

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: **Commercial (Traditional)** **Commercial Individual (Optimized)**

This request is: **Urgent** (life threatening) **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Immune Globulin (IVIG, SCIG)

Member and provider information

Last Name: _____

First Name: _____

ID #: _____

DOB: _____ Gender assigned at birth: _____

Primary Care Physician: _____

Prov. Phone: _____ Prov. Fax: _____

Requesting Provider: _____

Contact Name: _____

Provider Address: _____

Date: _____

Provider NPI: _____

Provider Signature: _____

The pages following this prior authorization form are the criteria Priority Health uses to make our coverage decision for this drug product for coverage. The prescriber must provide Priority Health with the documentation listed in the criteria, including, without limitation, the following information: (1) rationale for use, (2) progress notes (must include previous treatment failures and attempts to decrease the dose, if applicable), (3) history and examination (include history of significant infections), and (4) diagnostic tests (e.g. IgG, EMG, platelet count, spinal fluid tests, serum tests, biopsy findings).

Product and Billing Information

Intravenous Immune Globulin (preferred)*

- J1572 – Flebogamma/Flebogamma Dif
- J1569 – Gammagard Liquid/Gammagard ERC
- J1557 – Gammaplex
- J1561 – Gamunex-C/Gammaked
- J1568 – Octagam
- J1459 – Privigen

*Asceniv, Alyglo, Bivigam, Carimune, Gammagard S/D, Panzyga, Yimmugo not covered

Subcutaneous Immune Globulin (non-preferred)

- J1555 – Cuvitru
- J1551 – cutaquirig
- J1559 – Hizentra
- J1575 – HyQvia
- J1558 – Xembify

Start date (or date of next dose): _____

Route of administration: intravenous subcutaneous

Date of last dose (if applicable): _____

Patient's weight: _____

Dose (g/kg or mg/kg): _____

Patient's height: _____

Dosing frequency: _____

Trough IgG level: _____

Duration: _____

Date of IgG trough: _____

Number of nursing visits (if applicable): _____

ICD code(s): _____

Place of administration: Self-administered

Physician's office

Outpatient infusion

Facility: _____ NPI: _____ Fax: _____

Home infusion

Agency: _____ NPI: _____ Fax: _____

Billing: Physician to buy and bill
 Facility to buy and bill
 Specialty Pharmacy

Pharmacy: _____ NPI: _____ Fax: _____

IMMUNE GLOBULIN COVERAGE POLICY

Priority Health considers conditions not listed in the Immune Globulin Coverage Policy to be not medically necessary.

Required prescriber compliance

Compliance with the below statements is required for approval of an immune globulin request. Mark each box below to indicate you both understand and agree to the following:

- I agree to objectively monitor and document progress/improvement with immune globulin therapy. I understand that any requests to continue therapy will not be considered medically necessary without some type of objective quantitative assessment. Additionally, all requests for continuation of therapy must document the same baseline objective assessment performed prior to initiation of therapy.
- I agree to attempt to decrease/wean the dose for future requests when improvement has occurred and subsequently stop IVIG therapy if improvement is sustained with a dose reduction (this does not apply to authorizations for primary immunodeficiency as long as immunoglobulin levels are maintained in the appropriate range as referenced in Table 1).

Dosing requirements

Dosing should be calculated using adjusted body weight if the patient's:

- body mass index (BMI) is 30kg/m² or more; or
- actual body weight is 20% higher than his or her ideal body weight (IBW)

Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5 gram increment in adult patients):

Dosing formulas
BMI = 703 x (weight in pounds/height in inches ²)
IBW(kg) for males = 50 + [2.3 (height in inches – 60)]
IBW(kg) for females = 45.5 + [2.3 x (height in inches – 60)]
Adjusted body weight = IBW + 0.5 (actual body weight – IBW)

Refer to the covered dosing section of this policy for additional details about covered dosing.

Precertification requirements

Patient must meet all of the following criteria:

- Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings).
- Must provide documentation of previous treatment failures.
- In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect.
- Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage.

- Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary.
- If improvement does not occur with IVIG, continued infusion may not be considered medically necessary.
- The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the below diagnosis prior authorization criteria. Dosing recommendations are listed in Table 1.
- Coverage for subcutaneous immunoglobulin therapy requires trial and failure of at least one preferred intravenous immunoglobulin formulation listed above (i.e., poor venous access, documented adverse reactions).

The Medical Research Council (MRC) scale is the most commonly used grading of muscle strength.

