reimbursed.

There are a limited number of commercial plans to which the ACA contraceptive coverage requirements do not apply. In general, the best way to determine whether a patient's plan falls into any of these categories is to have her ask the plan administrator, or (in the case of an employer plan) the human resources department. Additionally, the following information may help to further clarify a patient's coverage policy.

Commercial plan coverage exceptions

"Grandfathered" plans do not have to comply with this requirement. The law only applies to "new" plans. Older plans were "grandfathered" into the system if they existed on or before the day the ACA was signed into law on March 23, 2010. In addition, to maintain "grandfathered" status, plans cannot change significantly, which means they cannot significantly cut benefits; increase cost-sharing; or change premium contributions by more than 5%. The number of "grandfathered" plans is declining. An estimated 26% of people with employer-sponsored insurance were in grandfathered plans in 2014, a decrease from 36% in 2013.

Some religious employers do not have to comply with this requirement. At the time of this publication, litigation regarding some employers' religious objections to the ACA's contraceptive coverage requirement was ongoing. For the most up-to-date information on which employers are exempt from the law's requirement and which employers have an accommodation that enables women enrolled in their health plans to have their prescription birth control covered directly by their insurers, please visit NWLC's website.8

Which LARC methods must be covered with no cost-sharing?

The ACA requires that applicable plans cover all FDA-approved methods of contraception for women. The government has consistently been clear that LARC methods must be covered. In guidance released in 2013, it affirmed that both IUDs and implantable rods must be covered under the ACA. Additional guidance from the federal government in 2015 has clarified that plans must cover at least one form of contraception in each method category for women listed on the FDA's Birth Control Guide. Insurers must ensure that plans comply with this guidance in the first health plan year that starts on or after July 10, 2015. Currently, there are three FDA-approved LARC methods on the FDA's guide:

- implantable rod,
- IUD copper, and
- IUD with progestin.¹¹

Which LARC-associated services must be covered with no cost-sharing?

Services related to a LARC method should be covered without cost-sharing. This includes "clinical services, including patient education and counseling, needed for provision of the contraceptive method," and "[s]ervices related to follow-up and management of side effects, counseling for continued adherence, and device removal." ¹³

What is allowed within "reasonable medical management"?

"Medical management" is broadly understood to encompass insurer practices that aim to control costs and promote efficient delivery of care. Insurers routinely use medical management techniques to govern the availability of benefits. Although plans are allowed to use "reasonable" medical management techniques, their ability to do this is limited under the law. Plans may use medical management techniques only *within* a birth control method category, not between categories. For example, plans may cover one IUD with progestin without cost-sharing while imposing cost-sharing on others. 14 Additionally, plans may impose cost-sharing for:

- Services and contraceptives provided at out-of-network providers and pharmacies. However, plans must cover out-ofnetwork services without cost-sharing if there is no provider in-network who can perform the service.
- Brand-name drugs and devices that have a generic equivalent as long as a generic equivalent is covered without cost-sharing.

If a plan uses medical management techniques within a specified birth control method category, it must have an "expedient exceptions process" so that the patient can access the specific birth control her health care provider determines is medically necessary. Medical necessity includes such factors as "severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider." The exceptions process must defer to the provider's determination. ¹⁵

Furthermore, any rule that, in effect, denies coverage without cost-sharing for an entire method category of contraception is not allowed. For example, a plan cannot say it only covers generic forms of birth control and therefore deny coverage for all IUDs.

How can a provider help a patient who has trouble accessing LARC methods without cost-sharing?

- 1. Confirm with the patient's health plan the documentation required for appropriate coverage without cost-sharing. See Section 4.5 for coding guidance.
- 2. If appropriate, contact the plan to request an exception, sometimes called a "waiver." Insurance plans subject to the

- ACA contraceptive coverage requirements must allow access to an off-formulary contraceptive if medically indicated.
- 3. Contact the plan's medical director to voice concerns with barriers to accessing care.
- 4. Contact (or direct the patient to contact) NWLC's CoverHer hotline (coverher.org, coverher@nwlc.org, 1-866-745-5487). NWLC can help the patient navigate this process.

2.2: Medicaid

The Medicaid landscape is changing in the United States and several trends are particularly important in the context of contraceptive coverage. Thanks to the ACA, many states are expanding Medicaid eligibility to include previously ineligible adults of reproductive age who will now receive coverage of all FDA-approved contraceptive methods. Additionally, some states are establishing or extending Medicaid family planning "expansion programs" that serve as an important source of contraceptive coverage for many low-income individuals. Other states are unfortunately phasing these expansion programs out. Finally, states have dramatically increased their use of managed care delivery systems, which in some cases has impeded access to covered contraceptives, particularly LARC methods.

Medicaid coverage requirements for LARC methods

Since 1972, federal law has required that all state Medicaid programs cover family planning services and supplies without cost-sharing for enrolled individuals of reproductive age. However, states have some flexibility when defining the specific package of family planning services and supplies that are covered. States also have flexibility to impose utilization controls, such as prior authorization, that limit the availability of covered services and supplies. For these reasons, Medicaid family planning coverage varies by state. While most, if not all, states cover LARC methods in some form, it is possible that states may have differing policies with regard to specific methods or the conditions under which they are covered. Providers should consult their state's Medicaid provider manual(s) for state-specific coverage details. Additionally, providers should monitor remittances from Medicaid to ensure that reimbursement and payment practices reflect the policies in the provider manual.

Medicaid laws and implementing policy principles call for the removal of LARC methods to be a covered Medicaid service. However, states have flexibility when determining payment policies (e.g. fee-for-service, bundled payments, global payments), which may, in effect, deny separate reimbursement for removal in some contexts. Some states have also been known to deny coverage of IUD removal absent a medical justification. Providers should consult their state Medicaid provider manual(s) for state-specific coverage details and for instructions about how to bill for LARC method removal when the services are covered.

If your state Medicaid program does not cover a particular LARC method or a related service such as removal, or if your state places inappropriate limits or restrictions on these services, please e-mail NHeLP at nhelp@healthlaw.org with "reproductive health" in the subject line.

Medicaid eligibility

To be eligible for Medicaid, an individual must be low-income, fit into an eligibility group, meet certain citizenship or immigration requirements, and be a resident of the state in which she is applying. States are required by federal law to cover specific eligibility groups (including pregnant women, children and teens, and very low-income adults with dependent children) and have the option to cover certain others. The rules for deciding whether an individual falls within a covered group can be complicated, and Medicaid benefits can differ between eligibility groups.

Historically, non-pregnant, non-disabled adults without dependent children were not eligible for Medicaid, regardless of income. Under the ACA, however, states have the option to expand Medicaid coverage to this group. This represents the largest eligibility expansion since the Medicaid program began and a tremendous opportunity for millions of low-income women and men to access affordable health care, including reproductive health services. Unfortunately, many states have not yet elected to implement this Medicaid expansion, creating a coverage gap for low-income people in these states.

Some state Medicaid programs extend coverage of family planning and related services to individuals who do not otherwise qualify for Medicaid. Eligibility criteria for these family planning expansion programs vary.

Find your state's Medicaid eligibility levels. 16

Find out if your state is implementing the ACA's Medicaid expansion. 17

Find state family planning expansions and eligibility criteria.¹⁸

Medicaid Alternative Benefit Plan coverage requirements for LARC methods

Since 2005, states have had the authority to enroll Medicaid enrollees, with some exceptions, in Alternative Benefit Plans (ABPs). The benefit packages in these ABPs mirror the benefits in certain specified commercial health plans. The ACA raised the significance of ABPs by designating them as the benefit packages offered to the majority of the ACA's Medicaid expansion population. (See *Medicaid eligibility.*)

While all state Medicaid plans are required to cover family planning services and supplies without cost-sharing, federal regulations now additionally require Medicaid ABPs to cover all of the preventive services that most commercial insurance plans must cover under the ACA, including all FDA-approved contraceptive methods, without cost-sharing. This means that millions of newly eligible low-income women who enroll through the Medicaid expansion will receive coverage of all LARC methods, no matter how the state defines its family planning benefit for the rest of its Medicaid program. Additionally, as explained in Section 2.1, the ACA contraceptive coverage requirements include patient education and counseling, related follow-up and side effect management, and importantly, LARC method removal. A growing number of states, including Idaho, West Virginia, and Kentucky, also enroll groups of Medicaid-eligible individuals other than the Medicaid expansion population into ABPs, who will also benefit from these requirements.

