Lumvoa™
veligrotug-vvze

Billing and Coding Guide

Indication: Lumvoa is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

Important Safety Information

Infusion Reactions: Lumvoa may cause infusion reactions. Infusion reactions have been reported in approximately 9% of patients treated with Lumvoa. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, fever, chills, headache, and fatigue. Infusion reactions may occur during or soon after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids, antihistamines, and antipyretics. In patients who experience an infusion reaction, consideration should be given to standard premedication and/or administering infusions at a slower infusion rate.

Please see additional Important Safety Information on page 11 and Full Prescribing Information.

Coding Overview

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This guide provides billing and coding guidance to support submission of claims for Lumvoa and associated infusion services. Coding requirements vary by health plan and site of care; verify plan-specific rules (codes, modifiers, NDC reporting) prior to submission.

The coding information discussed in this guide is provided for informational purposes only, is subject to change, and should not be construed as legal, reimbursement, or billing advice. The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. Providers are responsible for confirming payer-specific requirements.

Relevant ICD-10-CM codes for TED

ICD-10-CM codes identify the medical necessity for treatment. For Lumvoa, these codes confirm the diagnosis of TED and link the service rendered to the patient's clinical condition.[1]

Code[1]	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
H05.831	Thyroid orbitopathy, right orbit
H05.832	Thyroid orbitopathy, left orbit
H05.833	Thyroid orbitopathy, bilateral
H05.839	Thyroid orbitopathy, unspecified orbit

HCPCS drug codes

HCPCS codes identify the drug administered during treatment. Until a permanent J code is assigned for Lumvoa, providers may need to bill using unclassified or "not otherwise classified" (NOC) codes. Always confirm the appropriate HCPCS code with the patient's health plan before submitting a claim.

Code[2]	Description	Use Case
J3490	Unclassified drugs	Used for physician office and other CMS-1500 claims
J3590	Unclassified biologics	Used for physician office and other CMS-1500 claims
C9399	Unclassified drugs or biologics	Used for outpatient hospital claims

CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; TED, Thyroid Eye Disease.

Coding Overview (cont'd)

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CPT administration codes

CPT codes describe the administration process and infusion services associated with Lumvoa. These codes capture the duration and complexity of the infusion and any sequential administrations.

Code	Description	Notes
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Used for the initial hour of infusion[3]
96415	Each additional hour	Used for infusion times beyond 1 hour when using 96413 as the initial code[4]
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Used for therapeutic or prophylactic infusions; used for the initial hour when not billed under 96413[5]
96366	Each additional hour	Used for infusion times beyond 1 hour when 96365 is the initial code[5]
96375	Each additional sequential IV push of a new substance/drug	Used for additional agents administered during the same visit[5]

Home infusion codes

Code	Description	Notes
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	Used for initial visit for home infusion per date of service[6]
99602	Home infusion/specialty drug administration, per visit (each additional hour)	Used with 99601 if infusion exceeds 2 hours[6]
S5520	Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted central venous catheter (PICC) line insertion	Used for home infusion therapy supplies for a peripherally inserted central venous catheter line[7]
S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Not used with S9330 or S9331[8]
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	May be required by some health plans when a more specific per diem CPT code does not apply[8]
S9810	Home therapy; professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour (not used with any per diem code)	Not used in combination with any home infusion per diem code (eg, S9329, S9379)[8,9]

CPT, Current Procedure Terminology; IV, intravenous.

Coding Overview (cont'd)

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Modifiers

Modifiers are appended to CPT or HCPCS codes to provide additional claim details, such as wastage, 340B acquisition, or distinct procedures.

Modifier	Description	Notes
JW[10]	Drug amount discarded or not administered	Required when documenting discarded drug not administered to any patient
JZ[10]	Zero drug amount discarded or not administered	Required when zero drug is discarded
59[11]	Distinct procedural service	Used if multiple, separate services are billed on the same day
JG[10]	Drug or biological acquired with 340B Drug Pricing Program discount	Reported for informational purposes
TB[10]	Drug or biological acquired with 340B Drug Pricing Program discount	Reported for informational purposes by select 340B entities
SS[10]	Home infusion services provided in the infusion suite of the IV therapy provider	Used when home infusion services are provided in the infusion suite of the IV therapy provider

Place of service codes (examples)[12]

Code	Description
11	Office
12	Home
19	Off-campus outpatient hospital
22	On-campus outpatient hospital
49	Independent clinic

NDC reporting[13]

- 10-digit NDC 85166-001-01 → convert to 11-digit* for claim forms 85166-**0**001-01
- N4 + 11-digit NDC + unit-of-measure + quantity (health plan-specific formatting)

*FDA standard NDC has been "zero-filled" to ensure creation of an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in **bold**.

