Updated: 08/2019
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Request for Prior Authorization for Intravenous Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Intravenous Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Intravenous Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies Prior Authorization Criteria:
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%) Adults, Adolescents, and Children 6 years and older Intravenous dosage (Privigen)

	Adults, Adolescents, and Children 3 years of age and older Intavenous dosage (Asceniv) Adults and Adolescents 12 years of age or older Subcutaneous dosage (Gammagard Liquid 10%) Adults, Adolescents, and Children 2 years and older Subcutaneous dosage (Gamunex-C) Adults, Adolescents, and Children 2 years and older Subcutaneous dosage (Gammaked) Adults Cuvitru Adults, Adolescents, and Children 2 years and older Hizentra Adults, Adolescents, and Children 2 years and older Hyqvia Adults
For the treatment of immune thrombocytopenia/idiopathic thrombocytopenic purpura (ITP-chronic)	Intravenous dosage (Carimune NF) Adults, Infants, Children, and Adolescents Intravenous dosage (Flebogamma 10%) Adults, Adolescents, and Children 2 years and older Intravenous dosage (Gammagard S/D) Adults Intravenous dosage (Gammaked) Adults, Infants, Children, and Adolescents Intravenous dosage (Gamunex-C) Adults, Adolescents, Children, and Infants Intravenous dosage (Gammaplex 5%)

	Adults Intravenous dosage (Gammaplex 10%) Adults Intravenous dosage (Octagam 10%) Adults Intravenous dosage (Privigen 10%) Adults and Adolescents 15 years and older
Acute Idiopathic Thrombocytopenia	Intravenous dosage (Carimune NF) Adults, Infants, Children, and Adolescents Intravenous dosage (Gammaked) Adults, Infants, Children, and Adolescents Intravenous dosage (Gamunex-C) Adults, Adolescents, Children, and Infants
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)	Intravenous dosage (Gammagard S/D) Adults, Adolescents, and Children
For the treatment of Kawasaki disease	Intravenous dosage (Gammagard S/D) Infants, Children, and Adolescents.
For the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment	Intravenous infusion dosage (Gamunex-C or Gammaked) Adults Intravenous infusion dosage (Privigen 10%) Adults Hizentra Adults
For the maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability	Intravenous dosage (Gammagard Liquid 10%) Adults

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.

- For non-preferred agents, the member has had a trial and failure of a preferred agent or submitted a clinical reason for not having a trial of a preferred agent
- 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, IgA, 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 agmammaglobulinemia):
  - 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 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]).
  - 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
  - Documented recurrent or serious bacterial infections directly attributable to this deficiency.
  - 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).
  - Inadequate responsiveness to pneumococcal conjugate vaccine (Prevnar 13®) 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
  - IgG level must be below the normal range (more than 2 standard deviations below the age-specific mean) on at least two occasions.
  - 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.
    - 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 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 Purpora 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/µl) and 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, must be reevaluated for medical necessity for reauthorization.

Coverage may be provided with a diagnosis of for the treatment of Chronic Idiopathic Thrombocytopenia Purpora 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/µl.
- 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.
- Treatment is initiated within ten days of onset of fever.
- 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
- Oral aspirin is 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.
- 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 must be 18 years of age or older.
- Member has ONE of the following progressive symptoms present for at least 2 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 conduction block on one nerve or probable conduction block on two nerves.
- 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 with a diagnosis of PANDAS (pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections) and the following criteria is met:

- Member is between the ages of 3 and 13 years of age.
- Member must have a diagnosis of obsessive compulsive disorder, a tic disorder, or both
- Member must have moderate or greater severity of symptoms, with a score of greater than or equal to 20 on the Children s Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) and greater than or equal to 4 on the Clinical Global Impression Severity scale (CGI-S).
- Member must have acute onset within the previous six months of symptoms in a member that was previously well, or the first acute recurrence within the previous six months, after a period of relatively complete remission of symptoms.
- Member must have symptom onset or first exacerbation preceded within four months by a GAS (group A **streptococcal infection)** infection, as documented by positive throat culture, exposure to documented GAS infection (in a close contact, such as a sibling sharing a bedroom), and/or documented two-fold rise in one or more anti-GAS antibody titers such as anti-streptolysin O, anti-streptococcal DNAaseB, anti-carbohydrate antibodies and others.
- Onset/exacerbation of obsessive compulsive disorder, a tic disorder, or both is accompanied by at least three of the following 7 clinical signs and symptoms.
    - Markedly increased level of anxiety, particularly new onset of separation anxiety.
    - Emotional lability, irritability, aggressive behavior and/or personality change.
    - Sudden difficulties with concentration or learning.
    - Developmental regression ("baby-talk," temper tantrums; behaviors atypical for actual chronological age).
    - Sleep disorder (insomnia, night terrors, refusal to sleep alone).
    - Handwriting deterioration or other sign of motoric dysfunction (including new onset of motor hyperactivity, or presence of choreiform finger movements).
    - Urinary frequency or increased urge to urinate; daytime or night-time secondary enuresis.
- Medication must be prescribed by a pediatrician, psychiatrist, or infectious disease specialist.

