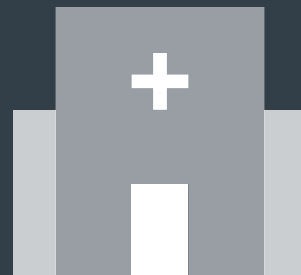




BILLING & CODING GUIDE

**STEP-BY-STEP GUIDE TO COVERAGE
DETERMINATION, CODING, CLAIM
SUBMISSION, AND REIMBURSEMENT**



UPLIZNA J-Code: J1823, 1 mg

WELCOME

The information contained in this guide is for informational purposes only. Billing and coding may vary by site of care, payor, and plan. UPLIZNA is commonly administered in the physician office, office-based infusion centers, hospital outpatient departments (HOPDs), hospital-based infusion centers, and in the home. This guide details coding, billing, coverage, and reimbursement for these sites of care. All claims that are submitted for UPLIZNA should be supported by documentation in the patient's medical record. It is the healthcare provider's responsibility to ensure proper billing and coding.

PATIENT COUNSELING AND MONITORING CONSIDERATIONS¹

Infections

Advise patients to contact their healthcare provider for any signs of infection during treatment or after the last dose of UPLIZNA. Signs include fever, chills, constant cough, or dysuria.

Advise patients that UPLIZNA may cause reactivation of hepatitis B infection and that monitoring will be required if they are at risk.

Advise patients that Progressive Multifocal Leukoencephalopathy (PML) has happened with drugs that are similar to UPLIZNA and may happen with UPLIZNA. Inform the patient that PML is characterized by a progression of deficits and usually leads to death or severe disability over weeks or months. Instruct the patient of the importance of contacting their healthcare provider if they develop any symptoms suggestive of PML. Inform the patient that typical symptoms associated with PML are diverse, progress over days or weeks, and include progressive weakness on 1 side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Vaccinations

Advise patients to complete any required vaccinations at least 4 weeks prior to initiation of UPLIZNA. Administration of live-attenuated or live vaccines is not recommended during UPLIZNA treatment and until B-cell repletion.

Females of Reproductive Potential

Advise females of reproductive potential that they should use effective contraception during treatment and for 6 months after UPLIZNA therapy.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

UPLIZNA (inebilizumab-cdon) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

IMPORTANT SAFETY INFORMATION

UPLIZNA is contraindicated in patients with:

- A history of life-threatening infusion reaction to UPLIZNA
- Active hepatitis B infection
- Active or untreated latent tuberculosis

WARNINGS AND PRECAUTIONS

Infusion Reactions: UPLIZNA can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine, and an anti-pyretic.

Infections: The most common infections reported by UPLIZNA-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining UPLIZNA with another immunosuppressive therapy.

The risk of Hepatitis B Virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with UPLIZNA. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (PML) were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

Reduction in Immunoglobulins: There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with UPLIZNA until B-cell repletion especially in patients with opportunistic or recurrent infections.

Fetal Risk: May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping UPLIZNA.

Adverse Reactions: The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.



TABLE OF CONTENTS

PHYSICIAN OFFICE AND OFFICE-BASED INFUSION CENTER..... 6

Codes and Billing Considerations 6

Place of Service (POS) Codes

National Drug Codes (NDCs)

International Classification of Diseases, 10th Edition with Clinical Modification (ICD-10-CM) Diagnosis Codes

Healthcare Common Procedure Coding System (HCPCS) Codes

Modifiers

Current Procedural Terminology (CPT®) Codes

Codes Used in Premedication

Codes Used in Laboratory Testing

Physician Office and Office-Based Infusion Center (CMS-1500/837P)

Professional Claim Form Completion 11

Special Billing Circumstances 12

Split Claim Billing for CMS-1500/837P

Specialty Pharmacy Acquisition of UPLIZNA

Alternative Sites of Care Referral 13

Claims Submission Checklist 13

HOSPITAL OUTPATIENT DEPARTMENT (HOPD) AND HOSPITAL-BASED INFUSION CENTER 14

Codes and Billing Considerations 14

POS Codes

On-Campus vs Off-Campus HOPD Designation

NDCs

ICD-10-CM Diagnosis Codes

Revenue Codes

HCPCS Codes

Modifiers

CPT® Codes

Codes Used in Premedication

Codes Used in Laboratory Testing

Outpatient Hospital and Hospital-Based Infusion Center UB-04 (CMS-1450/837I)

Institutional Claim Form Completion 20

Claims Submission Checklist 21





HOME INFUSION..... 22

Codes and Billing Considerations 22

POS Codes

NDCs

ICD-10-CM Diagnosis Codes

HCPCS Code

Modifiers

CPT® and HCPCS Codes for Infusion Service

Codes Used in Premedication

Codes Used in Laboratory Testing

Home Infusion (CMS-1500/837P) Professional Claim Form Completion..... 26

Special Billing Circumstances for Home Infusion..... 27

Split Claim Billing for CMS-1500/837P

Claims Submission Checklist 28

Split Claim Billing

REIMBURSEMENT CONSIDERATIONS BY PAYOR TYPE 29

Commercial Plans 29

Medicare Fee-for-Service (FFS) and Medicare Advantage..... 30

Medicare FFS in the Physician Office

Medicare FFS in the HOPD

Medicare Advantage

Sequestration

Medicaid Fee-for-Service and Managed Medicaid 31

NAVIGATING ACCESS AND REIMBURSEMENT CHALLENGES 32

Sample Letter of Medical Necessity..... 32

Sample Letter of Appeal 33

Considerations for Appealing Denied or Underpaid Claims 34

HORIZON BY YOUR SIDE 35

REFERENCES..... 36

The information in this guide is intended for informational purposes only and does not represent legal or billing advice. For specific guidance in this area, consult your own legal/billing advisor and billing/coding specialist, as it remains the responsibility of the provider to ensure the accuracy of claims submitted by the site of care.

Responsibility for properly submitting claims lies with the healthcare provider. We make no representations about the eligibility or guarantee of coverage, coding, or reimbursement for any claim. It is the responsibility of the healthcare provider to choose the most appropriate code as documented in the patient’s medical record and submit the appropriate codes and modifiers for services or items rendered or applied. Your patient’s enrollment in Horizon By Your Side does not guarantee reimbursement.

The content herein is based on information current as of January 2023 and may have changed. Any product, ancillary supplies, or services received free of charge cannot be billed to third-party payors, because doing so could be a violation of federal and/or state laws and/or third-party payor requirements.

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PHYSICIAN OFFICE AND OFFICE-BASED INFUSION CENTER

This section provides general coding information for UPLIZNA when administered in the physician office and office-based infusion center. The final coverage determination is not made until the payor receives and processes the claim for reimbursement. Coding for UPLIZNA may vary by payor and plan type. Contact payors for specific coding requirements for billing UPLIZNA.

