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A Guide to Lumvoa Access

Coverage, Reimbursement, and Support

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 22 and Full Prescribing Information.

Introduction

This guide provides practical resources that support key steps in the access and reimbursement process for Lumvoa.

The information presented in this guide is for informational purposes only, is subject to change, and is not intended as legal, billing, coding, or reimbursement 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. For direction on these topics, consult your legal or billing advisors and coding specialists, as your office is responsible for the accuracy of all submitted claims.

Please note that any product, ancillary supplies, or services provided free of charge cannot be billed to third party payers, as this may violate federal or state laws or payer requirements.

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Please see Important Safety Information on page 22 and Full Prescribing Information.

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Lumvoa Product Information

Indication: Lumvoa is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration[1]

Dosing and Administration[1]

Single IV infusion of 10 mg/kg once every 3 weeks for 12 weeks[1]

5 Total Infusions

Initial Infusion

45 minutes[1]

Subsequent Infusions

30 minutes[1]
if well tolerated

NOTE: For a complete description of all dosing and administration considerations for Lumvoa, please see Section 2 of the Full Prescribing Information.

How Supplied[1]	A sterile, preservative-free, slightly opalescent yellowish to brown solution in a single-dose vial containing 500 mg/10 mL.
Storage Requirements[1]	Refrigerate at 2 °C to 8 °C (36 °F to 46 °F) in original carton until time of use to protect from light. Do not freeze. Do not shake.
Packaging[1]	Each carton contains 1 single-dose, 10-mL glass vial.
Dimensions	Carton: 44.45 mm (L) × 35.72 mm (W) × 70.64 mm (H)
	Shipping Case: 286 mm (L) × 160 mm (W) × 152 mm (H)
ICD-10-CM Codes[2]	E05.00, H05.831, H05.832, H05.833, H05.839
HCPCS Codes (J-Codes)[3]	J3490, J3590, C9399
NDC[1]	10-Digit: 85166-001-01 11-Digit*: 85166-**0**001-01

*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**.

FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HIPAA, Health Insurance Portability and Accountability Act; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

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ViridianCares Is a Support Program to Help Your Patients Start and Stay on Treatment

Dedicated Patient Access Liaisons

- Personalized, one-on-one support to help your patients start and stay on treatment

VIRIDIAN™ *cares*

Insurance Coverage Support

- Assistance with benefits verification, prior authorization requirements, reimbursement, and required documentation

Financial Assistance Programs

- The ViridianCares Co-Pay Program offers co-pay assistance for eligible patients. Commercially insured patients may pay as little as $0* for both medication and infusion-related expenses†
- If your patients experience a change in coverage or have affordability concerns, ViridianCares will work closely with them to explore available financial assistance options†

Support services, including Co-Pay Program support, are available to eligible patients following submission of a completed Patient Enrollment Form. Healthcare providers may enroll patients at any stage of the treatment journey by completing, signing, and submitting the enrollment form using one of the following methods:

Complete form, ensure patient reviews and signs, then fax all 4 pages to **1-833-726-5151**

or

Complete the EZ Enroll enrollment form electronically at **ViridianCares.com**

To help your patients enroll, visit **ViridianCares.com** to download the enrollment form

It is crucial to complete all required fields and ensure your patient signs and dates the patient authorization to use/disclose health information.

For questions about enrollment in ViridianCares, call 1-866-VCARES1, Monday through Friday, 8 am to 8 pm ET

*Patients must be enrolled in ViridianCares and meet all eligibility requirements. Terms and conditions will apply.
†Please visit www.lumvoahcp.com for full terms and conditions.

ET, Eastern Time.

