



Billing & Coding Guide

Step-by-step guide to coverage determination, coding, claim submission, and reimbursement



UPLIZNA J-Code: J1823, 1 mg

INDICATIONS

UPLIZNA® (inebilizumab-cdon) is indicated in adult patients for the treatment of: anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); Immunoglobulin G4-related disease (IgG4-RD); anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+) generalized myasthenia gravis (gMG).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).

Welcome

The information contained in this guide is for informational purposes only and may not be all-inclusive. Billing and coding may vary by site of care, payer, and plan, and can change over time. 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. Amgen does not guarantee coverage or reimbursement.

Patient counseling and monitoring considerations

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 recovery.

Pregnancy

Instruct patients that if they are pregnant or plan to become pregnant while taking UPLIZNA, they should inform their healthcare provider. Advise females of reproductive potential that they should use effective contraception during treatment and for 6 months after UPLIZNA therapy. Advise patients to register with the UPLIZNA pregnancy exposure registry.

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UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

WARNINGS AND PRECAUTIONS

- **Infusion Reactions:** Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study 2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. 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 antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

- **Infections:** Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., HBsAg+), consult liver disease experts before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of 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. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Infections (cont'd):**

Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

- **Reductions 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 levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell-depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

ADVERSE REACTIONS

- The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo): urinary tract infection and arthralgia in NMOSD; urinary tract infection and lymphopenia in IgG4-RD; headache and infusion-related reactions in gMG.



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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 payer receives and processes the claim for reimbursement. Coding for UPLIZNA may vary by payer and plan type. Contact payers for specific coding requirements for billing UPLIZNA.

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

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:

POS Code	POS 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



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. 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 (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing 3 100 mg/10 mL single-dose vials

In addition to the NDC, some payers 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 suspension 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 payer 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 appropriate ICD-10-CM diagnosis codes for prescribing UPLIZNA when administered in a physician office and an office-based infusion center:

ICD-10-CM Diagnosis Code	Description
G36.0	Neuromyelitis optica [Devic] <ul style="list-style-type: none"> Demyelination in optic neuritis
D89.84	Immunoglobulin G4-related disease
G70.00*	Description: Myasthenia gravis without (acute) exacerbation
G70.01*	Description: Myasthenia gravis with (acute) exacerbation

*Other potential codes relevant to generalized myasthenia gravis include: G70 (Category: Myasthenia gravis and other myoneural disorders); G70.0 (Category: Generalized myasthenia gravis). Healthcare professionals are responsible for selecting the most appropriate codes based on the patient's medical record and payer requirements.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infusion Reactions: Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study 2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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	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 payers 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	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 due to character limits on the claim form
76*	Repeated procedural service	Modifier 76 is used to indicate that a service was repeated the same day subsequent to the original service. This modifier indicates the difference between duplicate services and repeated services
JZ*	Zero drug amount discarded/not administered to any patient	Add to J1823 when there was no discarded drug amount Modifier JZ is effective July 1, 2023, and is required on Medicare FFS claims with dates of service on/after July 1, 2023

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



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	Description
96413*	Chemotherapy administration, 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*	Chemotherapy administration, 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

*The term "chemotherapy" in 96401-96549 includes other highly complex drugs or highly complex biologic agents.

Check appropriate administration codes with individual payers.

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Please see Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





Codes used in premedication

Below are codes that may be appropriate for reporting select premedications administered to reduce the risk of infusion reaction:

HCPCS Drug Code	Description	Administration Time Prior to UPLIZNA Infusion
J2919	Injection, methylprednisolone sodium succinate, 5 mg	30 minutes
J1010	Injection, methylprednisolone acetate, 1 mg	30 minutes
J8499*	Prescription drug, oral, non-chemotherapeutic, NOS (not otherwise specified) [†]	30-60 minutes

*Some payers may require J8499 and/or NDC when reporting over-the-counter (OTC) drugs. Check payer-specific requirements to determine how to report these drugs.

[†]Use for OTC oral antihistamine and oral antipyretic.

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	Description
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
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 payer.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion Reactions (cont'd):

Administer pre-medication with a corticosteroid, an antihistamine, and an antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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.