A physician office or other entity entitled to bill and receive reimbursement for professional services uses the current Accredited Standards Committee (ASC) X12N Professional CMS-1500 paper form (or electronic format 837P) to submit claims to individual payors.²

Codes and Billing Considerations

Place of Service (POS) Codes

POS codes identify the location where a service was performed. The following POS codes may be appropriate when UPLIZNA is administered in the physician office or office-based infusion center:

Place of Service Code ³	Place of Service Name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
49	Independent clinic	A location, not part of a hospital and not described by any other place of service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only

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National Drug Codes (NDCs)

NDCs are used to identify a drug by brand and generic name, formulation, and package size. Although the UPLIZNA prescribing information lists the NDC as a 10-digit number, electronic data exchange requires the use of the 11-digit 5-4-2 format NDC on claim forms.⁴ You may need to add the NDC for UPLIZNA to your electronic medical record (EMR) system if it is not already included.

UPLIZNA for injection is a clear to slightly opalescent, colorless to slightly yellow solution supplied in a carton with 3 single-dose vials, each containing 100 mg/10 mL of UPLIZNA:

10-Digit NDC ¹ (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing three 100 mg/10 mL single-dose vials

In addition to the NDC, some payors may require a unit of measure qualifier and quantity to facilitate proper reimbursement. For UPLIZNA, the unit of measure qualifier is mL (milliliter) for liquid, solution, or suspension⁵ and the quantity is reported in number of milliliters. For example, use of 300 mg/30 mL would be reported as:

NDC and Unit of Measure for UPLIZNA 300 mg/30 mL
N475987015003 ML30

Check payor requirements for appropriate reporting of the NDC and unit of measure on the claim form.

Unit of Measure (UoM) reporting is impacted by split claim billing requirements. See Special Billing Circumstances for additional guidance.

International Classification of Diseases, 10th Revision with Clinical Modification (ICD-10-CM) Diagnosis Codes

ICD-10-CM codes report the medical necessity for services rendered. The following may be an appropriate ICD-10-CM diagnosis code for prescribing UPLIZNA when administered to treat NMOSD in the physician office and office-based infusion center:

ICD-10-CM Diagnosis Code ⁶	Description
G36.0	Neuromyelitis optica [Devic] <ul style="list-style-type: none"> Demyelination in optic neuritis

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Healthcare Common Procedure Coding System (HCPCS) Codes

HCPCS codes are used to report supplies such as drugs and other services. UPLIZNA has a permanent, product-specific HCPCS code: J1823 per 1 mg.

HCPCS Drug Code ⁷	Description
J1823	Injection, inebilizumab-cdon, 1 mg

When billing for UPLIZNA using J1823:

- One billing unit represents 1 mg of UPLIZNA; eg, UPLIZNA 300 mg = 300 billing units
- UPLIZNA should be billed based on the number of billing units, not milligrams or number of vials

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. They may be added to HCPCS and/or Current Procedural Terminology (CPT[®]) codes. If appropriate, more than 1 modifier may be used with a single procedure code.

Modifier ⁷	Description	Appropriate Use
59*	Distinct procedural service	Modifier 59 is used to identify procedures/services, other than evaluation and management (E/M) services, that are not normally reported together, but are appropriate under the circumstances It may be appropriate to add -59 to the UPLIZNA HCPCS code when submitting a split claim
JZ*	Zero drug amount discarded/not administered to any patient	Add to J1823 when there was no discarded drug Modifier JZ is effective January 1, 2023 and is required on Medicare claims with dates of service on/after July 1, 2023 ⁸

*Consult with individual payors for specific split billing/coding and other modifier preferences.

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CPT® Codes

CPT® codes are used to report procedures and other services. When billing for UPLIZNA and related premedications in the physician office or office-based infusion center, the following CPT® codes may be appropriate for the administration:

CPT® Code ⁹	Description
96413*	Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; up to 1 hour, single or initial substance/drug Note: This code may be used for UPLIZNA infusion, initial 90 minutes
96415*	Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; each additional hour. List separately in addition to code for primary procedure Note: This code may be used for UPLIZNA infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour Note: This code may be used for UPLIZNA infusion, initial 90 minutes
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour. List separately in addition to code for primary procedure. Note: This code may be used for UPLIZNA infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour. List separately in addition to code for primary procedure Note: This code may be used to report the intravenous administration of a corticosteroid on the same day as an UPLIZNA infusion

*Highly complex drugs, including biologic agents or chemotherapy codes, require clinical documentation in the medical record of the complexity involved beyond what is required for therapeutic infusion codes (963XX codes).¹⁰

Check appropriate administration codes with individual payors.

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Codes Used in Premedication

Prior to receiving UPLIZNA, premedications must be given to reduce the risk of an infusion reaction.¹ Below are the codes for premedications that must be given prior to each UPLIZNA infusion:

HCPCS Drug Code ⁷	Description	Administration Time Prior to UPLIZNA Infusion
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	30 minutes
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	30 minutes
J8499*	Prescription drug, oral, nonchemotherapeutic, NOS (Use for OTC oral antihistamine and oral antipyretic)	30-60 minutes

*Some payors may require J8499 and/or NDC when reporting OTC drugs. Check payor-specific requirements to determine how to report these drugs.

Codes Used in Laboratory Testing

The following CPT[®] codes may be appropriate to report laboratory testing services that assist with diagnosing adult patients with AQP4-IgG+ NMOSD.

CPT [®] Code ⁹	Description
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86053	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
86256	Fluorescent noninfectious agent antibody; titer, each antibody

Coding is based on documentation in the medical record. Verify appropriate codes with the payor.

Effective January 1, 2022, AQP4-IgG screening may be coded using 86051-86053. If positive, a titer may be coded using CPT[®] 86256. A titer may be billed after a screening of the same sample on the same date of service.

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Physician Office and Office-Based Infusion Center (CMS-1500/837P) Professional Claim Form Completion

The following is an example of how to complete the CMS-1500 (837P) Professional claim form for a patient who received UPLIZNA via intravenous infusion in the physician office or office-based infusion center.¹¹

Billing for a single infusion of UPLIZNA requires split claim billing due to character limits on the CMS-1500 form. See next page for an example of split claim billing.

