



LARCs: The Issue of Abandoned Units

BACKGROUND

In outpatient facilities such as physician offices and clinics, Long Acting Reversible Contraceptives (LARCs) can be stocked by the provider ahead of time or ordered as needed¹.

Pharmacy Benefit or “white bagging”: When a LARC method is covered as a pharmacy benefit, a pharmacy or specialty distributor bills the patient’s insurance carrier directly for the LARC method. This “white bagging” method requires the provider to charge the LARC device to a specific patient’s health insurance identification number through her plan’s specialty pharmacy. The Specialty Pharmacy will ship the IUD to the HCP’s office for the procedure and there is no out of pocket cost to the HCP. If the patient receives the LARC, the device is already paid for and the provider is compensated for the insertion through his or her usual billing.

Medical benefit or “buy and bill”: When a LARC method is covered as a medical benefit, a provider buys the LARC method directly from the manufacturer or a designated pharmacy or specialty distributor and bills the patient’s insurance carrier for the LARC method and insertion procedure. With the “buy and bill” approach, providers have the product on hand to insert when a woman enters their office. The drawback to this, however, is a provider needs to pay for the product upfront and risks absorbing the cost for unused (aka “abandoned”) devices.

Merck and Bayer only accept abandoned LARCs ordered for specific patients through specialty pharmacies (it is unclear with the Teva procedure).

Overview of Manufacturer’s Policy for Returning Abandoned LARCs

	Nexplanon (Merck)	Mirena/Skyla (Bayer)	Paraguard (Teva)
Definition of abandoned	A unit of NEXPLA NON will be considered “abandoned” if the unit is abandoned by an Eligible Patient for a duration of at least 120 days from the date of dispense, but no more than 180 days past the date of dispense, as	The IUD must be abandoned for at least 120 days (4 months) from date of dispense	90 days after shipment a Paraguard Access Specialist follows up with office to confirm Paraguard was placed in the intended Medicaid patient.

¹ UCSF Bixby Center for Global Reproductive Health. Intrauterine Devices & Implants: A Guide to Reimbursement. <http://larcprogram.ucsf.edu/obtaining-supplies>

	evidenced by the prescription label affixed to the product		
Qualifying for return	Must attest to have attempted at least 2 times to reach the patient to reschedule the appointment; and		
IUDs eligible for return	Must have obtained such Eligible Product from a Specialty Pharmacy; not purchased by the provider	Only those shipped by the Specialty Pharmacy under the Specialty Pharmacy Program (SPP) with a prescription label that includes an individual patient's name.	Not available for self-pay patients who have a prescription for Paragard® and have it sent to an office for placement.
Dispensing Specialty Pharmacy Role in return	Return the form to the dispensing specialty pharmacy to verify the eligibility of the return.	Return the form to the dispensing specialty pharmacy to verify the eligibility of the return.	Unclear
Third Party Administrator Role	TeleRx provides return identification number from specialty pharmacy and return mailing label and instructions	Genco Pharmaceutical Services sends provider an email with return authorization number, a postage-paid UPS label, and a Genco return authorization form.	Unclear
Reimbursement/Refunds	The prescriber has not paid for this unit	The prescriber has not paid for this unit. In no case can a unit that was purchased by the prescriber (eg, purchase of a wholesale unit) be returned through this program.	The Specialist inspects the returned unit to ensure it is in its original package — unused and unopened. If approved, the Specialist updates the system to reflect the returned device and reverses the claim.
Sample Form	http://www.txvendordrug.com/formulary/downloads/merck-abandoned-unit-	https://www.whcsupport.com/documents/PP-270-US-0276_Abandoned_Unit_	I also saw reference to a form, but have not found it

	form.pdf	FAQ_April2015.pdf	
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Specialty Pharmacies Used To Order LARCs

	Nexplanon (Merck)	Mirena/Skyla (Bayer)	Paraguard (Teva)	Liletta (Medicines360)
Specialty Pharmacies for “White Bagging”	Accredo or CVS Health	CVS Caremark, Walgreens, Prime Therapeutics, Cigna Specialty Pharmacy Services, Humana Specialty Pharmacy, Skyemed Pharmacy & Infusion Services (Tricare)	Women’s Health Access Solutions (Biologics, Inc.)	Accredo Specialty Pharmacy
Specialty Distributors for Buy and Bill	CuraScript and TheraCom(a CVS Caremark company)	Women’s Health Care Support Center	ParaGardDirect	ANDA

CMS RECOMMENDATIONS FOR LARC STOCKING

In a letter to state health officials², the CMS Center for Medicaid and CHIP Services (CMCS) suggested several policies to ensure same-day access to LARCS by stocking supplies.