Medicaid managed care plans

In its early years, Medicaid operated almost exclusively through a fee-for-service payment system in which providers were reimbursed directly by state Medicaid agencies for each service provided. Now, almost all state Medicaid agencies contract with managed care entities, including managed care organizations (MCOs), and nearly three quarters of Medicaid beneficiaries receive services through some type of managed care arrangement.

While most managed care arrangements require enrollees to obtain services from a specific network of providers, federal law protects access to covered reproductive health services by guaranteeing that Medicaid enrollees can seek covered family planning services from any Medicaid-participating provider. This protection is called "freedom of choice" and applies even when an enrollee of a managed care plan seeks family planning services out of network. Whether out-of-network providers should submit claims to the patient's managed care plan or directly to the state or other entity depends on the arrangement specified in the managed care plan's contract, and providers should consult their Medicaid provider manual(s) or state Medicaid agency for more information.

Some states "carve out" family planning services and supplies from contracts with MCOs that claim a religious objection. In these instances, the state Medicaid program must still ensure that enrollees have access to these benefits and will typically cover them directly through a fee-for-service billing system. However, some states may require a denial from the managed care plan before agreeing to pay the claim. Providers should consult their state's Medicaid provider manual(s) or state Medicaid agency for more information.

In addition, Medicaid managed care plans are permitted to place "appropriate" limits on covered services for the purpose of utilization control, unless their contract with the state prevents them from doing so. Some plans have used this flexibility to impose prior authorization and step therapy requirements that limit access to covered LARC methods.

Medicaid managed care utilization controls

If you encounter a utilization control policy in a Medicaid managed care plan that prevents access to a covered LARC method, please notify NHeLP at nhelp@healthlaw.org and include "reproductive health" in the subject line.

Medicaid coverage for adolescents

As explained above, states have some flexibility to determine the specific family planning services and supplies and related services that are covered for adults under their state Medicaid plans. Importantly, however, federal Medicaid law requires that states cover screening services and Medicaid diagnostic and treatment services that enrollees under 21 years old need, regardless of whether or not those services are otherwise covered for Medicaid-enrolled adults. This benefit is known as Early and Periodic Screening, Diagnostic, and Treatment (EPSDT).

While a state may establish tentative limits or require prior authorization before a treatment, service, or supply is covered for an adolescent, EPSDT requires coverage decisions to be made based on the needs of the individual. A state could not, for example, automatically deny coverage of a particular prescribed LARC method for an adolescent under a step therapy requirement without evaluating her needs for the prescribed service individually. Moreover, a decision to deny coverage of a prescribed service may be appealed by the enrollee (or her family) under the state's Medicaid fair hearing procedures.

For more information about coverage requirements for children and adolescents enrolled in Medicaid, see EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents.¹⁹

Medicaid family planning expansion programs

States have the option to extend coverage of family planning and related services to individuals who are not otherwise eligible for Medicaid. These programs are a critical source of contraceptive coverage for low-income individuals, particularly in states that have yet to expand their Medicaid programs. Eligibility for these programs may vary from state to state. As in the traditional Medicaid program, states have some flexibility when defining the scope of covered family planning and related services, and coverage can vary. Providers should consult their state's Medicaid provider manual(s) or state Medicaid agency for state-specific coverage details. Some state family planning expansion programs are implemented through a time-limited "waiver" and are set to expire sometime between 2015 and 2018. The Guttmacher Institute provides a regularly updated list²⁰ of state family planning expansion programs, expiration dates (where applicable), and eligibility criteria.

2.3: Other coverage

TRICARE

Plans that are part of the TRICARE military insurance system do not have to comply with the ACA requirement to cover contraception without cost-sharing. While the ACA does not apply to plans administered by the federal government, the government applied the contraceptive coverage requirement to its health insurance program for civilian federal employees. It was not able to do so for members of the military and their dependents. Although TRICARE covers several contraceptive methods, it does require cost-sharing for beneficiaries who are not active duty military personnel. At the time of this guide's publication, legislation to ensure all service men and women and their dependents who rely on the military for health care have comprehensive contraceptive coverage and counseling without cost-sharing was pending.

Medicare

At the time of this guide's publication, advocates are seeking clarity about complex coverage rules related to Medicare and coverage of LARC methods, particularly for individuals who are dually eligible for both Medicare and Medicaid. If you or your colleagues have experience billing Medicare for LARC methods or related services, please let us know by contacting NHeLP at nhelp@healthlaw.org and including "reproductive health" in the subject line.

SECTION 3: STOCKING

The US Centers for Disease Control and Prevention (CDC) and the US Office of Population Affairs (OPA) recommend stocking a broad range of contraceptive methods, including IUDs and implants.²¹ Having LARC methods in stock ahead of demand facilitates same-day provision and helps avoid pharmacy access problems for some patients. Research also supports the practice of stocking these methods for same-day provision, as there is no medical reason to require more than one visit for initiation of LARC methods for women without contraindications to these methods.²²

3.1: Forecasting without history of IUD or implant provision

If a practice has not stocked IUDs or implants before, it may be challenging to estimate patient demand. The Reproductive Health Supplies Coalition recommends forecasting demand for new contraceptive products based on a combination of patient, provider, and finance factors.²³ Figure 1 shows possible sources of information about each of these factors.

For example, if a provider is able to count the number of referrals given for LARC methods in the last year, this figure can be divided by 12 to find average monthly demand. A reasonable starting point might be to order a three-month supply.

A provider may also be able to assess demand by screening patients for their interest in LARC methods when they are scheduling an appointment or using a brief survey filled out in the waiting room. See Figure 2 for a sample survey.

Figure 1. Forecasting when demand is uncertain: Sources of information

Patient

- Annual female contraceptive patient population
- Any available historical information about demand, such as number of patients receiving referrals for LARC methods in the last year
- Annual provision of LARC methods from other practices with a similar patient population
- Patient survey of LARC method interest (Figure 2)

Provider

- Number of providers trained to place LARC methods
- Providers' comfort with offering same-day placement

Finance

- Number of patients with coverage that eliminates cost-sharing
- Available funds for procurement

Figure 2. Forecasting when demand is uncertain: Sample survey to assess patient interest

This quick survey is to help us better understand our patients' needs and interests. This is an anonymous survey, which means you cannot be identified by your answers. However, you do not need to answer questions you are uncomfortable answering.

What is your age?			
Have you heard of intrauterine devices (IUDs)?	Yes	No	Not sure
Would you like more information about IUDs?	Yes	No	Not sure
Are you interested in trying an IUD?	Yes	No	Already have one
Have you heard of the contraceptive implant?	Yes	No	Not sure
Would you like more information about implants?	Yes	No	Not sure
Are you interested in trying an implant?	Yes	No	Already have one

This survey is only intended to assess potential demand for LARC methods. Quality family planning care should include counseling patients on all methods regardless of how a patient responds to the survey.

Providers may find that the cost of the LARC method determines how many a practice can afford to stock. See Section 3.2 for more information on defraying the costs of procurement.

3.2: Obtaining supplies

In general, there are two ways that LARC methods can be covered by patients' health insurance plans: as a medical benefit or a pharmacy benefit.

When a LARC method is covered as a *medical benefit*, a provider:

- 1. Buys the LARC method directly from the manufacturer or a designated pharmacy or specialty distributor.
- 2. Bills the patient's insurance carrier for the LARC method and insertion procedure.

This is commonly described as "buy and bill."

When a LARC method is covered as a pharmacy benefit:

1. A pharmacy or specialty distributor bills the patient's insurance carrier directly for the LARC method.

2. A provider bills the patient's insurance carrier for related procedures and services.

Whether LARC methods for Medicaid enrollees must be billed by a pharmacy or stocked and billed by a provider upon insertion varies by state. Providers should consult their Medicaid provider manual(s) for state-specific coverage details.

