LUTRATE® DEPOT

(leuprolide acetate for depot suspension)

BILLING & CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

AVYXA

TABLE OF CONTENTS

The contents herein provide general coverage, coding, and payment information about LUTRATE® DEPOT (leuprolide acetate for depot suspension). The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA™ does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

LUTRATE® DEPOT (leuprolide acetate), for depot suspension is a gonadotropin-releasing hormone (GnRH) agonist indicated for treatment of advanced prostate cancer.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Hypersensitivity: LUTRATE DEPOT is contraindicated in patients with known hypersensitivity to GnRH agonists or any of the excipients in LUTRATE DEPOT.

WARNINGS AND PRECAUTIONS

Tumor Flare: LUTRATE DEPOT, like other GnRH agonists, causes increases in serum levels of testosterone to approximately 50% above baseline during the first weeks of treatment. Ureteral obstruction and spinal cord compression have been observed, which may contribute to paralysis with or without fatal complications. Transient worsening of symptoms may develop. Patients may experience a temporary increase in bone pain, which can be managed symptomatically.

Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed during the first few weeks of therapy.

Metabolic Syndrome: The use of GnRH agonists may lead to metabolic changes such as hyperglycemia, diabetes mellitus, and hyperlipidemia. Non-alcoholic fatty liver disease, including cirrhosis, occurred in the post-marketing setting. Hyperglycemia may represent new-onset diabetes mellitus or worsening of glycemic control in patients with pre-existing diabetes. Monitor for changes in serum lipids, blood glucose and/or glycosylated hemoglobin (HbA1c) in patients receiving a GnRH agonist and manage according to current treatment guidelines.

Cardiovascular Diseases: Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. The risk should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.

Effect on QT/QTc Interval: Androgen deprivation therapy may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Convulsions: Convulsions have been observed in patients on leuprolide acetate therapy. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above. Patients receiving a GnRH agonist who experience convulsion should be managed according to current clinical practice.

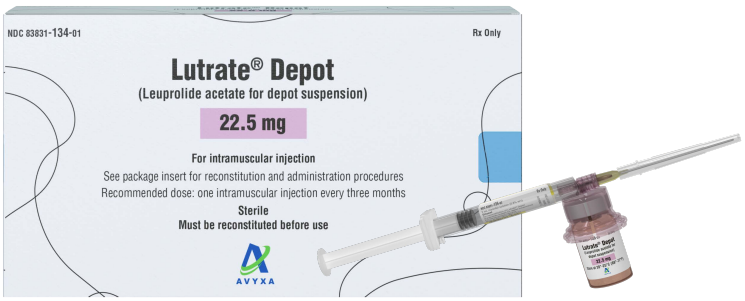
Continued on page 13.

LUTRATE® DEPOT

(leuprolide acetate for depot suspension)

Ordering Information

To order LUTRATE® DEPOT (leuprolide acetate for depot suspension), please contact one of these authorized specialty distributors and use the appropriate order number:



22.5 mg
NDC: 83831-0134-01

Institutions/Hospitals	22.5 mg
Cardinal Health Specialty	5976659
CENCORA - ASD Healthcare	10302021
McKesson Plasma & Biologics	3033396
Physician Offices	**22.5 mg**
Cardinal Health Specialty	5976659
Oncology Supply	10301925
McKesson Specialty Health	5020163
Besse Medical	10302010

Highlights

UNIQUE J-CODE[4]
J1954

- LUTRATE® DEPOT is supplied as 22.5 mg of leuprolide acetate
- Intramuscular injection
- For 3-month administration
- No refrigeration required
- Supplied as a commercial kit. Each kit contains:
  - One vial containing 22.5 mg of leuprolide acetate as lyophilized microspheres
  - One prefilled syringe containing 2 mL of mannitol for injection
  - One MIXJECT transfer device including one 20-gauge needle

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

AVYXASSIST™

Simplifying Patient Access, Providing Comprehensive Support.

AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services*

- Benefit verification
- Prior authorization requirements
- Appeals process information
- Referrals to 501(c)(3) foundations when applicable
- Free product assistance (uninsured or underinsured), bridge supply (coverage delays)
- Product replacement
- Copay assistance

COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as **$0** per dose*

TO ENROLL, PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS

Phone

866-939-8927
Monday through Friday
8 AM to 8 PM ET

CALL NOW

OR

Online

Click on the link below to begin your online enrollment

ENROLL NOW

OR

Fax

Download, print and fax the completed enrollment form to 833-852-3420

DOWNLOAD NOW

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

LUTRATE® DEPOT Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA™ concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA™ does not recommend using any diagnosis code in billing situations for LUTRATE® DEPOT (leuprolide acetate for depot suspension). The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs

Nearly all drugs in the United States are given a unique National Drug Code (NDC), which identifies all currently manufactured drugs and is maintained by the FDA.[2] NDCs are displayed on drug packing in a 10-digit format. Proper NDC billing requires an 11-digit number in a 5-4-2 format, listed below.

LUTRATE® DEPOT NDC[1]	Strength	Package
83831-0134-01	22.5 mg/vial	1 kit consisting of a LEUPROLIDE ACETATE MIXJECT single-dose delivery system.

HCPCS Code

HCPCS Level II codes identify most drugs and biologics administered in the physician's office and hospital outpatient department.[3]

LUTRATE® DEPOT Unique J-Code[4]	Description
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg

J-Code Billing Unit Conversion

Each 7.5 mg of **LUTRATE® DEPOT** equals one (1) service unit. When billing for quantities greater than 7.5 mg, indicate the total amount used as a multiple of service units on the claim form.[5]

Example:

Leuprolide Acetate MIXJECT Single-Dose Delivery System (22.5 mg/vial)	3 Service Units / Single-Dose Vial

NOTE: There are a few HCPCS codes for leuprolide acetate, however, there is only one code for **LUTRATE® DEPOT (J1954)**, so please make sure the HCPCS code matches the product purchased and administered.

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

CPT Drug Administration Codes

CPT codes are used to bill drug administration services provided in the physician's office and other outpatient settings.[6]

CPT Code	Description	Place of Service[7]
96402[8]	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.	• Physician Office (11) • Off-Campus Outpatient Hospital (19) • On-Campus Outpatient Hospital (22)

Revenue Codes

Claim Item	Revenue Code	Description	Place of Service[7]
LUTRATE® DEPOT	0636	Drugs Requiring Detailed Coding[9]	Off-Campus Outpatient Hospital (19)
Drug Administration	0331	Chemotherapy Administration – Injection[10]	On-Campus Outpatient Hospital (22)

LUTRATE® DEPOT is supplied as a kit. Medicare will pay for drug waste on single-use items that are medically necessary and appropriately documented in the patient's medical record. Medicare requires discarded drugs to be reported with the JW modifier on a separate line[11]; if there is no waste, LUTRATE® DEPOT must be billed on one line with the modifier-JZ.[12] Medicare requires this; please ascertain if other payers require JZ and JW modifiers.

Reporting Drug Waste (Modifier-JW)

Claim Line 1: Report the amount of LUTRATE® DEPOT given to the patient using the correct number of billing units for the **J1954** HCPCS code.

Claim Line 2: Report modifier-JW with the **J1954** HCPCS code and the appropriate number of billing units for any amount of discarded LUTRATE® DEPOT.

Reporting Zero Drug Waste (Modifier-JZ)

Claim Line 1: Report the amount of LUTRATE® DEPOT administered to the patient with the appropriate number of billing units for the **J1954** HCPCS code and JZ modifier, indicating zero waste.[13]

NOTE: The recommended dose of LUTRATE® DEPOT 22.5 mg for 3-month administration is one single-dose injection every 12 weeks. Due to different release characteristics, do not concurrently use a fractional or combination of doses of this or any depot formulation.[14] Reporting waste for LUTRATE® DEPOT is unlikely, as the vial size (22.5 mg) matches the recommended dosage (22.5 mg).

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

ICD Diagnosis Codes

It is best practice to code the most specific ICD-10-CM code within the indication to justify medical necessity.[15] LUTRATE® DEPOT 22.5 mg for 3-month administration (leuprolide acetate for depot suspension) is indicated for the treatment of advanced prostate cancer.[16]

International Classification of Disease, 10th Edition, Clinical Modification Codes for LUTRATE® DEPOT	
Indication	**ICD-10-CM Codes**
Prostate Cancer	C61

ICD Diagnosis Codes by Indication

The ICD-10-CM coding for LUTRATE® DEPOT varies by payer. Please check with each payer to determine the best coding per their policy.

