cutaquig®
Immune Globulin Subcutaneous (Human)-hipp, 16.5% solution

Billing and Coding Information

INDICATIONS AND USAGE

CUTAQUIG (Immune Globulin Subcutaneous [Human] - hipp) is a 16.5% immune globulin solution for subcutaneous infusion (IGSC), indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

SELECTED SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including CUTAQUIG. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. [*see Full Prescribing Information, Warnings and Precautions (5.2), Patient Counseling Information (17)*]**
- **For patients at risk of thrombosis, administer CUTAQUIG 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. [*see Full Prescribing Information, Warnings and Precautions (5.2)*]**

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for cutaquig. Coding and coverage policies change periodically and often without warning.

The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided in this document should not be considered a guarantee of coverage or reimbursement for cutaquig.

Please see Important Safety Information on pages 11-13 and click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Pfizerguide™

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Introduction and Pfizer IGuide™ Hub

For your patient claim submissions for cutaquig, Pfizer is committed to providing billing and coding information for the following FDA-approved indications:

Primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older[1]

We have developed this guide to provide you with general coding information and claims submission details for cutaquig.

Pfizer iguide™

When you've decided cutaquig is appropriate for your patient, Pfizer IGuide™ may help.

Enroll your patients in Pfizer IGuide™ for support

The Pfizer IGuide™ team can:

- Conduct a benefits verification to determine your patient's coverage for cutaquig including out-of-pocket costs
- Determine payer requirements and provide information about the prior authorization process and appeals process as needed*
- Enroll eligible patients within the cutaquig Co-Pay Program†

If you have any questions or need additional assistance, please call Pfizer IGuide™ at 1-844-448-4337, 8 AM to 8 PM ET, Monday through Friday

*Please note where a PA is required, the physician must submit required information directly to the patient's insurer.
†Terms and conditions apply. Patients must be 2 years or older to be eligible. Patients are not eligible if they are enrolled in a state or federal insurance program. Click here for full Terms and Conditions.

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Coding for Cutaquig

This section describes the types of codes that are likely to be most relevant to claims for cutaquig. Cutaquig is intended for subcutaneous use, using an infusion pump and compatible tubing and syringe(s).

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[2]

ICD-10-CM diagnosis codes are used for identifying and documenting a patient's specific diagnosis. These codes are used by all healthcare providers, and are recognized by all insurers.

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*
D80.2*	Selective deficiency of immunoglobulin A [IgA]
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
D81	**Combined immunodeficiencies**
D81.0*	Severe combined immunodeficiency [SCID] with reticular dysgenesis
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
D81.4	Nezelof's syndrome
D81.5*	Purine nucleoside phosphorylase [PNP] deficiency
D81.6*	Major histocompatibility complex class I deficiency *Bare lymphocyte syndrome*
D81.7*	Major histocompatibility complex class II deficiency
D81.89*	Other combined immunodeficiencies
D81.9*	Combined immunodeficiencies, unspecified *Severe combined immunodeficiency disorder [SCID] NOS*

*Medicare Part B-approved diagnosis codes for treatment with cutaquig in the home. All other diagnoses may qualify for coverage under Medicare Part D plans.[3]
NOS=not otherwise specified.

Table continues on the next page.

Please see Important Safety Information on pages 11-13 and click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Coding for Cutaquig (continued)

D82	**Immunodeficiency associated with major defects**
D82.0*	Wiskott-Aldrich syndrome *Immunodeficiency with thrombocytopenia and eczema*
D82.1*	Di George's syndrome *Pharyngeal pouch syndrome* *Thymic alymphoplasia* *Thymic aplasia or hypoplasia with immunodeficiency*
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus *X-linked lymphoproliferative disease*
D82.4*	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified
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*	Common variable immunodeficiency, unspecified
D84	**Other immunodeficiencies**
D84.9	Immunodeficiency, unspecified *Immunocompromised NOS* *Immunodeficient NOS* *Immunosuppressed NOS*
G11	**Hereditary ataxia**
G11.3*	Cerebellar ataxia with defective DNA repair *Ataxia telangiectasia [Louis-Bar]*

*Medicare Part B-approved diagnosis codes for treatment with cutaquig in the home.
All other diagnoses may qualify for coverage under Medicare Part D plans.[3]

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Coding for Cutaquig (continued)

Healthcare Common Procedure Coding System (HCPCS) Codes[4]

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and commercial payers. Cutaquig has a permanent J-code.