Each of these models for purchasing LARC methods has benefits and drawbacks. In general, the medical benefit approach may facilitate offering same-day placement of LARC methods, but may require a significant capital outlay. In general, the pharmacy benefit approach reduces the need for upfront capital, but may make it difficult to provide same-day placement. Patients and providers can both advocate for the model that will work best. Specifically, providers can advocate that both billing options should be available to them by giving an insurance plan medical director information regarding the benefits and safety of same-day placement of LARC methods. 244,25,26

Training Requirements and Opportunities

For a list of ongoing clinician training opportunities for LARC methods, including method-specific trainings from Bayer, Merck, and Teva, see the list compiled by ACOG.²⁷

The newest IUD on the US market, Liletta, is now available for ordering. To schedule a training, call (866) 563-3678.

To purchase contraceptive implants, practices must have at least one licensed clinician who has completed a Nexplanon training and received a training certificate containing a student ID number. Visit the Nexplanon website²⁸ to sign up for a training.

Stocking other instruments and supplies

In addition to stocking LARC methods, practices will need to stock the other instruments and supplies²⁹ commonly used for LARC method insertions and removals. Keep in mind that these supplies are part of the cost of providing LARC methods.

When the LARC method is covered as a medical benefit

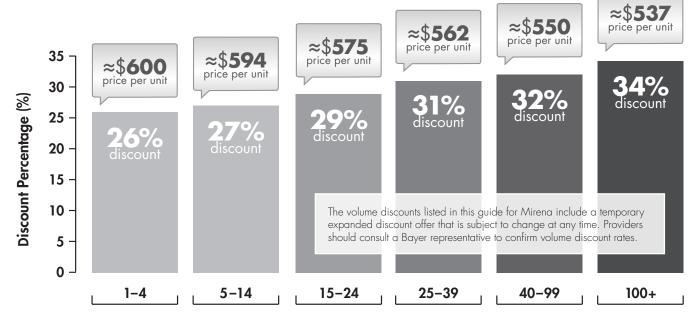
IUDs may need to be purchased directly from the manufacturers, or through a distributor, depending on the type of device. Implants can be purchased from the specialty pharmacies CVS Caremark or Curascript. When purchasing LARC methods, providers may be able to realize benefits from volume discounts, 90-day net terms, and other payment options.

LNG-IUS

Bayer offers a "buy and bill" option via the Women's Health Care Support Center to help providers stock its two LNG-IUS methods (Mirena® and Skyla®) in advance of patient request. They provide 90-day net terms, credit card or e-check payment, and tiered discounts (Figures 3 and 4). Providers can place a wholesale order by registering and ordering online, 30 completing and faxing a wholesale order form, 31 or calling 1-866-647-3646 at any time.

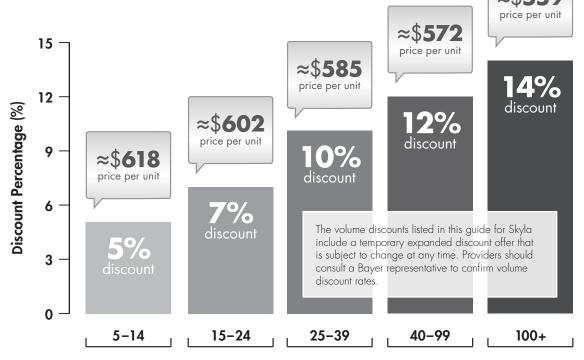
The Bayer online system provides support for ordering products, checking account status, making payments, and accessing any needed forms. Providers will need an email address, NPI number, and a clinician's state license number in order to register for the online system. A validation form is issued at the end of the registration process, which must be completed and returned to the fax number provided; access to the online system is granted within 48 hours. If the address on the clinician license is different from the shipping address, providers will also need to provide a letter of affiliation.³²





Number of Units Ordered

Figure 4. Tiered discounts for Skyla purchases³⁴



Number of Units Ordered

For wholesale orders placed online, providers have the option to pay for the entire order, make a partial payment, or be invoiced later. Wholesale orders using the paper form provide the option to pay for the entire order or be invoiced later.

The only distributor of the Medicines360 LNG-IUS, Liletta[™], is ANDA. ANDA offers a "buy and bill" option to help providers stock Liletta in advance of patient request. They provide 90-day net terms, credit card payment, and tiered discounts (Figure 5). Providers can place a wholesale order by registering and ordering online³⁵ or calling 855-545-3882 from 8:00 a.m. to 8:00 p.m. ET, Monday through Friday.

The online system allows providers to order products, check shipments, make payments, access forms and obtain reimbursement assistance. Providers will need an email address, NPI number, copy of the clinician state license and DEA number in order to register. To access 340B pricing, a provider will also need to supply an active 340B number and be registered with Apexus. ³⁶ No letter of affiliation is required when the clinician license and shipping address are in the same state. New accounts are activated within 48 hours. A practice may qualify for a line of credit; ask the ANDA representative after the account has been activated. Orders placed during business hours will be shipped for next day delivery.

For a practice placing its first order of fewer than 5 Liletta devices, ANDA offers a one-time "Ready Stock" program with 120-day terms.

Copper IUD

Currently the only manufacturer of a copper IUD is Teva, which offers "buy and bill" via ParaGardDirect to help providers stock copper IUDs (ParaGard®) in advance of patient request. This service allows 90-day net terms (despite the application stating they offer only 30-day net terms); payment by credit card, check, or a line of credit; and tiered pricing discounts (Figure 6). Providers can place a wholesale order by applying for an account³⁷ and ordering³⁸ online, or calling ParaGardDirect at 1-877-727-2427 between 8:30 a.m. to 8:00 p.m. ET, Monday through Friday.

To apply for an account, practices will need an email address, a DEA or Health Industry number, and a copy of a clinician's state license. If the address on the clinician license is different from the shipping address, the provider will also need to submit a letter of affiliation.³⁹

Figure 5. Tiered discounts for Liletta purchases

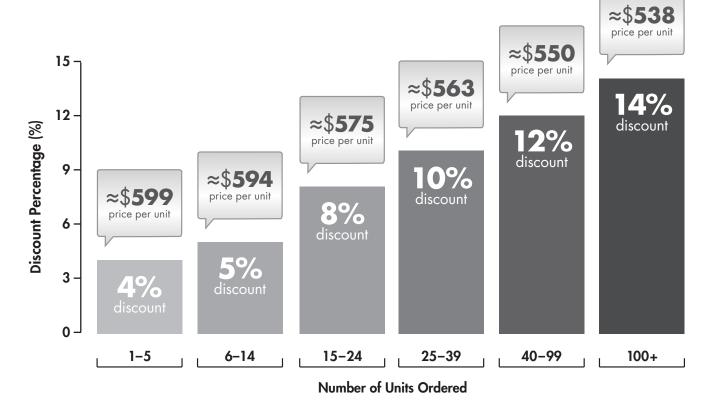
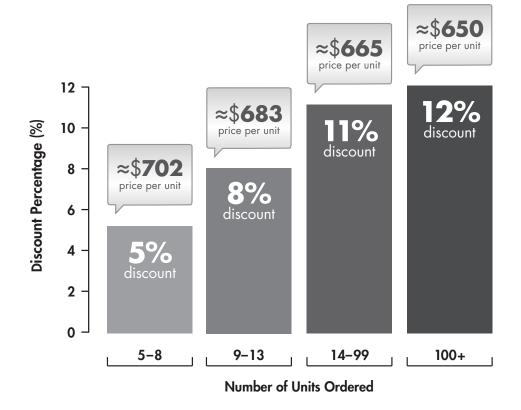


Figure 6. Tiered discounts for ParaGard purchases



Some providers may not immediately be eligible for a line of credit with ParaGardDirect when first opening an account; however, most will qualify for one after establishing a credit history with the company. The payment terms remain the same regardless of how invoices are paid.

Implant

Currently the only implant available is manufactured by Merck (Nexplanon®), which offers two "buy and bill" options via CuraScript and CVS Caremark to help providers stock the implant in advance of patient request. Both specialty distributors provide 90-day net terms, credit card payments or lines of credit, and a 2% discount for orders paid with a credit card or within 90 days if invoiced. Neither distributor offers volume discounts for the implant. Providers may request assistance with determining which distributor to use and be directly connected to both distributors by calling Merck at 1-877-467-5266 from 8:00 a.m. to 8:00 p.m. ET, Monday through Friday. Both distributors require that any providers purchasing implants must first complete the required Merck training program.