- 1** **Items 1-13¹²:** Enter the patient's personal and insurance information.
- 2** **Item 19¹²:** Enter a comment regarding UPLIZNA split claim billing (detailed instructions on next page). **Note:** Item 19 has a 71-character limit.
- 3** **Item 21¹²:** Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; eg, ICD-10-CM G36.0 *Neuromyelitis optica [Devic]*.
- 4** **Item 23¹²:** Enter the Prior Authorization (PA) number (if applicable).
- 5** **Item 24A¹²:** Enter the NDC number in the shaded area above the date of service.
 - Qualifier N4 should be added before the 11-digit NDC
 - N475987015003
 - Confirm with individual payor how NDC numbers should be notated on the claim (ie, some may require unit of measure qualifier and quantity of drug)
- 6** **Item 24B¹²:** Enter the appropriate place of service code (eg, 11 for physician office or 49 for independent clinic [office-based infusion center]).
- 7** **Item 24D¹²:** Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® (96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour for the administration) codes. *Include any additional modifiers as required by the payor.*
- 8** **Item 24E¹²:** Enter the letter that corresponds to the ICD-10-CM code reported in Item 21.
- 9** **Item 24F¹²:** Enter charges for the line-item service (up to the 7 character limit). See next page for detailed instructions regarding split claims billing.
- 10** **Item 24G¹²:** Document the number of billing units used for each line item.
 - When billing for UPLIZNA with J1823, 1 billing unit represents 1 mg of UPLIZNA. UPLIZNA should be billed based on billing units, not the number of milligrams or vials
 - See next page for detailed instructions regarding split claims billing





Special Billing Circumstances

UPLIZNA Requires Split Claim Billing for CMS-1500/837P

The CMS-1500 paper professional claim form (and electronic 837P) has character limitations for each field. The charge fields (24F and 28 on the CMS-1500, and Loop ID 2400/Segment SV102 and Loop ID 2300/Segment CLM02 on the 837P) for dollar amounts have a 7-character limit (the highest value allowed on a single claim form is \$99,999.99). Claims with charges over this amount must be billed on multiple claim forms (ie, split claim billing).¹³

Billing for a single infusion of UPLIZNA requires split claim billing since UPLIZNA charges typically exceed the maximum charge character limits. Charges on claims may be done in multiple ways, as long as the charges on a single claim do not exceed \$99,999.99.

An explanation for multiple claims for 1 date of service is typically required in the Additional Claim Information field of the claim form. Below is **one example** (for illustrative purposes only) of how an UPLIZNA claim may be split. **Consult with individual payors regarding split claim billing preferences.**

CMS-1500 (837P) Claim 1¹⁴

1 → 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Claim 1 of 2: Dollar amount exceeds line amount	20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO		\$ CHARGES						
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.:		22. RESUBMISSION CODE ORIGINAL REF. NO.		23. PRIOR AUTHORIZATION NUMBER					
A. G36.0 B. C. D.		E. F. G. H. I. J. K. L.							
24. A. DATE(S) OF SERVICE From To	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPSCS MODIFIER	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OF UNITS	H. EPST [®] Form Pln	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
MM DD YY MM DD YY	MM DD YY	11	J1823 JZ	A	XXXXX XX	200	5	PH	
MM DD YY MM DD YY	MM DD YY	11	96365	A	4	X XX	1	NPI	

- 1 **Item 19. Additional Claim Information:** Indicate that this is a split claim. Example: **Claim 1 of 2: dollar amount exceeds line amount.** Note: Item 19 has a 71-character limit.
- 2 **Item 24A. Date(s) of Service:** Enter the appropriate UoM for the claim. Example: 200 mg = 200 units = ML20.
- 3 **Item 24D. Procedures, Services, or Supplies:** Indicate appropriate HCPCS and CPT® codes. Example: J1823 (Injection, inebilizumab-cdon, 1 mg) and 96365 (intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour for the administration). *Include any additional modifiers as required by payor.*
- 4 **Item 24F. Charges:** Indicate charges for first claim (up to the 7-character limit). Example: enter dollar amount for 200 units of UPLIZNA.
- 5 **Item 24G. Days or Units:** Enter the number of units. Example: 200 units for 200 mg of UPLIZNA.

CMS-1500 (837P) Claim 2¹⁴

6 → 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Claim 2 of 2: Remaining dollar amount from claim 1 exceeds line amount	20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO		\$ CHARGES						
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.:		22. RESUBMISSION CODE ORIGINAL REF. NO.		23. PRIOR AUTHORIZATION NUMBER					
A. G36.0 B. C. D.		E. F. G. H. I. J. K. L.							
24. A. DATE(S) OF SERVICE From To	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPSCS MODIFIER	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OF UNITS	H. EPST [®] Form Pln	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
MM DD YY MM DD YY	MM DD YY	11	J1823 JZ	A	XXXXX XX	100	10	NPI	
MM DD YY MM DD YY	MM DD YY	11	96365	A	9	0 00	1	NPI	

- 6 **Item 19. Additional Claim Information:** Indicate that this is a split claim. Example: **Claim 2 of 2: remaining dollar amount from claim 1 exceeds line amount.**
- 7 **Item 24A. Date(s) of Service:** Enter the appropriate UoM for the claim. Example: 100 mg = 100 units = ML10.
- 8 **Item 24D. Procedures, Services, or Supplies:** Indicate appropriate HCPCS and CPT® codes. Example: J1823 (Injection, inebilizumab-cdon, 1 mg) and 96365 (intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour for the administration). *Include any additional modifiers as required by payor.*
- 9 **Item 24F. Charges:** Indicate charges for the second claim (up to the 7-character limit). Example: enter dollar amount for 100 units of UPLIZNA. The administration code on the second claim may be billed with 0.00.
- 10 **Item 24G. Days or Units:** Enter the number of units. Example: 100 units for 100 mg of UPLIZNA. The unit for the administration code may be 1 on the second claim.

Split claim billing requirements vary by payor. Consult with individual payors regarding individual split billing requirements.

Specialty Pharmacy Acquisition of UPLIZNA

When UPLIZNA is acquired through a specialty pharmacy, certain billing procedures on the CMS-1500 (837P) claim form may apply:

- Enter the appropriate ICD-10-CM diagnosis code
- Enter the appropriate CPT® code for UPLIZNA administration

Drug identification for specialty pharmacy varies by payor. Confirm with the payor if the drug should be identified by:





- Adding the drug specific HCPCS, J1823, for UPLIZNA as a line item with a "0" in the units and charge fields
- Adding a comment in Item 19 that UPLIZNA J1823 was obtained from a specialty pharmacy





Alternative Sites of Care Referral






Providers who wish to prescribe UPLIZNA—but do not have in-office infusion capabilities to administer it—can refer patients to sites of care to receive treatment (eg, office-based infusion center). When referring patients to alternate providers for UPLIZNA treatment, the prescribing or referring physician should be prepared to supply several pieces of information and appropriate documentation to the provider administering UPLIZNA to assist with fulfilling payor requirements. Necessary documentation may include:

-  Prescription/infusion order
-  Diagnosis and supporting documentation
-  Letter of medical necessity
-  Chart notes

Referring physicians should coordinate closely with the site of care to ensure all necessary documentation is accurate, thorough, and complete.

Claims Submission Checklist

The following checklist provides an overview of requirements that may be necessary when submitting claims for UPLIZNA. Check with individual payors for specific coding requirements.

