

IVIG AND SCIG Therapies

All requests for IVIG AND SCIG Therapies require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

IVIG AND SCIG Therapies Prior Authorization Criteria:

For all requests for IVIG AND SCIG Therapies all of the following criteria must be met:

Disclaimer: All requests for Intravenous (IVIG-Bivagam ®, Carimune NF ®, Flebogamama ® DIF, Gammagard®, Gammagard S/D ®, Gammaked ®, Gammaplex ®, Gamunex ®, Octagam ®, Privigen®) & Subcutaneous Immune Globulin (SCIG- Cuvitru ®, Gammagard ®, Gammaked®, Gamunex-C®, Hizentra®, HqQvia®) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided for all FDA approved indications. Certain diagnosis (es) may require additional criteria as listed below:

Indication	Medication
For the treatment of primary immunodeficiency (e.g., agammaglobulinemia or hypogammaglobulinemia)	Intravenous dosage (Bivigam) Adults, Adolescents, and Children 6 years and older Intravenous dosage (Carimune NF) Adults, Adolescents, Children, and Infants Intravenous dosage (Flebogamma 10%) Adults Intravenous dosage (Flebogamma 5% or Gammagard Liquid or Gammagard S/D) Adults, Adolescents, and Children 2 years and older Intravenous dosage (Gammaplex 5%) Adults, Adolescents, and Children 2 years and older Intravenous dosage (Gammaplex 10%) Adults Intravenous dosage (Gamunex-C or Gammaked) Adults, Adolescents, Children, and Infants Intravenous dosage (Octagam 5%)

	<p>Adults, Adolescents, and Children 6 years and older</p> <p>Intravenous dosage (Privigen) Adults, Adolescents, and Children 3 years of age and older</p> <p>Subcutaneous dosage (Gammagard Liquid 10%) Adults, Adolescents, and Children 2 years and older</p> <p>Subcutaneous dosage (Gamunex-C) Adults, Adolescents, and Children 2 years and older</p> <p>Subcutaneous dosage (Gammaked) Adults</p> <p>Cuvitru Adults, Adolescents, and Children 2 years and older</p> <p>Hizentra Adults, Adolescents, and Children 2 years and older</p> <p>Hyqvia Adults</p>
<p>For the treatment of immune thrombocytopenia/idiopathic thrombocytopenic purpura (ITP-chronic)</p>	<p>Intravenous dosage (Carimune NF) Adults, Infants, Children, and Adolescents</p> <p>Intravenous dosage (Flebogamma 10%) Adults, Adolescents, and Children 2 years and older</p> <p>Intravenous dosage (Gammagard S/D) Adults</p> <p>Intravenous dosage (Gammaked) Adults, Infants, Children, and Adolescents</p> <p>Intravenous dosage (Gamunex-C) Adults, Adolescents, Children, and Infants</p> <p>Intravenous dosage (Gammplex 5%)</p>

	<p>Adults</p> <p>Intravenous dosage (Gammaplex 10%) Adults</p> <p>Intravenous dosage (Octagam 10%) Adults</p> <p>Intravenous dosage (Privigen 10%) Adults and Adolescents 15 years and older</p>
Acute Idiopathic Thrombocytopenia	<p>Intravenous dosage (Carimune NF) Adults, Infants, Children, and Adolescents</p> <p>Intravenous dosage (Gammaked) Adults, Infants, Children, and Adolescents</p> <p>Intravenous dosage (Gamunex-C) Adults, Adolescents, Children, and Infants</p>
For bacterial infection prophylaxis in immunocompromised patients for the prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL)	<p>Intravenous dosage (Gammagard S/D) Adults, Adolescents, and Children</p>
For the treatment of Kawasaki disease	<p>Intravenous dosage (Gammagard S/D) Infants, Children, and Adolescents.</p>
For the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment	<p>Intravenous infusion dosage (Gamunex-C or Gammaked) Adults</p> <p>Intravenous infusion dosage (Privigen 10%) Adults</p> <p>Hizentra Adults</p>
For the maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability	<p>Intravenous dosage (Gammagard Liquid 10%) Adults</p>

For all requests for Intravenous Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies all of the following criteria must be met:

- There are documented clinical notes including appropriate positive findings on diagnostic testing and/or biopsy results.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of for the treatment of primary immunodeficiency and the following criteria is met:

