

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 Takeda cannot guarantee success in obtaining insurance payments.

Indication

CUVITRU is an Immune Globulin Subcutaneous (Human), 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.

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)



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 $\geq 5\%$ 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.