Prostate Cancer: ICD-10-CM Diagnosis Coding[17]	
ICD-10 Code	**Descriptor**
C61	Malignant neoplasm of prostate

Sample Claim Form CMS-1450 (UB-04)

Form Locator (FL) 42

(Electronic Claim Form =Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for **LUTRATE® DEPOT** to your revenue code, 0636 Drugs requiring detailed coding.

Additionally, enter an appropriate revenue code for the administration service, such as 0331 for chemotherapy administration - injection or others based on the cost center where the service was performed.

FL 43

(NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed.

If required, list the N4 indicator first, then the 11-digit NDC code. In the third place, list the unit measurement code and, last, the quantity.

FL 44

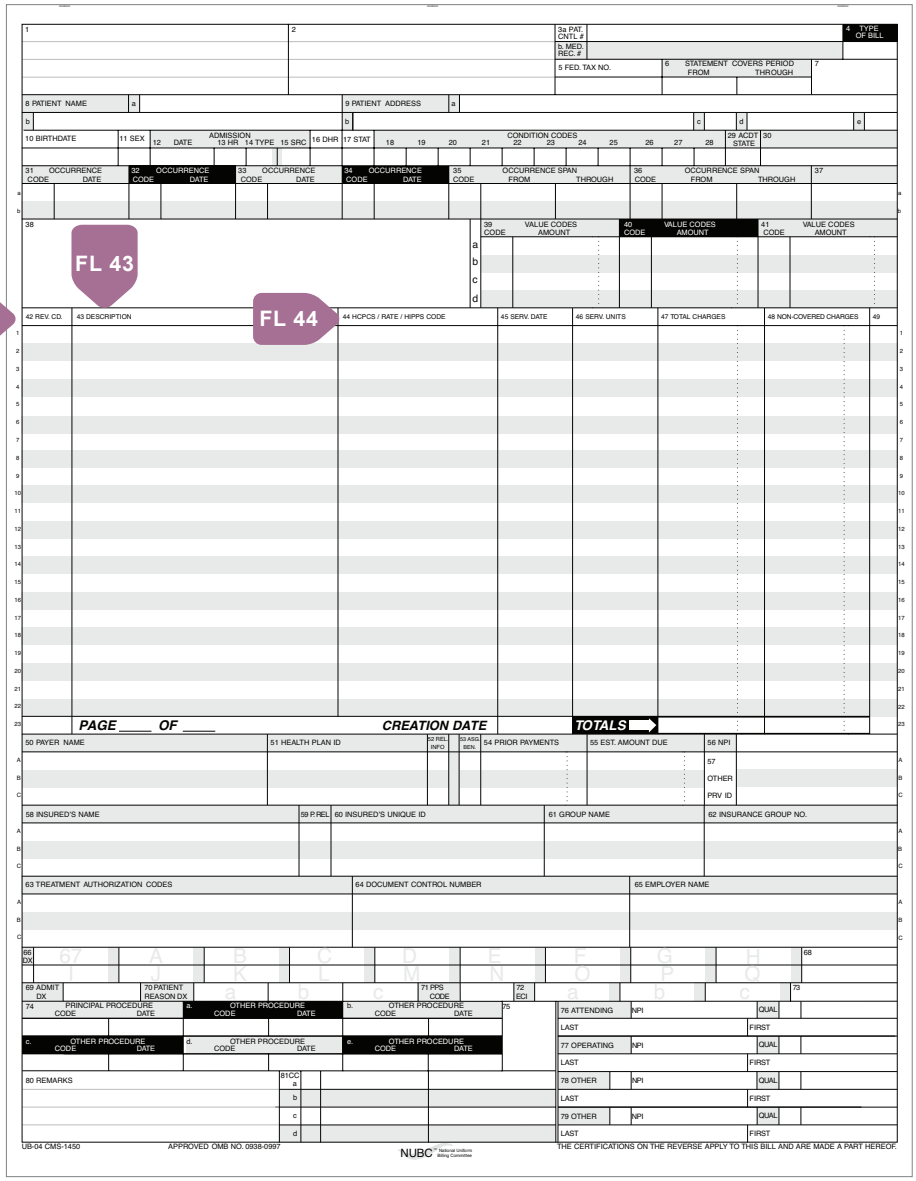
(Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP:

Enter the appropriate HCPCS code: **J1954 - Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg**

LUTRATE® DEPOT is packaged as a single-dose vial. Medicare requires drug waste be reported with the JW[1] modifier on a separate line. If there is no waste, **LUTRATE® DEPOT** must be billed on one line with modifier-JZ[2]. Medicare requires this; please ascertain if other payers require JZ and JW modifiers.