CPT, Current Procedure Terminology; HCPCS, Healthcare Common Procedure Coding System; HIPAA, Health Insurance Portability and Accountability Act; IV, intravenous; NDC, National Drug Code.

Site-of-care coding differences

Billing and reimbursement processes vary by site of service. While ICD-10-CM diagnosis codes, CPT codes, and PA requirements generally remain consistent across sites, the claim form type, HCPCS code, modifiers, and POS codes may differ based on where Lumvoa is administered.[12]

The table below highlights the key coding and billing elements that differ by site of care.

Element	Specialty Infusion Center/Home Infusion	Physician's Office/ Office-Based Infusion Center	Hospital Outpatient Department
Claim Form Type[14]	CMS-1500 (837P)	CMS-1500 (837P)	CMS-1450 (UB-04/837I)
HCPCS Drug Code[2]	J3490, J3590	J3490, J3590	C9399
Modifiers[10]	JW, JZ	JW, JZ	JW, JZ, JG/TB
POS[12,14]	12 (home); 49 (independent clinic)	11 (office); 49 (independent clinic)	*Not applicable for CMS-1450 claims; setting determined by revenue codes*

Billing codes may change once a permanent J-code is assigned.

VIRIDIAN™ cares

ViridianCares helps sites of care manage co-pay claims reimbursement for eligible patients. Fax claims with the required documentation to 1-833-726-5151.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedure Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; PA, prior authorization; POS, place of service.

CMS-1500 Form Completion

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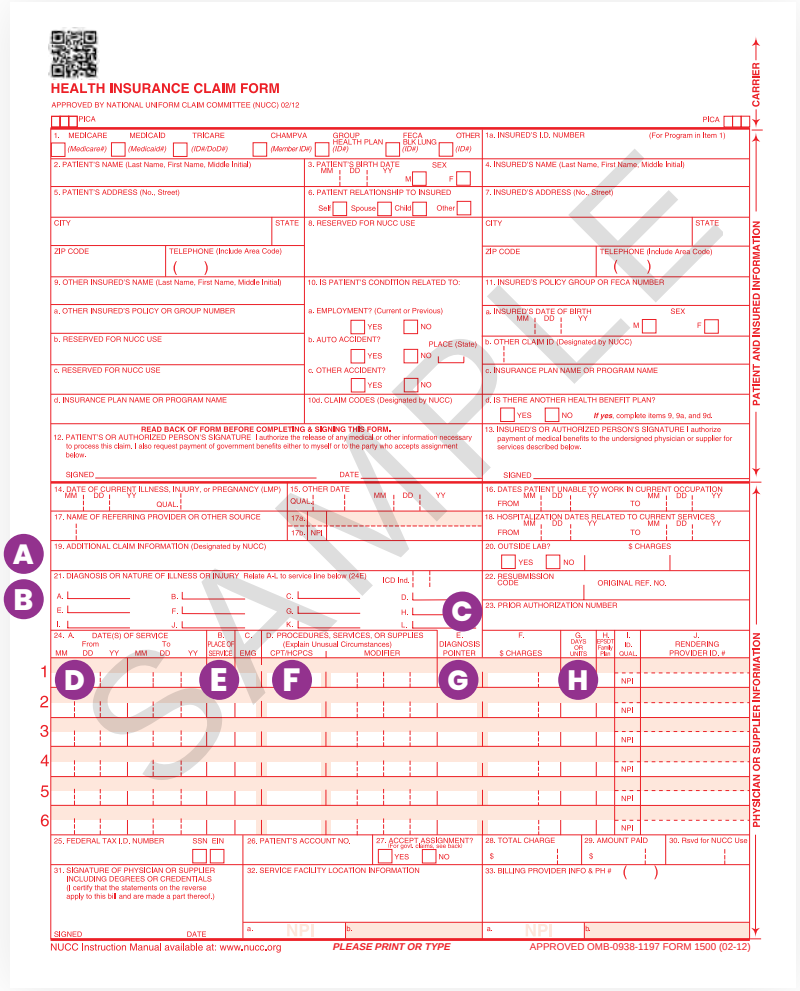
Sample claim form CMS-1500 (physician's office)

The following is an example of how to complete the CMS-1500 (837P) claim form for a patient who received Lumvoa via IV infusion in the physician office or office-based infusion center.