To order from CuraScript, you must first establish an account. Call 1-866-844-0148 and the Nexplanon team will help you apply for an account. A provider will need an email address, DEA number, federal tax ID number, a clinician's state license number, and a student ID number from the Nexplanon training certificate to complete the application. Bank references are also required if a provider is seeking a line of credit. To get access to 340B pricing, providers must supply their active 340B number. Curascript will confirm your access to 340B prices, which may take 5 to 15 days. Once an application is complete, an account is usually set up within 48 hours. To place an order using a CuraScript account, providers should call 1-866-844-0148 or order online. Orders received by 6:00 p.m. ET are processed that day and shipped second-day delivery. Overnight shipping is also available upon request.

To order from CVS Caremark, providers should contact a customer service representative at 1-866-318-3492 and request a "Buy and Bill Order Form." For wholesale purchases, a provider will need to complete a wholesale agreement and a letter of affiliation for each clinician in the practice. To make either an individual or wholesale purchase, a provider will need an email address, NPI number, a clinician's state license number, and a student ID number from the Nexplanon training certificate. Orders received by 4:00 pm ET are processed that day and shipped second-day delivery. Overnight shipping is also available upon request.

When the LARC method is covered as a pharmacy benefit

LARC methods are sometimes covered as a pharmacy benefit, which may make stocking the methods ahead of time challenging. It can take up to seven days to receive products ordered via the various specialty pharmacy programs (SPPs).

LNG-IUS

All three distributors of the Bayer LNG-IUS methods —CVS Caremark, Prime Therapeutics, and Walgreens—offer an SPP option. Providers should complete the Specialty Pharmacy Prescription Request form⁴¹ and include patient authorization when sending the completed form to the chosen pharmacy distributor. The Mirena website includes detailed instructions⁴² for completing these forms.

If a patient orders a Bayer LNG-IUS via specialty pharmacy and does not return for the insertion visit for four or more months, the provider may be able to return the unit and obtain a refund. Providers should refer to the Bayer Abandoned Unit Program Frequently Asked Questions for more details.⁴³

The Medicines 360 LNG-IUS is available through Accredo Specialty Pharmacy. Providers should call 877-ACCREDO to place an order. Each order requires a copy of the patient's insurance card, basic patient demographics, and a prescription. If a patient intends to use the Liletta Patient Assistance Program (see Section 4.3), the provider should supply the Liletta card number along with the order. It may take up to 7 days to verify a referral; once complete, the product is sent to the practice by overnight mail.

Copper IUD

Women's Health Access Solutions is the SPP for the copper IUD. A provider must complete the Patient Referral and Patient Authorization forms.⁴⁴ In order to have the copper IUD delivered directly, a provider should select "Prescriber office will use Specialty Pharmacy" under the form's section, "How do you intend to obtain ParaGard?"

Implant

Prescription orders may be placed for individual patients using the same distributors as for wholesale. Send the prescription using the CuraScript Benefit Verification Form (1-866-844-0148) or the CVS Caremark Service Request Form (1-866-318-3492).

Patients purchase LARC methods using a payment plan

Patients wishing to use an implant or copper IUD are able to arrange staggered payment plans with credit cards through Curascript or Teva Women's Health,⁴⁵ respectively. For an implant, a patient may choose to make three or six monthly payments. For a copper IUD, a patient may choose to make four or 12 monthly payments. In both cases, patients must provide a clinician's name, address, phone, and fax number to place an order, and the LARC method is shipped directly to the clinician. For details about these programs, see Section 4.4. Other LARC methods do not have staggered payment plans available.

3.3: Are supplies available at lower costs?

A provider may be eligible for drugs and devices at a reduced cost through the 340B program or a group purchasing organization (GPO) such as the California Family Health Council's Co-op⁴⁶ or Afaxys GPO services.⁴⁷ These distributors can offer 340B pricing for eligible entities registered on the Health Resources and Services Administration (HRSA) website.⁴⁸ A provider may use a product purchased through 340B pricing with any patient who meets HRSA's definition of an eligible patient,⁴⁹ and should contact the wholesaler or GPO for more information on available discounts. Note that GPOs are prohibited for hospitals but all other 340B-eligible entities may use them.⁵⁰

In addition, Afaxys GPO members may qualify for discounts on the Bayer LNG-IUS devices separate from 340B pricing. To learn about these discounts, contact Bayer by calling (877) 229-3750 or emailing bhcpharm.customerservice@bayer.com.

Some patients may qualify for reduced cost IUDs through the manufacturers' patient assistance programs such as ARCH Patient Assistance Program for Mirena and Skyla.⁵¹ Refer to Section 4.4 for more information on how patients can access these programs.

340B pricing for LNG-IUS devices

Federal law requires that 340B pricing be at least 23% lower for a name brand product and 14% lower for a generic product, using the average manufacturer retail price as the basis. 52 Manufacturers may, however, set the price at a lower level of their choosing. For example, Liletta has a 340B price of \$50. Medicines 360 does not intend to adjust this price over time.

3.4: What to do with too much (or too little) stock

If a health center uses a fixed ordering system—meaning drugs and devices are ordered on a predetermined schedule—and finds that it runs low or has more stock than needed, try implementing a minimum/maximum inventory control system. The Pocket Guide to Managing Contraceptive Supplies has the worksheets needed to calculate minimum and maximum stock levels.⁵³

Who can answer other questions about ordering?

Each manufacturer of IUDs and implants has specialty support for ordering and reimbursement questions. Providers that have an account with any of the wholesale groups discussed above should contact them directly. Providers can also contact the manufacturer representative assigned to them for additional guidance.

To find a local representative:

LNG-IUS: For Mirena and Skyla, call 1-888-842-2937 and request a visit from a representative. For Liletta, call 1-855-545-3882 and follow the prompts to request a field sales representative.

Copper IUD: call 1-877-PARAGARD and ask for customer service or email paragardrequest@tevawomenshealth.com.

Implant: call the National Service Center at 1-800-NSC-MERCK and request to be contacted by a representative

SECTION 4: OBTAINING REIMBURSEMENTS

Contracting

If you need support contracting with any of the payers discussed in this section, see this resource⁵⁴ or contact NFPRHA at info@nfprha.org.

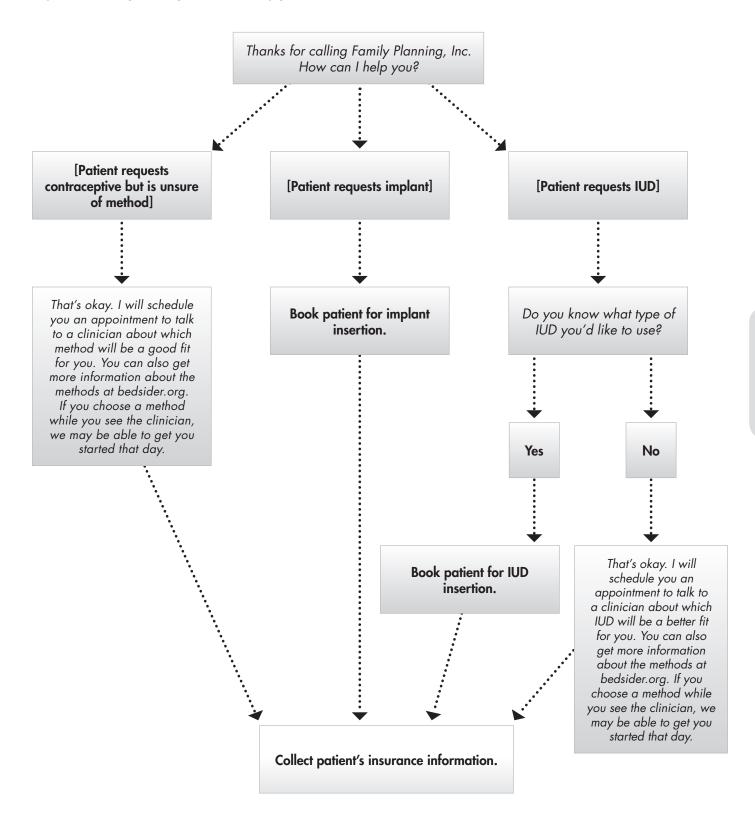
Submitting claims and receiving appropriate reimbursement for LARC methods, as well as receiving payment for associated services such as counseling, placement, and removal, are important means of supporting the continued ability of providers to offer LARC methods to patients. The high up-front costs of these LARC methods can challenge cash flow if reimbursements are not received in a timely manner. The information in this section will assist offices in setting up systems that can help improve reimbursement processes for supplies (drugs or devices) and payment for services (counseling, placement, and removal).