For administration, enter the appropriate code or codes for intramuscular injection.

As an example, chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic requires CPT code 96402.



Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

FL 45

(Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46

(Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed. Enter the number of service units for each item.

FL 63

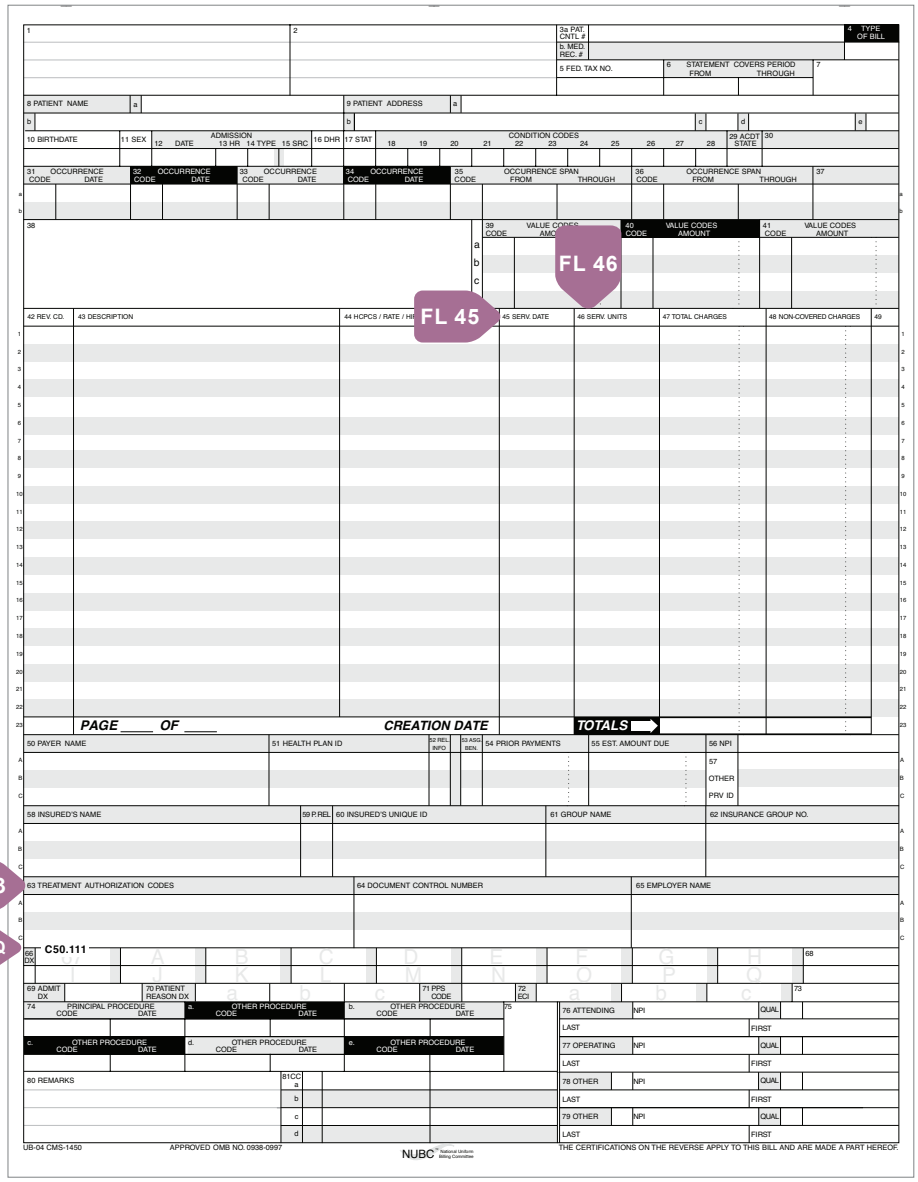
(Electronic Claim Form = Loop 2300,REF/G1/02):

Enter treatment authorization code.

FL 67A-Q

(Electronic Claim Form = Loop 2300, HI01-2 (HI01-1=BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible. The code listed here is an example: **C61, Malignant neoplasm of prostate**



[1]Since January 1, 2017, Medicare has required Modifier-JW for waste. Check with other payers as to their requirements for identifying waste.