- **A Item 19:** Add clarifying note if using unclassified code (eg, "Unclassified biologic – Lumvoa")
- **B Item 21:** Enter ICD-10-CM code
- **C Item 23:** Enter the Prior Authorization number (if applicable)
- **D Item 24A:** Enter the NDC number in the shaded area above the date of service
  - Enter N4 before NDC
  - 11-digit NDC
  - NDC unit of measure
  - NDC quantity

  Note: Confirm with individual health plan how NDC numbers should be notated on claim form
- **E Item 24B:** POS code
- **F Item 24D:** CPT/HCPCS codes and modifiers
- **G Item 24E:** Enter letter (A-L) corresponding to the diagnosis in Item 21
- **H Item 24G:** Number of billing units used for each line item



Sample values shown for illustrative purposes only.

Important Reminder

Lumvoa dose may differ between infusions. Always submit the updated patient weight with each claim to support accurate billing. The example form illustrates how weight-based dosing should be documented (see pages 7 and 8)

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedure Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code; POS, place of service.

CMS-1500 Form Completion (cont'd)

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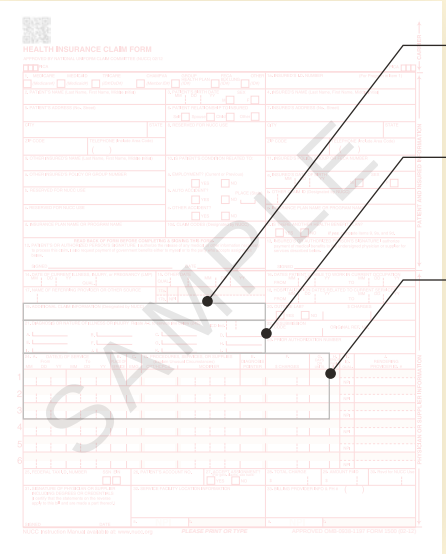
Example weight-based dose (independent clinic)

This example shows how a CMS-1500 claim may be completed for a weight-based dose of Lumvoa administered in an independent clinic. Key fields displayed include the ICD-10-CM diagnosis code, drug and infusion administration codes, NDC, POS, and billing units. Drug wastage from the single-use vial is shown on a separate service line using the JW modifier, with administered and discarded amounts listed separately. For the definitions of JW and JZ modifiers, see the modifier table on page 4.

Drug	Lumvoa
Dosing	10 mg/kg
Patient weight	78 kg
Total dose	780 mg administered
Vial size	500 mg
Vials required	2 vials × 500 mg = 1000 mg
Wastage	220 mg discarded
POS	49 (independent clinic)
Number of billing units	780

Example assumes on-label dosing.

CMS-1500 Form*



Item 19

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

1 billing unit = 1 mg. Total drawn 1000 mg; administered 780 mg; wasted 220 mg (JW)

Item 21

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)

A. **H05.833** B. _____ C. _____

Items 24A-G

	24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	G. DAYS OR UNITS
1	**N4 XXXX-XXXX-XX MG 780**							
			49		**J3490**		**A**	**780**
2	**N4 XXXX-XXXX-XX MG 780**							
			49		**J3490**	**JW**	**A**	**220**
3	**N4 XXXX-XXXX-XX MG 780**							
			49		**96365**		**A**	**1**

Sample values shown for illustrative purposes only.

*Note: The CPT codes included on this sample form are examples. Please confirm correct CPT codes for site of care prior to form submission.

CMS, Centers for Medicare & Medicaid Services; CPT, current procedural terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; NUCC, National Uniform Claim Committee; POS, place of service.

CMS-1500 Form Completion (cont'd)

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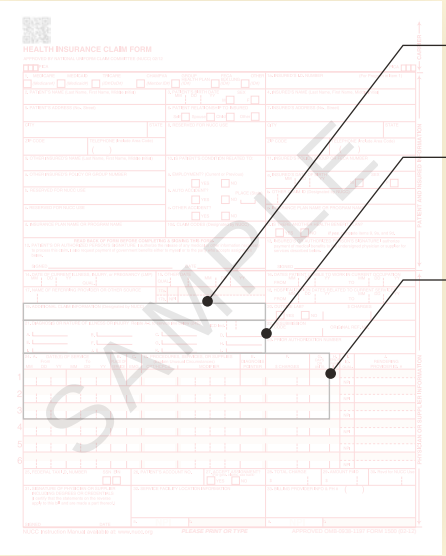
Example weight-based dose (home infusion)

This example shows how a CMS-1500 claim may be completed for a weight-based dose of Lumvoa administered in the home setting. The form displays the ICD-10-CM diagnosis code, drug and infusion administration codes, NDC, POS, billing units, and any applicable home infusion nursing service codes. Drug wastage from the single-use vial is shown on a separate service line using the JW modifier, with administered and discarded amounts listed separately. For the definitions of JW and JZ modifiers, see the modifier table on page 4.

