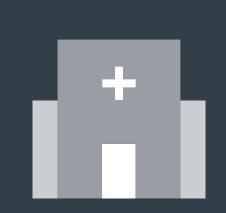


CODING AT A GLANCE



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

Please see additional Important Safety Information on page 9 and <u>Full Prescribing Information</u> at UPLIZNAhcp.com.

SAMPLE CODES AND BILLING CONSIDERATIONS

Туре	Code	Description	
ICD-10-CM ¹	G36.0	Neuromyelitis optica [Devic] • Demyelination in optic neuritis	
HCPCS ²	J1823	Injection, inebilizumab-cdon, 1 mg	
NDC ³ *	10-digit: 75987-150-03 11-digit: 75987-0150-03	Inebilizumab, 1 carton containing three 100 mg/10 mL single-dose vials Check with carrier for NDC format requirements	
CPT® (administration procedures) ⁴	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)	

CPT® codes continued on next page.

CPT®, Current Procedural Terminology; EMR, electronic medical record; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code. CPT Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association, 2022.

[†]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).⁶ Payor requirements regarding the use of CPT administration codes may vary. Check payor requirements for UPLIZNA appropriate CPT administration codes.

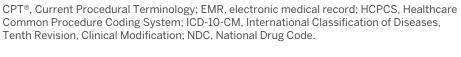


^{*}NDC codes: Payor requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires the use of the 11-digit NDC. Check payor requirements for appropriate reporting of the NDC. You may need to add the NDC for UPLIZNA to your EMR system if not already included.

SAMPLE CODES AND BILLING CONSIDERATIONS (CONT'D)

Туре	Code	Description	
CPT® (administration procedures) ⁴	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	
Revenue Codes ⁷	025x 0636 026x	Pharmacy Drugs requiring detailed coding Intravenous therapy	

The \boldsymbol{x} placeholder at the end of the revenue code indicates that a fourth digit is required.





SAMPLE CODES AND BILLING CONSIDERATIONS (CONT'D)

Codes Used in Laboratory Testing

The following CPT® codes may be appropriate to report laboratory testing services to assist with diagnosing neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are aquaporin-4-immunoglobulin G (AQP4-lgG) antibody positive.*

CPT® Code⁴	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	

^{*}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.

Codes Used in Premedication

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

HCPCS Drug Code ²	Description	Administration Time Prior to UPLIZNA Infusion
J2919	Injection, methylprednisolone sodium succinate, 5 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 over-the-counter (OTC) drugs. Check payor-specific requirements to determine how to report these drugs.



SAMPLE CODES AND BILLING CONSIDERATIONS (CONT'D)

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 ^{2,4}	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.

Billing for a single infusion of UPLIZNA requires split claim billing due to character limits on the CMS-1500 form (and its electronic equivalent 837P) used in physician offices, office-based infusion centers, and home sites of care. The charge fields for dollar amounts (24F and 28 on the CMS-1500 and Loop ID 2400/Segment SV102 and Loop ID 2300/Segment CLM02 on the 837P) 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).

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 because it remains your responsibility to ensure the accuracy of the claims your site of care submits.

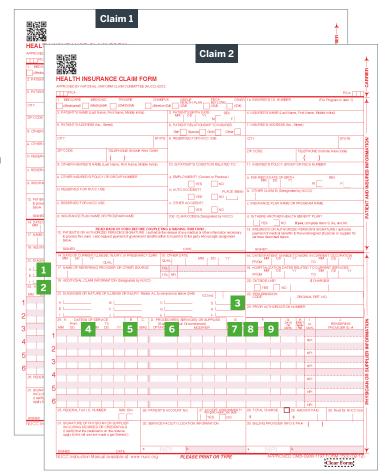
inehilizumah-cdon

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 particular claim. It is the responsibility of the healthcare provider to choose the most appropriate code as documented in the patient's medical chart and submit the appropriate codes, charges, and modifiers for services or items rendered or applied. Your patient's enrollment in Amgen By Your Side will in no way guarantee reimbursement. The content herein is based on information current as of September 2022 and may have changed.