Note: LARC methods are most commonly included as a medical benefit in health insurance plans. However, some plans may cover LARC methods as a pharmacy benefit, which may affect a provider's ability to submit claims for the methods. See Section 3 for more information on medical vs. pharmacy benefits.

4.1: Before a patient's appointment

As described in Section 2, there are coverage requirements that apply to both commercial and public insurance plans. Collecting information about a patient's insurance status prior to an appointment can facilitate same-day placement of LARC methods by clarifying what requirements pertain to the patient's coverage. Furthermore, patients may not always know which contraceptive method they want while making their appointment, so it is important to provide them with information regarding methods before the appointment to assist with the provision of any contraceptive method, including LARC methods. One way to facilitate this is to provide staff with a brief script exploring which contraceptive methods, if any, interest a patient (Figure 7).

Figure 7. Sample script: Scheduling patients for LARC methods



4.2: Working with patients covered by public payers

As covered in Section 2, Medicaid coverage of family planning can vary between states and plans. State Medicaid programs are required to cover family planning services and supplies without cost-sharing, but the specifics of that coverage vary. Additionally, Medicaid ABPs must cover all FDA-approved contraceptive methods as required by the ACA. Information about covered services and a Medicaid program's reimbursement policies can be found in provider manuals that each state Medicaid agency should make available online. Be aware that some reimbursement policies may also be contained in supplemental Medicaid provider bulletins or notifications. The National Association of Medicaid Directors provides current links⁵⁵ to state Medicaid programs' websites.

Medicaid managed care plans may have their own unique reimbursement policies for LARC methods. Providers should refer to the plan's reimbursement policies or consult the managed care plan's provider relations representative.

It is a best practice for providers to research the coverage details of various public plans and create job aids to provide staff with quickly accessible information. Figure 8 is a sample job aid to demonstrate the coverage in different Medicaid plans.

NOTE: Patients enrolled in Medicaid cannot be charged a copay for covered family planning services or supplies, including LARC methods.

Additionally, verifying the benefits of a patient's individual health plan will help providers ensure coverage prior to the time of service. Going through this step prior to a patient's appointment can help to determine if coverage exists, and if not, what steps the patient and provider can take at the time of the visit to review alternative support methods discussed later in this section under *Self-Pay Patients*. Benefits verification is discussed in more detail below.

A note about Medicaid managed care

Medicaid managed care plans may have a different and complex set of coverage rules and requirements. Therefore, it is important that providers research the intricacies of each managed care plan encountered and not assume that its reimbursement policies are the same as Medicaid coverage administered directly by a state agency.

4.3: Working with patients covered by commercial payers

Commercial payers offer varying levels of coverage for family planning services (see Section 2 for details on coverage requirements). However, patients may not have a clear understanding of the details of their own plan's coverage. It is a best practice for providers to research the coverage details of various plans and

Figure 8. Sample job aid: Medicaid coverage of LARC methods

(Note: For illustrative purposes only. Coverage varies by state.)

Medicaid Plan	Implant	Implant insertion	Implant removal	LNG-IUS	Copper IUD	IUD insertion	IUD removal
Full Benefit Medicaid	Yes	Yes	Yes	Yes	Yes, w/ prior authorization	Yes, all	Yes
Medicaid Family Planning Expansion	Yes	Yes	Yes	Yes	Yes	Yes, all	Yes
Medicaid Managed Care	Yes	Yes	Yes	Yes	Yes, w/ prior authorization	Yes, all	Yes, w/ medical justification

Figure 9. Sample job aid: Commercial insurance coverage of LARC methods

(Note: For illustrative purposes only. Coverage varies by plan.)

Plan	Implant	Implant insertion	Implant removal	LNG-IUS	Copper IUD	IUD insertion	IUD removal
Plan A	Yes	Yes	Yes	Yes	Yes, w/ prior authorization	Yes	Yes
Plan B (Grandfathered Plan)	Yes, w/ co-pay	Yes, w/ prior authorization	Yes, w/ co-pay	Yes, w/ co-pay	Yes, w/ co-pay	Yes, w/ prior authorization	Yes, w/ co-pay
Plan C (Grandfathered Plan)	Yes	Yes	Yes	Yes, w/ referral	Yes, w/ referral	Yes	Yes

create job aids to provide staff with quickly accessible information. Figure 9 is a sample job aid to demonstrate the coverage in different commercial plans.

NOTE: Patients enrolled in plans subject to the ACA's contraceptive coverage requirement (see Section 2) cannot be charged a copay for covered contraceptive methods, including LARC, or related counseling, follow-up, side effect management, or removal.

It is in the interest of both the provider and the patient to individually verify a patient's insurance benefits, preferably before the visit. This process will confirm whether the patient's coverage is active, as well as any cost-sharing, prior authorization, or referral requirements for LARC methods. Commercial payers are increasingly offering benefit verification online, which can cut down on the amount of time it takes for health center staff

to devote to the process. Instantaneous verification also allows staff to confirm insurance benefits even when offering same-day appointment scheduling. A provider should collect the necessary demographic information from the patient included in Figure 10 to facilitate benefit verification. Best practices for collecting this information include requesting it from the patient at the time the appointment is made and making a copy of the patient's insurance benefit card during the appointment.

Manufacturer benefit verification services

Teva Women's Health offers a benefits verification process specifically for ParaGard through its Access Solutions Program. Providers can register online⁵⁶ to gain access to this free program to facilitate patient benefits verification. The turnaround for verification results through this program is usually 24-48 hours.

Figure 10. Demographic information collection for insurance verification

If patient is using insurance, always ask if she is the policy holder.

If patient is the policy holder, request:

• Name of insurance, member ID, and group ID number.

If patient is NOT the policy holder, request this additional information about the policy holder:

• Name, date of birth, relationship to patient, address, and Social Security number.

Bayer offers third-party benefit investigation services at no cost to providers. To gain access to these services, complete the Bayer Women's HealthCare Support Benefit Investigation Request Form.⁵⁷ Benefit investigation results will be provided within 48 hours through a third-party contractor. Curascript provides benefit investigation services for Nexplanon. Call Curascript at 1-866-389-7928 to request a Patient referral form for benefit verification.

Liletta Access Connect offers real-time benefit verification though its online portal.⁵⁸ To register for the site, a practice must provide its NPI number, clinician license number, basic contact information, and Medicaid number if applicable. A representative will confirm registration within one business day. After registration is confirmed, log in and click on benefit verification. To complete the form, a provider will need patient name, date of birth, plan name, and member number (see Section 4.3 for more information about collecting benefit verification information). Results should be available immediately; if not, phone support is available on weekdays from 8:00 a.m. to 8:00 p.m. ET at 855-545-3882.

If a patient with commercial insurance faces barriers to coverage

The information collected during the benefits verification process can be used to help educate a patient about her coverage and financial responsibility prior to her visit. If a provider discovers that a patient is facing barriers to coverage of LARC methods, the patient should be referred to NWLC's CoverHer hotline. ⁵⁹ This hotline provides personalized instructions on how to navigate the health insurance process to ensure women get the coverage for preventive services they are guaranteed under the ACA. Patients can contact CoverHer directly at coverher.org, 1-866-745-5487, or coverher@nwlc.org.

A note about religiously affiliated employers

There are several legal challenges related to religiously affiliated employers offering coverage for birth control services. Until the courts finalize this matter, it is best to refer patients with religious employers that are exempt from or are not otherwise required to comply with the preventive services requirements to resources in Section 4.4.

