Uplizna™ Billing and Coding Guide

uplizna™
inebilizumab-cdon

Sample Coding

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Type	Code	Description
ICD-10-CM*	G36.0	Neuromyelitis optica (Devic)
HCPCS*	J3590	Unclassified biologics (commercial and Medicare)
	C9399	Unclassified biologics (OPPS*: Medicare)
NDC*	10-digit: 72677-551-01 11-digit: 72677-0551-01	Inebilizumab, one carton containing three 100 mg/10 mL single-dose vials Check with carrier for NDC format requirements
CPT* (administration procedures)	96413	Injection and intravenous infusion chemotherapy, other highly complex drug or high complex biologic agent administration up to 1 hour, single or initial substance/drug
	96415	Injection and intravenous infusion chemotherapy, other highly complex drug or high complex biologic agent administration each additional hour (list separately in addition to code for primary procedure)
	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)

* ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; HCPCS = Healthcare Common Procedure Coding System; NDC = National Drug Code; CPT = Current Procedural Terminology; OPPS = Outpatient Prospective Payment System

These codes are not all inclusive. Appropriate codes vary by patient, payer and setting for care. Correct coding is the responsibility of the provider submitting the claim. Viela Bio does not make any representation or guarantee for reimbursement or coverage.

See Important Safety Information on Page 4.
Please see full Prescribing Information at www.Uplizna.com.

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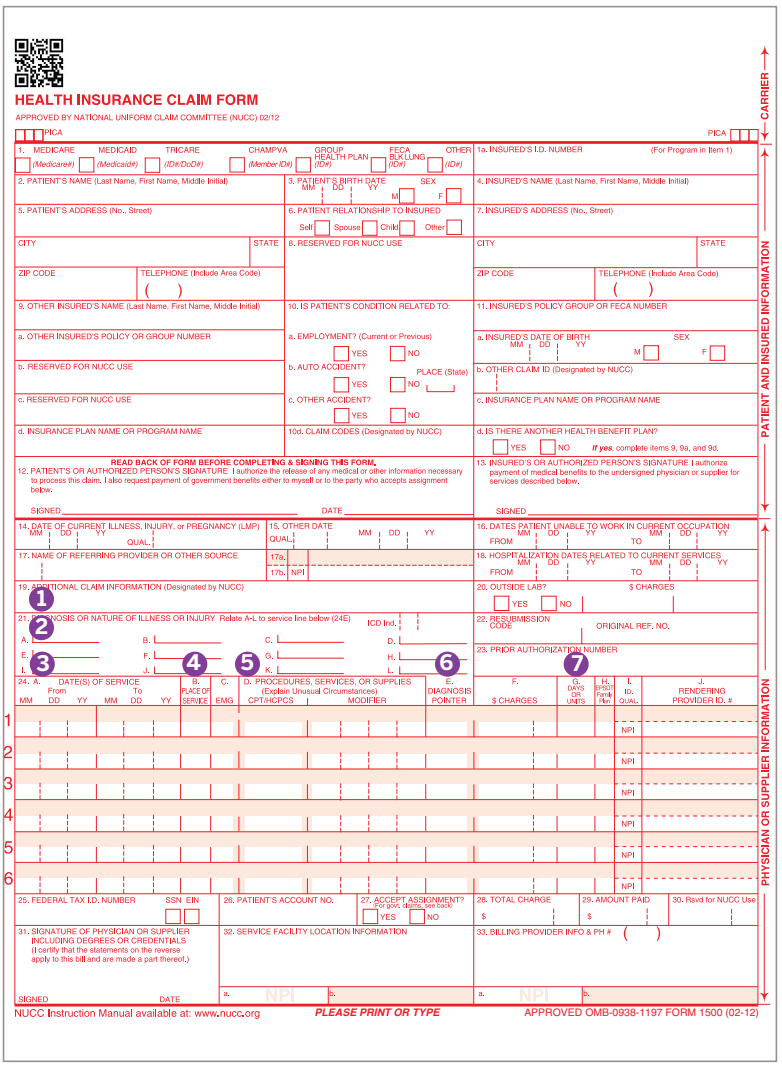
CMS-1500 and CMS-1450 Commercial and Medicare Coding

Procedure	CPT Code
Office visit, new patient	99201-99205
Office visit, established patient	99211-99215
Hospital outpatient visit (CMS-1450 Medicare only)	G0463
Prolonged service without direct patient contact by the physician or non-physician practitioner	99358

Please refer to the most current CPT code book for additional guidance.