Drug	Lumvoa
Dosing	10 mg/kg
Patient weight	75 kg
Total dose	750 mg administered
Vial size	500 mg
Vials required	2 vials × 500 mg = 1000 mg
Wastage	250 mg discarded
POS	12 (home infusion)
Number of billing units	750

Example assumes on-label dosing.

CMS-1500 Form*



Item 19

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

1 billing unit = 1 mg. Total drawn 1000 mg; administered 750 mg; wasted 250 mg (JW)

Item 21

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)

A. **H05.833** B. _____ C. _____

Items 24A-G

	24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	G. DAYS OR UNITS
1	**N4 XXXX-XXXX-XX MG 750**							
			12		**J3490**		**A**	**750**
2	**N4 XXXX-XXXX-XX MG 750**							
			12		**J3490**	**JW**	**A**	**250**
3	**N4 XXXX-XXXX-XX MG 750**							
			12		**99601**		**A**	**1**

Sample values shown for illustrative purposes only.

*Note: The CPT codes included on this sample form are examples. Please confirm correct CPT codes for site of care prior to form submission.

CMS, Centers for Medicare & Medicaid Services; CPT, current procedural terminology; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; NUCC, National Uniform Claim Committee; POS, place of service.

CMS-1450 (UB-04) Form Completion

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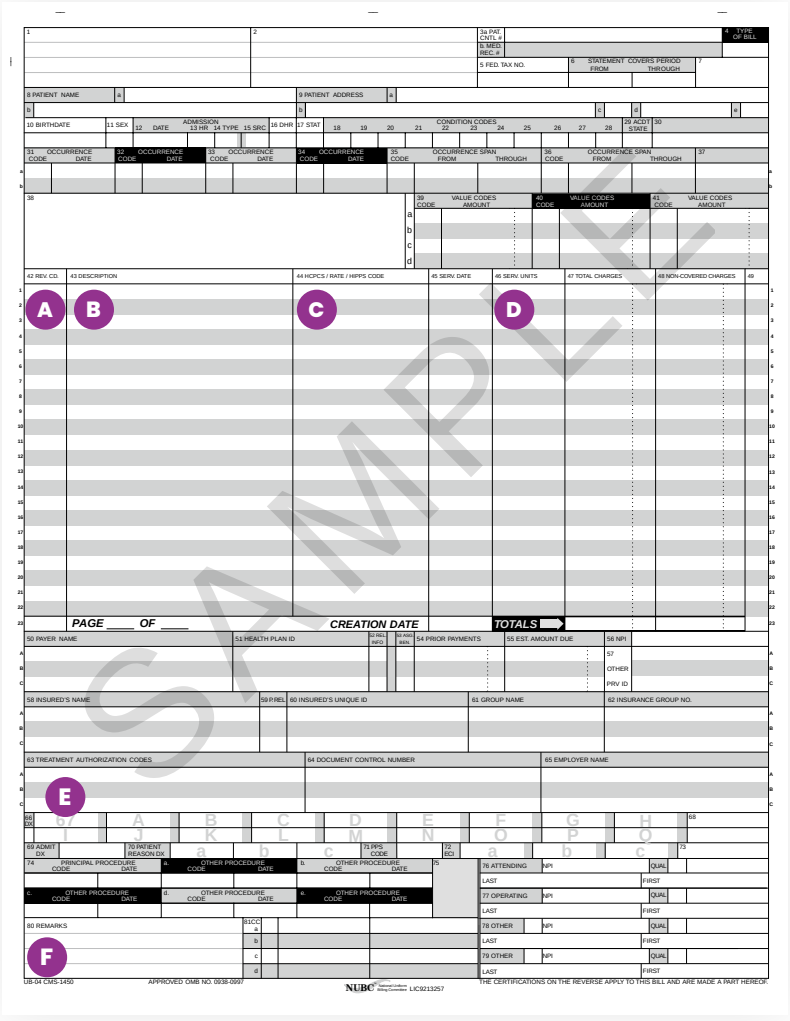
Sample claim form CMS-1450 (UB-04, hospital outpatient)

The following is an example of how to complete the CMS-1450 (UB-04) claim form for a patient who received Lumvoa via IV infusion in the hospital outpatient infusion center.