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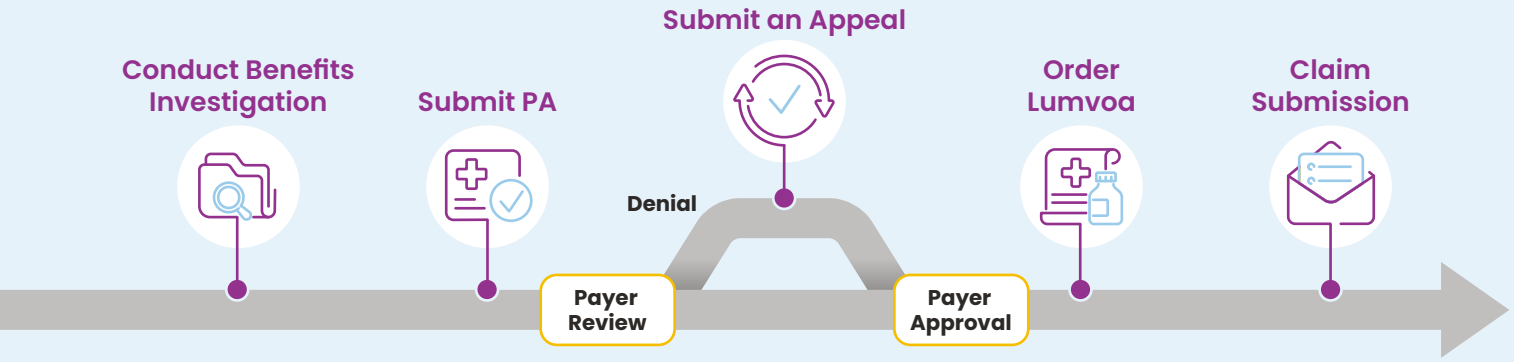
Getting Patients Started and Navigating Reimbursement

The following sections in this guide highlight key steps for access and reimbursement for Lumvoa, from starting a patient on therapy through submitting a complete claim.

Key steps in the access process for healthcare providers and sites of care

Click on the icons for more information



Access Support

VIRIDIAN™ cares

ViridianCares can provide tools and education to support benefits verification, prior authorization, and claim submission.

Proactive scheduling and coordination between the office and infusion site can help minimize avoidable delays once coverage is confirmed and keep patients on track with the recommended Lumvoa dosing schedule.

Visit lumvoahcp.com/resources to download access resources to support you at each step of the access and reimbursement process

PA, prior authorization.

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Infusion Site Coordination

Lumvoa is administered via IV infusion, and sites of care may include: physician office/office-based infusion, hospital outpatient department, stand-alone infusion center, and home infusion.

Site of care selection considerations:

- Health plan preference and network requirements
- Patient-specific needs and clinical appropriateness
- Administration cost variability by setting
- Acquisition pathway implications (buy-and-bill vs specialty pharmacy)

If your office does not administer infusions, prompt referral to an in-network infusion site can reduce scheduling delays and help patients start therapy sooner.

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If your office does not have a preferred infusion site, ViridianCares can assist once the completed enrollment form is submitted. A Patient Access Liaison can help identify an infusion center.

For enrollment or more information on ViridianCares, see page 5

IV, intravenous.

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Please see Important Safety Information on page 22 and Full Prescribing Information.

Benefits Investigation

Lumvoa is administered via IV infusion; therefore, many health plans manage coverage and administration under the medical benefit, and requirements vary by health plan. Conducting a benefits investigation helps identify plan-specific rules and reduces the risk of avoidable delays or denials.

A benefits investigation can help with:

Prior authorization and required documentation for Lumvoa	Identify PA requirements and clinical documentation needed for Lumvoa approval
Site of care considerations	Determine payer-preferred or in-network infusion sites and understand site-specific criteria that may affect Lumvoa access
Product acquisition requirements	Confirm whether Lumvoa should be obtained through buy-and-bill or specialty pharmacy fulfillment, and understand associated billing responsibilities
Claims submission	Review correct coding and billing requirements for Lumvoa treatment initiation and continuation
Benefits coordination	Confirm coordination of benefits requirements and documentation needs when patients have multiple health plans

If Lumvoa is not covered, the healthcare provider may need to request a medical exception; see page 11.

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ViridianCares can assist with benefits verification to review coverage benefits

IV, intravenous; PA, prior authorization.

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Obtaining Prior Authorization for Lumvoa Treatment

Health insurance plans may require PA, precertification, and/or coverage determination prior to infusion therapies, and requirements may vary by health plan. Complete, policy-aligned documentation is essential to avoid delays.