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 1-13:** Enter the patient's personal and insurance information.
- 2** **Item 19:** Enter a comment regarding UPLIZNA split claim billing (detailed instructions on next page). **Note:** Item 19 has a 71-character limit.
- 3** **Item 21:** Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; Please see list of potential ICD-10-CM codes on Page 8.
- 4** **Item 23:** Enter the Prior Authorization (PA) number (if applicable).
- 5** **Item 24A:** 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 payer how NDC numbers should be notated on the claim (ie, some may require unit of measure qualifier and quantity of drug)
- 6** **Item 24B:** Enter the appropriate POS code (eg, 11 for physician office or 49 for independent clinic [office-based infusion center]).
- 7** **Item 24D:** Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® codes (see list of potential CPT codes on Page 10). *Include any additional modifiers as required by the payer.*
- 8** **Item 24E:** Enter the letter that corresponds to the ICD-10-CM code reported in Item 21.
- 9** **Item 24F:** 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 24G:** 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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections: Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





Special billing circumstances for physician office or office-based infusion center

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).

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 payers regarding split claim billing preferences.**

CMS-1500 (837P) Claim 1

1 → 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Claim 1 of 2: Dollar amount exceeds line amount	20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
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		
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OF UNITS H. EPSDT (Pain) I. ID. QUAL. J. RENDERING PROVIDER ID. #		
N475987015 003 ML20		
MM DD YY MM DD YY 11 J1823 JZ A XXXXX XX 200 5		
MM DD YY MM DD YY 11 XXXXX A 4 X XX 1 NPI		

- 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.
- Item 24A. Date(s) of service:** Enter the appropriate UoM for the claim. Example: 200 mg = 200 units = ML20.
- Item 24D. Procedures, services, or supplies:** Indicate appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg) and CPT® codes (Please see list of potential CPT codes on Page 10). *Include any additional modifiers as required by the payer.*
- Item 24F. Charges:** Indicate charges for the first claim (up to the 7-character limit). Example: enter dollar amount for 200 units of UPLIZNA.
- Item 24G. Days or units:** Enter the number of units. Example: 200 units for 200 mg of UPLIZNA.

CMS-1500 (837P) Claim 2

6 → 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Claim 2 of 2: Remaining dollar amount from claim 1 exceeds line amount	20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
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		
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OF UNITS H. EPSDT (Pain) I. ID. QUAL. J. RENDERING PROVIDER ID. #		
N475987015 003 ML10		
MM DD YY MM DD YY 11 J1823 JZ A XXXXX XX 100 10		
MM DD YY MM DD YY 11 XXXXX A 9 0 00 1 NPI		

- 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.
- Item 24A. Date(s) of service:** Enter the appropriate UoM for the claim. Example: 100 mg = 100 units = ML10.
- Item 24D. Procedures, services, or supplies:** Indicate appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg) and CPT codes (Please see list of potential CPT codes on Page 10). *Include any additional modifiers as required by the payer.*
- 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.
- 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 payer. Consult with individual payers 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

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Drug identification for specialty pharmacy varies by payer. Confirm with the payer 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 centers). 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 payer 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

Split claim billing

The following checklist provides an overview of requirements that may be necessary when submitting claims for UPLIZNA. Check with individual payers 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 payer split claim billing requirements for UPLIZNA**
- ✓ **Have the PA or predetermination approval on file**
- ✓ **Confirm with the payer how NDC numbers and unit of measure should be reported on the claim form**
- ✓ **Include any additional documentation required by the payer**

Please see Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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 payer receives and processes the claim for reimbursement. Coding for UPLIZNA may vary by payer and plan type. Contact payers 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).

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:

POS Code	POS 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 hospital outpatient departments. The 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. 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 hospital outpatient departments. In addition, there are a number of exceptions that may be applicable to an off-campus entity that can impact the level of reimbursement the entity receives for services, and there are modifiers that are used depending upon whether an exception applies (PO [Excepted service provided at an off-campus, outpatient, provider-based department of a hospital]) or does not apply (PN [Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital]). Whether an entity is considered on-campus or off-campus and whether, for off-campus entities, services are excepted or not, are complicated determinations that are based on the unique nature of the entity and the services being furnished. Each entity must assess these factors and confirm its status with its payer.