Sample CMS-1500 Form

Use to submit claims to commercial insurance or Medicare for Uplizna administered in the physician's office



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

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

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From To MM DD YY MM DD YY | 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. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI

2 NPI

3 NPI

4 NPI

5 NPI

6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

1 Item 19

When completing a claim for a drug that does not have a permanent HCPCS code, include the drug name, drug strength, unit of measure, number of units administered, total dosage, route of administration, and 11-digit NDC. Information required may vary, please check with payer to confirm.

2 Item 21

Indicate the diagnosis using the ICD-10-CM code that supports medical justification for NMOSD (see page 1 for ICD codes).

3 Item 24A

If line item NDC information is required, enter it in the shaded portion of Item 24A.

4 Item 24B

Enter the applicable two digit Place of Service (POS) code based on the patient's administration site.

5 Item 24D

Indicate appropriate CPT and HCPCS codes. See pages 1 and 2 of this guide for codes.

6 Item 24E

Refer to the diagnosis for this service (see item 21 above). Enter only 1 diagnosis pointer per line.

7 Item 24G

Enter the number of units.

See Important Safety Information on Page 4.
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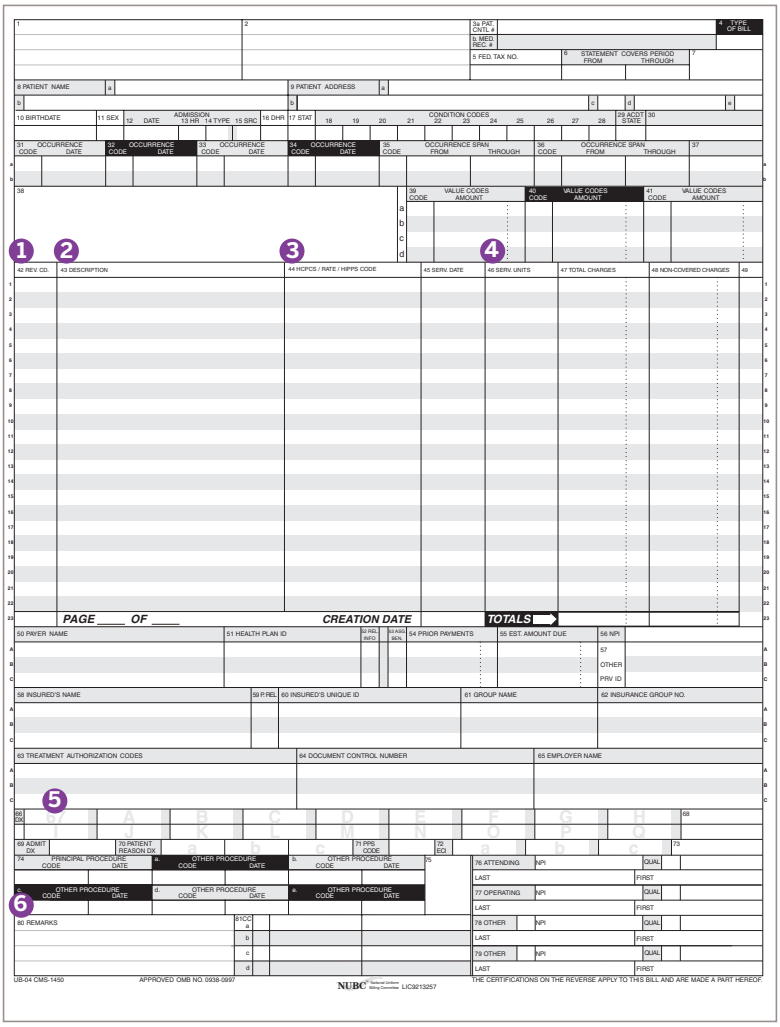
Sample CMS-1450 Form

Use to submit claims to commercial insurance or Medicare for Uplizna administered in the hospital outpatient setting



1 Locator Box 42
List revenue codes in ascending order.

2 Locator Box 43
Enter narrative description of corresponding revenue codes (eg, clinic, lab general). If line item NDC information is required, enter it in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.

3 Locator Box 44
Indicate appropriate CPT and HCPCS codes as required by the payer. See pages 1 and 2 of this guide for codes.

4 Locator Box 46
Enter the number of units. For billing Uplizna with a miscellaneous/unclassified HCPCS code (J3590), enter 1 unit.

5 Locator Box 67
Indicate the diagnosis using the ICD-10-CM code that supports medical justification for NMOSD (see page 1 for ICD codes).

6 Locator Box 80
When completing a claim for a drug that does not have a permanent HCPCS code, include the drug name, drug strength, unit of measure, number of units administered, total dosage, route of administration, and 11-digit NDC. Information required may vary, please check with payer to confirm.

If you have any questions, contact Viela VIPs at 833-842-8477.

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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.

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