PA and Required Documentation Checklist for the Healthcare Provider Office and Site of Care:

Diagnosis and Clinical Criteria

- ☐ TED diagnosis, documented by treating specialist
- ☐ Correct ICD-10-CM codes (eg, E05.00, H05.831, H05.832, H05.833, H05.839[2]; see page 13)
  - Use the most precise diagnosis code available. TED codes vary by laterality and specificity[2]
- ☐ Disease status: active vs chronic
- ☐ Disease severity (eg, moderate-to-severe)
- ☐ Documentation of clinically significant disease burden, including:
  - Clinical activity score (CAS) and symptoms supporting inflammatory activity
  - Proptosis measurements (mm)
  - Diplopia grade and functional impact
  - Lid retraction (mm)
  - Risk of vision loss
  - Impact on daily activities
- ☐ Relevant comorbidities (eg, Graves' disease)

Prior Treatment History (as Required by Health Plan)

- ☐ Oral/IV corticosteroids or other immunosuppressive therapies (dose, duration, response/intolerance)
- ☐ IGF-1R inhibitor therapy (eg, TEPEZZA® [teprotumumab-trbw])
- ☐ Radiation therapy and/or prior surgery
- ☐ Reason prior treatments were insufficient, contraindicated, or not durable

Thyroid Status and Relevant Laboratory Testing Results

- ☐ Indicate whether patient is euthyroid or receiving treatment to maintain euthyroid state, and include recent free T3 and free T4 values

Continued on next page

TEPEZZA® (teprotumumab-trbw) is a registered trademark of Amgen Inc.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IGF-1R, insulin-like growth factor-1 receptor; IV, intravenous; PA, prior authorization; T3, triiodothyronine; T4, thyroxine; TED, Thyroid Eye Disease.

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Obtaining Prior Authorization for Lumvoa Treatment (cont'd)

PA and Required Documentation Checklist for the Healthcare Provider Office and Site of Care (cont'd):

Required Forms and Supporting Documentation

- ☐ Completed PA form (plan-specific)
- ☐ Chart notes from the latest visit including documentation of proper diagnosis code(s), all relevant assessments, and baseline photographs and measurements (if applicable)
- ☐ Letter of Medical Necessity (recommended). See example letter of medical necessity here: **lumvoahcp.com/resources**
- ☐ Prescription documented in consultation with endocrinologist, ophthalmologist, or other specialist
- ☐ Lumvoa Prescribing Information (as needed)
- ☐ Infusion plan, including dose per kg, schedule, and planned site of care
- ☐ Confirm accuracy of all coding prior to PA submission (see **page 13** for billing and coding)

Site-of-Care Requirements

- ☐ Verify health plan requirements for infusion location
- ☐ Confirm network participation to avoid out-of-network claims
- ☐ Document site-of-care alignment in the PA submission when required

Thoroughly complete every PA form section and attach requested supporting documentation; missing/incomplete information is a common reason for denial.

- Use a standardized electronic health record template to help ensure consistent and complete clinical documentation. Ensure laterality is consistent across:
  - Diagnosis codes
  - Clinical narrative
  - Photos or imaging labels
- Keep updated notes for appeals. Plans often request "most recent clinical documentation"
- Use health plan's preferred submission pathway
  - Submit electronically via health plan portal when allowed
  - If faxing, retain confirmation receipts
  - Some commercial plans require submission via CoverMyMeds® or other electronic PA tools

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ViridianCares can provide prior authorization support, including identification of relevant forms, follow-up, and site-of-care coordination.

CoverMyMeds® is a registered trademark of CoverMyMeds LLC.

PA, prior authorization.

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Navigating Medical Exceptions and Appeals

A medical exception is a formal request for a health plan to cover Lumvoa when the patient does not meet the plan's published coverage criteria. Exceptions may be submitted before or after a formal denial, depending on plan design.

Common triggers for exceptions:

- Lumvoa is not listed on formulary/medical policy
- Clinical scenario is patient-specific and not addressed by standard criteria
- Plan requires use of a preferred product or treatment (step edit)
- Plan mandates a specific site of care or network vendor that is not clinically appropriate
- Plan requires a specialty pharmacy channel not available in-network

Key recommendations for a medical exception request for the healthcare provider office and site of care:

Start with a **benefits investigation** to identify the exact requirement related to the exception (see page 8)

Submit a **patient-specific clinical rationale** that includes supporting clinical documentation (see page 9)

Include a **letter of medical necessity** even if not explicitly required. See example letter of medical necessity here: lumvoahcp.com/resources

Appealing a denial of PA or medical exception:

- Identify the specific denial reason(s) and required next actions
  - Determine whether denial is administrative (missing information) or clinical (policy criteria not met)
- Submit a written appeal that **matches the denial language** and includes supporting documentation. See example appeal letter here: lumvoahcp.com/resources
- Follow health plan timelines; pursue external review if available after internal appeals are exhausted
- Consider a **peer-to-peer review** (if the plan allows)

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A Patient Access Liaison can help support your patient through the appeals process

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PA, prior authorization.

