Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Sample CMS-1500 Claim Form for CUVITRU™

Box 21: Enter the patient's diagnosis/condition based on the International Classification of Diseases-10 (ICD-10) code. Use the ICD-10 code to the highest level of specificity for the date of service. Enter diagnoses/conditions in priority order if applicable.[1]

Box 24: Medicaid and some commercial payers may require the National Drug Code (NDC) number in the shaded portion of the line item in fields 24A-24G. If applicable, the following should be entered: The qualifier "N4" (left-justified), immediately followed by the NDC number. Providers typically need to report the NDC number in an 11-digit format (eg, 0944-2850-01 would be reported as N400944285001).[1]

Next, the NDC should be followed by: a space for separation, followed by the dispensing unit of measure qualifier (eg, ML [milliliter]), immediately followed by the quantity (number of units up to 3 decimal places).[1]

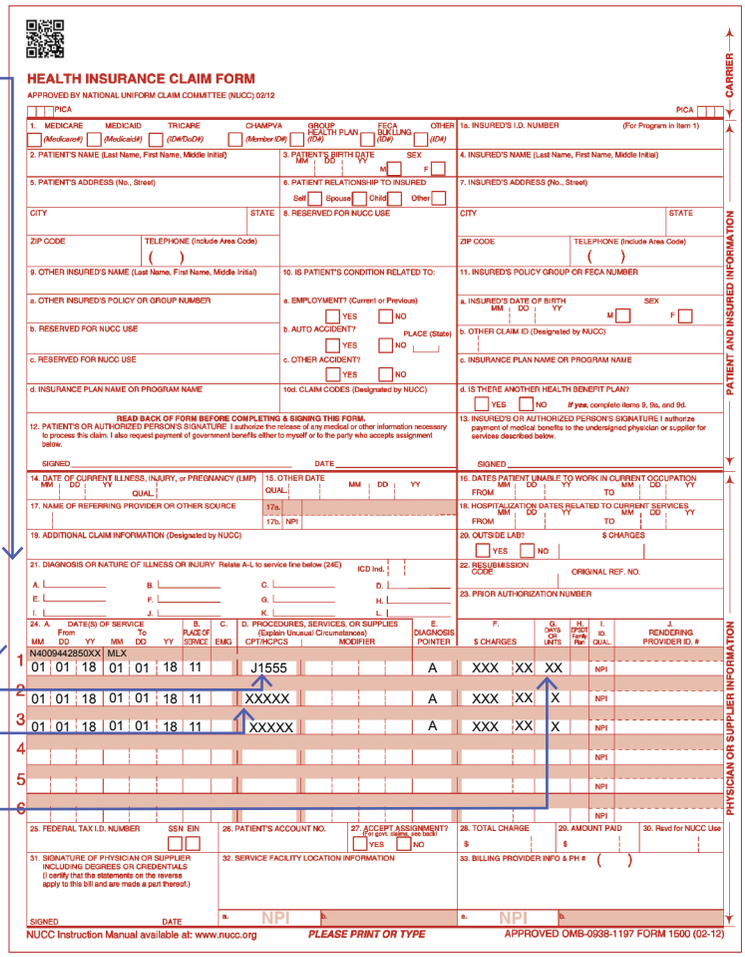
Box 24D Line 1: Unique CUVITRU Healthcare Common Procedure Coding System (HCPCS) code is **J1555** [Injection, immune globulin (CUVITRU), 100 mg], effective January 1, 2018.[2]

Box 24D Line 2: Appropriate Current Procedural Terminology (CPT) code to represent related administration procedure (refer to CPT codes listed on this page).[3]

Box 24G Line 1: Enter the number of J1555 billing units.[1,2]

The information contained here is provided for informational purposes only and is not intended to provide billing or coding instruction for a specific claim. Every reasonable effort has been made to verify the accuracy of the information, which is current as of December 2017.

It is the responsibility of healthcare providers to submit true, accurate, and complete claims for products and services rendered. Healthcare providers make the ultimate determination as to when to use a specific product based on clinical appropriateness for a particular patient. Third-party payment for medical products and services is affected by numerous factors, and Shire cannot guarantee success in obtaining insurance payments.



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 MM DD YY QUAL.

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 MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N4009442850XX MLX											
1 01 01 18	01 01 18	11		J1555		A	XXX	XX	XX		NPI
2 01 01 18	01 01 18	11		XXXXX		A	XXX	XX	X		NPI
3 01 01 18	01 01 18	11		XXXXX		A	XXX	XX	X		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

The following presentations of CUVITRU [Immune Globulin Subcutaneous (Human)] 20% are available.[4]

NDC Number	Volume	Grams Protein [Immune Globulin Subcutaneous (Human) 20%]	J1555-Billing Units [Injection, immune globulin (CUVITRU), 100mg][2]
0944-2850-01	5 mL	1.0	10 units
0944-2850-03	10 mL	2.0	20 units
0944-2850-05	20 mL	4.0	40 units
0944-2850-07	40 mL	8.0	80 units

CPT Code	Description[3]
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)

Indication

CUVITRU is an Immune Globulin Subcutaneous (Human) (IGSC), 20% Solution indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.

CUVITRU is for subcutaneous infusion only.

Important Safety Information

BOXED WARNING: THROMBOSIS

Thrombosis may occur with immune globulin products, including CUVITRU. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.

For patients at risk of thrombosis, administer CUVITRU at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Please scroll for additional Important Safety Information and click here for Full Prescribing Information.

Shire

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Important Safety Information (continued)

CONTRAINDICATIONS

CUVITRU is contraindicated in patients who have had an anaphylactic or severe systemic hypersensitivity reaction to the subcutaneous administration of human immune globulin and in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human immune globulin treatment.

WARNINGS and PRECAUTIONS

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human immune globulin. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Renal Dysfunction/Failure: Monitor renal function and urine output and consider lower, more frequent dosing in patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure.

Thrombosis: Monitor for signs and symptoms of thrombosis and assess blood viscosity for those at risk for hyperviscosity.

Aseptic Meningitis Syndrome (AMS): Monitor for clinical signs and symptoms of AMS.

Hemolysis: Monitor for clinical signs and symptoms of hemolysis and delayed hemolytic anemia.

Transfusion-Related Acute Lung Injury (TRALI): Monitor for pulmonary adverse reactions associated with TRALI.

Transmittable Infectious Agents: Because CUVITRU is made from human plasma, it may carry a risk of transmitting infectious agents, such as viruses and other pathogens. No confirmed cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with CUVITRU.

Interference with Laboratory Tests: False positive serological test results, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

ADVERSE REACTIONS

The most common adverse reactions observed in clinical trials in ≥ 5% of patients were: local adverse reactions, systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

Please click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

REFERENCES

1. Centers for Medicare and Medicaid Services. Transmittal 3083. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3083CP.pdf. Accessed November 27, 2017.
2. Centers for Medicare and Medicaid Services. 2018 Alpha-Numeric HCPCS. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-Alpha-Numeric-HCPCS-File-.html. Accessed November 27, 2017.
3. American Medical Association. Code manager. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=1&keyword=96369. Accessed November 27, 2017.
4. CUVITRU [Prescribing Information]. Westlake Village, CA: Baxalta US Inc.

S36719 12/17

Shire
www.shire.com