Scale:

0	= no muscle improvement
1	= flicker of muscle movement
2	= trace movement but not able to fully overcome gravity
3	= just able to overcome gravity
4	= moves against resistance, but weak
5	= full strength against resistance

INCAT Disability scale of the arm or leg:

Arm disability:

0	= no upper limb problems
1	= symptoms, in one or both arms, not affecting the ability to perform any of the following functions: doing all zips and buttons; washing or brushing hair; using a knife and fork together; handing small coins
2	= symptoms, in one arm or both arms, affecting but not preventing any of the above mentioned functions
3	= symptoms, in one arm or both arms, preventing one or two of the above mentioned functions
4	= symptoms, in one arm or both arms, preventing three or all of the functions listed, but some purposeful movements still possible
5	= inability to use either arm for any purposeful movement

Leg disability:

0	= walking not affected
1	= walking affected, but walks independently outdoors
2	= usually uses unilateral support (stick, single crutch, one arm) to walk outdoors
3	= usually uses bilateral support (sticks, crutches, frame, two arms) to walk outdoors
4	= usually uses wheelchair to travel outdoors, but able to stand and walk a few steps with help
5	= restricted to wheelchair, unable to stand and walk a few steps with help

General documentation requirements

When requesting immune globulin for a patient not previously approved by Priority Health, the request must include the patient's history of previous therapies, when the therapies were tried, and the result of the therapies. Provide a relevant copy of the patient's medical record.

Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy.

Specific documentation requirements

Specific documentation requirements are listed under the following sections:

1. Primary immunodeficiency
2. Hematologic conditions
3. Neurological conditions
4. Autoimmune disorders
5. Dermatological conditions

Section 1: specific documentation requirements for primary immunodeficiency

Priority Health covers immune globulin for the following primary immunodeficiencies:

- Hypogammaglobulinemia, unspecified
- Selective IgM immunodeficiency
- Other selective immunoglobulin deficiencies
- X-linked agammaglobulinemia
- X-linked immunodeficiency with hyper IgM
- Combined immunodeficiency (SCID)
- Common variable hypoglobulinemia
- Wiskott-Aldrich Syndrome

For all primary immunodeficiencies and secondary immunosuppression, the following criteria must be met:

1. Patient's IgG level is less than 200 mg/dL

—or—

2. Patient has a history of *multiple hard to treat infections**;
3. The patient has a deficiency in producing antibodies in response to vaccination;
4. Baseline titers were drawn before challenging with vaccination; *and*
5. Titers were drawn between 4 and 8 weeks of vaccination (less than 70% of antigens are in protective range)

**Multiple hard to treat infections* means:

- a. four or more ear infections within 1 year;
- b. two or more serious sinus infections within 1 year;
- c. two or more months of antibiotics with little effect;
- d. two or more pneumonias within 1 year;
- e. recurrent or deep skin abscesses;
- f. need for intravenous antibiotics to clear infections; *or*
- g. two or more deep-seated infection including septicemia

In addition, for secondary immunosuppression, immune globulin is covered when the patient's hypogammaglobulinemia is caused by solid organ transplant, extensive surgery, allograft rejection, hematological malignancy, extensive burns, or collagen-vascular disease.

For chronic lymphoid leukemia (CLL), the following criteria must be met:

1. Patient has a history of *multiple hard to treat infections**;
2. The patient has a deficiency in producing antibodies in response to vaccination;
3. Baseline titers were drawn before challenging with vaccination; *and*
4. Titers were drawn between four and eight weeks of vaccination (less than 70% of antigens are in protective range)

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- b. two or more serious sinus infections within 1 year;
- c. two or more months of antibiotics with little effect;
- d. two or more pneumonias within 1 year;
- e. recurrent or deep skin abscesses;
- f. need for intravenous antibiotics to clear infections; *or*
- g. two or more deep-seated infection including septicemia

Section 2: specific documentation requirements for hematologic conditions

For **primary thrombocytopenia**, the following requirements must be met:

1. For treatment of acute ITP, a rapid rise in platelet count must be medically necessary. Medically necessary means:
 - a. immune globulin is used before surgery and the platelet count is less than 100,000/mm³;
 - b. patient has acute bleeding and platelet count is less than 30,000/mm³; *or*
 - c. patient is at risk for intracerebral hemorrhage (i.e. platelet is less than 20,000/mm³)
2. For treatment of chronic ITP, the patient:
 - a. must be age 10 or older;
 - b. must have a platelet count less than 30,000/mm³ for children or less than 20,000/mm³ for adults;
 - c. has illness present for more than six months; *and*
 - d. failed, has a contraindication to, or is intolerant to corticosteroid therapy

For renewals, achievement and maintenance of a platelet count equal to or greater than $50 \times 10^9/L$ and documented in the patient's medical record indicates a disease response.