- Member must not have a history of rheumatic fever, including Sydenham chorea (the neurologic manifestation).
- Member must not have a presence of symptoms consistent with autism, schizophrenia, or other psychotic disorder (unless psychotic symptoms have onset coincident with the possible PANDAS and are attributed to OCD).
- Member must not have presence of a neurological disorder other than a tic disorder.
- Member must not have an IQ of less than 70.
- Member must not have presence of serious or unstable medical illness or psychiatric or behavioral symptoms that would make participation unsafe or study procedures too difficult to tolerate.
- **Initial Duration of Approval:** 6 weeks

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.

Immunoglobulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapies **PRIOR AUTHORIZATION FORM**	
Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158 If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6253 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:
Health Options ID:	Member weight: _____pounds or _____kg
REQUESTED DRUG INFORMATION	
Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ 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)	
Initial Authorization (Please attach all relevant documents with request)	

1. Does the member have documented clinical notes including appropriate positive findings on diagnostic and or biopsy results? ☐ Yes ☐ No
2. Will medication be used for chronic use?
   ☐ Yes ☐ No

3. Does the member have ONE of the following diagnoses?
   a. Common Variable Immunodeficiency (CVID) ☐ Yes ☐ No
      i. If yes, please answer ALL of the following:
         1. 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
         2. Does the member have documented recurrent bacterial infections?
            ☐ Yes ☐ No
         3. Does the member have failure to prophylactic antibiotic therapy?
            ☐ Yes ☐ No

   b. Congenital Agammaglobulinemia (X-linked agmammaglobulinemia) ☐ Yes ☐ No
      i. If yes, please answer ALL of the following:
         1. 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
         2. Does the member have documented recurrent bacterial infections?
            ☐ Yes ☐ No

   c. Hypogammaglobulinemia (excluding IgA deficiency) ☐ Yes ☐ No

      i. If yes, please answer ALL of the following:
         1. 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
         2. 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
         3. Are underlying conditions such as asthma or allergic rhinitis that may predispose member to recurrent infections being medically managed where applicable? ☐ Yes ☐ No

   d. Selective IgG subclass deficiency ☐ Yes ☐ No
      i. If yes, please answer ALL of the following:
         1. 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
         2. Does the member have unexplained recurrent or persistent severe bacterial infections despite appropriate treatment? ☐ Yes ☐ No
         3. Does the member inadequate response to protein and polysaccharide antigens, as determined by ALL of the following? ☐ Yes ☐ No

            a. 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).

            b. 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]).

e. Severe Combined Immunodeficiency (SCID) ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. Does the member have laboratory findings of all the following below the normal reference range: T cells, IgA, IgE and IgM ?
         ☐ Yes ☐ No
      2. Does the member have documented recurrent or serious bacterial infections directly attributable to this deficiency? ☐ Yes ☐ No

f. Specific Antibody Deficiency (SAD) ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions
      1. Does the member have documented normal serum IgG, IgA, and IgM?
         ☐ Yes ☐ No
      2. Does the member have normal responses to protein antigens (tetanus and diphtheria toxoid or HiB) measured 3 – 4 weeks after immunization? ☐ Yes ☐ No
      3. Does the member have inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by ONE of the following?
         ☐ Yes ☐ No
         a. Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
         b. Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
      4. Does the member have inadequate responsiveness to pneumococcal conjugate vaccine (Prevnar 13®) 4–8 weeks after vaccination as defined by ONE of the following? ☐ Yes ☐ No
         a. Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
         b. Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype).
      5. Does the member have unexplained recurrent or persistent severe bacterial infections despite appropriate treatments? ☐ Yes ☐ No

g. Wiskott-Aldrich Syndrome ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. 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
      2. Does the member have documented recurrent or serious bacterial infections? ☐ Yes ☐ No

h. X-linked immunodeficiency with hyperimmunoglobulin M ☐ Yes ☐ No

   i. If yes, please answer ALL of the following questions:
      1. 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
      2. Is there documented recurrent bacterial infections? ☐ Yes ☐ No

i. Acute Idiopathic Thrombocytopenia Purpora ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:

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

j. Chronic Idiopathic Thrombocytopenia Purpora ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. Have other causes of thrombocytopenia been ruled out by history and peripheral smear?
         ☐ Yes ☐ No
      2. Is member unresponsive to four days of corticosteroid therapy?
         ☐ Yes ☐ No
      3. Has member had a splenectomy?
         ☐ Yes ☐ No
      4. Is member obtaining IVIG to defer or avoid splenectomy?
         ☐ Yes ☐ No
      5. Are platelet counts persistently at or below 20,000/µl?
         ☐ Yes ☐ No

k. 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)
   ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. Does member have an immunoglobulin G (IgG) level less than 600mg/dl or does member have evidence of specific antibody deficiency?
         ☐ Yes ☐ No
      2. 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

l. Kawasaki Disease ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. Has fever been present for at least 5 days? ☐ Yes ☐ No
      2. Will treatment be initiated within 10 days of onset of fever?
         ☐ Yes ☐ No
      3. Which of the following symptoms be present?
         a. Mucous membrane changes such as a red tongue and dry fissured lips ☐ Yes ☐ No
         b. Swelling of the hands and feet ☐ Yes ☐ No
         c. Enlarged lymph nodes in the neck ☐ Yes ☐ No
         d. Diffuse red rash covering most of the body
            ☐ Yes ☐ No
         e. Redness of the eyes
            ☐ Yes ☐ No
      4. 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

m. Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment ☐ Yes ☐ No

i. If yes, please answer ALL of the following questions:
   1. 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
   2. Does the member have a nerve conduction study showing diffuse demyelination?
      ☐ Yes ☐ No
   3. Is the member intolerant or refractory to therapeutic doses of corticosteroids for a duration of 1 month? ☐ Yes ☐ No

n. Maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability ☐ Yes ☐ No
   i. If yes, please answer ALL of the following questions:
      1. Is member 18 years of age or older? ☐ Yes ☐ No
      2. Does the member have ONE of the following progressive symptoms present for at least 2 months? ☐ Yes ☐ No
         a. Asymmetric limb weakness,
         b. Motor involvement having a motor nerve distribution in two or more nerves.
      3. Does member have objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs?
         ☐ Yes ☐ No
      4. Does member have definite conduction block on one nerve or probable conduction block on two nerves?
         ☐ Yes ☐ No
      5. Does member have normal sensory nerve conduction in upper limb segments with CB and normal sensory nerve action potential (SNAP) amplitudes? ☐ Yes ☐ No

o. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) ☐ Yes ☐ No

   i. Is member between the ages of 3 and 13 years of age?
      ☐ Yes ☐ No

   ii. Does the member have a diagnosis of obsessive compulsive disorder, a tic disorder, or both?
      ☐ Yes ☐ No

   iii. Does the member have moderate or greater severity of symptoms, with a score of greater than or equal to 20 on the Children s Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) and greater than or equal to 4 on the Clinical Global Impression Severity scale (CGI-S)?
      ☐ Yes ☐ No

   iv. Does the member have acute onset within the previous six months of symptoms in a member that was previously well, or the first acute recurrence within the previous six months, after a period of relatively complete remission of symptoms?
      ☐ Yes ☐ No

   v. Does the member have symptom onset or first exacerbation preceded within four months by a GAS (group A streptococcal infection**)** infection, as documented by positive throat culture, exposure to documented GAS infection (in a close contact, such as a sibling sharing a bedroom), and/or documented two-fold rise in one or more anti-GAS antibody titers such as anti-streptolysin O, anti-streptococcal DNAaseB, anti-carbohydrate antibodies and others?
      ☐ Yes ☐ No

   vi. Is the onset/exacerbation of obsessive compulsive disorder, a tic disorder, or both is accompanied by at least three of the following 7 clinical signs and symptoms?
      a. Markedly increased level of anxiety, particularly new onset of separation anxiety.
         ☐ Yes ☐ No

b. Emotional lability, irritability, aggressive behavior and/or personality change.
☐ Yes ☐ No

c. Sudden difficulties with concentration or learning.
☐ Yes ☐ No

d. Developmental regression ("baby-talk," temper tantrums; behaviors atypical for actual chronological age).
☐ Yes ☐ No

e. Sleep disorder (insomnia, night terrors, refusal to sleep alone).
☐ Yes ☐ No

f. Handwriting deterioration or other sign of motoric dysfunction (including new onset of motor hyperactivity, or presence of choreiform finger movements).
☐ Yes ☐ No

g. Urinary frequency or increased urge to urinate; daytime or night-time secondary enuresis.
☐ Yes ☐ No

