

Prior Authorization Criteria  
**Immune Globulin Products**

All requests for Immune Globulin Products require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Immune Globulin Products include ASCENIV, BIVIGAM, Carimune, Carimune NF, Flebogamma, Flebogamma DIF, Gamimune N, Gammagard, Gammagard S/D, Gammaked, Gammplex, Gamunex, Gamunex-C, Octagam, Panzyga, Privigen, Cutaquig, Cuvitru, HyQvia, Hizentra, Xemblify, Gamastan, Gamastan S/D. New products with this classification will require the same documentation.

For all requests for Immune Globulin Products, all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines

Coverage may be provided with a diagnosis of **Common Variable Immunodeficiency (CVID)**, **Hypogammaglobulinemia** (excluding IgA deficiency), or **X-linked immunodeficiency with hyperimmunoglobulin M** if the following criteria are met:

- IgG level must be  $\leq 500$ mg/dL or more than 2 standard deviations below the age-specific mean on at least two occasions.
- Documented recurrent, severe, or unusual infections and poor response to antibiotics.
- Failure of prophylactic antibiotic therapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Member must have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Congenital Agammaglobulinemia (X-linked agammaglobulinemia)** or **Severe Combined Immunodeficiency (SCID)** if the following criteria are met:

- IgG levels must be  $\leq 200$ mg/dL.
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Member must have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Selective IgG subclass deficiency or Specific Antibody Deficiency (SAD)** if the following criteria are met:



- Normal total serum IgG, IgA, and IgM with deficiency of one or more IgG subclasses (as applicable) with levels more than 2 standard deviations below the age-specific mean assessed on at least two occasions.
- Documented recurrent, severe, or unusual infections and poor response to antibiotics.
- For Selective IgG subclass deficiency: Inadequate response to protein or polysaccharide antigens, as determined by appropriate titers
- For Specific Antibody Deficiency: Normal response to protein antigens and inadequate response to pneumococcal vaccines, as determined by appropriate titers
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Member must have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Wiskott-Aldrich Syndrome** if the following criteria are met:

- IgG level must be  $\leq 500\text{mg/dL}$  or more than 2 standard deviations below the age-specific mean on at least two occasions.
- Documented recurrent, severe, or unusual infections and poor response to antibiotics.
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Member must have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Acute Idiopathic Thrombocytopenic Purpura** if ONE of the following criteria is met:

- Member is using medication for management of acute bleeding due to severe thrombocytopenia (platelet counts less than  $30,000/\mu\text{l}$ )
- Member is using to increase platelet counts prior to invasive major surgical procedures.
- Member has severe thrombocytopenia (platelet counts less than  $20,000/\mu\text{l}$ ) considered to be at risk for intracerebral hemorrhage.
- **Initial Duration of Approval:** 5 days
- **Reauthorization Criteria:**
  - Member must be reevaluated for medical necessity for reauthorization.
- **Reauthorization Duration of Approval:** 5 days

Coverage may be provided with a diagnosis of **Chronic Idiopathic Thrombocytopenic Purpura** if the following criteria is met:

- Other causes of thrombocytopenia have been ruled out by history and peripheral smear.
- Member has diagnosis for  $\geq 3$  months with platelet counts persistently at or below  $20,000/\mu\text{l}$ .
- Member is contraindicated or refractory to glucocorticoid therapy
- **Initial Duration of Approval:** 5 days
- **Reauthorization Criteria:**



- Member must have documentation of clinical benefit from immune globulin therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **B-cell Chronic Lymphocytic Leukemia (CLL)** if the following criteria are met:

- Treatment is being used to prevent bacterial infections
- Member has an IgG levels of less than 600mg/dl or evidence of specific antibody deficiency.
- Member has recurrent bacterial infection as evidenced by one severe bacterial infection within preceding 6 months or at least two bacterial infections in a 1-year period.
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Member must have documentation of clinical benefit from immune globulin therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for the diagnosis of **Kawasaki disease** if the following criteria are met:

- Fever present for at least 5 days.
- Four of the following markers are present:
  - Mucous membrane changes such as a red tongue and dry fissured lips
  - Swelling of the hands and feet
  - Enlarged lymph nodes in the neck
  - Diffuse red rash covering most of the body
  - Redness of the eyes
  - CRP  $\geq 3.0$ mg/dL and ESR  $\geq 40$ mm/hr
  - Positive ECHO
- Oral aspirin is used concurrently until inflammatory markers normalize, unless contraindicated.
- **Initial Duration of Approval:** 2 weeks
- **Reauthorization Criteria:**
  - Member must have documentation that treatment with first infusion failed.
- **Reauthorization Duration of Approval:** 2 weeks

Coverage may be provided for the diagnosis of **chronic inflammatory demyelinating polyneuropathy (CIDP)** if the following criteria are met:

- Treatment is being used to improve neuromuscular disability and impairment
- Member has moderate to severe functional disability that affects activities of daily life with slowly progressive or relapsing course over 2 months or longer.
- Nerve conduction study has been completed showing diffuse demyelination.
- Member is intolerant or refractory to therapeutic doses of corticosteroids for a duration of 1 month.
- **Initial Duration of Approval:** 3 months
- **Reauthorization Criteria:**



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- Member must have documentation of clinical benefit from immune globulin therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for the diagnosis of **multifocal motor neuropathy** if the following criteria are met:

- Treatment is being used to improve muscle strength and disability
- Member has progressive, asymmetric limb weakness
- Member has definite conduction block on one motor nerve or probable conduction block on two or more motor nerves.
- Member has no objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs.
- The following signs of upper motor neuron involvement are absent: spastic tone, clonus, extensor plantar response and pseudobulbar palsy
- **Initial Duration of Approval:** 3 months
- **Reauthorization Criteria:**
  - Member must have documentation of clinical benefit from immune globulin therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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Updated: 10/2020  
PARP Approved: 01/2021

**IMMUNE GLOBULIN PRODUCTS  
PRIOR AUTHORIZATION FORM – PAGE 1 of 3**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health<sup>SM</sup> Pharmacy Services. **FAX:** (888) 245-2049  
If needed, you may call to speak to a Pharmacy Services Representative.  
**PHONE:** (800) 392-1147 Monday through Friday 8:30am to 5:00pm

**PROVIDER INFORMATION**

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

**MEMBER INFORMATION**

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

**REQUESTED DRUG INFORMATION**

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No		Date Medication Initiated:

**Billing Information**

This medication will be billed:  at a pharmacy **OR**  medically, JCODE: \_\_\_\_\_  
Place of Service:  Hospital  Provider's office  Member's home  Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

**MEDICAL HISTORY (Complete for ALL requests)**

Diagnosis:	ICD Code:
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- Primary Immunodeficiency, ICD10: \_\_\_\_\_
  - Common Variable Immunodeficiency (CVID) (aka Hypogammaglobulinemia, acquired agammaglobulinemia)
  - X-linked Immunodeficiency with Hyperimmunoglobulin M
  - Severe Combined Immunodeficiency (SCID)
  - Congenital agammaglobulinemia (aka Bruton or X-linked agammaglobulinemia)
  - Wiskott-Aldrich Syndrome
  - Selective IgG subclass deficiency
  - Specific Antibody Deficiency
  - Other: \_\_\_\_\_

Please provide the IgG level on 2 different dates: 1: \_\_\_\_\_ 2: \_\_\_\_\_

Does the member have recurrent, severe, or unusual infections and poor response to antibiotics?  Yes  No

Has prophylactic antibiotic therapy been tried?  Yes  No

For Selective IgG subclass deficiency and Specific Antibody Deficiency:

- Please provide the IgG subclass that is deficient and the current level: \_\_\_\_\_
- Does the member have inadequate response to protein or polysaccharide antigens per titers?  Yes  No
- Does the member have normal response to protein antigens and inadequate response to pneumococcal vaccines per titers?  Yes  No