Please see Important Safety Information on page 22 and Full Prescribing Information.

Ordering Lumvoa

Lumvoa is available through an authorized specialty pharmacy and distributor network.

Authorized Specialty Pharmacy

Accredo®
1-800-803-2523
www.accredo.com/raretherapies/prescribers

Authorized Distributor Network

BioCareSD
1-800-304-3064
www.biocare-us.com

CuraScript Specialty Distribution
1-877-599-7748
www.curascript.com

Cardinal Health SPD
1-855-855-0708
www.cardinalhealth.com

Cardinal Health PR 120, Inc. Specialty Pharmaceutical Division
1-787-625-4200
www.cardinalhealth.pr

Metro Medical Supply, Inc.
1-800-768-2002
www.metromedical.com

ASD Healthcare
1-800-746-6273
www.asdhealthcare.com

Besse Medical Supply
1-800-543-2111
www.besse.com

Oncology Supply
1-800-633-7555
www.oncologysupply.com

McKesson Specialty Health
1-855-477-9800
www.mckesson.com

McKesson Plasma & Biologics
1-877-625-2566
www.mckesson.com

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Coding Overview

This section provides coding and billing guidance to support claims submission 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.

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.[2]

Code[2]	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[3]	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.

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Coding Overview (cont'd)

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[4]
96415	Each additional hour	Used for infusion times beyond 1 hour when using 96413 as the initial code[5]
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[6]
96366	Each additional hour	Used for infusion times beyond 1 hour when 96365 is the initial code[6]
96375	Each additional sequential IV push of a new substance/drug	Used for additional agents administered during the same visit[6]

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[7]
99602	Home infusion/specialty drug administration, per visit (each additional hour)	Used with 99601 if infusion exceeds 2 hours[7]
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[8]
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[9]
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[9]
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)[9,10]

CPT, Current Procedure Terminology.

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Coding Overview (cont'd)

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[11]	Drug amount discarded or not administered	Required when documenting discarded drug not administered to any patient
JZ[11]	Zero drug amount discarded or not administered	Required when zero drug is discarded
59[12]	Distinct procedural service	Used if multiple, separate services are billed on the same day
JG[11]	Drug or biological acquired with 340B Drug Pricing Program discount	Reported for informational purposes
TB[11]	Drug or biological acquired with 340B Drug Pricing Program discount	Reported for informational purposes by select 340B entities
SS[11]	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)[13]

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

NDC reporting[1]

- 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.

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Please see Important Safety Information on page 22 and Full Prescribing Information.

Coding Overview (cont'd)

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.[13]

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[3]	J3490, J3590	J3490, J3590	C9399
Modifiers[11]	JW, JZ	JW, JZ	JW, JZ, JG/TB
POS[13,14]	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.

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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.

