LILETTA® Billing and Coding Guide

While all coding decisions should be made by the physician based on an independent review of the patient's condition, below are codes you may find helpful when billing for LILETTA. Depending upon individual payer policies, some combination of the following codes may be appropriate for submitting outpatient claims for patients who have received LILETTA.

Billing Codes for LILETTA

CODE SET	CODE	DESCRIPTION
HCPCS* (J-code)	J7297	LILETTA, 52 mg
ICD-10†	Z30.014	Encounter for initial prescription of intrauterine contraceptive device
	Z30.430	Encounter for insertion of intrauterine contraceptive device
	Z30.431	Encounter for surveillance of intrauterine contraceptive device
	Z30.432	Encounter for removal of intrauterine contraceptive device
	Z30.433	Encounter for removal and reinsertion of intrauterine contraceptive device
	Modifier 25	If same day insertion, added to indicate 2 distinct services were provided—Evaluation Management (E/M) services and insertion
Single-Handed Inserter National Drug Code (NDC)	0023-5858-01	LILETTA is a levonorgestrel-releasing intrauterine system consisting of a T-shaped polyethylene frame with a drug reservoir containing 52 mg of levonorgestrel, packaged with a sterile inserter
CPT‡	58300	Insertion, intrauterine device
	58301	Removal, intrauterine device
For 340B eligible entities only: 340B and Family Planning Modifiers*	FP	Required for state family planning SPA and waiver programs
	UD	Required in many states, for 340B purchased product
	U8	Required in Texas for 340B discounted product

Visit LILETTAAccessConnect.com or call 855-LILETTA (855.545.3882) for billing and coding support.

Disclaimer: This guide is presented for informational purposes only. It represents no statement, promise, or guarantee by Allergan concerning coverage and/or levels of reimbursement, payment, or charge and is not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for services provided to his or her patient. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this guide, the information may not be current or comprehensive when you view it. Please consult the applicable payer organization with regard to local or actual coverage, reimbursement policies, and determination processes. Allergan does not endorse any individual plans. Formulary coverage does not imply efficacy or safety.

INDICATION

LILETTA® is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 5 years. The system should be replaced after 5 years if continued use is desired.

IMPORTANT SAFETY INFORMATION

Who is not appropriate for LILETTA

Use of LILETTA is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids, if they distort the uterine cavity and would be incompatible with correct IUS placement; known or suspected breast cancer or other hormone-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; infected abortion in the past 3 months; unexplained uterine bleeding; current IUS; acute pelvic inflammatory disease (PID) or endometritis or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of LILETTA.

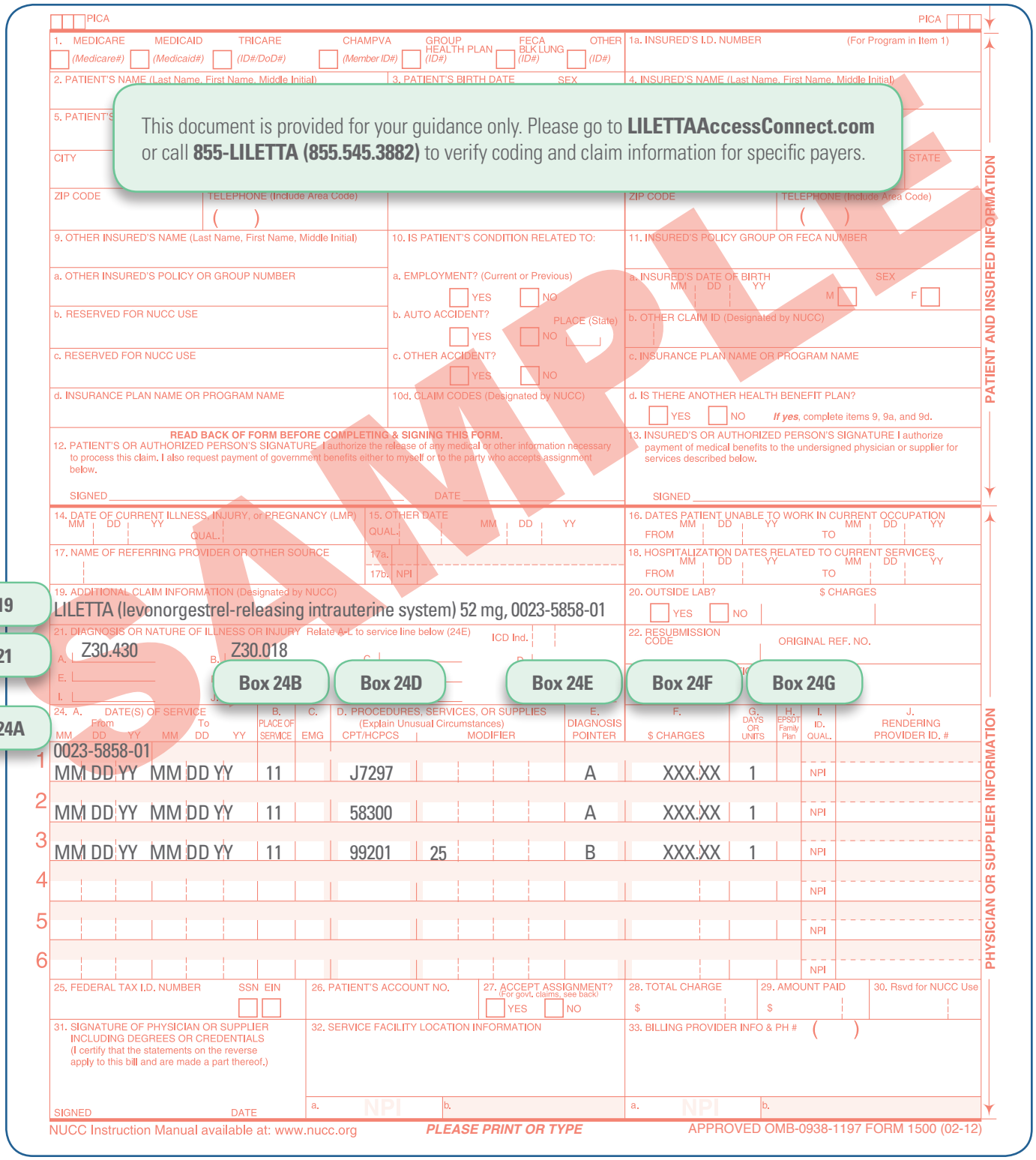
*Healthcare Common Procedure Coding System.
†International Classification of Diseases, 10th Revision.
‡Current Procedural Terminology. © 2012 American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations System/Defense Federal Acquisition Regulation Supplement restrictions apply to government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Please see additional Important Safety Information throughout and click here for the full LILETTA Prescribing Information.