[2]Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers with no discarded amounts.

***Electronic Claims Reference**: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 19, 2025. https://www.cgsmedicare.com/pdf/asc_837i_5010a2_2014.pdf*

Sample Claim Form CMS-1500

Item 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record.

An example code for this drug is ***C61 - Malignant neoplasm of prostate***

Use Item 21 B-L fields for secondary diagnoses.

Item 23

(Electronic Claim Form = Loop 2300, REF02)

Enter prior authorization number if one exists.

Item 24A-B

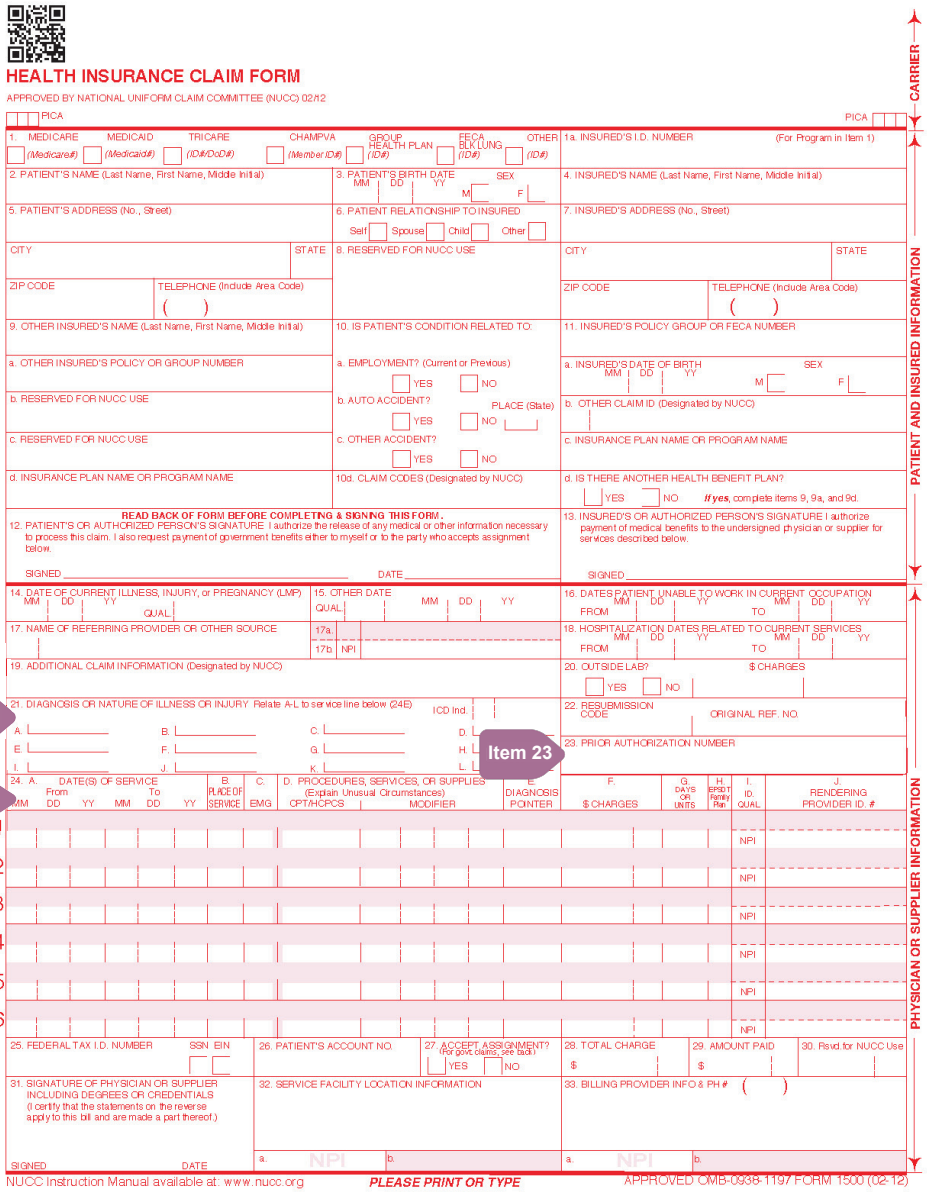
(Electronic Claim Form: Item 24A (Electronic Claims = Loop 2400, DTP02; Item 24B (Loop 2300/2400, Segment CLM05-1/SV105):

Item 24A (Electronic Claims = Loop 2400, DTP02;

Item 24B (Loop 2300/2400, Segment CLM05-1/SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Physician Office = 11

In the third space, list the unit measurement code, and last, the quantity.