-  Use J1823 per 1 billing unit for UPLIZNA and include supporting information when necessary
 - A 300-mg dose of UPLIZNA would be reported with 300 billing units. Enter the number of billing units specific to each split claim. Example: 200 billing units may be on Claim 1, and 100 billing units may be on Claim 2
-  Confirm with the payor split claim billing requirements for UPLIZNA
-  Have the PA or predetermination approval on file
-  Confirm with the payor how NDC numbers and a unit of measure should be reported on the claim form
-  Include any additional documentation required by the payor

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HOSPITAL OUTPATIENT DEPARTMENT (HOPD) AND HOSPITAL-BASED INFUSION CENTER

This section provides general coding information for UPLIZNA when administered in the hospital outpatient department (HOPD) (on and off campus) and hospital-based infusion center. The final coverage determination is not made until the payor receives and processes the claim for reimbursement. Coding for UPLIZNA may vary by payor and plan type. Contact payors for specific coding requirements for billing UPLIZNA.

The products and services provided in the HOPD are billed using the CMS-1450/UB-04 institutional claim form or its electronic claim equivalent (837I).¹⁵

Codes and Billing Considerations

POS Codes

POS codes identify the location where a service was performed by a healthcare provider. The following POS codes may be appropriate for a healthcare provider to report on a CMS-1500 claim form for professional services when UPLIZNA is administered in the HOPD (on and off campus) and hospital-based infusion center:

Place of Service Code ³	Place of Service Name	Description
22	On campus-outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
19	Off campus-outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

On-Campus vs Off-Campus HOPD Designation

The Medicare reimbursement policies vary for HOPDs that are on campus (POS 22) vs off campus (POS 19). To bill and be reimbursed appropriately, facilities must understand the nuances of what is considered on and off campus for outpatient hospital departments. Centers for Medicare & Medicaid Services (CMS) defines HOPD on-campus locations as the physical area immediately adjacent to the healthcare provider's main buildings, as well as other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.¹⁶ HOPD off-campus locations are paid under the Medicare Physician Fee Schedule (MPFS) rate, which is triggered when modifier PN is added to the claim form. HOPDs that are on campus are reimbursed at the facility rate.¹⁷

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NDCs

NDCs are used to identify a drug by brand and generic name, formulation, and package size. Although the UPLIZNA prescribing information lists the NDC as a 10-digit number, electronic data exchange requires the use of the 11-digit 5-4-2 format NDC on claim forms.⁴ You may need to add the NDC for UPLIZNA to your EMR system if not already included.

UPLIZNA for injection is a clear to slightly opalescent, colorless to slightly yellow solution supplied in a carton with 3 single-dose vials, each containing 100 mg/10 mL of UPLIZNA:

10-Digit NDC ¹ (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing three 100 mg/10 mL single-dose vials

In addition to the NDC, some payors may require a unit of measure qualifier and quantity to enable proper reimbursement. For UPLIZNA, the unit of measure qualifier is mL (milliliter) for liquid, solution, or suspension⁵ and the quantity is reported in number of mLs. For example, use of 300 mg/30 mL would be reported as:

NDC and Unit of Measure for UPLIZNA 300 mg/30 mL
N475987015003 ML30

Check payor requirements for appropriate reporting of the NDC and unit of measure on the claim form.

ICD-10-CM Diagnosis Codes

ICD-10-CM codes report the medical necessity for services rendered. The following may be an appropriate ICD-10-CM diagnosis code for prescribing UPLIZNA when administered to treat NMOSD in the HOPD (on and off campus) and hospital-based infusion center:

ICD-10-CM Diagnosis Code ⁶	Description
G36.0	Neuromyelitis optica [Devic] <ul style="list-style-type: none"> Demyelination in optic neuritis

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).



Revenue Codes

Revenue codes are used on the CMS-1450 (837I) claim form to map a specific charge to a cost center. The following are revenue codes that an HOPD (on and off campus) may use to track costs for services associated with UPLIZNA:

Revenue Code ¹⁸	Description
025x	Pharmacy
0636	Drugs requiring detailed coding
026x	Intravenous therapy

The **x** placeholder at the end of the revenue code indicates that a fourth digit is required.

HCPCS Codes

HCPCS codes are used to report supplies such as drugs and other services. UPLIZNA has a permanent, product-specific HCPCS code: J1823 per 1 mg.

HCPCS Drug Code ⁷	Description
J1823	Injection, inebilizumab-cdon, 1 mg

When billing for UPLIZNA using J1823:

- One billing unit represents 1 mg of UPLIZNA; eg, UPLIZNA 300 mg = 300 billing units
- UPLIZNA should be billed based on the number of billing units, not milligrams or number of vials



Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. They may be added to HCPCS and/or CPT® codes. If appropriate, more than 1 modifier may be used with a single procedure code.

Hospitals paid under the Medicare Outpatient Prospective Payment System (OPPS) must report pricing modifiers to the UPLIZNA HCPCS code to identify certain conditions:

- Modifier JG or TB (singular Modifier) used to report drug acquisition under a 340B Drug Discount Program
- Modifiers PO and PN are used to report services performed at off-campus provider-based departments (PBD) of a hospital

Modifier ^{7,9,19}	Description	Appropriate Use
JG*	Drug or biological acquired with 340B Drug Pricing Program discount reported for informational purposes	Modifier JG is required on HCPCS codes for non-pass-through drugs (status indicator K). This modifier will be reported on claims for UPLIZNA with effective dates of service on/after October 1, 2024
TB*	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Modifier TB is required on HCPCS codes for drugs with pass-through payment status (status indicator G). UPLIZNA has a status indicator of G through September 30, 2024
JZ*	Zero drug amount discarded/not administered to any patient	Add to J1823 when there was no discarded drug Modifier JZ is effective January 1, 2023 and is required on Medicare Fee For Service (FFS) claims with dates of service on/after July 1, 2023 ⁸
PN	Non-expected service provided at an off-campus, outpatient, provider-based department of a hospital	Modifier PN is required on services from non-expected off-campus PBDs (located greater than 250 yards from the main campus)
PO	Expected service provided at an off-campus, outpatient, provider-based department of a hospital	Modifier PO is required on services from expected off-campus PBDs of a hospital (located within 250 yards from the main campus)

*Consult with individual payors for specific modifier preferences.

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).



CPT® Codes

CPT® codes are used to report procedures and other services. When billing for UPLIZNA and related premedications in the HOPD (on and off campus) and hospital-based infusion center, the following CPT® codes may be appropriate for the administration:

CPT® Code ⁹	Description
96413*	Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; up to 1 hour, single or initial substance/drug Note: This code may be used for UPLIZNA infusion, initial 90 minutes
96415*	Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; each additional hour. List separately in addition to code for primary procedure Note: This code may be used for UPLIZNA infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour Note: This code may be used for UPLIZNA infusion, initial 90 minutes
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour. List separately in addition to code for primary procedure. Note: This code may be used for UPLIZNA infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour. List separately in addition to code for primary procedure Note: This code may be used to report the intravenous administration of a corticosteroid on the same day as UPLIZNA infusion

*Highly complex drugs, including biologic agents or chemotherapy codes, require clinical documentation in the medical record of the complexity involved beyond what is required for therapeutic infusion codes (963xx codes).¹⁰

Check appropriate administration code with individual payors.