Please see Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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. 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 (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing 3 100 mg/10 mL single-dose vials

In addition to the NDC, some payers 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 suspension 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 payer 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 appropriate ICD-10-CM diagnosis codes for prescribing UPLIZNA when administered in the HOPD (on and off campus) and hospital-based infusion center:

ICD-10-CM Diagnosis Code	Description
G36.0	Neuromyelitis optica [Devic] <ul style="list-style-type: none"> Demyelination in optic neuritis
D89.84	Immunoglobulin G4-related disease
G70.00*	Description: Myasthenia gravis without (acute) exacerbation
G70.01*	Description: Myasthenia gravis with (acute) exacerbation

*Other potential codes relevant to generalized myasthenia gravis include: G70 (Category: Myasthenia gravis and other myoneural disorders); G70.0 (Category: Generalized myasthenia gravis). Healthcare professionals are responsible for selecting the most appropriate codes based on the patient's medical record and payer requirements.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd):

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants:

If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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	Description
0250	Pharmacy, general
0260	Intravenous therapy, general
0636	Drugs requiring detailed coding

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	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 payers 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 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	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	Effective January 1, 2025, all 340B covered entities must report modifier TB on claims, even if they previously reported modifier JG
JZ	Zero drug amount discarded/not administered to any patient	Add to J1823 when there was no discarded drug amount Modifier JZ is effective July 1, 2023, and is required on Medicare FFS claims with dates of service on/after July 1, 2023
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)

The table above describes Medicare policy. Consult with individual payers for specific modifier preferences.



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	Description
96413*	Chemotherapy administration, 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*	Chemotherapy administration, 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

*The term "chemotherapy" in 96401-96549 includes other highly complex drugs or highly complex biologic agents.

Check appropriate administration code with individual payers.

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Please see Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





Codes used in premedication

Below are codes that may be appropriate for reporting select premedications administered to reduce the risk of infusion reaction:

HCPCS Drug Code	Description	Administration Time Prior to UPLIZNA Infusion
J2919	Injection, methylprednisolone sodium succinate, 5 mg	30 minutes
J1010	Injection, methylprednisolone acetate, 1 mg	30 minutes
J8499*	Prescription drug, oral, non-chemotherapeutic, NOS (not otherwise specified) [†]	30-60 minutes

*Some payers may require J8499 and/or NDC when reporting over-the-counter (OTC) drugs. Check payer-specific requirements to determine how to report these drugs.

[†]Use for OTC oral antihistamine and oral antipyretic.

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	Description
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
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 payer.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd):

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., HBsAg+), consult liver disease experts before starting and during treatment.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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.

The image shows a sample CMS-1450 Institutional Claim Form. Numbered callouts point to the following fields:

- 1:** Patient Name (FL 8-15) and Patient Address (FL 50-65).
- 2:** Revenue codes (FL 42).
- 3:** Code description for HCPCS (FL 43).
- 4:** HCPCS code (FL 44).
- 5:** Units (FL 46).
- 6:** ICD-10-CM diagnosis code (FL 67, A-Q).

- 1 Field locator (FL) 8-15 and 50-65:** Enter the patient's personal and insurance information.
- 2 FL 42:** Enter the revenue codes. Please see list of potential revenue codes on Page 17.
- 3 FL 43:** 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 payer how NDC numbers should be reported on the claim (ie, some may require unit of measure and quantity of drug)
- 4 FL 44:** Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® codes (see list of potential CPT codes on Page 19). *Include any additional modifiers required by the payer.*
- 5 FL 46:** 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-Q:** Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; Please see list of potential ICD-10 codes on Page 16.

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IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd):





Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of 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. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis.