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CMS-1500 Form Completion

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

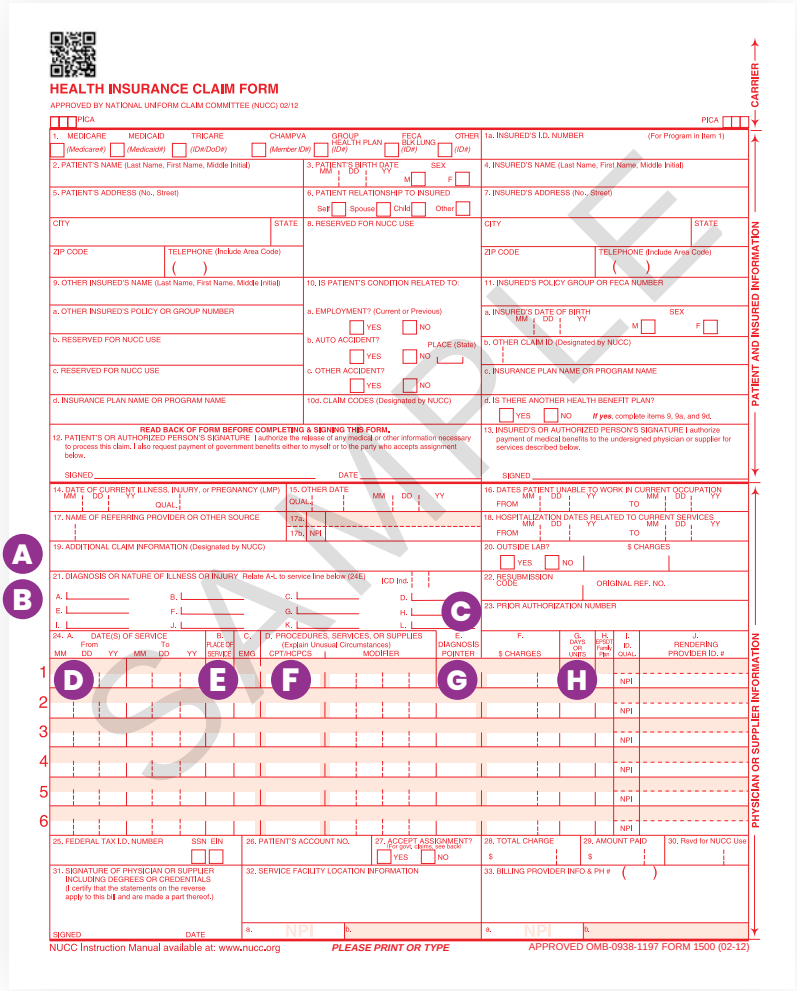
Note: Confirm with individual health plan how NDC numbers should be notated on claim form

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 18 and 19)

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.

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CMS-1500 Form Completion (cont'd)

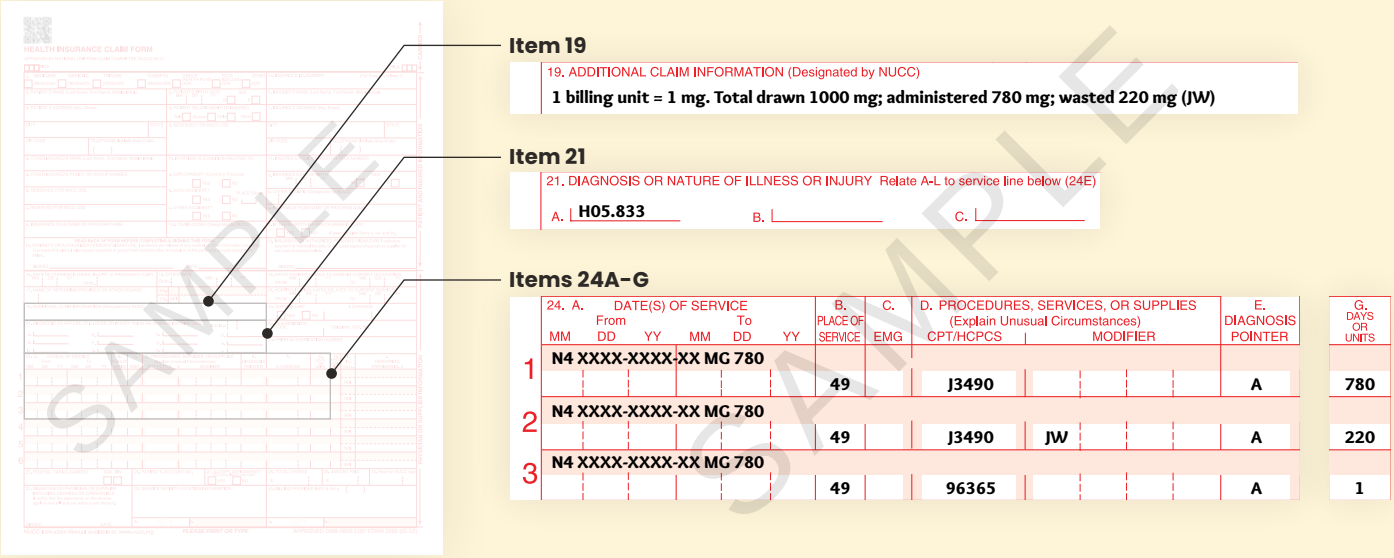
Example weight-based dose (independent clinic)

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 15.

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*



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; POS, place of service.