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**IMMUNE GLOBULIN PRODUCTS  
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 3**

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**If needed, you may call to speak to a Pharmacy Services Representative.**

**PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm**

**MEMBER INFORMATION**

<b>Member Name:</b>	<b>DOB:</b>
<b>Gateway ID:</b>	<b>Member weight:</b>
	<b>Height:</b>

**MEDICAL HISTORY (Complete for ALL requests)**

Idiopathic Thrombocytopenic Purpura (ITP), ICD-10: \_\_\_\_\_

- Acute management of severe thrombocytopenia. Platelet count: \_\_\_\_\_
- Using prior to invasive surgical procedure. Please describe: \_\_\_\_\_
- Chronic treatment:
  - Have other causes of thrombocytopenia been ruled out?  Yes  No
  - Have corticosteroids been tried?  Yes  No
  - Has the member had platelet counts  $\leq 20,000/\mu\text{l}$ ?  Yes  No
    - If yes, how long have the platelet counts been that low?   $< 3$  months   $\geq 3$  months

Please provide the current platelet count: \_\_\_\_\_

B-cell Chronic Lymphocytic Leukemia (CLL), ICD-10: \_\_\_\_\_

- Is this being used to prevent bacterial infections?  Yes  No
- Please provide the IgG level: \_\_\_\_\_
- Does the member have a history of serious or recurrent bacterial infections?  Yes  No
  - How many severe bacterial infections in the past 6 months? \_\_\_\_\_

How many bacterial infections in the past year? \_\_\_\_\_

Kawasaki disease, ICD10: \_\_\_\_\_

- Does the member have a fever?  Yes  No
- How long has the fever been present?  Less than 5 days  5 days or longer
- Which of the following apply to the member?
  - Mucous membrane changes such as a red tongue and dry fissured lips
  - Swelling of the hands and feet
  - Enlarged lymph nodes in the neck
  - Diffuse red rash covering most of the body
  - Redness of the eyes
  - CRP  $\geq 3.0\text{mg/dL}$  and ESR  $\geq 40\text{mm/hr}$
  - Positive ECHO

Will this be used in combination with aspirin?  Yes  No

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), ICD10: \_\_\_\_\_

- Is treatment being used to improve neuromuscular disability and impairment?  Yes  No
- Does the member have moderate to severe functional disability that affects activities of daily living?  Yes  No
- How long has the functional disability been present?  Less than 2 months  2 months or more
- Has a nerve conduction study been completed?  Yes  No
  - Does the study confirm diffuse demyelination?  Yes  No

Have corticosteroids been tried for at least 1 month?  Yes  No

Multifocal motor neuropathy, ICD10: \_\_\_\_\_

- Is treatment being used to improve muscle strength and disability?  Yes  No
- Which of the following apply to the member?
  - Progressive, asymmetric limb weakness
  - Definite conduction block on at least one motor nerve
  - Probable conduction block on at least 2 motor nerves
  - No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs
  - Upper motor neuron involvement such as spastic tone, clonus, extensor plantar response, pseudobulbar palsy

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PARP Approved: 01/2021

**IMMUNE GLOBULIN PRODUCTS  
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 3 of 3**

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If needed, you may call to speak to a Pharmacy Services Representative.

PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

**MEMBER INFORMATION**

<b>Member Name:</b>	<b>DOB:</b>
<b>Gateway ID:</b>	<b>Member weight:</b> <b>Height:</b>

**CURRENT or PREVIOUS THERAPY**

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

**REAUTHORIZATION**

Has the member experienced a significant improvement with treatment?    Yes    No

For primary immunodeficiency indications: has there been a reduction in frequency or severity of infections?  
 Yes    No

**SUPPORTING INFORMATION or CLINICAL RATIONALE**


<b>Prescribing Provider Signature</b>	<b>Date</b>