For **ITP in pregnancy and fetal alloimmune thrombocytopenia**, one of the following criteria must be met:

1. the patient is refractory to steroids with a platelet count less than 10,000/mm³ during her third trimester;
2. the platelet count is less than 30,000/mm³ and associated with bleeding prior to vaginal delivery or C-section;
3. the patient previously delivered infants with autoimmune thrombocytopenia;
4. at 20 weeks gestation or later, cordocentesis reveals fetal platelets less than 20,000/mm³; *or*
5. screening reveals platelet alloantibodies

For **neonatal alloimmune thrombocytopenia**, immune globulin is not covered for routine use. Both of the following criteria must be met:

1. the patient is severely thrombocytopenic (i.e. a platelet count less than 30,000/mm³) and/or symptomatic; *and*
2. the neonate failed, has a contraindication to, or is intolerant to platelet transfusions

For **post-transfusion purpura**, one of the following criteria must be met:

1. platelet count is less than 10,000/mm³; *or*
2. the patient experienced bleeding complications due to thrombocytopenia

For **autoimmune hemolytic anemia**, immune globulin is not covered for routine use. All the following criteria must be met:

The patient:

1. has warm-type AIHA;
2. failed, has a contraindication to, or intolerance to corticosteroid therapy; *and*
3. had a splenectomy or is the patient at high risk for post-splenectomy sepsis

For **immune-mediated neutropenia**, which is not covered for routine use, all of the following criteria must be met:

The patient:

1. has a serious clinical infection related to neutropenia; *and*
2. failed to respond to both (1) corticosteroids and (2) filgrastim or pegfilgrastim therapies

For **anemia due to pure red cell aplasia secondary to chronic parvovirus B19 infection**, all of the following criteria must be met:

The patient:

1. has severe, refractory anemia;
2. has documented erythrovirus B19 viremia; *and*
3. was evaluated for underlying conditions that could lead to aplasia

For **anemia due to pure red cell aplasia, immunologic subtype**, the patient must have:

1. failed, have a contraindication to, or be intolerant to corticosteroid therapy;
2. failed, have a contraindication to, or be intolerant to cyclosporine; *and*
3. failed, have a contraindication to, or be intolerant to cyclophosphamide

For **allogeneic bone marrow or stem cell transplant**, all of the following criteria must be met:

1. Immune globulin is used for prevention of acute graft-versus-host disease or infection (e.g. cytomegalovirus); and
2. the transplant was between 0 to 99 days before starting immune globulin

Immune globulin is approved for allogeneic bone marrow or stem cell transplant for 3 months. Continuation of immune globulin is approved when:

- a. the patient's IgG is less than or equal to 400 mg/dL; *and*
- b. treatment duration does not exceed 360 days measured from the date of the transplant

For **complications of transplanted solid organ (e.g. heart, kidney, liver, lung, pancreas) or bone marrow transplant**, one of the following criteria must be met:

Immune globulin is used to:

1. suppress panel reactive anti-HLA antibodies prior to transplantation;
2. treat antibody mediated rejection of solid organ transplantation; *or*
3. prevent cytomegalovirus-induced pneumonitis

For **human immunodeficiency virus infection** (HIV): immune globulin is covered for patients with HIV to reduce significant bacterial infections in patients age 13 or younger who also have evidence of a *humoral immunologic defect** with presence of bacterial infections.

* *Humoral immunologic defect* means:

- a. recurrent serious bacterial infections despite appropriate prophylactic antibiotic therapy;
- b. demonstrated antibody deficiency to common antigens (i.e. measles, pneumococcal, and/or H. flue type B vaccine) as demonstrated by poor antibody titers;
- c. bronchiectasis suboptimally responsive to antimicrobial and pulmonary therapy; *or*
- d. HIV-associated thrombocytopenia despite antiretroviral therapy

Section 3: specific documentation requirements for neurological conditions

For **Guillain-Barré syndrome**, Priority Health considers immune globulin an equivalent alternative to plasma exchange in children and adults. Immune globulin is covered when all the following criteria are met:

1. The patient has severe disease and is requiring aid to stand and/or walk; *and*
2. Immune globulin is started within 4 weeks of symptom onset; *and*

The initial approval is limited to one dose. A maximum of two doses are covered. The second dose is covered when the patient has an inadequate response to the first dose of immune globulin and will be given within 3 weeks of the first dose.

For **myasthenia gravis** (MG), immune globulin is not covered for routine use. Coverage is limited to patients with severe MG to treat *acute, severe decompensation** when other treatments have been unsuccessful or are contraindicated and given concomitantly with either glucocorticoids or other immunosuppressive therapy (e.g. azathioprine, cyclosporine).