SAMPLE CMS-1500 FORM

Use to submit claims to commercial insurance or Medicare for UPLIZNA administered in physician offices, office-based infusion centers, or home sites of care. Billing for a single infusion of UPLIZNA requires split claim billing due to character limits on the CMS-1500 form used in physician offices, office-based infusion centers, and home sites of care. See next page for an example of split claim billing.

- 1 Item 19^{9,10}
 - The maximum number of characters allowed for any dollar amount field on the CMS-1500 or 837P form is 7. When more characters are needed, splitting the billing on separate claims may be required. Indicate that this is a split claim. Example: Claim 1 of 2: Dollar amount exceeds line amount. Check with individual payors to confirm the information needed. **Note**: Item 19 has a 71-character limit.
- 2 Item 219
 Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter, eg, ICD-10-CM G36.0 Neuromyelitis optica [Devic].
- Item 23°
 Enter the prior authorization number (if applicable).
- Qualifier N4 should be added before the 11-digit NDC (eg, N475987015003).
- Enter the appropriate place of service code (eg, 11 for physician office or 49 for independent clinic [office-based infusion center]).



- 6 Item 24D9
 - 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.
- 7 Item 24E9: Enter the letter that corresponds to the ICD-10-CM code reported in Item 21.
- Item 24F9: Indicate charges for first claim (up to the 7-character limit). Example: Enter dollar amount for 200 units of UPLIZNA
- 9 Item 24G9: Enter the number of units. Example: 200 units for 200 mg of UPLIZNA.

Refer to the UPLIZNA Billing & Coding Guide for more detailed information about sample codes and additional resources.



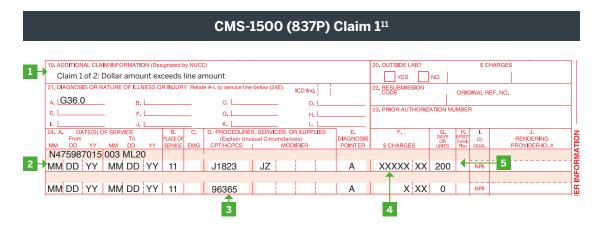
SPECIAL BILLING CIRCUMSTANCES

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 for dollar amounts (24F and 28 on the CMS-1500 and Loop ID 2400/Segment SV102 and Loop ID 2300/Segment CLM02 on the 837P) 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).¹⁰

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.**



1 Item 19. Additional Claim Information:

Indicate that this is a split claim.

Example: Claim 1 of 2: dollar amount of dose 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:

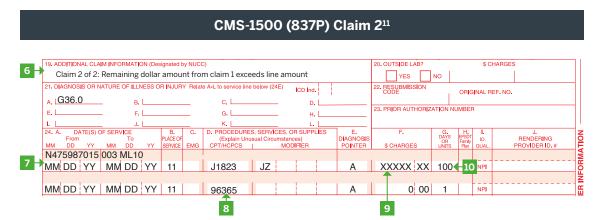
Indicate appropriate HCPCS and CPT® codes. Example: J1823 (Injection, inebilizumab-cdon, 1 mg) and 96365 (intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]; initial, up to 1 hour for the administration). *Include any additional modifiers as required by the payor.*

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.



6 Item 19. Additional Claim Information:

Indicate that this is a split claim.

Example: Claim 2 of 2: remaining dollar amount from claim 1 dose exceeds line amount.

7 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 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 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.

Example: 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.