Claims submission checklist

The following checklist provides an overview of requirements that may be necessary when submitting claims for UPLIZNA. Please check with individual payers 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 payer how NDC numbers should be reported on the claim form**
-  **Include any additional documentation required by the payer**



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 payer and plan type. For example, commercial payers 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. Contact payers 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 payer 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:

POS Code	POS Name	Description
12	Home	Location, other than a 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. 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 (Per prescribing information)	11-Digit NDC (For claim forms)	Description
75987-150-03	75987-0150-03	One carton containing 3 100 mg/10 mL single-dose vials

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

Progressive Multifocal Leukoencephalopathy (PML) (cont'd): At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





In addition to the NDC, some payers 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 suspension 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 payer 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 appropriate ICD-10-CM diagnosis codes for prescribing UPLIZNA when administered in the home:

ICD-10-CM Diagnosis Code	Description
G36.0	Neuromyelitis optica [Devic] <ul style="list-style-type: none"> Demyelination in optic neuritis
D89.84	Immunoglobulin G4-related disease
G70.00*	Description: Myasthenia gravis without (acute) exacerbation
G70.01*	Description: Myasthenia gravis with (acute) exacerbation

*Other potential codes relevant to generalized myasthenia gravis include: G70 (Category: Myasthenia gravis and other myoneural disorders); G70.0 (Category: Generalized myasthenia gravis). Healthcare professionals are responsible for selecting the most appropriate codes based on the patient's medical record and payer requirements.

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	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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

Tuberculosis

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

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payers 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. The following modifiers may be used for claims over \$99,999, per Medicare Administrative Contractor (MAC) guidance.

Modifier	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 due to character limits on the claim form
76	Repeated procedural service	Modifier 76 is used to indicate that a service was repeated the same day subsequent to the original service. This modifier indicates the difference between duplicate services and repeated services
JZ	Zero drug amount discarded/not administered to any patient	Add to J1823 when there was no discarded drug amount Modifier JZ is effective July 1, 2023, and is required on Medicare FFS claims with dates of service on/after July 1, 2023

The table above describes Medicare policy. Consult with individual payers for specific modifier preferences.

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 depending on the payer:

Codes	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 payer.

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Please see **Important Safety Information throughout and on pages 3-4** and **UPLIZNA full Prescribing Information at [UPLIZNAhcp.com](https://www.uplizna.com).**





Codes used in premedication

Prior to receiving UPLIZNA, premedications must be given to reduce the risk of an infusion reaction. Below are codes that may be appropriate for reporting select UPLIZNA premedications:

HCPCS Drug Code	Description	Administration Time Prior to UPLIZNA Infusion
J2919	Injection, methylprednisolone sodium succinate, 5 mg	30 minutes
J1010	Injection, methylprednisolone acetate, 1 mg	30 minutes
J8499*	Prescription drug, oral, non-chemotherapeutic, NOS (not otherwise specified) [†]	30-60 minutes

*Some payers may require J8499 and/or NDC when reporting over-the-counter (OTC) drugs. Check payer-specific requirements to determine how to report these drugs.

[†]Use for OTC oral antihistamine and oral antipyretic.

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	Description
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
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 payer.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

Tuberculosis (cont'd):

Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection.

Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).





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.

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 1-13:** Enter the patient's personal and insurance information.
- 2** **Item 19:** Enter a comment regarding UPLIZNA split claim billing (detailed instructions on next page). **Note:** Item 19 has a 71-character limit.
- 3** **Item 21:** Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter; Please see list of potential ICD-10 codes on Page 24.
- 4** **Item 23:** Enter the PA number (if applicable).
- 5** **Item 24A:** 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 payer how NDC numbers should be notated on the claim (ie, some may require unit of measure qualifier and quantity of drug)
- 6** **Item 24B:** Enter the appropriate POS code (ie, 12 for home).
- 7** **Item 24D:** Enter the appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg for UPLIZNA) and CPT® codes (see list of potential CPT codes on Page 25). *Include any additional modifiers as required by the payer.*
- 8** **Item 24E:** Enter the letter that corresponds to the ICD-10-CM code reported in Item 21.
- 9** **Item 24F:** 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 24G:** 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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd):

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Please see additional Important Safety Information throughout and on pages 3-4 and UPLIZNA full Prescribing Information at UPLIZNAhcp.com.





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 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).