vii. Will the medication be prescribed by a pediatrician, psychiatrist, or infectious disease specialist?
☐ Yes ☐ No

viii. Does the member must have a history of rheumatic fever, including Sydenham chorea (the neurologic manifestation)?
☐ Yes ☐ No

ix. Does the Member must have a presence of symptoms consistent with autism, schizophrenia, or other psychotic disorder (unless psychotic symptoms have onset coincident with the possible PANDAS and are attributed to OCD)?
☐ Yes ☐ No

x. Doe the member must have presence of a neurological disorder other than a tic disorder?
☐ Yes ☐ No

xi. Does the member have an IQ of less than 70?
☐ Yes ☐ No
i.

xii. Does the member must not have presence of serious or unstable medical illness or psychiatric or behavioral symptoms that would make participation unsafe or study procedures too difficult to tolerate?
☐ Yes ☐ No

Reauthorization (Please attach all relevant documents with request):

1. Does the member have ONE of the following diagnoses?

a. Common Variable Immunodeficiency (CVID) ☐ Yes ☐ No

i. If yes, does the member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No

b. Congenital Agammaglobulinemia (X-linked agmammaglobulinemia) ☐ Yes ☐ No
i. If yes, please answer ALL of the following:

1. Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No
2. Does member have documentation of IgG trough level measured prior to therapy? ☐ Yes ☐ No
3. Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? ☐ Yes ☐ No

c. Hypogammaglobulinemia (excluding IgA deficiency) ☐ Yes ☐ No
   i. If yes, does the member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No

d. Selective IgG subclass deficiency ☐ Yes ☐ No
   i. If yes, does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No

e. Severe Combined Immunodeficiency (SCID) ☐ Yes ☐ No
   i. If yes, please answer ALL of the following:
      1. Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No
      2. Does member have documentation of IgG trough level measured prior to therapy? ☐ Yes ☐ No
      3. Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? ☐ Yes ☐ No

f. Specific Antibody Deficiency (SAD) ☐ Yes ☐ No
   i. If yes, does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No

g. Wiskott-Aldrich Syndrome ☐ Yes ☐ No
   i. If yes, please answer ALL of the following:
      1. Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No
      2. Does member have documentation of IgG trough level measured prior to therapy? ☐ Yes ☐ No
      3. Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? ☐ Yes ☐ No

h. X-linked immunodeficiency with hyperimmunoglobulin M ☐ Yes ☐ No

   i. If yes, please answer ALL of the following:
      1. Does member have clinical documentation that immune globulin therapy has reduced the number and severity of clinical infections? ☐ Yes ☐ No
      2. Does member have documentation of IgG trough level measured prior to therapy? ☐ Yes ☐ No
      3. Does member have documentation of IgG trough levels that has increased or remain stabilized from baseline within the last 6 months? ☐ Yes ☐ No

i. Chronic Idiopathic Thrombocytopenia Purpora ☐ Yes ☐ No

   i. If yes, does member have clinical documentation of clinical benefit from immune globulin therapy? ☐ Yes ☐ No

j. 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)
☐ Yes ☐ No
   i. If yes, does member have documentation of active disease? ☐ Yes ☐ No

k. Kawasaki Disease ☐ Yes ☐ No
   i. If yes, does member have documentation that treatment with first infusion failed?
   ☐ Yes ☐ No

l. Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment ☐ Yes ☐ No
   i. If yes, does member have clinical documentation of clinical benefit from immune globulin therapy?
   ☐ Yes ☐ No

m. Maintenance treatment of multifocal motor neuropathy to improve muscle strength and disability ☐ Yes ☐ No
   i. If yes, does member have clinical documentation of clinical benefit from immune globulin therapy?
   ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why / Current)**

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

Highmark Delaware Health Options

Updated: 08/2019
DMMA Approved: 09/2019

DRUG NAME **PRIOR AUTHORIZATION FORM**	
Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158 If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6253 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:
Health Options ID:	Member weight: _____pounds or _____kg
REQUESTED DRUG INFORMATION	
Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No	

Highmark Delaware HEALTH OPTIONS

Updated: 08/2019
DMMA Approved: 09/2019

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)

******Fill in questions as needed****** If you add content to this section that increases the request form to two pages, please have a section on page two that identifies which member the request is being submitted.

☐

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Add questions as needed

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

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

This page is only to be used if the form extends to a second page.

DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158

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

PHONE: (844) 325-6253 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

******Fill in questions as needed****** If you add content to this section that increases the request form to two pages, please have a section on page two that identifies which member the request is being submitted.

☐

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION
Add questions as needed
Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No Please describe:
SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date