CMS suggested, to the extent permissible, for state to allow publicly funded providers of family planning services who also serve Medicaid patients to pre-purchase and stock their inventories with LARC methods and bill Medicaid or the pertinent third-party payer for the LARC when it is used.

CMS also encouraged states to direct pharmacies and providers to utilize programs already established by manufacturers that facilitate stocking providers with LARCs for medical benefit coverage, as well as those that facilitate the return of, and reimbursement by manufacturers to states for unused LARCs dispensed under the pharmacy benefit.

² CMS CMCS, Re: Medicaid Family Planning Services and Supplies, SHO # 16-008. June 14, 2016. <https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf>

CMS suggested states could seek to establish new arrangements with LARC manufacturers to increase Medicaid beneficiary access to their LARCs. In one pilot the LARC manufacturer proactively furnishes providers with its LARCs without upfront costs. At a reasonable time post-implantation or administration, the manufacturer bills the provider for the cost of the LARC to ensure providers have had the time to be reimbursed by third party payers, including state Medicaid programs.

CMS is also interested in exploring with states the use of section 1115(a) demonstration authority to make available administrative funding at the 90 percent federal matching (authorized by section 1903(a)(5) of the Social Security Act) for states to maintain an inventory of LARCs for providers who furnish covered medical assistance for eligible individuals. Under this waiver, the state would incur an administrative expense to purchase a stock for a Medicaid provider for use by Medicaid beneficiaries.

EXAMPLES OF STATE POLICIES ON STOCKING LARCS

Illinois Medicaid: Effective June 15, 2012: Providers cannot return IUDs to the pharmacy. In order to reduce waste, providers should use “unused” IUDs in other Medical Assistance patients. The provider must maintain a log that tracks those “unused” IUDs. For each “unused” IUD, the log entry must include the name and RIN of the patient for whom the IUD was ordered, and the name and RIN of the patient in whom the IUD was inserted, along with the date of insertion.

- <http://www.hfs.illinois.gov/html/060112n.html>

Texas Medicaid: Providers can prescribe and obtain long-acting reversible contraception (LARC) products that are on the Medicaid and Healthy Texas Women (HTW) Program drug formularies from certain specialty pharmacies for women participating in Medicaid and HTW. LARC products are only available through a limited number of specialty pharmacies that work with LARC manufacturers. Providers who prescribe and obtain LARC products through the specialty pharmacies listed will be able to return unused and unopened LARC products to the manufacturer's third-party processor. However, LARC products are also available as a medical benefit and providers will continue to have the option to receive reimbursement for LARC as a clinician-administered drug.

- <http://www.txvendordrug.com/formulary/downloads/long-acting-reversible-contraception-faq.pdf>

CMS Examples of Payment Strategies Allowing LARCs Stocking: In an April 2016 CMCH Informational Bulletin³, CMS outlined a number of strategies to improve access to LARCs including Medicaid payment strategies to allow providers to stock LARCs.

³ CMS, CMCS Informational Bulletin. “State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception.” April 8, 2016.
<https://www.medicaid.gov/federal-policy-guidance/downloads/CIB040816.pdf>

South Carolina Medicaid: South Carolina Department of Health and Human Services addressed the initial costs to providers for stocking LARC devices in its South Carolina Birth Outcomes Initiative (SCBOI) “specialty benefit” in the spring of 2014. The new payment policy allows a physician to order a LARC device for a specific Medicaid recipient which is shipped to the physician’s office by a specialty pharmacy which is designated by either the state Medicaid agency’s Pharmacy Benefit Manager or by the individual MCO’s. The device can be shipped overnight and is billed directly to Medicaid FFS or the MCO so that the physician does not incur the initial cost of the device. The physician’s office has 30 days to insert the LARC for the specific patient for which it was ordered and bill Medicaid the insertion fee only, or to return the unopened device to the specialty pharmacy if the device is not used. The cost of the device is then credited back to Medicaid or the MCO.

- <https://www.scdhhs.gov/organizations/boi>

Louisiana Medicaid: The state added LARC devices to the physician schedule rather than just the pharmacy schedule, which allows the physician to store the device in office and not have to provide it to a specific individual.