* *acute, severe decompensation* means the patient:

1. has myasthenic crisis (i.e. impending respiratory or bulbar compromise);
2. is experiencing disease exacerbation and/or decompensation, such as difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity;

When immune globulin is used to bridge immunosuppressive therapies, immune globulin is only covered until the immunosuppressive therapy takes effect, and the patient is:

1. unable to use or tolerate glucocorticoid therapy; *and*
2. being started on immunosuppressive therapies, such as azathioprine, mycophenolate, or cyclosporine

For **Eaton-Lambert syndrome**, all the following criteria must be met:

The patient:

1. failed, has a contraindication to, or has an intolerance to cholinesterase inhibitors used in combination with guanidine or an aminopyridine; *and*
2. failed, has a contraindication to, or has an intolerance to corticosteroid therapy and immunosuppressive therapy (e.g. azathioprine, cyclosporine)

For **polyneuropathy (chronic inflammatory demyelinating)**, all of the following criteria must be met:

1. The patient had a progressive or relapsing course of disease over at least 2 months;
2. The patient has abnormal or absent deep tendon reflexes in upper or lower limbs;
3. Baseline strength and weakness (and current strength and weakness for continuation requests) is documented in the patient's medical record using an objective clinical measuring tool (e.g. INCAT, MRC, 6-minute timed walking test, Rankin, Modified Rankin); *and*
4. Electrodiagnostic testing indicates demyelination, documented by one of the following demyelination criteria:
 - a. partial motor conduction block in two or more motor nerves or in one nerve plus one other demyelination criterion listed in (b)-(g) in one or more other nerves;
 - b. distal CMAP duration increase in one or more nerves plus one other demyelination criterion listed in (a) or (c)-(g) in one or more other nerves;
 - c. abnormal temporal dispersion conduction must be present in two or more motor nerves;
 - d. reduced conduction velocity in two or more motor nerves;
 - e. prolonged distal motor latency in two or more motor nerves;
 - f. absent F wave in two or more motor nerves plus one other demyelination criterion listed in (a)-(e) or (g) in one or more other nerves; or
 - g. prolonged F wave latency in two or more motor nerves

For **multifocal motor neuropathy**, all of the following criteria must be met:

1. The patient has progressive, symptomatic multifocal motor neuropathy (characterized limb weakness or motor involvement having a motor nerve distribution in at least two nerves);
2. Electrophysiological findings rule out other possible conditions that may not respond to immune globulin; *and*
3. Baseline strength and weakness (and current strength and weakness for continuation requests) is documented in the patient's medical record using an objective clinical measuring tool (e.g. INCAT, MRC, 6-minute timed walking test, Rankin, Modified Rankin)

For **stiff-man syndrome**, immune globulin is covered for patients with *severe active illness** when other treatment interventions have been *unsuccessful or intolerable*** and a baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam).

* *Severe active illness* means the patient is positive for anti-glutamic acid decarboxylase (GAD) antibody.

** *Unsuccessful or intolerable* treatment interventions means the patient failed, has a contraindication to, or intolerance to:

1. two or more benzodiazepine therapies;
2. baclofen; *and*
3. corticosteroid therapy

Section 4: specific documentation requirements for autoimmune disorders

Immune globulin is not covered for routine use in autoimmune disorders.

Immune globulin is covered for the following conditions for patients with severe active illness and other interventions have been unsuccessful or intolerable (i.e. the patient has treatment resistance to first- and second-line therapies).

For **dermatomyositis and polymyositis**, all of the below criteria must be met:

1. A baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam and improvement in CPK);
2. The condition is confirmed by biopsy; *and*
3. The patient:
 - a. has severe active disease state;
 - b. has muscle weakness in all upper and/or lower limbs;
 - c. failed, has a contraindication to, or intolerance to corticosteroid therapy; *and*
 - d. failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine

For **systemic sclerosis dermatomyositis overlap syndrome**, all the following criteria must be met:

1. the patient failed, has a contraindication to, or intolerance to corticosteroid therapy;
2. the patient failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine, methotrexate, cyclophosphamide, and cyclosporine; *and*
3. the prescriber must indication in advance what objective clinical endpoints will be used to determine efficacy of immune globulin therapy (Priority Health will use this criteria to evaluate ongoing effectiveness of treatment)

For **Kawasaki disease**, all of the following criteria must be met:

1. fever is present in patient for at least 5 days;
2. treatment is initiated within 10 days of onset of fever; *and*
3. concomitant aspirin treatment be given with immune globulin

For **severe vasculitic syndrome**, specify which syndrome the patient has: systemic (polyarteritis nodosa), Churg-Strauss Vasculitis, or livedoid vasculitis (atrophie blanche).