- For diagnosis of Common Variable Immunodeficiency (CVID):
 - IgG level must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
 - IgA, or IgM level must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
 - Documented recurrent bacterial infections
 - Failure of prophylactic antibiotic therapy
 - **Initial Duration of Approval:** 3 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
- For diagnosis of Congenital Agammaglobulinemia (X-linked agammaglobulinemia):
 - IgA, IgG and IgM levels must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
 - Documented recurrent bacterial infections.
 - **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.
 - Documentation of IgG trough level measured prior to therapy.
 - Documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months.
 - **Reauthorization Duration of Approval:** 6 months
- For diagnosis of Hypogammaglobulinemia (excluding IgA deficiency):
 - IgG level must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
 - History of recurrent bacterial sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy or failure of prophylactic antibiotic therapy.
 - Attestation must be provided that underlying conditions such as asthma or allergic rhinitis that may predispose member to recurrent infections are medically managed where applicable.
 - **Initial Duration of Approval:** 3 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 month
- For diagnosis of Selective IgG subclass deficiency:
 - Deficiency of one or more IgG subclasses below the normal range (more than 2 standard deviations below the age-specific mean) assessed on at least two occasions.
 - Unexplained recurrent or persistent severe bacterial infections despite appropriate treatment.
 - Inadequate response to protein and/or polysaccharide antigens, as determined by ONE of the following:
 - Documented inability to mount an antibody response to protein antigens (Serum antibody titers to tetanus and / or diphtheria should be obtained prior to immunization with diphtheria and / or tetanus vaccine and 3 to 4 weeks after immunization. An inadequate response is defined as less than a 4-fold rise in antibody titer and lack of protective antibody level).
 - Documented inability to mount an adequate antibody response to polysaccharide antigens (Serum antibody titers to ≥ 14 pneumococcus serotypes should be measured prior to immunization and 4 to 8 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine. An inadequate response is defined as less than a 4-fold rise in titer over baseline in at least 30 % of serotypes tested (in at least 50 % of serotypes tested in children aged 2 to 5 years) and lack of protective antibody level [i.e., specific IgG concentration less than 1.3 mcg/ml]).
 - **Initial Duration of Approval:** 3 months
 - **Reauthorization Criteria:**
 - Member must have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections.
 - Member must be reevaluated for medical necessity of immune globulin one year after initiating therapy.
 - **Reauthorization Duration of Approval:** 9 months
- For diagnosis of Severe Combined Immunodeficiency (SCID):
 - Laboratory findings of all the following below the normal reference range: T cells, IgA, IgE and IgM
 - **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.
 - Documentation of IgG trough level measured prior to therapy.
 - Documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months.
 - **Reauthorization Duration of Approval:** 6 months
- For diagnosis of Specific Antibody Deficiency (SAD):

- Documented normal serum IgG, IgA, and IgM.
- Normal responses to protein antigens (tetanus and diphtheria toxoid or HiB) measured 3 – 4 weeks after immunization.
- Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by:
 - Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
 - Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
- Unexplained recurrent or persistent severe bacterial infections despite appropriate treatment.
- **Initial Duration of Approval:** 3 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

- For diagnosis of Wiskott-Aldrich Syndrome
 - Documented recurrent or serious bacterial infections.
 - **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:** 6 months

- For diagnosis of X-linked immunodeficiency with hyperimmunoglobulin M
 - IgG levels must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
 - Documented recurrent bacterial infections.
 - **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.
 - Documentation of IgG trough level measured prior to therapy.
 - Documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 month.
 - **Reauthorization Duration of Approval:** 6 months.

Coverage may be provided with a diagnosis of for the treatment of Acute Idiopathic Thrombocytopenia Purpura and the following criteria is met:

- Member must meet ONE of the following
 - Member is using medication for management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/ μ l)
 - Member is using medication to increase platelet counts prior to invasive major surgical procedures.

- Member has severe thrombocytopenia (platelet counts less than 20,000/ μ l) considered to be at risk for intracerebral hemorrhage.
- **Initial Duration of Approval:** 5 days, must be reevaluated for medical necessity for reauthorization.

Coverage may be provided with a diagnosis of for the treatment of Chronic Idiopathic Thrombocytopenia Purpura and the following criteria is met:

- Other causes of thrombocytopenia have been ruled out by history and peripheral smear.
- Member is unresponsive to four days of corticosteroid therapy.
- Member must meet ONE of the of the following:
 - Member has had a splenectomy.
 - Member is obtaining IVIG to defer or avoid splenectomy.
- Platelet counts persistently at or below 20,000/ μ l.
- **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 bacterial infection prophylaxis in immunocompromised patients for the prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL) and the following criteria is met:

- Member has an immunoglobulin G (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:** 3 months
- **Reauthorization Criteria:**
 - Member must have documentation of active disease.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for the treatment of Kawasaki disease and the following criteria is met:

- Fever present for at least 5 days.
- Member must meet ONE of the following:
 - Treatment is initiated within ten days of onset of fever.
 - If diagnosis is made more than 10 days after onset of the diagnosis, member has fever or coronary abnormalities in the presence of clinical and laboratory signs (elevated C-reactive protein, and/or elevated erythrocyte sedimentation rate) of ongoing inflammation.
- Four of the following five symptoms 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
- Member must be receiving concurrent high-dose aspirin therapy.
- **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 treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment:

- Symmetric or focal neurologic deficits with slowly progressive or relapsing course over 2 months or longer with neurophysiological abnormalities.
- Nerve conduction study 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 with a for the maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability:

- Member has ONE of the following progressive symptoms present for at least 1 months:
 - Asymmetric limb weakness
 - Motor involvement having a motor nerve distribution in two or more nerves.
- Member has no objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs.
- Member has definite or probable conduction block on one nerve.
- Normal sensory nerve conduction in upper limb segments with CB and normal sensory nerve action potential (SNAP) amplitudes.
- **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.



Updated: 07/2018
PARP Approved: 07/2018

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.

**Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
PRIOR AUTHORIZATION FORM – PAGE 1 of 5**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM 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:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

DOSING INFORMATION

Member Height: _____ inches	Member weight: _____ pounds or _____ kg
Member BMI: _____	If BMI <30; Ideal Body Weight: _____ If BMI >30; Actual Body Weight: _____

Is the ideal/adjusted body weight appropriate to use as the member's dosing weight? Yes No
If yes, the member's ideal/adjusted body weight will be used to calculate the member's dose. If no, the member's actual body weight will be used to calculate the dose.

Prescribed dose (mg/kg): _____

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
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 (if medically please provide a 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-10 code:** _____

Does the member have documented clinical notes including appropriate positive findings on diagnostic and/or biopsy results?
 Yes No

For Common Variable Immunodeficiency (CVID):

Does the member have IgG, IgA, and IgM levels below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions? Yes No

Does the member have documented recurrent bacterial infections? Yes No

Does the member have failure to prophylactic antibiotic therapy? Yes No

For Congenital Agammaglobulinemia (X-linked agammaglobulinemia):

Does the member have IgG, IgA, and IgM levels below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions? Yes No

Does the member have documented recurrent bacterial infections? Yes No

For Hypogammaglobulinemia (excluding IgA deficiency):

Does the member have IgG levels below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions? Yes No

**Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
PRIOR AUTHORIZATION FORM – PAGE 2 of 5**

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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

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

MEDICAL HISTORY (Complete for ALL requests) - CONTINUED

For Hypogammaglobulinemia (excluding IgA deficiency) - continued:

Does the patient have a history of recurrent bacterial sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy or was there failure of prophylactic antibiotic therapy? Yes No
Are underlying conditions such as asthma or allergic rhinitis that may predispose member to recurrent infections being medically managed where applicable? Yes No

For Selective IgG subclass deficiency:

Does the member have a deficiency of one or more IgG subclasses below the normal range (more than 2 standard deviations below the age-specific mean) assessed on at least two occasions? Yes No

Does the member have unexplained recurrent or persistent severe bacterial infections despite appropriate treatment?

Yes No

Does the member inadequate response to protein and polysaccharide antigens, as determined by ALL of the following?

- Documented inability to mount an antibody response to protein antigens (Serum antibody titers to tetanus and / or diphtheria should be obtained prior to immunization with diphtheria and / or tetanus vaccine and 3 to 4 weeks after immunization. An inadequate response is defined as less than a 4-fold rise in antibody titer and lack of protective antibody level).
- Documented inability to mount an adequate antibody response to polysaccharide antigens (Serum antibody titers to ≥ 14 pneumococcus serotypes should be measured prior to immunization and 3 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine. An inadequate response is defined as less than a 4-fold rise in titer over baseline in at least 30 % of serotypes tested (in at least 50 % of serotypes tested in children aged 2 to 5 years) and lack of protective antibody level [i.e., specific IgG concentration less than 1.3 mcg/ml]).

Yes No

For Severe Combined Immunodeficiency:

Does the member have laboratory findings of all the following below the normal reference range: T cells, IgA, IgE and IgM ?

Yes No

Does the member have documented recurrent or serious bacterial infections directly attributable to this deficiency? Yes No

For Specific Antibody Deficiency (SAD):

Does the member have documented normal serum IgG, IgA, and IgM? Yes No

Does the member have normal responses to protein antigens (tetanus and diphtheria toxoid or HiB) measured 3 – 4 weeks after immunization? Yes No

Does the member have inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by ONE of the following?

- Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
- Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).

Yes No

Does the member have inadequate responsiveness to pneumococcal conjugate vaccine (Prevnar 13®) 4–8 weeks after vaccination as defined by ONE of the following?

- Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
- Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).

Yes No

Does the member have unexplained recurrent or persistent severe bacterial infections despite appropriate treatments? Yes No

For Wiskott-Aldrich Syndrome:

Does the member have IgG level below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions? Yes No

Does the member have documented recurrent or serious bacterial infections? Yes No

**Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
PRIOR AUTHORIZATION FORM – PAGE 3 of 5**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM 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

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

MEDICAL HISTORY (Complete for ALL requests) - CONTINUED

For X-linked immunodeficiency with hyperimmunoglobulin M:

Does the member have IgG levels below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions? Yes No
Is there documented recurrent bacterial infections? Yes No

For Acute Idiopathic Thrombocytopenia Purpura:

Is member using medication for management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/ μ l) and to increase platelet counts prior to invasive major surgical procedures? Yes No
Does member have severe thrombocytopenia (platelet counts less than 20,000/ μ l) considered to be at risk for intracerebral hemorrhage? Yes No

For Chronic Idiopathic Thrombocytopenia Purpura:

Have other causes of thrombocytopenia been ruled out by history and peripheral smear? Yes No
Is member unresponsive to four days of corticosteroid therapy? Yes No
Has member had a splenectomy? Yes No
Is member obtaining IVIG to defer or avoid splenectomy? Yes No
Are platelet counts persistently at or below 20,000/ μ l? Yes No

For Bacterial infection prophylaxis in immunocompromised patients for the prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL)

Does member have an immunoglobulin G (IgG) level less than 600mg/dl or does member have evidence of specific antibody deficiency? Yes No
Does member have 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? Yes No

For Kawasaki Disease:

Has the fever been present for at least 5 days? Yes No
Will treatment be initiated within 10 days of onset of fever? Yes No
Which of the following symptoms be present? *Please select all that 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

Will oral aspirin be used concurrently as follows: oral aspirin 100 mg/kg daily until the 14th day of illness, then 3-5 mg/kg for a period of five weeks? Yes No

For treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment:

Does the member have symmetric or focal neurologic deficits with slowly progressive or relapsing course over 2 months or longer with neurophysiological abnormalities? Yes No
Does the member have a nerve conduction study showing diffuse demyelination? Yes No
Is the member intolerant or refractory to therapeutic doses of corticosteroids for a duration of 1 month? Yes No

For maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability:

Is member 18 years of age or older? Yes No

**Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
PRIOR AUTHORIZATION FORM – PAGE 4 of 5**

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

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

MEDICAL HISTORY (Complete for ALL requests) - CONTINUED

For maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability - continued:

Does the member have ONE of the following progressive symptoms present for at least 2 months? Yes No

- Asymmetric limb weakness
- Motor involvement having a motor nerve distribution in two or more nerves.

Does member have objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs?
 Yes No

Does member have definite conduction block on one nerve or probable conduction block on two nerves? Yes No

Does member have normal sensory nerve conduction in upper limb segments with CB and normal sensory nerve action potential (SNAP) amplitudes? Yes No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

For Common Variable Immunodeficiency (CVID):

Does the member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? Yes No

For Congenital Agammaglobulinemia (X-linked agammaglobulinemia):

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

Does member have documentation of IgG trough level measured prior to therapy? Yes No

Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? Yes No

For Hypogammaglobulinemia (excluding IgA deficiency):

Does the member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? Yes No

For Selective IgG subclass deficiency:

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

For Severe Combined Immunodeficiency:

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

Does member have documentation of IgG trough level measured prior to therapy? Yes No

Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? Yes No

For Specific Antibody Deficiency (SAD):

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

**Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
PRIOR AUTHORIZATION FORM – PAGE 5 of 5**

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

REAUTHORIZATION - CONTINUED

For Wiskott-Aldrich Syndrome:

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

Does member have documentation of IgG trough level measured prior to therapy? Yes No

Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? Yes No

For X-linked immunodeficiency with hyperimmunoglobulin M:

Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections?
 Yes No

Does member have documentation of IgG trough level measured prior to therapy? Yes No

Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? Yes No

For Chronic Idiopathic Thrombocytopenia Purpura:

Does member have clinical documentation of clinical benefit from immune globulin therapy? Yes No

For Bacterial infection prophylaxis in immunocompromised patients for the prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL):

Does member have documentation of active disease? Yes No

For Kawasaki Disease:

Does member have documentation that treatment with first infusion failed? Yes No

For treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment:

Does member have clinical documentation of clinical benefit from immune globulin therapy? Yes No

For maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability:

Does member have clinical documentation of clinical benefit from immune globulin therapy? Yes No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date