Another option for commercially insured patients who want an LNG-IUS but do not have coverage (see Section 2.1 for details on coverage exceptions) is the Liletta Patient Savings Program, which is a form of co-pay assistance. A patient may qualify for this program if she resides in the U.S. or Puerto Rico, has commercial health insurance, has an out-of-pocket expense for a Liletta device greater than \$75, and does not participate in any public health insurance plans (e.g. Medicaid).

To help patients use this program, a practice must first register by calling 855-706-4508. The practice is then supplied with Liletta Access Cards and patient education materials. The cards function similarly to a debit card, and the amount of money allocated to a card depends on a patient's out-of-pocket expense for a Liletta. The card will provide a maximum savings of \$500. The patient activates the card by going to LilettaCard.com or calling 855-706-4508. Once activated, the card can be used toward the purchase of a Liletta from the practice (if buy and bill), directly from the specialty pharmacy, or to receive a rebate. To obtain a rebate, a patient must have an explanation of benefits (EOB) form from her health insurance plan and upload it to LilettaCard.com or fax it to 888-683-4991.

Please note that this program does not cover expenses associated with office visits. At the time of publication, this program is set to expire on September 30th, 2015. Devices must be prescribed in advance of this date to qualify for this program. An EOB must be submitted within 60 days of this date to qualify for a rebate.

4.4: Working with self-pay patients

Unfortunately, some patients may not have access to any insurance coverage or may choose not to use coverage for other reasons. There are some financial support options available for these patients.

Manufacturer assistance programs

Manufacturers of the various LARC methods have programs to provide financial assistance to patients who meet specific qualifications.

LNG-IUS

Bayer HealthCare Pharmaceuticals established the ARCH Patient Assistance Program to assist low-income patients who do not have insurance coverage for the LARC methods Mirena or Skyla. To qualify, patients must be US residents who do not have access to insurance coverage for an LNG-IUS. The ARCH Program also assesses applicants' income levels to determine eligibility. Eligible women may have a free LARC method sent to their health care provider, but the program does not cover fees associated with

the insertion or removal procedures. To apply, both a patient and her provider must complete a form.⁶⁰ The application will be reviewed within approximately two business days of receipt of a complete application packet. Note that this program used to limit the number of LARC methods an entity could receive each year, but in February 2015 the program was re-launched without such limits. More information is available online.⁶¹

Copper IUD

The patient assistance program for ParaGard was discontinued as of July 2014. However, the distributor, ParaGardDirect, allows patients to purchase this method from them directly using a four- or 12-month installment payment plan option. Patients should contact the distributor at 1-877-PARAGARD. See Section 3.2 for more information about patient payment plans.

Implant

The distributors of the implant, Curascript and CVS Caremark, offer installment payment options for patients. Curascript offers a 6-month installment payment option with no credit check, while CVS CareMark offers a 3-month installment payment option. To apply for these programs, a healthcare provider must contact the distributors and request instructions for referring patients to the program. See Section 3.2 for the distributor contact information.

Title X family planning program

More than 4,200 family planning health centers across the country make up the network of providers funded by the Title X family planning program administered through the OPA. These providers receive funding to help cover the cost of providing voluntary family planning services and related preventive health services to low-income or uninsured individuals. Title X-funded providers are required by law to charge no fees to patients whose income is at or below 100% of the federal poverty level (FPL). Additionally, these providers must have a schedule of discounts, based on ability to pay, that applies to individuals with family incomes between 101% and 250% of the FPL.

Title X-funded providers may be able to provide assistance to patients who have no other coverage for LARC methods. Visit the OPA website⁶² to find Title X providers, or contact the National Family Planning & Reproductive Health Association⁶³ for help connecting with a state's Title X program.

NOTE: Discounted pharmaceuticals are available to Title X clinics and other covered entities via the 340B Drug Pricing Program. For more information on 340B pricing, see Section 3.3.

Other low-cost clinical settings

Some academic medical institutions – including hospitals, medical schools, and schools of nursing – have health centers that provide low-cost family planning care or provide free LARC methods through grant funding or under research protocols. Providers and patients can check with local hospitals or medical schools to see if such care is available.

For example, the Department of Family and Social Medicine at Montefiore Medical Center in the Bronx, New York, established the getLARC program to provide funding and technical assistance to US family medicine residency programs to improve resident training in IUDs and implants. Grants awarded through this program may support the stocking of LARC methods, so getLARC-funded programs⁶⁴ should be considered as a resource when patients need to explore alternative financial support options.

Additionally, the Bixby Center for Global Reproductive Health at UCSF houses the Ryan Residency Training Program, which aims to integrate and enhance family planning training for obstetrics and gynecology residents. Ryan Program-supported locations⁶⁵ may be able to offer support for patients in need of affordable access to LARC methods.

In many communities, Planned Parenthood and other community providers offer sliding fee scales or other low-cost alternatives for care. Bedsider has a clinic locator⁶⁶ search function that might be helpful for patients seeking low-cost family planning services. In addition, the Association of Reproductive Health Professionals has a LARC-specific provider locator tool.⁶⁷

4.5: Coding for LARC methods and procedures

Providers should be aware that payers may have specific requirements for coding preventive services covered by the ACA. Providers should check with their payers for guidance regarding appropriate coding because patients' cost-sharing requirements may be affected.

Correct coding can result in more appropriate compensation for services. To help practices receive appropriate payment for providing LARC methods, the following information can be helpful. Updates to this Quick Coding Guide⁶⁸ are available at the ACOG website, as is a Billing Quiz⁶⁹ that delves into further detail.

Basic contraceptive implant coding

The insertion and/or removal of the implant are reported using one of the following CPT®* codes:

- 11981 Insertion, non-biodegradable drug delivery implant
- 11982 Removal, non-biodegradable drug delivery implant
- **11983** Removal with reinsertion, non-biodegradable drug delivery implant

The diagnostic coding will vary, but usually will be selected from the Encounter for Contraceptive Management code series - V25 in ICD-9-CM or Z30 in ICD-10-CM. These codes are:

- **V25.5** Encounter for contraceptive management, insertion of implantable subdermal contraceptive or
- **Z30.018** Encounter for initial prescription of other contraceptives in ICD-10-CM.
- **V25.43** Surveillance of previously prescribed contraceptive method; implantable subdermal contraceptive or
- **Z30.49** For checking, reinsertion, or removal of the implant in ICD-10-CM.

Note: ICD-10 codes are scheduled to go into effect October 1, 2015. They may not be reported prior to effective date.

The CPT procedure codes do not include the cost of the supply. Report the supply separately using a HCPCS (Healthcare Procedural Coding System) code:

J7307 Etonogestrel [contraceptive] implant system, including implant and supplies

Basic IUD coding

The insertion and/or removal of IUDs are reported using one of the following CPT codes:

58300 Insertion of IUD

58301 Removal of IUD

Most IUD services will be linked to a diagnosis code from the V25 series (Encounter for Contraceptive Management) or the Z30 series in ICD-10-CM:

- **V25.11** Insertion of intrauterine contraceptive device or
- **Z30.430** Encounter for insertion of intrauterine contraceptive device in ICD-10-CM.
- V25.12 Removal of intrauterine contraceptive device or
- **Z30.432** Encounter for removal of intrauterine contraceptive device in ICD-10-CM.
- V25.13 Removal and reinsertion of intrauterine contraceptive device or
- **Z30.433** Encounter for removal and reinsertion of intrauterine contraceptive device in ICD-10-CM.
- **V25.42** Surveillance of previously prescribed contraceptive method, intrauterine device or
- **Z30.431** Encounter for routine checking of intrauterine contraceptive device in ICD-10-CM.

The CPT procedure codes do not include the cost of the supply. Report the supply separately using a HCPCS code:

- **J7300** Intrauterine copper contraceptive
- J7301 Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg
- **J7302** Levonorgestrel-releasing intrauterine contraceptive system, 52 mg

Reporting contraceptive services with other services

Under some circumstances, an Evaluation and Management (E/M) services code, a procedure code, and a HCPCS code, may all be reported. Documentation must support each billing code.