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).





Codes Used in Premedication

Prior to receiving UPLIZNA, premedications must be given to reduce the risk of an infusion reaction.¹ Below are the premedications that must be given prior to each UPLIZNA infusion:

HCPSC Drug Code ^{7,9}	Description	Administration Time Prior to UPLIZNA Infusion
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	30 minutes
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	30 minutes
J8499*	Prescription drug, oral, nonchemotherapeutic, NOS (Use for OTC oral antihistamine and oral antipyretic)	30-60 minutes

*Some payors may require J8499 and/or NDC when reporting OTC drugs. Check payor-specific requirements to determine how to report these drugs.

Codes Used in Laboratory Testing

The following CPT[®] codes may be appropriate to report laboratory testing services to assist with diagnosing adult patients with AQP4-IgG+ NMOSD.

CPT [®] Code ⁹	Description
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86053	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
86256	Fluorescent noninfectious agent antibody; titer, each antibody

Coding is based on documentation in the medical record. Verify appropriate codes with the payor.

Effective January 1, 2022, AQP4-IgG screening may be coded using 86051-86053. If positive, a titer may be coded using CPT[®] 86256. A titer may be billed after a screening of the same sample on the same date of service.

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).



Outpatient Hospital and Hospital-Based Infusion Center UB-04 (CMS-1450/837I) Institutional Claim Form Completion

The following is an example of how to complete the CMS-1450 (837I) Institutional claim form for a patient who received UPLIZNA via intravenous infusion in an HOPD or Hospital-Based Infusion Center.¹⁹

1 Field Locator (FL) 8-15 and 50-65¹⁵: Enter the patient's personal and insurance information.

2 FL 42¹⁵: Enter the revenue codes.

- UPLIZNA will likely be reported with revenue code 0636 (Drugs requiring detailed coding) and UPLIZNA administration will likely be reported with revenue code 0260 (IV Therapy General).¹⁸ (Other revenue codes may apply)

3 FL 43¹⁵: Enter the corresponding code description for the HCPCS listed in FL44.

- Enter the NDC number in the unshaded area in FL43
 - Qualifier N4 should be added before the 11-digit NDC
 - N475987015003 ML30
 - Confirm with individual payor how NDC numbers should be reported on the claim (ie, some may require unit of measure and quantity of drug)

4 FL 44¹⁵: Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® (96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; up to 1 hour for the administration code for the initial infusion. Include any additional modifiers required by the payor.

5 FL 46¹⁵: Document the number of units used for each line item.

- When billing for UPLIZNA with J1823, 1 unit represents 1 mg of UPLIZNA. UPLIZNA should be billed based on units, not the number of milligrams
 - A 300 mg dose of UPLIZNA would be reported with 300 billing units

6 FL 67, A-Q¹⁵: Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; eg, ICD-10-CM G36.0 Neuromyelitis optica [Devic].

- 1** Field Locator (FL) 8-15 and 50-65¹⁵: Enter the patient's personal and insurance information.
- 2** FL 42¹⁵: Enter the revenue codes.
 - UPLIZNA will likely be reported with revenue code 0636 (Drugs requiring detailed coding) and UPLIZNA administration will likely be reported with revenue code 0260 (IV Therapy General).¹⁸ (Other revenue codes may apply)
- 3** FL 43¹⁵: Enter the corresponding code description for the HCPCS listed in FL44.
 - Enter the NDC number in the unshaded area in FL43
 - Qualifier N4 should be added before the 11-digit NDC
 - N475987015003 ML30
 - Confirm with individual payor how NDC numbers should be reported on the claim (ie, some may require unit of measure and quantity of drug)
- 4** FL 44¹⁵: Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® (96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; up to 1 hour for the administration code for the initial infusion. Include any additional modifiers required by the payor.
- 5** FL 46¹⁵: Document the number of units used for each line item.
 - When billing for UPLIZNA with J1823, 1 unit represents 1 mg of UPLIZNA. UPLIZNA should be billed based on units, not the number of milligrams
 - A 300 mg dose of UPLIZNA would be reported with 300 billing units
- 6** FL 67, A-Q¹⁵: Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; eg, ICD-10-CM G36.0 Neuromyelitis optica [Devic].





Claims Submission Checklist

The following checklist provides an overview of requirements that may be necessary when submitting claims for UPLIZNA. Please check with individual payors for specific coding requirements.



Use J1823 per 1 billing unit for UPLIZNA and include supporting information when necessary

- A 300-mg dose of UPLIZNA would be reported with 300 billing units



Have the PA or predetermination approval on file



Confirm with the payor how NDC numbers should be reported on the claim form



Include any additional documentation required by the payor



HOME INFUSION

This section provides general billing and coding information for UPLIZNA when administered in the home. Coverage and coding for UPLIZNA may vary by payor and plan type. For example, commercial payors may cover and reimburse providers separately for drugs, services, and procedures; however, Medicare FFS does not cover drugs, such as UPLIZNA, in the home site of care. In addition, as a point of clarification, although UPLIZNA may be administered in the home via infusion, the Medicare Part B Home Infusion Therapy (HIT) benefit does not apply, as the HIT benefit applies only to drugs that require infusion using a Medicare Durable Medical Equipment (DME)–covered infusion pump.^{20,23} Contact payors for specific coverage and coding requirements for billing UPLIZNA.

The products and services provided in the home setting are billed using the professional CMS-1500 claim form or its electronic claim equivalent (837P). The final coverage determination is not made until the payor receives and processes the claim for reimbursement.

Codes and Billing Considerations

POS Codes

POS codes identify the location where a service was performed. The following POS code may be appropriate when UPLIZNA is administered in the home:

Place of Service Code ³	Place of Service Name	Description
12	Home	Location, other than hospital or other facility, where the patient receives care in a private residence

NDCs

NDCs are used to identify a drug by brand and generic name, formulation, and package size. Although the UPLIZNA prescribing information lists the NDC as a 10-digit number, electronic data exchange requires the use of the 11-digit 5-4-2 format NDC on claim forms.⁴ You may need to add the NDC for UPLIZNA to your EMR system if it is not already included.

UPLIZNA for injection is a clear to slightly opalescent, colorless to slightly yellow solution supplied in a carton with 3 single-dose vials, each containing 100 mg/10 mL of UPLIZNA:

10-Digit NDC ¹ (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing three 100 mg/10 mL single-dose vials

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).



In addition to the NDC, some payors may require a unit of measure qualifier and quantity to facilitate proper reimbursement. For UPLIZNA, the unit of measure qualifier is mL (milliliter) for liquid, solution, or suspension⁵ and the quantity is reported in number of mLs. For example, use of 300 mg/30 mL would be reported as:

NDC and Unit of Measure for UPLIZNA 300 mg/30 mL

N475987015003 **ML30**

Check payor requirements for appropriate reporting of the NDC and unit of measure on the claim form.

