

Billing and Coding Information

OCTAGAM 10% INDICATIONS AND USAGE

OCTAGAM® 10% [Immune Globulin Intravenous (Human)] liquid is indicated for the treatment of chronic immune thrombocytopenic purpura (cITP) to rapidly raise platelet counts to control or prevent bleeding in adults and for dermatomyositis (DM) in adults.

SELECTED SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% liquid. 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.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10%. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.

OCTAGAM 5% INDICATIONS AND USAGE

OCTAGAM® 5% [Immune Globulin Intravenous (Human)] liquid is indicated for the treatment of primary humoral immunodeficiency (PI).

SELECTED SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 5% liquid. 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.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 5%. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 5% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 5% liquid 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.

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The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for OCTAGAM. 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 OCTAGAM.

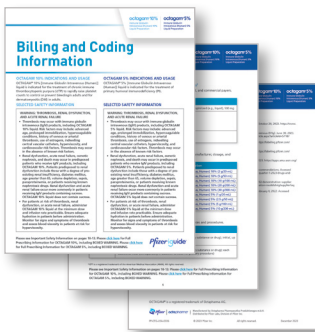
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Introduction and Pfizer IGuide™ Hub

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



- Primary humoral immunodeficiency (PI) in patients 2 years of age and older
- Chronic immune thrombocytopenia (cITP) in adults
- Dermatomyositis (DM) in adults



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



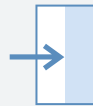
When you've decided OCTAGAM is appropriate for your patient, Pfizer IGuide™ may help.

Enroll your patients in Pfizer IGuide™ for support

The Pfizer IGuide™ team can:



Conduct a benefits verification to determine your patient's coverage for OCTAGAM 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 OCTAGAM 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 OCTAGAM

This section describes the types of codes that are likely to be most relevant to claims for OCTAGAM. OCTAGAM is a solution for infusion to be administered intravenously (IV) in a hospital, infusion center, doctor’s office, or at home by a trained healthcare provider.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes²

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.

ICD-10-CM	Description
DM	
M33.10	Other dermatomyositis, organ involvement unspecified
ITP	
D69	Purpura and other hemorrhagic conditions
D69.3	<i>Immune thrombocytopenia purpura Hemorrhagic (thrombocytopenic) purpura Idiopathic thrombocytopenic purpura Tidal platelet dysgenesis</i>
PI	
D80	Immunodeficiency with predominantly antibody defects
D80.0*	<i>Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)</i>
D80.1	<i>Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS</i>
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
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	<i>Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency</i>
D80.9	Immunodeficiency with predominantly antibody defects, unspecified

Table continues on the next page.

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

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Coding for OCTAGAM (continued)

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 <i>Bare lymphocyte syndrome</i>
D81.7*	Major histocompatibility complex class II deficiency
D81.89*	Other combined immunodeficiencies
D81.9*	Combined immunodeficiencies, unspecified <i>Severe combined immunodeficiency disorder [SCID] NOS</i>
D82	Immunodeficiency associated with major defects
D82.0*	Wiskott-Aldrich syndrome <i>Immunodeficiency with thrombocytopenia and eczema</i>
D82.1*	Di George's syndrome <i>Pharyngeal pouch syndrome</i> <i>Thymic aplasia</i> <i>Thymic aplasia or hypoplasia with immunodeficiency</i>
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus <i>X-linked lymphoproliferative disease</i>
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	Immunodeficiency, unspecified
D84.9	Immunodeficiency, unspecified
G11	Hereditary Ataxia
G11.3*	Cerebellar ataxia with defective DNA repair <i>Ataxia telangiectasia [Louis-Bar]</i>

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

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Coding for OCTAGAM (continued)

Healthcare Common Procedure Coding System (HCPCS) Codes²

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

Code	Description
J1568	Injection, immune globulin, (OCTAGAM), intravenous, non-lyophilized (e.g., liquid), 500 mg
Additional information required by most payers on claim forms:	<ul style="list-style-type: none"> • Branded/generic name • Strength • Dosage administered • Route of administration • National Drug Code (NDC)
Some payers may also request:	<ul style="list-style-type: none"> • Package insert • Drug purchase invoice • Documentation to support medical necessity

OCTAGAM National Drug Codes (NDC)^{3,4}

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
00069-6002-01	00069-6002-02	Octagam (Immune Globulin Intravenous, Human) 10% (2 g/20 mL)
00069-6550-01	00069-6550-02	Octagam (Immune Globulin Intravenous, Human) 10% (5 g/50 mL)
00069-6111-01	00069-6111-02	Octagam (Immune Globulin Intravenous, Human) 10% (10 g/100 mL)
00069-6237-01	00069-6237-02	Octagam (Immune Globulin Intravenous, Human) 10% (20 g/200 mL)
00069-6339-01	00069-6339-02	Octagam (Immune Globulin Intravenous, Human) 10% (30 g/300 mL)
00069-8400-01	00069-8400-02	Octagam (Immune Globulin Intravenous, Human) 5% (1 g/20 mL)
00069-8425-01	00069-8425-02	Octagam (Immune Globulin Intravenous, Human) 5% (2.5 g/50 mL)
00069-8451-01	00069-8451-02	Octagam (Immune Globulin Intravenous, Human) 5% (5 g/100 mL)
00069-8476-01	00069-8476-02	Octagam (Immune Globulin Intravenous, Human) 5% (10 g/200 mL)