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E/M Services Code

If a patient comes in to discuss contraception options but no procedure is provided at that visit:

- If the discussion takes place during a preventive visit (99381–99387 or 99391–99397), it is included in the Preventive Medicine code. The discussion is not reported separately.
- If the discussion takes place during an E/M office or outpatient visit (99201–99215), an E/M services code may be reported if an E/M service (including history, physical examination, or medical decision making or time spent counseling) is documented. Link the E/M code to ICD-9-CM diagnosis code V25.09 (General family planning counseling and advice) or ICD-10-CM diagnosis code Z30.09 (Encounter for other general counseling and advice on contraception).

E/M Services Code and Procedure Code

If discussion of contraceptive options takes place during the same encounter as a procedure, such as insertion of a contraceptive implant or IUD, it may or may not be appropriate to report both an E/M services code and the procedure code:

- If the clinician and patient discuss a number of contraceptive options, decide on a method, and then an implant or IUD is inserted during the visit, an E/M service may be reported, depending on the documentation.
- If the patient comes into the office and states, "I want an IUD," followed by a brief discussion of the benefits and risks and the insertion, an E/M service is not reported since the E/M services are not significant and separate.
- If the patient comes in for another reason, such as an annual exam, and during the same visit a procedure is performed, then both the E/M services code and procedure may be reported.

If reporting both an E/M service and a procedure, the documentation must indicate a significant, separately identifiable E/M service. The documentation must indicate either the key components (history, physical examination, and medical decision making) or time spent counseling. In order to report an evaluation and management visit based on time, more than 50% of the visit must be spent counseling the patient. When time is the determining factor for the selection of the level of service, documentation should include the following:

- The total length of time spent by the physician with the patient,
- The time spent in counseling and/or coordination of care activities, and
- A description of the content of the counseling and/or coordination of care activities.

Note the "typical times" listed in outpatient E/M services codes 99201–99215. For example, if an established patient is seen for 25 minutes, including 15 minutes spent counseling, report code 99214—this code lists a "typical time" of 25 minutes. The level

of history, physical examination, and medical decision making do not matter in selecting this code. Not all payers recognize time spent counseling. Providers should consult third-party payers before instituting this coding practice to ensure compliance with specific plan guidelines.

A modifier 25 (significant, separately identifiable E/M service on the same day as a procedure or other service) is added to the E/M code to indicate that this service was significant and separately identifiable from the insertion. This indicates that two distinct services were provided: an E/M service and a procedure.

Coding guidance for specific LARC clinical scenarios can also be found on the ACOG LARC Program⁷⁰ website and the ACOG Department of Coding and Nomenclature⁷¹ website.

ACOG Fellows and their staff can submit specific coding questions to the ACOG Department of Health Economics and Coding at the coding ticket database: acogcoding.freshdesk.com. Questions are answered in the order received, usually within 3–5 weeks. There is no charge for this service.

4.6: Concerns about inadequate reimbursements

The CAI LARC Modeling Tool⁷² may be helpful to providers who do not currently offer LARC methods out of a concern that available reimbursements would result in a financial loss to a practice. This tool uses information about a practice's estimated LARC demand, payer mix, and reimbursement rates to explore the costs associated with provision of each LARC method. It may also help identify payers with anomalously low reimbursement rates and provide information useful in future contract negotiations. Efficacy and patient satisfaction rates for LARC methods can also be useful during discussions with third-party payers to negotiate increases in reimbursement rates.

Providers that experience decreased reimbursement rates for Mirena LNG-IUS devices due to reimbursement adjustments in the market may be eligible for loss-offsetting rebates from the manufacturer. To be eligible for a rebate:

- The device was purchased sometime between April 1, 2015 and June 30, 2015.
- The device was used on a date of service between July 1, 2015 and December 31, 2015.
- The payer responsible for reimbursement of the device has reduced its reimbursement rate for HCPCS code J7302, which resulted in a payment at less than the provider's net acquisition cost.

Providers should refer to the Mirena Rebate Program policy⁷³ for more information on submitting a rebate request.

SECTION 5: REPLACEMENTS AND REFUNDS

5.1: Failed insertions and replacement of LARC methods

Occasionally, a clinician will open the packaging of a LARC method but the product is ultimately not used by a patient. This can occur due to error or accident (e.g., non-sterile technique), or an insertion that is discontinued for medical reasons or at the patient's request. Although rare, there are also occasionally mechanical defects in the products that render them unusable.

The course of action when confronted with these circumstances depends on the primary payer for the LARC method and whether the product was issued as a benefit for a specific patient or was purchased as "buy and bill." In general, commercial plans will reimburse the cost of LARC methods lost during failed insertions. In general, most public payers do not reimburse the cost of LARC methods lost during failed insertions. Providers should check with specific payers to determine their reimbursement policies for failed insertions. For any payer that *does* reimburse this cost, there is an important additional consideration: if the patient wishes to attempt another insertion and the plan limits the number of LARC methods covered within a specific timeframe, it may be beneficial to pursue reimbursement for the lost product from the manufacturer.

Requesting replacement LARC methods from manufacturers

Manufacturers of LARC methods provide replacement products under some conditions; however, they do not supply credit refunds. Providers should always keep the LARC method and record its lot number to facilitate a request for a replacement product from the manufacturer. The LARC method may need to be sent to the manufacturer as proof of the failed insertion or product defect.

Copper IUD

Teva Women's Health considers replacement requests for ParaGard on a case-by-case basis, and has published a detailed replacement policy. Providers should call 1-877-PARAGARD to request a replacement IUD. A representative will send a Replacement Product Request form and may also supply a postage-paid envelope. Providers must send the completed form and IUD within 30 days of receipt. A replacement product will be shipped within six weeks. The replacement process must be initiated at various times depending on the reason the device is unused:

- IUD was dropped or contaminated initiate replacement request within one week of drop or contamination;
- insertion was discontinued for medical reasons initiate replacement request within 30 days of failed insertion procedure; or
- product has defect no time limit to request a replacement.

LNG-IUS

Bayer considers replacements for Mirena or Skyla on a case-by-case basis and has not published a formal replacement policy. If the failed insertion occurred within the last 60 days, a provider may be eligible for a replacement product. A provider should initiate a replacement request by contacting its Bayer representative if the IUD was dropped, contaminated, or there was a failed insertion. If there is a defect in the product, initiate a replacement request by contacting the Bayer technical complaint center at 1-888-842-2937 or product.complaint@bayer.com.

Actavis considers replacements for Liletta on a case-by-case basis, whether caused by contamination or a defect in the product. The published return policy⁷⁵ is available online. Providers that need a replacement should save the device and contact Actavis within one week by phone at 855-545-3882 (select option 6) or complete and return a replacement request form⁷⁶ by email or fax. A Liletta representative will authorize a return and send a paid shipping label within 2 business days. The contaminated or defective device must be returned within 30 days of contacting Actavis. After reviewing the returned device, Actavis will make a determination of whether to issue a replacement device.

Implant

Merck considers replacements for Nexplanon on a case-by-case basis and at the time of this guide's publication is formalizing a replacement policy for publication. Providers should initiate a replacement request as soon as possible to help expedite replacement. Call the Merck Information Center for Nexplanon at 1-877-467-5266, select Nexplanon, and then select for adverse event and product failures. The Information Center representative will provide details about what information is needed, but a best practice has been to document the procedure by taking a photo of the implant, recording its lot number, and recording a detailed explanation of the reason for the discontinued insertion. Alternatively, a provider's Merck representative may be able to help facilitate the process.

5.2: IUD expulsion

Patients who choose an IUD and experience an expulsion may wish to attempt a second placement. Some payers limit the number of IUDs that a woman can obtain within a certain timeframe. If that is the case, a provider may be able to help a patient obtain a replacement product from the manufacturer.

Copper IUD

Patients who chose a copper IUD but experience an expulsion or removal for some other medical reason may be able to obtain a replacement product under certain conditions. If it has been 90 days or less since the IUD was inserted, Teva Women's Health will consider providing a replacement product on a case-by-case basis. Providers should call 1-877-PARAGARD to initiate the replacement request within 30 days of the patient's visit. Providers are not required to keep the expelled IUD in this instance; if ParaGardDirect requests the expelled product, providers should contact their Teva representative for assistance.

