Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Billing and Coding Guide

CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% can be self-administered at home after training by a healthcare provider. Depending on your patient's preference, the reimbursement process will differ. This guide contains the following information necessary to bill payers for CUVITRU:

- Healthcare Common Procedure Coding System (HCPCS) codes
- National Drug Code (NDC) numbers
- Current Procedural Terminology (CPT®) codes
- The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes

The codes are not a comprehensive listing. The provider is responsible for ensuring accurate and appropriate diagnostic coding to obtain reimbursement. Please check with the payer to verify the codes and any special billing requirements.

INDICATION

CUVITRU is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years. CUVITRU is for subcutaneous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) 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.

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Administrative Codes

HCPCS CODES

J-Codes[1]

The most common Healthcare Common Procedure Coding System (HCPCS) codes are called J-codes, which are used to primarily identify an injectable drug product or biologic.[2]

J-Codes	Code Description
J1555	Injection, immune globulin (CUVITRU), 100 mg

DME and Supply Codes

HCPCS is divided into 2 principal subsystems, referred to as level I and level II of the HCPCS. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the Current Procedural Terminology (CPT®) codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.[3]

HCPCS Codes	Code Description
External Infusion Pump	
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, for infusion less than 8 hours
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single, or multi-channel
External Infusion Pump Supplies	
A4221	Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)
A4222	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
K0552	Supplies for external non-insulin drug infusion pump, syringe type cartridge, sterile, each

DME=durable medical equipment.

Please scroll for Important Safety Information including Boxed Warning regarding Thrombosis and click here for Full Prescribing Information.

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Administrative Codes

CPT Codes[4]

A Current Procedural Terminology (CPT®) code is a 5-digit number used to identify medical services and procedures performed by healthcare professionals (HCPs). These codes are maintained by the American Medical Association (AMA).[5]

Subcutaneous Administration

The following CPT codes apply to administration services performed by a healthcare provider concurrent with infusion.[4]

CPT Codes	Code Description
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	Each additional hour (list separately in addition to code for primary procedure)

NDC[6]

A National Drug Code (NDC) is a unique 3-segment number that serves as a universal product identifier for a drug.[7]

NDC	Volume	Grams Protein [Immune Globulin Subcutaneous (Human)] 20%	J1555-Billing Units[1] [Injection, immune globulin (CUVITRU), 100 mg Globulin Subcutaneous (Human)] 20%
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

Administrative Codes

ICD-10 Diagnostic Codes[8]

The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) are diagnostic codes that must be used for all healthcare services provided in the United States.[9] These ICD-10 codes are not an exhaustive list of all possible or required billing and coding options for CUVITRU and is not intended to provide reimbursement advice.

The provider is responsible for ensuring accurate and appropriate diagnostic coding to obtain reimbursement.

D80	Immunodeficiency With Predominantly Antibody Defects
D80.0	Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)
D80.1	Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.8	Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency
D80.9	Immunodeficiency with predominantly antibody defects, unspecified

Administrative Codes

ICD-10 Diagnostic Codes[8]

D81	Combined Immunodeficiencies
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified Severe combined immunodeficiency disorder [SCID] NOS

D83	Common Variable Immunodeficiency
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Combined variable immunodeficiency, unspecified

References

1. American Academy of Professional Coders. CPT® codes lookup. Accessed July 11, 2022. https://www.aapc.com/codes/cpt-codes-range

2. HCPCScodes.org. 2019 HCPCS codes: J codes. August 1, 2022. https://hcpcscodes.org/jcodes

3. Centers for Medicare and Medicaid Services. HCPCS coding questions. August 1, 2022. https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS_Coding_Questions

4. American Academy of Professional Coders. HCPCS codes lookup. Accessed July 11, 2022. https://www.aapc.com/codes/hcpcs-codes-range/

5. American Medical Association. CPT® overview and code approval. Accessed August 1, 2022. https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval

6. CUVITRU. Prescribing Information. Baxalta; 2022.

7. US Food and Drug Administration. National Drug Code database background information. August 1, 2022. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information

8. ICD Codes. ICD-10-CM chapters. Accessed July 11, 2022. https://www.cms.gov/files/zip/2022-code-tables-tabular-and-index-updated-02012022.zip

9. Centers for Disease Control and Prevention. International Classification of Diseases, (ICD-10-CM/PCS) transition – background. Last reviewed November 6, 2015. Accessed August 1, 2022. https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm

Important Safety Information (continued)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to subcutaneous administration of human IG.
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human IG.

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to starting infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome: Has been reported with use of IG and may occur more frequently in females. Conduct a thorough neurological exam on patients exhibiting signs and symptoms to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

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

Interference with Lab Tests: False positive serological test results and certain assay readings, 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 including mild or moderate pain, erythema, and pruritus, and systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella and varicella).

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

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