Code	Description
J1551	Injection, immune globulin (cutaquig), 100 mg
Additional information required by most payers on claim forms:	• Branded/generic name • Strength • Dosage administered • Route of administration • National Drug Code (NDC)
Some payers may also request:	• Package insert • Drug purchase invoice • Documentation to support medical necessity

Cutaquig National Drug Codes (NDC)[1]

An NDC is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. NDCs are used for billing drugs and biologicals.

Billing NDC	Carton NDC	Concentration
00069-1061-02	00069-1061-01	1 g/6 mL
00069-1476-02	00069-1476-01	2 g/12 mL
00069-1509-02	00069-1509-01	4 g/24 mL
00069-1965-02	00069-1965-01	8 g/48 mL

Current Procedural Terminology (CPT®)* Codes[5]

CPT codes describe the medical, surgical, diagnostic, and therapeutic services and procedures.

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	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
96371†	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump start-up with establishment of new subcutaneous infusion site(s) (list separately in addition to code for primary procedure)

†Can only be billed once per encounter.

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Coding for Cutaquig (continued)

Home Infusion Services[4-6]

HCPCS per diem S-codes are used by commercial and Medicaid payers to report drugs, services, and supplies. These codes are not payable by Medicare. Medicare may recognize G-codes for the professional services associated with home infusions.

Code	Description
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

The Medicare Home Infusion Therapy (HIT) services benefit covers professional services for the provision of home infusion drugs provided by a qualified HIT supplier. The following G-codes are established for the HIT benefit:

Code	Description
G0069	Professional services for the administration of subcutaneous immunotherapy of other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0089	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes

Used primarily by commercial payers, nursing visits are billable using the following codes:

Code	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)

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Coding for Cutaquig (continued)

Billing for Medicare Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs)[3]

The Medicare Part B DME benefit covers subcutaneously infused cutaquig for treatment for PI requiring an external infusion pump for administration. Suppliers of DME, supplies and drugs, submit Part B DME claims to the appropriate DME MAC using 837P, the electronic version of the CMS-1500 claim form.

Code	Description
J1551-JB	Injection, immune globulin (cutaquig), 100 mg

- To specify subcutaneous (SC) administration, Medicare requires the modifier-JB accompany the HCPCS code J1551 on claims billed to the DME MACs
- Unit of service: claims for cutaquig must be submitted using the HCPCS code J1551
- One unit of service equals one hundred (100) mg

Billing for External Pumps and Supplies[3,4]

When the billing provider furnishes an external infusion pump for patient use, the following codes may be used to bill for the pump if it meets the requirements of the code description.

Code	Description	Reimbursable for infusion of cutaquig under Medicare Part B?
External Infusion Pumps		
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater	Yes
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient	Yes
External Infusion Pump Supplies		
K0552	Supplies for external non-insulin drug infusion pump, syringe-type cartridge, sterile, each	Yes, in conjunction with E0779 pump
A4221	Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)	Yes
A4222	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)	Yes, in conjunction with E0781 pump