Liletta® (levonorgestrel-releasing intrauterine system) 52 mg

CMS-1500 Sample Form

Use the example below when billing for LILETTA.



This document is provided for your guidance only. Please go to **LILETTAAccessConnect.com** or call **855-LILETTA (855.545.3882)** to verify coding and claim information for specific payers.

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CMS-1500 Form Instructions

Box 19: Remarks/Comments Field
- List the brand and generic name, NDC, and total units

Box 21: Diagnosis Codes
- List appropriate ICD-10 diagnosis codes for LILETTA

Shaded Area Above Box 24A: NDC and Qualifier
- List the 11-digit NDC with the prefix N4

Box 24A: Date of Service
- List the date when services occurred

Box 24B: Place of Service
- Enter "11" for services provided in office

Box 24D: Procedures, Services, or Supplies
- Enter the HCPCS code on line 1 and the CPT code on line 2
- List appropriate E/M code (eg, 99201) and modifier "25" when billing for contraception consultation

Box 24E: Diagnosis Pointer
- Enter the letter from Box 21 corresponding to the primary diagnosis of each code listed in 24D

Box 24F: Charges
- Enter the total charge assigned to each service or procedure listed in 24D

Box 24G: Days or Units
- Enter the number of units of service for each code listed in 24D

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IMPORTANT SAFETY INFORMATION (continued)

Clinical considerations for use and removal of LILETTA

Use LILETTA with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia; exceptionally severe or frequent headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing LILETTA if the following arise during use: uterine or cervical malignancy or jaundice. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. If LILETTA is displaced (eg, expelled or perforated the uterus), remove it.

Pregnancy-related risks with LILETTA

If pregnancy should occur with LILETTA in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with LILETTA. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Educate her about PID or endometritis

Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. One woman diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. PID and endometritis are often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Inform women about the possibility of PID or endometritis and that these infections can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

Expect changes in bleeding patterns with LILETTA

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation. If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUSs like LILETTA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is essential to minimize serious infections such as GAS.

Perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may also occur at any time during use. Perforation may reduce contraceptive efficacy. If perforation is suspected, locate and remove LILETTA as soon as possible. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted.

Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection.

Delay LILETTA insertion a minimum of 4 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out.

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.

In the LILETTA clinical trial, the most common adverse reactions (≥5% users) were vaginal bacterial infections (18.6%), vulvovaginal mycotic infections (18.6%), acne (14.9%), nausea or vomiting (9.8%), dyspareunia (9.1%), headache (8.9%), breast tenderness or pain (8.3%), pelvic discomfort or pain (8.3%), anxiety (8.1%), abdominal discomfort or pain (7.8%), depression (6.9%), dysmenorrhea (6.1%), mood changes (5.8%), increased weight (5.7%), back pain (5.5%), and vaginal discharge (5.4%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of LILETTA and then yearly or more often if clinically indicated.

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