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 payers regarding split claim billing preferences.**

CMS-1500 (837P) Claim 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.							
A. XXXX B. C. D.																					
E. F. G. H.																					
I. J. K. L.																					
23. PRIOR AUTHORIZATION NUMBER																					
24. A. DATE(S) OF SERVICE		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. ICD-9/10 PLAN		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
MM DD YY MM DD YY		MM DD YY				J1823				A		XXXXX XX		200		5		NPI			
MM DD YY MM DD YY		12				XXXXX				A		4		X XX		1		NPI			

- 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.
- Item 24A. Date(s) of service:** Enter the appropriate UoM for the claim. Example: 200 mg = 200 units = ML20.
- Item 24D. Procedures, services, or supplies:** Indicate appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg) and CPT® codes (Please see list of potential CPT codes on Page 25). *Include any additional modifiers as required by the payer.*
- Item 24F. Charges:** Indicate charges for first claim (up to the 7-character limit). Example: enter dollar amount for 200 units of UPLIZNA.
- Item 24G. Days or units:** Enter the number of units. Example: 200 units for 200 mg of UPLIZNA.

CMS-1500 (837P) Claim 2

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.							
A. XXXX B. C. D.																					
E. F. G. H.																					
I. J. K. L.																					
23. PRIOR AUTHORIZATION NUMBER																					
24. A. DATE(S) OF SERVICE		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. ICD-9/10 PLAN		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
MM DD YY MM DD YY		MM DD YY				J1823				A		XXXXX XX		100		10		NPI			
MM DD YY MM DD YY		12				XXXXX				A		9		0 00		1		NPI			

- 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.
- Item 24A. Date(s) of service:** Enter the appropriate UoM for the claim. Example: 100 mg = 100 units = ML10.
- Item 24D. Procedures, services, or supplies:** Indicate appropriate HCPCS (J1823 Injection, inebilizumab-cdon, 1 mg) and CPT codes (Please see list of potential CPT codes on Page 25). *Include any additional modifiers as required by the payer.*
- 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.
- 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 payer. Consult with individual payers 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 payers 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 payer split claim billing requirements for UPLIZNA**

-  **Have the PA or predetermination approval on file**

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

-  **Include any additional documentation required by the payer**



Reimbursement considerations by payer type

Commercial plans

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



Identify your most frequent payers



Locate copies of your contracts with these payers



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 payer and your site of care's designated payer relations representative



Store the contracts in a central location for easy access



Medicare FFS 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. The ASP rate for UPLIZNA is 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 Physician Fee Schedule Look-Up Tool located on the CMS webpage: <https://www.cms.gov/medicare/physician-fee-schedule/search/overview>

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).

- 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 at the OPPS 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 payers.

Sequestration

Remember that, under current law, sequestration (the Medicare 2% payment adjustment) remains in effect.



Medicaid FFS and Managed Medicaid

Reimbursement for UPLIZNA can vary based on whether a patient enrolls in a traditional Medicaid FFS 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 MPFS
- Usual, customary, and reasonable reimbursement
- Percentage of billed charges



Navigating access and reimbursement challenges

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 payer and submit a corrected claim



If an appeal is necessary, verify the appeals process with the payer, 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 appeal process usually take?
- How will the payer 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 payer 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 explore **tools and resources** supporting patient access, visit UPLIZNAhcp.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd):

Vaccinations (cont'd): Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

Please see additional Important Safety Information throughout and on pages 3-4 and [full Prescribing Information](https://UPLIZNAhcp.com) at UPLIZNAhcp.com.



Amgen By Your Side

Amgen 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. **Amgen By Your Side** is a support program for patients prescribed UPLIZNA. After your patient has enrolled, they will be paired with a dedicated support partner, called a Patient Access Liaison (PAL). Their PAL can be a partner, providing nonmedical education to help them navigate their unique treatment experience—including information on insurance, financial support options, important appointment-related information, and other patient support services.



Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as prescribed.

Call **1-844-469-4297** Monday through Friday, 9 AM to 8 PM ET or visit AmgenByYourSide.com



For additional support resources, visit UPLIZNAhcp.com

Please see Important Safety Information throughout and on pages 3-4 and UPLIZNA [full Prescribing Information](https://UPLIZNAhcp.com) at UPLIZNAhcp.com.