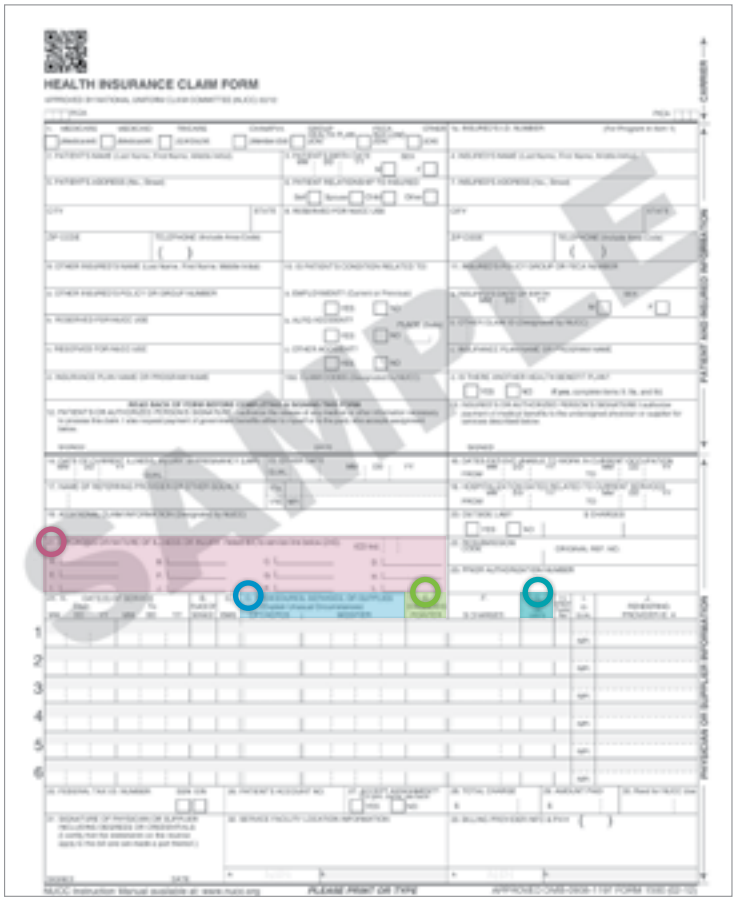
Codes are subject to change.

Please see Important Safety Information on pages 11-13 and click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Sample Health Insurance Claim Form

This section offers providers guidance in submitting accurate claims for administration of cutaquig.

Sample Health Insurance Claim Form (CMS-1500)



Item 21: Diagnosis or Nature of Illness or Injury

- Enter the applicable ICD indicator to identify which version of ICD codes is being reported
  - Enter "**0**" for ICD-10-CM between the vertical, dotted lines in the upper right-hand area of the field
- Enter appropriate ICD-10-CM diagnosis code(s) starting on Item 21, Line A

Item 24D: Procedures, Services, or Supplies

- Enter the CPT or HCPCS code(s) and modifiers from the appropriate code set in effect on the date of service
  - Enter applicable HCPCS codes **(J1551, S9338, G0089, G0069)**
  - Supplies: Enter code that best describes supplies provided **(K0552, A4221, A4222)**
  - Include CPT codes for infusion **(96369, 96370, 96371, 99601, 99602)**
- For Medicare claims, enter **Modifier-JB** (administered subcutaneously) on the same line as cutaquig **(J1551-JB)**

Item 24E: Diagnosis Pointer

- Enter the diagnosis code reference letter(s) (pointer) as shown in Item 21 to relate the date of service and the procedures performed to the primary diagnosis. **The reference letter(s) should be A–L**
- For Medicare claims, only 1-line letter from Item 21 should be entered in Item 24E for each HCPCS code reported in Item 24D

Item 24G: Days or Units

- Enter the number of units used for each line item
  - Cutaquig should be billed based on units, not the number of milligrams
  - One unit represents 100 mg of cutaquig, therefore, 1 g=10 units

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Cutaquig Co-Pay Program

cutaquig®
Immune Globulin Subcutaneous
(Human)-hipp, 16.5% solution

Cutaquig Co-Pay Assistance is Available for Eligible Patients*

Eligible, commercially insured patients may reduce out-of-pocket costs by up to $12,500 per year or the costs of a patient's co-pay in a 12-month period, whichever is less.

*Terms and conditions apply. Patients must be 2 years or older to be eligible. Patients are not eligible if they are enrolled in a state or federal insurance program.

Click here **for full Terms and Conditions.**

If you have any questions about the available co-pay assistance through the Cutaquig Co-Pay Program, please call Pfizer IGuide™ at 1-844-448-4337, 8 AM to 8 PM ET, Monday through Friday.

