

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.



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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

- 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.



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.

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.

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.	<ul style="list-style-type: none"> Physician Office (11) Off-Campus Outpatient Hospital (19) On-Campus Outpatient Hospital (22)

CPT codes, descriptions, and other data only are copyright 2025 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. 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.

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 line¹¹; 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 42

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 JW¹ modifier on a separate line. If there is no waste, **LUTRATE® DEPOT** must be billed on one line with modifier-JZ². 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.

1. PATIENT NAME		2. PATIENT ADDRESS		3a. PAT. CONT. #		4. TYPE OF BILL	
5. MED. RES. #		6. STATEMENT COVERS PERIOD FROM		7. THROUGH		8. FED. TAX NO.	
9. PATIENT NAME		10. PATIENT ADDRESS		11. SEX		12. DATE	
13. ADMISSION		14. TYPE		15. SRC		16. DHR	
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1128. 1129.		1130. 1131.		1132. 1133.		1134. 1135.	
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1168. 1169.		1170. 1171.		1172. 1173.		1174. 1175.	
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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**

UB-04 CMS-1450

APPROVED OMB NO. 0938-0997

NUBO

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

FL 45

FL 46

FL 63

FL 67A-Q

[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_5010a_2_2014.pdf

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Please see Important Safety Information on pages 3 and 13
and full [Prescribing Information](#) for LUTRATE® DEPOT.

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.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street)	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
CITY STATE		CITY STATE	
ZIP CODE TELEPHONE (Include Area Code)		ZIP CODE TELEPHONE (Include Area Code)	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER			
a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>			
b. OTHER CLAIM ID (Designated by NUCC)			
c. INSURANCE PLAN NAME OR PROGRAM NAME			
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d			
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.			
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.			
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY QUAL			
15. OTHER DATE MM DD YY QUAL			
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY			
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI			
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY			
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)			
20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES			
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: Relate A-L to service line below (245) ICD Ind			
22. RESUBMISSION CODE ORIGINAL REF. NO.			
23. PRIOR AUTHORIZATION NUMBER			
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS F. \$ CHARGES G. DAYS OR UNITS H. I.D. QUAL I. J. RENDERING PROVIDER ID. #			
25. FEDERAL TAX I.D. NUMBER SSN EIN			
26. PATIENT'S ACCOUNT NO.			
27. ACCEPT ASSIGNMENT? YES <input type="checkbox"/> NO <input type="checkbox"/>			
28. TOTAL CHARGE \$			
29. AMOUNT PAID \$			
30. Paid for NUCC Use			
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof)			
32. SERVICE FACILITY LOCATION INFORMATION			
33. BILLING PROVIDER INFO & PH # ()			
SIGNED DATE a. NPI b. NPI			

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

LUTRATE® DEPOT must be billed on one line with modifier-JZ². 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 JW¹ modifier on a separate line. If there is no waste, **LUTRATE® DEPOT** must be billed on one line with modifier-JZ². 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.

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.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
3. PATIENT'S BIRTH DATE MM DD YY		7. INSURED'S ADDRESS (No., Street)	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
8. RESERVED FOR NUCC USE		9. RESERVED FOR NUCC USE	
10. IS PATIENT'S CONDITION RELATED TO: a. OTHER INSURED'S POLICY OR GROUP NUMBER b. RESERVED FOR NUCC USE c. OTHER ACCIDENT? d. INSURANCE PLAN NAME OR PROGRAM NAME		11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.) SIGNED _____ DATE _____		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.) SIGNED _____	
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY QUAL		15. OTHER DATE QUAL MM DD YY	
16. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY 19. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> CHARGES \$	
20. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below G24E) A. _____ B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____	
22. DATE(S) OF SERVICE From MM DD YY To MM DD YY		23. PROCEDURES, SERVICE (Explain Unusual Circumstances) CPT/HCPCS Item 24D Item 24E Item 24G	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY		25. FEDERAL TAX I.D. NUMBER SSN EIN	
26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (For G01-G03, see 1031) YES <input type="checkbox"/> NO <input type="checkbox"/>	
28. TOTAL CHARGE \$		29. AMOUNT PAID \$	
30. BILLING PROVIDER INFO & PH # ()		31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)	
32. SERVICE FACILITY LOCATION INFORMATION a. NPI b. NPI		33. BILLING PROVIDER INFO & PH # () a. NPI b. NPI	

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APPROVED OMB-0938-1197 FORM 1500 (02-12)

- [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.

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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

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

References:

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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%20confict%20with,zero%20instead%20of%20the%20asterisk>
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