LUTRATE® DEPOT must be billed on one line with modifier-JZ[2]. Medicare requires

Item 24D

(Electronic Claim Form = Loop 2400, Segment SV101)

Enter the appropriate HCPCS code: **J1954 - Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg**

LUTRATE® DEPOT is packaged as a single-dose vial. Medicare requires drug waste be reported with the JW[1] modifier on a separate line. If there is no waste, **LUTRATE® DEPOT** must be billed on one line with modifier-JZ[2]. Medicare requires this; please ascertain if other players require JZ and JW modifiers.

For administration, enter the appropriate code or codes for intramuscular injection. As an example, chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic requires CPT code 96402.

Item 24E

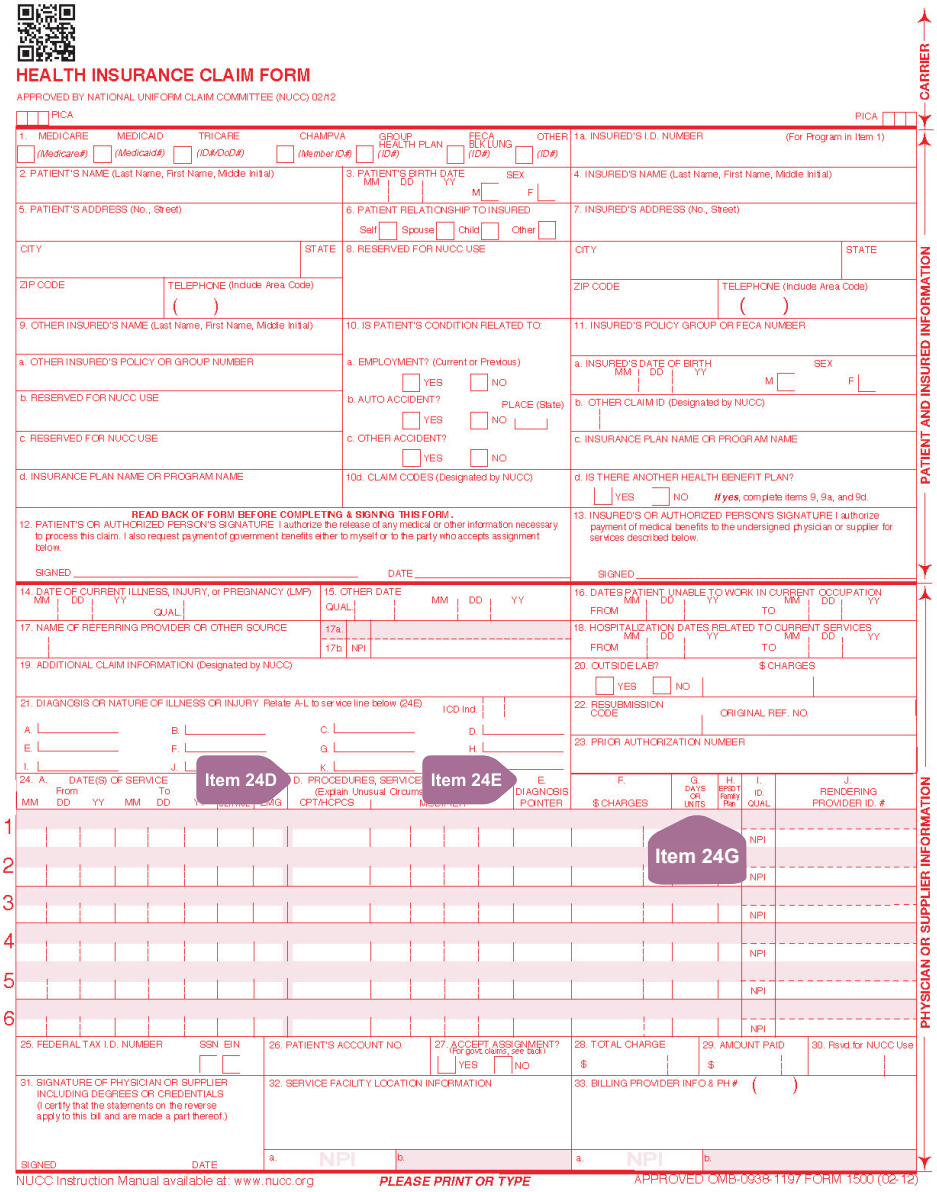
(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with **LUTRATE® DEPOT** and drug administration code(s) in Item 21.