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Indications and Usage and Important Safety Information

INDICATIONS AND USAGE

CUTAQUIG (Immune Globulin Subcutaneous [Human] - hipp) is a 16.5% immune globulin solution for subcutaneous infusion (IGSC), indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including CUTAQUIG. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. [*see Full Prescribing Information, Warnings and Precautions (5.2), Patient Counseling Information (17)*]**
- **For patients at risk of thrombosis, administer CUTAQUIG 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. [*see Full Prescribing Information, Warnings and Precautions (5.2)*]**

Contraindications

CUTAQUIG is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the subcutaneous administration of human immune globulin or to any of the components of CUTAQUIG, such as Polysorbate 80, and in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.

Warnings and Precautions

Severe hypersensitivity reactions may occur with CUTAQUIG, even in patients who tolerated previous treatment with human immune globulin. If a hypersensitivity reaction occurs, discontinue the CUTAQUIG infusion immediately and initiate appropriate treatment. IgA-deficient patients with anti-IgA antibodies are at greater risk of severe reactions.

Thrombosis may occur following treatment with immune globulin products, including CUTAQUIG. For patients at risk of thrombosis, administer CUTAQUIG 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 for hyperviscosity.

Falsely elevated blood glucose readings may occur during and after the infusion of CUTAQUIG with some glucometer and test strip systems. When administering CUTAQUIG, measure blood glucose with a glucose-specific method.

Please click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Indications and Usage and Important Safety Information

IMPORTANT SAFETY INFORMATION (CONTINUED)

Warnings and Precautions (continued)

Aseptic meningitis syndrome (AMS) can occur with CUTAQUIG. AMS has been reported after the use of human immune globulin administered intravenously and subcutaneously and may occur within 2 days following treatment. Discontinuation of immunoglobulin treatment has resulted in remission within several days without sequelae.

Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with use of human immune globulin, especially those containing sucrose. CUTAQUIG does not contain sucrose.

Monitor patients for signs and symptoms of renal dysfunction. Monitor blood urea nitrogen, serum creatinine, and urine output in patients at risk of acute renal failure. Monitor CUTAQUIG recipients for clinical signs and symptoms of hemolysis, particularly patients with pre-existing anemia and/or cardiovascular or pulmonary compromise. Consider appropriate confirmatory laboratory testing if signs and symptoms of hemolysis are present after CUTAQUIG infusion.

Non-cardiogenic pulmonary edema may occur in patients administered human immune globulin products. Monitor for pulmonary adverse reactions. If transfusion-related acute lung injury is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient's serum.

CUTAQUIG is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease agent, and, theoretically, the Creutzfeldt-Jakob disease agent.

Adverse Reactions

The most common adverse reactions (≥5% of study subjects) were local infusion site reactions (such as redness, swelling, itching), headache, fever, dermatitis, asthma, diarrhea, and cough.

Drug Interactions

After infusion of CUTAQUIG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield false positive serological test results, with the potential for misleading interpretation.

The passive transfer of antibodies with immunoglobulin administration may interfere with the response to live virus vaccines such as measles, mumps, rubella, and varicella.

Please click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Indications and Usage and Important Safety Information

IMPORTANT SAFETY INFORMATION (CONTINUED)

Use in Specific Populations

It is not known whether CUTAQUIG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

No human data are available to indicate the presence or absence of drug-associated risk to lactation and breastfeeding.

Overall safety and efficacy findings in pediatric age group were comparable to those seen in adults. However, infusion site reactions were more commonly observed in adults compared to the pediatric population.

Safety and effectiveness of CUTAQUIG in pediatric patients below the age of 2 have not been established.

Clinical studies of CUTAQUIG did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, to reduce the risk of hyperviscosity and precipitation of cardiac, renal, or hepatic adverse reaction, and of concomitant disease or other drug therapy.

The risk information provided here is not comprehensive; see full Prescribing Information and Boxed Warning for CUTAQUIG.

You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Please click here for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

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