Current Procedural Terminology (CPT®)* Codes⁵

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

Code	Description
96365	IV infusion, for therapy and prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour
96366	IV infusion, for therapy and prophylaxis or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)

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Coding for OCTAGAM (continued)

Codes for Home Infusion/Specialty Pharmacy

Home Infusion Therapy⁶

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. Use the SS modifier for items and services provided in the infusion suite of the home infusion therapy provider. See payer contract/billing guidelines for details..

HCPCS 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

IVIg Demonstration⁶⁻⁸

The Medicare IVIg Demonstration provides a bundled payment under Medicare Part B for items and services that are necessary for the in-home administration of IVIg for the treatment of PI. J1568 (Injection, immune globulin, [OCTAGAM], intravenous, non-lyophilized [e.g., liquid], 500 mg) is covered under the demonstration and should be used for OCTAGAM for dates of service prior to July 1, 2023. The demonstration has been extended through December 31, 2023. A permanent benefit for IVIg items and services begins January 1, 2024.

HCPCS Code	Description
Q2052	Services, supplies, and accessories used in the home under the Medicare IVIg demonstration

Codes are subject to change.

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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Sample Health Insurance Claim Form

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

Sample Health Insurance Claim Form (CMS-1500)

The image shows a sample CMS-1500 Health Insurance Claim Form. Key sections are annotated with colored circles and lines:

- Item 21 (Diagnosis or Nature of Illness or Injury):** A red circle highlights the ICD-10-CM code field (A-L).
- Item 24D (Procedures, Services, or Supplies):** A blue circle highlights the CPT/HCPCS code field (D).
- Item 24E (Diagnosis Pointer):** A green circle highlights the pointer field (E).
- Item 24G (Days or Units):** A blue circle highlights the units field (G).

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 (J1568, S9338)
 - Include applicable CPT codes for IV infusion (96365, 96366)

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
 - OCTAGAM should be billed based on units, not the number of milligrams
 - One unit represents 500 mg of OCTAGAM, therefore, 1 g=2 units

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octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

octagam® 5%

Immune Globulin
Intravenous (Human) 5%
Liquid Preparation

OCTAGAM Co-Pay Program

octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

octagam® 5%

Immune Globulin
Intravenous (Human) 5%
Liquid Preparation



OCTAGAM 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 OCTAGAM Co-Pay Program, please call Pfizer IGuide™ at 1-844-448-4337, 8 AM to 8 PM ET, Monday through Friday.

*Pfizer*iguide™

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OCTAGAM 10% Indication and Usage and Important Safety Information

INDICATIONS AND USAGE

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IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% liquid. 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.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10%. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.**

Dosing and Administration

Patients with dermatomyositis are at increased risk for thromboembolic events; monitor carefully and do not exceed an infusion rate of 0.04 mL/kg/min.

Contraindications

OCTAGAM 10% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Warnings and Precautions

OCTAGAM 10% liquid may cause hypersensitivity in patients with a corn allergy. OCTAGAM 10% liquid contains maltose, which is derived from corn.

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.

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OCTAGAM 10% Indication and Usage and Important Safety Information

IMPORTANT SAFETY INFORMATION (CONTINUED)

Warnings and Precautions (continued)

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 10% liquid.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 10% liquid. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 10% liquid, especially with high doses or rapid infusion.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 10% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

Adverse Reactions

cITP - The most common adverse reactions reported in >5% of study subjects were headache, fever, and increased heart rate.

DM - The most common adverse reactions reported in >5% of study subjects were headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, increased heart rate, dyspnea, and infusion site reactions.

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OCTAGAM 5% Indication and Usage and Important Safety Information

INDICATIONS AND USAGE

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IMPORTANT SAFETY INFORMATION

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- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 5%. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 5% liquid does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 5% liquid 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.**

OCTAGAM 5% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 5% liquid is contraindicated in patients with acute hypersensitivity reaction to corn. OCTAGAM 5% liquid contains maltose, a disaccharide sugar, which is derived from corn. Patients known to have corn allergies should avoid using OCTAGAM 5% liquid.

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 5% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 5% liquid.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 5% liquid, especially with high doses or rapid infusion.

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OCTAGAM 5% Indication and Usage and Important Safety Information

IMPORTANT SAFETY INFORMATION (CONTINUED)

Warnings and Precautions (continued)

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 5% liquid. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 5% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache and nausea. The most serious adverse reactions in treatment with OCTAGAM 5% liquid have been immediate anaphylactic reactions, aseptic meningitis, and hemolytic anemia.

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.

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References

1. National Center for Health Statistics. Comprehensive listing ICD-10-CM files. Accessed October 20, 2023. <https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>
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