SAMPLE CMS-1450/UB-04 FORM

Use to submit claims to commercial insurance or Medicare for UPLIZNA administered in the hospital outpatient department or hospital-based infusion center.¹²

FL 42¹³

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). (Other revenue codes may apply)

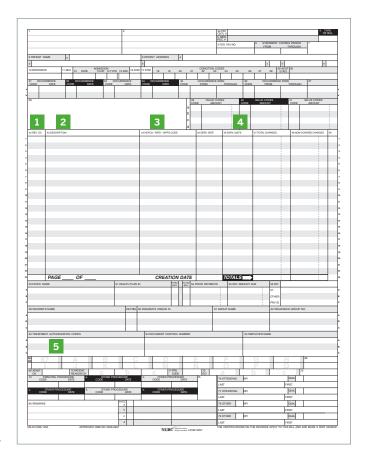
2 FL 43¹³

Enter the corresponding code description for the HCPCS listed in FL44.

- Enter the NDC number in the unshaded area in FI 43
 - Qualifier N4 should be added before the 11-digit NDC
- Eg, N475987015003
- Confirm with individual payor how NDC numbers should be reported on the claim (ie, some may require unit of measure and quantity of drug)

3 FL 44¹³

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). Include any additional modifiers required by the payor.



7 FL 46¹³

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

FL 67¹³

Enter the appropriate ICD-10-CM diagnosis code(s) for the encounter, eg, ICD-10-CM G36.0 Neuromyelitis optica [Devic].

Call 1-844-469-4297 or visit <u>UPLIZNAhcp.com</u> to initiate enrollment for your patient in the Amgen By Your Side patient support program by submitting the patient enrollment form. Your patient must complete enrollment to access our patient-focused services and resources.



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.

Please see Full Prescribing Information at UPLIZNAhcp.com.



REFERENCES

1. National Center for Health Statistics. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). ICD-10-CM FY2023 Full PDF June 2022. Accessed December 6, 2022. https://ftp. cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2023 2. Centers for Medicare & Medicaid Services. July 2024 Alpha-Numeric HCPCS File. Accessed August 1, 2024. Available at https://www.cms.gov/ medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update 3. UPLIZNA (inebilizumab-cdon) [prescribing information] Horizon. 4. American Medical Association. CPT 2022 Professional Edition. AMA; 2021. 5. Federal Register. Future Format of the National Drug Code: public hearing; request for comments. August 7, 2018. Accessed December 6, 2022. https://www.federalregister.gov/documents/2018/08/07/2018-16807/futureformat-of-the-national-drug-code-public-hearing-request-for-comments 6. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Complex Drug Administration Coding (A58532). Original effective date: January 1, 2021. Accessed December 6, 2022. https://www.cms.gov/medicare-coverage-Revenue Codes. Revised June 28, 2022. Accessed December 6, 2022. https://med.noridianmedicare.com/web/ jea/topics/claim-submission/revenue-codes 8. Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Accessed December 6, 2022. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/ Downloads/CMS1500.pdf 9. National Uniform Claim Committee. 1500 Health Insurance Claim Form Reference Instruction Manual for Form Version 02/12. July 2022. Accessed December 6, 2022. https://www.nucc.org/ images/stories/PDF/1500_claim_form_instruction_manual_2022_07-v10a.pdf 10. Novitas Solutions. 837 Professional (Part B) 5010 expectations. Accessed December 6, 2022. https://www.novitas-solutions.com/ webcenter/content/conn/UCM_Repository/uuid/dDocName:00004779 11. Noridian Healthcare Solutions. Submitting claims when the billed amount exceeds \$99,999.99. August 8, 2022. Accessed December 6, 2022. https://med.noridianmedicare.com/web/jddme/claims-appeals/claim-submission/exceeds-99-999-99 12. Centers for Medicare & Medicaid Services. CMS-1450: Medicare Uniform Instructional Provider Bill and Supporting Regulations. July 19, 2019. Accessed December 6, 2022. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450 13. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 25 – Completing and Processing the Form CMS-1450 Data Set. Revised August 6, 2021. Accessed December 6, 2022. https://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/downloads/clm104c25.pdf