**UoM reporting is impacted by split claim billing requirements.
See Special Billing Circumstances for additional guidance.**

ICD-10-CM Diagnosis Codes

ICD-10-CM codes report the medical necessity for services rendered. The following may be an appropriate ICD-10-CM diagnosis code for prescribing UPLIZNA when administered to treat NMOSD in the home:

ICD-10-CM Diagnosis Code ⁶	Description
G36.0	Neuromyelitis optica [Devic] • Demyelination in optic neuritis

HCPCS Code

HCPCS codes are used to report supplies such as drugs and other services. UPLIZNA has a permanent, product-specific HCPCS code: J1823 per 1 mg.

HCPCS Drug Code ⁷	Description
J1823	Injection, inebilizumab-cdon, 1 mg

When billing for UPLIZNA using J1823:

- One billing unit represents 1 mg of UPLIZNA; eg, UPLIZNA 300 mg = 300 billing units
- UPLIZNA should be billed based on the number of billing units, not milligrams or number of vials

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. They may be added to HCPCS and/or CPT[®] codes. If appropriate, more than 1 modifier may be used with a single procedure code.

Modifier ⁹	Description	Appropriate Use
59*	Distinct procedural service	Modifier 59 is used to identify procedures/services, other than evaluation and management (E/M) services, that are not normally reported together, but are appropriate under the circumstances It may be appropriate to add "-59" to the UPLIZNA HCPCS code when submitting a split claim

*Consult with individual payors for specific split billing preferences.

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).

UPLIZNA
inebilizumab-cdon





CPT® and HCPCS Codes for Infusion Service

When billing for UPLIZNA and related premedications in the home, the following CPT® and HCPCS codes may be appropriate for administration in the home depending on the payor:

CPT® Code ^{7,9}	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure)
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 (do not use this code with S9330 or S9331)
S9331	Home infusion therapy, intermittent (less than 24 hours) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
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
S9810	Home therapy; professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour (do not use this code with any per diem code)

Note: This is not an all-inclusive list as codes for home services may vary by payor.



Codes Used in Premedication

Prior to receiving UPLIZNA, premedications must be given to reduce the risk of an infusion reaction.¹ Below are the premedications that must be given prior to each UPLIZNA infusion:

HCPDS Drug Code ^{7,9}	Description	Administration Time Prior to UPLIZNA Infusion
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	30 minutes
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	30 minutes
J8499*	Prescription drug, oral, nonchemotherapeutic, NOS (Use for OTC oral antihistamine and oral antipyretic)	30-60 minutes

*Some payors may require J8499 and/or NDC when reporting OTC drugs. Check payor-specific requirements to determine how to report these drugs.

Codes Used in Laboratory Testing

The following CPT[®] codes may be appropriate to report laboratory testing services to assist with diagnosing adult patients with AQP4-IgG+ NMOSD.

CPT [®] Code ⁹	Description
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86053	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
86256	Fluorescent noninfectious agent antibody; titer, each antibody

Coding is based on documentation in the medical record. Verify appropriate codes with the payor

Effective January 1, 2022, AQP4-IgG screening may be coded using 86051-86053. If positive, a titer may be coded using CPT[®] 86256. A titer may be billed after a screening of the same sample on the same date of service.

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).



Home Infusion (CMS-1500/837P) Professional Claim Form Completion

The following is an example of how to complete the CMS-1500 paper claim form (electronic version 837P) for a patient who received UPLIZNA via intravenous infusion in the home.¹¹

Billing for a single infusion of UPLIZNA requires split claim billing due to character limits on the CMS-1500 form. See next page for an example of split claim billing.

- 1 **Items 1-13¹²:** Enter the patient's personal and insurance information.
- 2 **Item 19¹²:** Enter a comment regarding UPLIZNA split claim billing (detailed instructions on next page). **Note:** Item 19 has a 71-character limit.
- 3 **Item 21¹²:** Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; eg, ICD-10-CM G36.0 *Neuromyelitis optica [Devic]*.
- 4 **Item 23¹²:** Enter the PA number (if applicable).
- 5 **Item 24A¹²:** Enter the NDC number in the shaded area above the date of service.
 - Qualifier N4 should be added before the 11-digit NDC
 - N475987015003
 - Confirm with individual payor how NDC numbers should be notated on the claim (ie, some may require unit of measure qualifier and quantity of drug)
- 6 **Item 24B¹²:** Enter the appropriate place of service code (ie, 12 for home).
- 7 **Item 24D¹²:** Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® (99601 Home infusion/specialty drug administration codes per visit [up to 2 hours; and up to 1 hour for the initial administration]). *Include any additional modifiers as required by the payor.*
- 8 **Item 24E¹²:** Enter the letter that corresponds to the ICD-10-CM code reported in Item 21.
- 9 **Item 24F¹²:** Enter charges for the line-item service (up to the 7 character limit). See next page for detailed instructions regarding split claims billing.
- 10 **Item 24G¹²:** Document the number of billing units used for each line item.
 - When billing for UPLIZNA with J1823, 1 billing unit represents 1 mg of UPLIZNA. UPLIZNA should be billed based on billing units, not the number of milligrams or vials
 - See next page for detailed instructions regarding split claims billing





Special Billing Circumstances for Home Infusion

UPLIZNA Requires Split Claim Billing for CMS-1500/837P

The CMS-1500 paper professional claim form (and electronic 837P) has character limitations for each field. The charge fields (24F and 28) for dollar amounts have a 7-character limit (the highest value allowed on a single claim form is \$99,999.99). Claims with charges over this amount must be billed on multiple claim forms (ie, split claim billing).¹³

Billing for a single infusion of UPLIZNA requires split claim billing since UPLIZNA charges typically exceed the maximum charge character limits. Charges on claims may be done in multiple ways, as long as the charges on a single claim do not exceed \$99,999.99.

An explanation for multiple claims for 1 date of service is typically required in the Additional Claim Information field of the claim form. Below is **one example** (for illustrative purposes only) of how an UPLIZNA claim may be split. **Consult with individual payors regarding split claim billing preferences.**

CMS-1500 (837P) Claim 1¹⁴

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)											20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO		\$ CHARGES	
1 Claim 1 of 2: Dollar amount exceeds line amount														
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY - Relate A-L to service line below (24E) ICD Ind.:											22. RESUBMISSION CODE		ORIGINAL REF. NO.	
A. G36.0 B. C. D.														
E. F. G. H.														
I. J. K. L.											23. PRIOR AUTHORIZATION NUMBER			
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. I. ID. QUAL. J. RENDERING PROVIDER ID. #														
MM DD YY MM DD YY 12 N475987015 003 ML20														
MM DD YY MM DD YY 12 J1823											XXXXX XX		200 5 NPI	
MM DD YY MM DD YY 12 99601											4 X XX		1 NPI	

- 1 **Item 19. Additional Claim Information:** Indicate that this is a split claim. Example: **Claim 1 of 2: dollar amount exceeds line amount.** **Note:** Item 19 has a 71-character limit.
- 2 **Item 24A. Date(s) of Service:** Enter the appropriate UoM for the claim. Example: 200 mg = 200 units = ML20.
- 3 **Item 24D. Procedures, Services, or Supplies:** Indicate appropriate HCPCS and CPT® codes. Example: J1823 (Injection, inebilizumab-cdon, 1 mg) and 99601 Home infusion/specialty drug administration, per visit (up to 2 hours); initial, up to 1 hour for the administration. *Include any additional modifiers as required by the payor.*
- 4 **Item 24F. Charges:** Indicate charges for first claim (up to the 7-character limit). Example: enter dollar amount for 200 units of UPLIZNA.
- 5 **Item 24G. Days or Units:** Enter the number of units. Example: 200 units for 200 mg of UPLIZNA.