- **A** **FL 42:** Revenue codes 0636 (drug) and 0260 (infusion)
- **B** **FL 43:** Include NDC with unit of measure
- **C** **FL 44:** HCPCS and CPT (96413)
- **D** **FL 46:** Number of billing units administered
- **E** **FL 67:** ICD-10-CM code
- **F** **FL 80:** Used to document drug name, dose calculation, and wastage



Sample values shown for illustrative purposes only.

Important Reminder

Lumvoa dose may differ between infusions. Always submit the updated patient weight with each claim to support accurate billing. The example form illustrates how weight-based dosing should be documented (see page 10)

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; FL, Form Locator; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

CMS-1450 (UB-04) Form Completion (cont'd)

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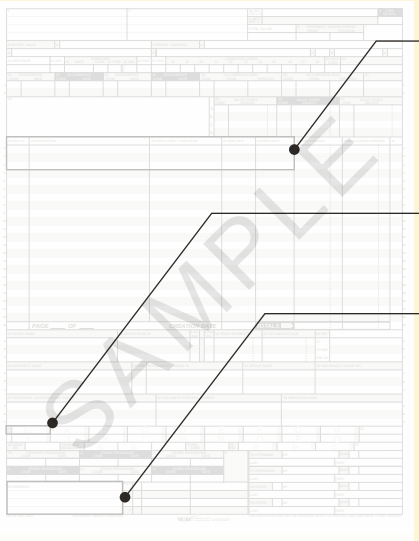
Example weight-based dose (hospital outpatient department)

This example shows how a CMS-1450 (UB-04) claim may be completed for Lumvoa administered in a hospital outpatient department. The form displays the HCPCS drug code, infusion administration code, NDC, revenue codes, and total billing units. Drug wastage from the single-use vial is reported on a separate service line using the JW modifier, with administered and discarded amounts listed separately. Field 80 includes a brief notation summarizing total drawn, administered, and wasted drug. For the definitions of JW and JZ modifiers, see the modifier table on page 4.

Drug	Lumvoa
Dosing	10 mg/kg
Patient weight	83 kg
Total dose	830 mg administered
Vial size	500 mg
Vials required	2 vials × 500 mg = 1000 mg
Wastage	170 mg discarded
Number of billing units	830

Example assumes on-label dosing.

CMS-1450 Form



FL 42-46

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	0636	Veligrotug - administered amount	J3490		830
2	0636	Veligrotug - wastage	J3490 JW		170
3	0260	IV infusion - initial	96365		1

FL 67

66 DX H05.833

FL 80

80 REMARKS

Veligrotug administered 830 mg. Total amount 1000 mg from 2 vials of 500 mg each. 170 mg discarded in accordance with FDA labeling; JW modifier applied.

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997

Sample values shown for illustrative purposes only.

CMS, Centers for Medicare & Medicaid Services; FDA, US Food and Drug Administration; FL, Form Locator; HCPCS, Healthcare Common Procedural Coding System; IV, intravenous; NDC, National Drug Code.

Important Safety Information

Infusion Reactions: Lumvoa may cause infusion reactions. Infusion reactions have been reported in approximately 9% of patients treated with Lumvoa. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, fever, chills, headache, and fatigue. Infusion reactions may occur during or soon after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids, antihistamines, and antipyretics. In patients who experience an infusion reaction, consideration should be given to standard premedication and/or administering infusions at a slower infusion rate.

Inflammatory Bowel Disease: Lumvoa may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients receiving insulin-like growth factor-1 receptor inhibitors without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD, including patients without a history of IBD. If IBD is suspected, discontinue use of Lumvoa.

Hyperglycemia: Hyperglycemia or increased blood glucose may occur in patients treated with Lumvoa. In clinical trials, 12% of patients, of whom one-half had preexisting diabetes or impaired glucose tolerance, experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with Lumvoa. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving Lumvoa. Continued monitoring after treatment is recommended for patients who experience hyperglycemia while on Lumvoa.

Hearing Impairment Including Hearing Loss: Lumvoa may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with Lumvoa and consider the benefit-risk of treatment with patients.

Most Common Adverse Events: Most common adverse reactions (incidence of 5% or more) are muscle spasms, headache, hearing impairment, hyperglycemia, fatigue, diarrhea, ear discomfort, infusion-related reaction, nausea, nasopharyngitis, blood creatine phosphokinase increased, dry skin, and hypertension.

Females of Reproductive Potential: Appropriate forms of contraception should be implemented prior to initiation, during treatment, and for 6 months following the last dose of Lumvoa.

Lumvoa (500 mg) is an injection for infusion.

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