Section 5: specific documentation requirements for dermatologic conditions

Immune globulin is not covered for routine use in dermatologic conditions.

Priority Health considers immune globulin medically necessary for the following conditions:

1. Toxic epiderma necrolysis
2. Stevens-Johnson Syndrome, with or without toxic epidermal necrolysis overlap syndrome
3. Pyoderma gangrenosum, but only when the patient:
 - a. failed, has a contraindication to, or intolerance to corticosteroid therapy
 - b. failed, has a contraindication to, or intolerance to cyclosporine
 - c. first tried two of the following other treatments:
 - i. conventional immunosuppressive medications (in addition to cyclosporine)
 - ii. Dapsone
 - iii. minocycline
 - iv. TNF-alpha inhibitors
4. Autoimmune mucocutaneous blistering disease
5. Mucous membrane pemphigoid without ocular involvement
6. Mucous membrane pemphigoid with ocular involvement
7. Epidermolysis bullosa
8. linear IgA dermatosis

For **conditions listed in 4-11 above**, all the following criteria must be met:

- a. a baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam);

- b. the condition :
 - I. is rapidly progressing, extensive, or debilitating; *and*
 - II. has been confirmed by a biopsy
- c. *and* the patient:
 - I. failed, has a contraindication to, or intolerance to corticosteroid therapy
 - II. failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine

Additional information

1. Use of immune globulin in HLA-identical sibling transplants or autologous transplants is not considered medically necessary.
2. Additional conditions may be covered for members covered under an HMO/EPO, POS, PPO, ASO, Individual, or Medicaid policy, including:(LCD 996.85) allogenic bone marrow transplant in adults up to 4 months following transplantation,
 - a. (LCD 771.81, 771.83, 790.7) patients with established bacterial sepsis.
3. A diagnosis of high-risk pregnancy with history of previously affected infant with fetal-neonatal thrombocytopenia is not covered for members with a HMO/EPO, POS, PPO, ASO, Individual, or Medicaid policy.

Covered dosing

Indication	Initial dose (mg/kg)	Maintenance dose (mg/kg)	Frequency	Trough target (mg/dL)
Infectious diseases				
Kawasaki	400 mg/kg for 4 days or a single dose of 1-2 g/kg			
Pediatric HIV infection	400 mg/kg		every 28 days	
Autoimmune disorders				
Dermatomyositis & Polymyositis		1-2 g/kg	monthly	
Autoimmune mucocutaneous blistering diseases	up to 2 g/kg	up to 2 g/kg per course of therapy	Divided doses over 3 to 5 days every 3 to 4 weeks, monthly up to 6 months	
Neurological disorders				
Acute & demyelinating polyneuropathies, Guillain-Barre syndrome	400 mg/kg per day for 5 days	250-400 mg/kg	3 weeks	
CIDP		1 g/kg	3 weeks	NA
Multifocal motor neuropathy	400 mg/kg per day for 5 days	2 g/kg	6 weeks	NA- Objective evidence of improved EMG or improved muscle strength
		1 g/kg	3 weeks	
Multiple sclerosis (relapsing remitting)				
Myasthenia gravis & Lambert-Eaton myasthenia	400 mg/kg per day for 5 days	not covered	not covered	
Stiff person syndrome				
Cancer-related Treatments				
Allogenic bone marrow transplant	100-500 mg/kg		monthly	400-600 mg/dL
Chronic B-cell lymphocytic leukemia (CLL)				
Multiple myeloma				
Primary immunodeficiency disorders				
X-linked agammaglobulinemia, X-linked agammaglobulinemia with hyper-IgM, Hypogammaglobulinemia, Combined immunodeficiency syndromes (including Wiskott-Aldrich syndrome, SCID)	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	monthly intravenously — or — weekly subcutaneously	700-800 mg/dL — or — average of low and high (every 3 months)
Common variable immunodeficiency (CVID)	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	monthly intravenously — or — weekly subcutaneously	700-800 mg/dL — or — average of low and high
IgG subclass deficiency	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	400 mg/kg intravenously — or — 100 mg/kg subcutaneously	monthly intravenously — or — weekly subcutaneously	700-800 mg/dL — or — average of low and high
Acute idiopathic thrombocytopenia purpura (ITP)	1 g/kg over 1 or 2 consecutive days — or — 400 mg/kg over 2 to 5 consecutive days			
Chronic ITP	1 or 2 g/kg total over 2 to 5 days	800-1,000 mg/kg	every 2 to 6 weeks based on platelet counts	

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