CMS-1500 (837P) Claim 2¹⁴

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)											20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO		\$ CHARGES	
6 Claim 2 of 2: Remaining dollar amount from claim 1 exceeds line amount														
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY - Relate A-L to service line below (24E) ICD Ind.:											22. RESUBMISSION CODE		ORIGINAL REF. NO.	
A. G36.0 B. C. D.														
E. F. G. H.														
I. J. K. L.											23. PRIOR AUTHORIZATION NUMBER			
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. I. ID. QUAL. J. RENDERING PROVIDER ID. #														
7 N475987015 003 ML10														
MM DD YY MM DD YY 12 J1823											XXXXX XX		100 10 NPI	
MM DD YY MM DD YY 12 99601											9 0 00		1 NPI	

- 6 **Item 19. Additional Claim Information:** Indicate that this is a split claim. Example: **Claim 2 of 2: remaining dollar amount from claim 1 exceeds line amount.** **Note:** Item 19 has a 71-character field limit.
- 7 **Item 24A. Date(s) of Service:** Enter the appropriate UoM for the claim. Example: 100 mg = 100 units = ML10.
- 8 **Item 24D. Procedures, Services, or Supplies:** Indicate appropriate HCPCS and CPT® codes. Example: J1823 (Injection, inebilizumab-cdon, 1 mg) and 99601 Home infusion/specialty drug administration, per visit (up to 2 hours); initial, up to 1 hour for the administration). *Include any additional modifiers as required by the payor.*
- 9 **Item 24F. Charges:** Indicate charges for the second claim (up to the 7-character limit). Example: enter dollar amount for 100 units of UPLIZNA. The administration code on the second claim may be billed with 0.00.
- 10 **Item 24G. Days or Units:** Enter the number of units. Example: 100 units for 100 mg of UPLIZNA. The unit for the administration code may be 1 on the second claim.

Split claim billing requirements vary by payor. Consult with individual payors regarding individual split billing requirements.








Claims Submission Checklist


Split Claim Billing


The following checklist provides an overview of requirements that may be necessary when submitting claims for UPLIZNA. Check with individual payors for specific coding requirements.

-  Use J1823 per 1 billing unit for UPLIZNA and include supporting information when necessary
 - A 300-mg dose of UPLIZNA would be reported with 300 billing units. Enter the number of billing units specific to each split claim. Example: 200 billing units may be on Claim 1, and 100 billing units may be on Claim 2

-  Confirm with the payor split claim billing requirements for UPLIZNA

-  Have the PA or predetermination approval on file

-  Confirm with the payor how NDC numbers and unit of measure should be reported on the claim form

-  Include any additional documentation required by the payor



REIMBURSEMENT CONSIDERATIONS BY PAYOR TYPE

Commercial Plans

For commercial payors, reimbursement for drugs and professional services depends significantly on the contracts negotiated between healthcare providers and the payor. The following list provides some important information you need to consider regarding your commercial payor contracts:



Identify your top payors



Locate copies of your contracts with these payors



Review the contracts to determine payment methodology for:

- Administration of infusion therapy
- Other related services (eg, laboratory monitoring, etc.)



Determine how frequently rates are updated

- Annually, biannually, quarterly, other?



Review any product acquisition terms



Determine the contract term, renewal date, and termination time frame



Document contact information for the payor and your site of care's designated payor relations representative



Store the contracts in a central location for easy access



Medicare FFS²¹ and Medicare Advantage

Reimbursement for UPLIZNA and its administration varies by site of care and type of Medicare plan.

Medicare FFS in the Physician Office

Medicare uses the reimbursement methodology of Average Sales Price (ASP) plus 6% (ASP + 4.3% with sequestration impact) for drugs.²¹ The ASP rate for UPLIZNA will be listed on the ASP Drug Pricing File, which is located on the CMS webpage: <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice>

Drug administration services are reimbursed based on the Medicare Physician Fee Schedule (MPFS). Rates are listed in the MPFS Look-Up Tool located on the CMS webpage: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/pfslookup>

Medicare FFS in the HOPD

UPLIZNA administered in the HOPD uses the reimbursement methodology of ASP plus 6% (ASP + 4.3% with sequestration impact).

Drug administration services are reimbursed based on the Outpatient Prospective Payment System (OPPS).

The payment rates for UPLIZNA and its administration in the HOPD are available on the CMS webpage: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>

The Medicare payment for certain services also varies for HOPDs that are classified as excepted vs non-excepted off-campus PBDs (POS 19).¹⁷

- An excepted off-campus PBD of a hospital is one that is located within 250 yards of the main hospital campus. Services provided by the excepted off-campus PBD must attach informational modifier PO to all services and are paid the OPPS rate
- A non-excepted off-campus PBD of a hospital is one that is located greater than 250 yards from the main campus. All services must have modifier PN attached, which will trigger payment to be made under the MPFS at a rate of 40% of the OPPS rate (known as the Patient Financial Services (PFS) Relativity Adjuster). Although modifier PN is required on all line items, the payment reduction applies to services like intravenous infusion but does not apply to drugs such as UPLIZNA. Services provided by excepted off-campus PBDs are paid at the OPPS facility rate

Medicare Advantage

The reimbursement methodology for UPLIZNA and its administration to a patient on a Medicare Advantage plan varies by plan, as these plans are administered by various commercial payors.

Sequestration

Sequestration (the Medicare 2% payment adjustment) is set to expire in 2031.²²



Medicaid FFS and Managed Medicaid

Reimbursement for UPLIZNA can vary based on whether a patient enrolls in a traditional FFS Medicaid plan or in a Managed Medicaid plan. In many states, reimbursement for traditional Medicaid is based on each state's publicly available fee schedule. However, reimbursement methodologies for Managed Medicaid plans will vary and may not be publicly accessible.

