HIGHMARK WHOLECARE

Updated: 05/2024
PARP Approved: 06/2024

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 Alyglo, Asceniv, Bivigam, Carimune, Carimune NF, Flebogamma, Flebogamma DIF, Gamimune N, Gammagard, Gammagard S/D, Gammaked, Gammaplex, 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 ≤500mg/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 ≤ 200mg/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 ≤500mg/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 Immune Thrombocytopenia (ITP, also known as 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/µl)
- Member is using to increase platelet counts prior to invasive major surgical procedures.
- Member has severe thrombocytopenia (platelet counts less than 20,000/µl) 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 Immune Thrombocytopenia (ITP, also known as 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 ≥3 months with platelet counts persistently at or below 20,000/µl.
- 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 ≥3.0mg/dL and ESR ≥40mm/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:**

        - 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 the diagnosis of **dermatomyositis** if the following criteria are met:

- Member is intolerant or refractory to therapeutic doses of BOTH of the following:
    - Corticosteroid
    - Immunosuppressant (e.g. azathioprine, methotrexate)
- **Initial Duration of Approval:** 4 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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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 Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 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? ☐ Yes ☐ 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:

For Primary Immunodeficiency, please indicate which type:

- ☐ 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

For dermatomyositis:

What has been tried: ☐ Corticosteroids ☐ Immunosuppressants (please indicate which ones below)

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MEMBER INFORMATION

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

MEDICAL HISTORY (Complete for ALL requests)

For Immune Thrombocytopenia (Idiopathic Thrombocytopenic Purpura ITP), indicate the reason for treatment:

- ☐ 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 ≤ 20,000/µl? ☐ Yes ☐ No
    - If yes, how long have the platelet counts been that low? ☐ < 3 months ☐ ≥ 3 months
  - Provide the current platelet count: _____

For B-cell Chronic Lymphocytic Leukemia (CLL):

- 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? _____

For Kawasaki disease:

- 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 ≥3.0mg/dL and ESR ≥40mm/hr
  - ☐ Positive ECHO
- Will this be used in combination with aspirin? ☐ Yes ☐ No

For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):

- 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

For Multifocal motor neuropathy:

- 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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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 3

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MEMBER INFORMATION

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

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has the member experienced clinical benefit from 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

Prescribing Provider Signature	Date