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CMS-1500 Form Completion (cont'd)

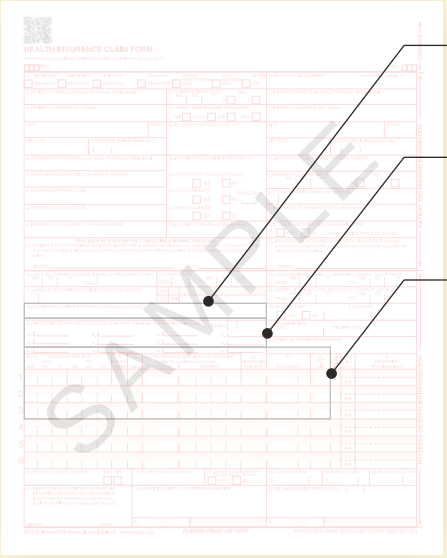
Example weight-based dose (home infusion)

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 15.

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; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; POS, place of service.

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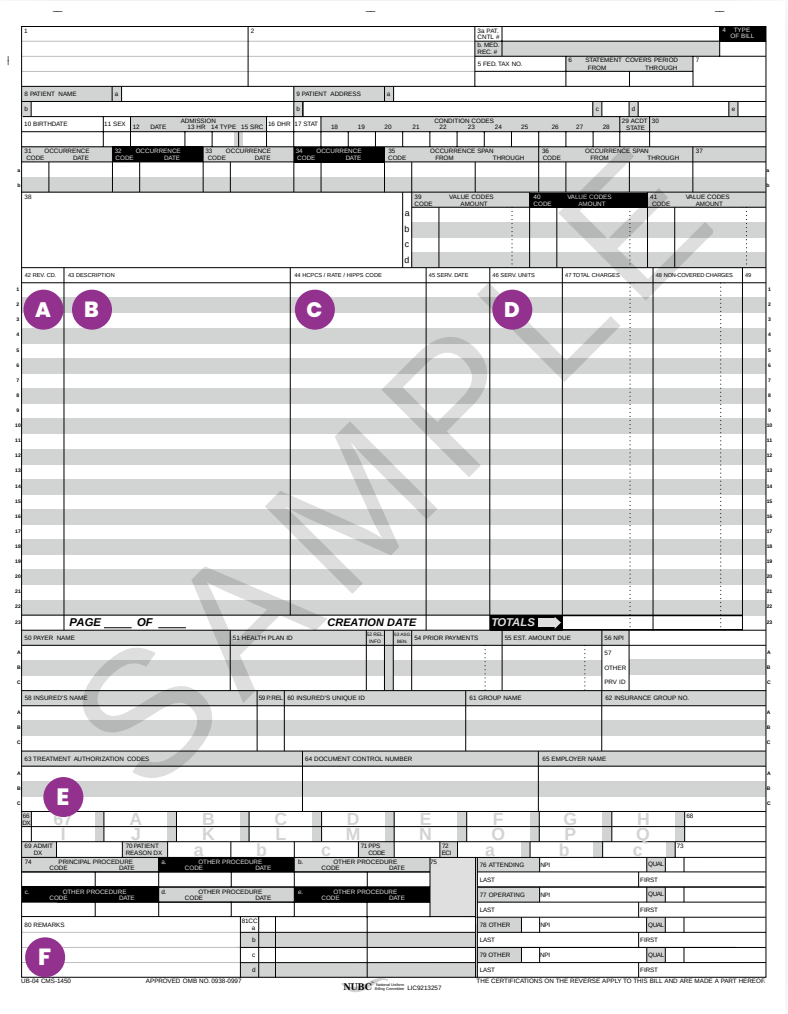
CMS-1450 (UB-04) Form Completion

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 21)

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.

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

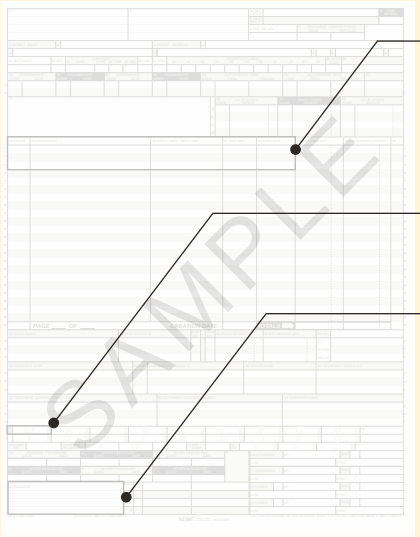
Example weight-based dose (hospital outpatient department)

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 15.

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.

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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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