Drug reimbursement for traditional Medicaid and Managed Medicaid may include:

- Percentage (\pm) of average wholesale price (AWP)
- Percentage (\pm) of Wholesale Acquisition Cost (WAC)
- Percentage (\pm) of ASP
- Invoice price

Medicaid programs may also use a variety of methods to determine the reimbursement for drug administration associated with UPLIZNA, which include:

- Fee schedule–based reimbursement
- Percentage of the Medicare Physician Fee Schedule
- Usual, customary, and reasonable reimbursement
- Percentage of billed charges

Please see Important Safety Information on page 3
and see [Full Prescribing Information](#).



NAVIGATING ACCESS AND REIMBURSEMENT CHALLENGES

Sample Letter of Medical Necessity

[Office letterhead]

[Date]

[Contact name of medical director or other payer representative]
[Contact title]
[Name of health insurance company]
[Mailing address]

Re:
Letter of Medical Necessity for J1823; UPLIZNA® (inebilizumab-cdon), injection, 1 mg
Patient: [Patient name]
Group/Policy Number: [Number]
Date(s) of Service: [Dates]
Diagnosis: G36.0, neuromyelitis optica [Devic]

Dear [Contact name or department],

I am writing on behalf of my patient, [Patient name], to document medical necessity for treatment with UPLIZNA® (inebilizumab-cdon). UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. On behalf of [Patient name], I am requesting approval for use and subsequent payment for the treatments.

Medical History and Diagnosis
[Patient name] is [a/an] [age]-year-old [male/female] diagnosed with NMOSD. [Patient name] has been in my care since [DATE]. As a result of NMOSD, my patient [enter brief description of patient history]. Additionally, [Patient name] has tried [previous treatments] and [outcomes]. [If patient has been on UPLIZNA therapy, include outcomes experienced and consider including the effect of continuity of care.] The attached medical records document [Patient name]'s clinical condition and the medical necessity for treatments with UPLIZNA.

- [Diagnosis/ICD-10-CM code: Neuromyelitis optica [Devic]/G36.0]
- [Diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) antibodies]
- [Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist]
- [Documentation of failure or of inadequate response to previous therapy (≥1 relapse in the past 12 months or ≥2 relapses in the past 24 months)]
- [Any relevant clinical/chart notes]

Based on the above facts, I have made the assessment that UPLIZNA is indicated and medically necessary for [Patient name]. The plan of treatment is to administer an initial dose of 300 mg of UPLIZNA via intravenous (IV) infusion on [date], followed [2 weeks later/on date] by a second 300-mg dose. Subsequent single 300-mg doses of UPLIZNA via IV infusion will follow every 6 months thereafter, starting 6 months from the date of the first infusion.

Please consider coverage of UPLIZNA for [Patient name] and approve use and subsequent payment for UPLIZNA as planned. Please refer to the enclosed Prescribing Information for UPLIZNA. If you have any further

P-UPZ-00093



To download the sample letter of medical necessity, [click here](#)

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).

UPLIZNA[®]
inebilizumab-cdon



Sample Letter of Appeal

[Office letterhead]

[Date]

[Prior authorization department]
[Name of health insurance company]
[Mailing address]

Re: Patient: [Patient Name]
Group/Policy Number: [Number]
Date of birth: [MM/DD/YYYY]
Diagnosis: [Code & description]

To Whom It May Concern:

My name is [HCP's name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [Patient Name], to request coverage for UPLIZNA® (inebilizumab-cdon). [Patient Name] has been under my care for [X months] for the treatment of neuromyelitis optica spectrum disorder (NMOSD).

I understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, I believe that an initial dose of UPLIZNA 300 mg, given as 2 separate intravenous (IV) infusions 2 weeks apart, with subsequent 300-mg IV doses given every 6 months thereafter starting from the date of the first infusion, is the appropriate treatment for my patient. In support of my recommendation for UPLIZNA treatment, I have provided an overview of my patient's relevant clinical history below.

[Provide a brief medical history, including diagnosis, allergies, existing comorbidities, patient lifestyle modifications as a result of living with NMOSD, and International Classification of Diseases (ICD) code(s). If patient has been on UPLIZNA therapy, include outcomes experienced and consider including the effect of continuity of care.]

[Include documentation relating to criteria:

- Diagnosis/ICD-10-CM code: Neuromyelitis optica [Devic]/G36.0
- Diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) antibodies
- Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist
- Documentation of failure or of inadequate response to previous therapy (≥1 relapse in the past 12 months or ≥2 relapses in the past 24 months)
- Any relevant clinical/chart notes
- Specialized test results, if available, including CSF examination, spinal taps, MRIs, or CT/CAT scans]

The reason(s) for which you are denying coverage limits the access of UPLIZNA for my patient who has a high unmet medical need for a rare autoimmune disease of the central nervous system affecting the optic nerves and spinal cord. UPLIZNA is an FDA-approved treatment for NMOSD and has a favorable efficacy and safety profile. [Discuss rationale for using UPLIZNA vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's likely prognosis or disease progression without treatment with product.]

P-UPZ-00113



To download the sample letter of appeal, [click here](#)

Please see Important Safety Information on page 3 and see [Full Prescribing Information](#).





Considerations for Appealing Denied or Underpaid Claims

After checking your contract, if you still believe a claim for UPLIZNA has been improperly reimbursed or denied, you may consider submitting an appeal.



Review the explanation of benefits to determine what has been denied or underpaid (eg, drug, administration, both) and the reason(s).

- If the underpayment or denial was due to a technical billing error, verify/obtain specific directions from the payor and submit a corrected claim



If an appeal is necessary, verify the appeals process with the payor, including:

- Is there a particular form that must be completed?
- Can the appeal be conducted over the phone, or must it be in writing?
- To whom should the appeal be directed?
- What information must be included with the appeal (eg, copy of original claim, explanation of benefits, PA number, other supporting documentation)?
- How long does the appeals process usually take?
- How will the payor communicate the appeal decision?



Review the appeal request for accuracy, including the patient identification numbers, coding, and requested information.



File the appeal as soon as possible and within filing time limits.



Request that the payor have a specialist who is currently treating patients with UPLIZNA review the claim for medical necessity.



Reconcile claims appeal responses promptly and thoroughly to ensure the appeal has been processed appropriately.



Record the appeal result (eg, payment amount or if further action is required).



To download the sample letter of appeal, [click here](#)



HORIZON BY YOUR SIDE

Horizon Therapeutics is committed to assisting patients throughout their access and treatment journey. We have developed this Billing and Coding Guide to provide you with the information you need to help with the reimbursement process for UPLIZNA. **Horizon By Your Side** is a patient support program with team members who provide education about PAs, medical exceptions, and appeal processes.



Horizon By Your Side has team members who educate about navigating insurance processes and accessing treatment on your patient's behalf.

Simplify access for your patients through Horizon By Your Side. Just call **833-842-8477** or visit UPLIZNAhcp.com to initiate enrollment for your patient by submitting the Patient Enrollment Form (PEF). Your patient must complete enrollment to access these patient-focused services and resources.



For additional support resources,
visit UPLIZNAhcp.com/access-and-support/resources

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