Item 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of service units for each item.



[1] Since January 1, 2017, Medicare has required Modifier-JW for waste. Check with other payers as to their requirements for identifying waste.

[2] Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers with no discarded amounts.

Electronic Claims Reference: *ASC 8371 Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 19, 2025. https://www.cgsmedicare.com/pdf/asc_837i_5010a2_2014.pdf*

Please see Important Safety Information on pages 3 and 13 and full Prescribing Information for LUTRATE® DEPOT.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), may occur in patients receiving LUTRATE DEPOT; including cases with visceral involvement and/or requiring skin grafts.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (e.g., a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy).

If a SCAR is suspected, interrupt LUTRATE DEPOT until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other grade 4 skin reactions, permanently discontinue LUTRATE DEPOT.

Laboratory Tests: Monitor serum levels of testosterone following injection of LUTRATE DEPOT 22.5 mg for 3-month administration. In the majority of patients, testosterone levels increased above baseline during the first week, and then declined thereafter to castrate levels (< 50 ng/dL) within four weeks.

Embryo-Fetal Toxicity: LUTRATE DEPOT may cause fetal harm when administered to a pregnant woman. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.

ADVERSE REACTIONS

Most common adverse reactions (incidence > 10%) are hot flushes, upper respiratory infection, fatigue, diarrhea, pollakiuria, arthralgia, and injection site pain.

As with other GnRH agonist, other adverse reactions, including decreased bone density and rare cases of pituitary apoplexy may occur.

USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential: LUTRATE DEPOT may impair fertility. Counsel patients on pregnancy planning and prevention.

Pediatric: The safety and effectiveness of LUTRATE DEPOT in pediatric patients have not been established.

Please see full Prescribing Information of LUTRATE DEPOT.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

Notes

References:

1. AVYXA™. LUTRATE® DEPOT, Full Prescribing Information. Section 16. How Supplied/Storage and Handling.
2. FDA. National Drug Code Database Background Information. U.S. Food and Drug Administration. Section 2. NDC Number. Revised March 20, 2017. Accessed August 22, 2025. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information# :~:text=Because%20of%20a%20 conf ict%20with,zero%20instead%20of%20the%20asterisk
3. CMS. Healthcare Common Procedure Coding System Level II Coding Procedures. Revised January 10, 2025. Accessed August 22, 2025. www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system
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6. American Medical Association. (2024). 2025 AMA CPT Professional Edition. ISBN 978-1-64016-304-1. ISSN 0276-8283. About CPT. Section VII. Accessed August 22, 2025.
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10. Noridian Healthcare Solutions. Revenue Codes. Radiology Therapeutic and/of Chemotherapy Administration. Code 0331 – Chemotherapy Administration - injection. Updated March 18, 2024. Accessed August 22, 2025.
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12. CMS. Billing and Coding: Approved Drugs and Pharmaceuticals, Includes Cancer Chemotherapeutic Agents. Article ID A53049. JZ Modifier Requirement. Page 9. Updated November 9, 2023. Accessed August 22, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53049&ver=98
13. CMS. Billing and Coding: JW and JZ Modifier Billing Guidelines. Article ID A55932. Page 3. Revised March 21, 2024. Accessed August 22, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932
14. AVYXA™. LUTRATE® DEPOT, Full Prescribing Information. Section 2 Dosage and Administration. Section 2.1 LUTRATE® DEPOT 22.5 mg for 3-month administration.
15. American Academy of Professional Coders (AAPC). (2024) 2025 ICD-10-CM Expert Edition. eBook ISBN 978-1-635277-494. Section I. Conventions, General Coding Guidelines, and Chapter-Specific Guidelines. B. General Coding Guidelines. 2. Level of Detail in Coding. Page 13.
16. AVYXA™. LUTRATE® DEPOT, Full Prescribing Information. Section 1. Indications and Usage.
17. American Academy of Professional Coders (AAPC). (2024) 2025 ICD-10-CM Expert Edition. eBook ISBN 978-1-635277-494. Chapter 2 Neoplasms. Malignant neoplasms of male genital organs (C60-C63). ICD-10-CM Code C61. Page 1037.

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