LNG-IUS

Bayer will consider replacement of expelled products on a caseby-case basis. Providers should contact their Bayer representative for assistance.

The published replacement policy for Liletta specifies that devices inserted in patients are not eligible for replacement.

SECTION 6: SPECIAL CIRCUMSTANCES

Reimbursement and payment for LARC services in some clinical situations may carry additional challenges depending on the site of care, other services provided during the LARC-related visit, or other issues. The following sections may assist providers in receiving appropriate reimbursement and payment in these situations, and may provide guidance in advocating for improved coverage from state agencies or commercial payers.

Providers who experience challenges in offering LARC under these special circumstances may find it helpful to contact colleagues to learn whether they, too, have experienced similar challenges and how they may have overcome them. When working on solutions to these types of barriers, persistence often pays off!

6.1: Immediate post-abortion insertion

Receiving appropriate reimbursement and payment for LARC services provided immediately following an abortion procedure can be challenging. While many payers cover the placement of a LARC method immediately after an abortion, payers may have policies that deny or lower reimbursement for an additional procedure provided on the same day as an abortion.

Medicaid enrollees can choose to receive family planning services from any qualified Medicaid provider, including abortion providers. Medicaid managed care enrollees can receive contraceptive services from any qualified Medicaid provider, including those outside their managed care networks.

Federal Medicaid law allows reimbursement for covered services and supplies that are provided during an abortion visit, even if the abortion does not qualify for Medicaid coverage, so long as those services and supplies are distinguished from and not attributable to the uncovered abortion. However, it appears that some states may have policies in place that create barriers to billing for contraceptive services provided on the same day as an abortion. Title X funds and 340B pricing are available for immediate postabortion LARC insertion as long as those services and supplies are billed correctly and as a separate procedure. However, there may be other institutional limitations or perceived barriers that create obstacles for implementation.

Billing for multiple services provided during a single visit often results in reduced payments and reimbursement, and can be a barrier to LARC provision with both public payers and commercial plans. ^{78, 79} Some providers have patients return for LARC methods at a separate visit to avoid reduced rates. This additional barrier often results in the patient not coming back to obtain contraception at all.

Improvements in LARC method coverage post-abortion

Advocates in some states have been working to improve Medicaid coverage, reimbursement, and payment policies for LARC methods provided immediately post-abortion. For example:

- Advocates in New York are working with the health department to improve state Medicaid coverage for same-day, post-abortion IUD insertion. Currently, providers can bill fee-for-service Medicaid for the LARC method but not the insertion fee. The New York State Department of Health submitted a Medicaid state plan amendment⁸⁰ to CMS to have the insertion procedure paid through Medicaid. However, these proposed changes would apply to fee-for-service Medicaid only. In Medicaid managed care plans, there is wide variation in reimbursement for the LARC method and payment for insertion. Advocates and the state are working to ensure these changes apply to Medicaid managed care plans as well.
- In Oregon, the Medicaid program (Oregon Health Plan) covers both the LARC method and insertion post-abortion. Oregon's family planning expansion program (CCARE) began covering the LARC method in 2013, and advocates are working to also obtain coverage for the insertion.

Reducing the cost of same-day abortion and contraception

Another strategy to reduce the overall costs of same day abortion and contraception for self-pay patients is utilizing a justice fund to assist with the cost of abortion care. There are two national justice funds, which may be able to provide financial support as well as identify local justice funds available.

National Abortion Federation: 1-800-772-9100

National Network of Abortion Funds: 1-866-592-1901

Strategies for same-day LARC

In many cases a patient may not have abortion coverage or may choose not to use her coverage because of privacy or confidentiality concerns. This patient may still have and want to use coverage for a LARC method immediately post-abortion. Documenting these two services in two separate encounters may be acceptable according to the state or plan's billing rules about covered services, patient confidentiality, and patient preferences. Providers should check the relevant billing policies to make sure this approach is acceptable in the patient's particular circumstances.

If it is acceptable to bill for abortion and LARC provision encounters separately, begin when the patient chooses a LARC method on the same day as her abortion procedure. Here are the steps:

- If needed, conduct a benefit verification inquiry with the patient's insurance plan carrier. See Section 4.3 for additional information about benefit verification.
- Collect any relevant co-pay or deductible that may apply to the contraceptive portion of the patient's visit. Note that non-grandfathered plans are required to cover contraception without cost-sharing. See Section 2.1 for more information about cost-sharing.
- The clinician fills out one encounter form documenting the two procedures. If documenting the encounter in an electronic health record, the clinician may want to open a separate note for the contraception counseling with a distinct diagnosis code in order to document that the E/M services associated with the contraception portion of the visit are distinct and separately identifiable.
- The billing office then produces one claim form for the insurance entity, only for the contraception portion of the visit. The insurance claim should include the procedure code for contraceptive initiation, product J code, diagnosis codes, and E/M code. A CPT code for the tray/supplies may also be recorded, though will often not be reimbursed separately as supplies are generally valued into the procedure code.

This process protects the patient's privacy and helps mitigate the cost of abortion care and LARC methods provided at the same visit.

6.2: Immediate postpartum insertion

The immediate postpartum period – prior to hospital discharge—can be an opportune time to offer contraception. Women may be more motivated to use contraception after giving birth and are known to not be pregnant. Insertion of LARC methods immediately postpartum can also provide access to these methods for women who may not have insurance coverage after delivery or who may not attend their scheduled postpartum follow up visit.

There are several barriers to provision of LARC methods in the immediate postpartum setting including a lack of provider training, difficulty with stocking issues within the hospital setting, and challenges with obtaining a reimbursement. Payment for delivery is often made using a "global fee" that does not specifically reimburse hospitals for the cost of LARC methods or the insertion procedure on a fee-for-service basis.

As of July 2015, at least 12 Medicaid programs have published guidance providing a mechanism for LARC methods to be reimbursed when provided immediately postpartum in the hospital setting, and one state has clarified that commercial payers are able to separately reimburse for immediate postpartum insertion. An updated list⁸¹ of these policies is available from the ACOG LARC Program.

There are efforts in many other states to advocate for similar changes and to request that commercial payers also include a mechanism for reimbursement separate from the global fee for LARC methods provided immediately postpartum. Materials from the Association of State and Territorial Health Officials⁸² and ACOG⁸³ may provide helpful advocacy resources.

6.3: Copper IUD as EC

The copper IUD is an effective option for patients seeking emergency contraception.84 However, these LARC methods need to be in stock to offer this service. Coding for this service includes a diagnosis code for emergency contraception and the appropriate supply coding for the IUD.

Coding for a copper IUD used as an emergency contraceptive is as follows:

Diagnosis code:

V25.03 (Encounter for emergency contraceptive counseling and prescription) or

Z30.012 (Encounter for prescription of emergency contraception) in ICD-10-CM.

Device code:

J7300 (Intrauterine copper contraceptive)

Procedure code:

58300 (Insertion of intrauterine device)

SECTION 7: REMOVAL

Women using LARC methods must always be free to discontinue use, even absent a medical reason for doing so. Additionally, there may be medical reasons or side effects that require removal of LARC methods. Federal law reflects these standards of care. As discussed in Section 2, all commercial plans and Medicaid ABPs subject to the ACA's contraceptive coverage requirements must also cover LARC method removal without cost-sharing. Additionally, federal Medicaid law requires coverage of medically necessary services and provides that each individual be free from coercion or mental pressure and free to choose her method of family planning.

In spite of these requirements, providers may encounter problematic coverage or reimbursement policies for removal of LARC methods. For example, some public or commercial plans may have payment policies (e.g. bundled payments, global payments) that, in effect, deny separate reimbursement for removal in some contexts. Providers should consult state Medicaid provider manual(s) or plan materials for details about a particular plan's coverage policies.

Some states have also been known to deny coverage of IUD removal absent a medical justification. If your state Medicaid program does not cover removal of LARC methods, or if your state places inappropriate limits or restrictions on removal, please email NHeLP at nhelp@healthlaw.org with "reproductive health" in the subject line.

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