PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	**Immune globulin (IVIG and SCIG):** **Intravenous (IVIG)**: Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen, Yimmugo, Gammagard Liquid ERC, Qivigy **Subcutaneous (SCIG):** Cutaquig, Cuvitru, Hizentra, HyQvia, Xembify
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Human immune globulin or immunoglobulin (IG) products are used to treat a wide range of conditions from autoimmune or inflammatory disorders to infections and idiopathic diseases. IG functions as antibodies in the immune system. IgG is the most common type. They are derived from human plasma, so product availability varies based on the supply dependency on the donor pool. There is not substantial evidence that one product is more effective than another. IVIG and SCIG products are not interchangeable. SCIG can allow for patient self-administration but requires a larger quantity than IVIG due to bioavailability differences. Primary Immunodeficiency (PI) was the first FDA-approved indication for immunoglobulin therapy. There are hundreds of types of PI's, not all of which require IG replacement.

Dosing should be based on ideal body weight (IBW) or adjusted body weight (adjBW) rather than actual/total body weight (TBW)

Immune globulin will be considered for coverage when the following criteria are met:

Autoimmune Bullous Disease

For **initial** authorization:

1. Medication is prescribed by or in consultation with a dermatologist or immunologist; AND
2. Member has tried and failed systemic corticosteroids and/or immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil); AND
3. Member has a documented, confirmed diagnosis of one of the following:
   a) Bullous pemphigoid
   b) Epidermolysis bullosa acquisita
   c) Linear IgA bullous dermatosis
   d) Mucous membrane (cicatricial) pemphigoid
   e) Pemphigoid gestationis
   f) Pemphigus foliaceus
   g) Pemphigus vulgaris; AND

4. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
5. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 2g/kg divided over 5 consecutive days, repeated every 4 weeks if needed.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:
1. Chart notes must show documentation of improvement of signs and symptoms of disease (i.e., blistering or corticosteroid dose reduction); AND
2. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

For **initial** authorization:
1. Medication must be prescribed by or in consultation with a neurologist; AND
2. Member has a documented diagnosis of CIDP confirmed by electrodiagnostic studies (motor and sensory nerve conduction studies); AND
3. Symptoms of motor weakness and/or sensory disturbances have been present for at least 2 months; AND
4. Member has impairment of activities of daily living due to disabling symptoms; AND
5. Member must meet at least one of the following:
   a) Trial and failure of or contraindication to a steroid regimen (oral or IV) for at least 12 weeks
   b) Rapidly progressive disease
   c) Motor CIDP (no sensory involvement); AND
6. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
7. **Dosage allowed/Quantity limit:** See dosing information in individual drug package insert (Gammaked, Gamunex-C, Privigen, Hizentra, Panzyga, HyQvia, Gammagard liquid). Note: SCIG is not recommended for induction treatment but is recommended for maintenance.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:
1. Member has improvement of neuromuscular disability and impairment, with sustained stability since initiation of therapy; AND
2. Members who are stable on maintenance IVIG should be assessed periodically to determine if the dose and/or frequency can be reduced to the lowest effective and establish the need for continued treatment.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Dermatomyositis or Polymyositis

For **initial** authorization:
1. Medication must be prescribed by a neurologist, rheumatologist, or dermatologist; AND
2. Member has a diagnosis of dermatomyositis or polymyositis confirmed by muscle biopsy; AND

3. Member has tried and failed a systemic corticosteroid and/or non-steroid immunosuppressant (e.g., azathioprine, methotrexate, cyclosporine, mycophenolate mofetil) for at least 4 weeks; AND
4. Member has active disease (e.g., myositis, dysphagia, refractory skin disease); AND
5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
6. **Dosage allowed/Quantity limit:** 2g/kg IV divided in equal doses given over 2-5 consecutive days every 4 weeks in adults (per Octagam 10% labeling for dermatomyositis).

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Member has significantly improved muscle strength sustained since initiation of IG therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)

For **initial** authorization:
1. Member is a newborn, and thrombocytopenia persists after transfusion of antigen-negative compatible platelet; OR
2. Member is pregnant and has diagnosis of F/NAIT with one or more of the following:
   a) Family history of disease
   b) Platelet alloantibodies found on screening
   c) Previously affected pregnancy; AND
3. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
4. **Dosage allowed/Quantity limit:** See dosage and administration information in individual drug package insert.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Medication will not be reauthorized for continuous use.

Guillain-Barre Syndrome (GBS)

For **initial** authorization:
1. Medication is prescribed by or in consultation with a neurologist; AND
2. Member has a documented diagnosis of Guillain-Barre Syndrome with bilateral weakness of limbs; AND
3. Member meets one or more of the following:
   a) Unable to walk independently beyond 10 meters
   b) Rapidly progressive weakness
   c) Severe autonomic or swallowing difficulty
   d) Respiratory insufficiency; AND
4. IG therapy is being initiated within 2 weeks of symptom onset; AND

5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
6. **Dosage allowed/Quantity limit:** Consult clinical literature. For example, 0.4g/kg/day x 5 days in adults.

If all the above requirements are met, the medication will be approved for 1 month (1 course).

For **reauthorization**:
1. Member responded to initial course of therapy, as evidenced by improved/stabilized disability or weakness; AND
2. Member is experiencing deterioration following initial response to treatment.

If all the above requirements are met, the medication will be approved for an additional 1 month (1 course). Further renewal will NOT be considered after a total of 2 courses.

Immune Thrombocytopenia (ITP)

For **initial** authorization:
1. Initial therapy (Member diagnosed with ITP within the past 3 months):
   a) Children (< 18 years of age):
      i) Moderate or severe bleeding (e.g., grade 3 or higher); OR
      ii) High risk for bleeding* (see Appendix A); OR
      iii) Rapid increase in platelets is required*; OR
      iv) Failure of corticosteroids to control bleeding.
   b) Adults (≥ 18 years of age):
      i) Platelet count < 30,000/mcL; OR
      ii) Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding*, or rapid increase in platelets is required*; AND
      iii) Corticosteroid therapy is contraindicated or has failed to increase platelet count.
2. Chronic/persistent ITP (≥ 3 months from diagnosis):
   a) Platelet count < 30,000/mcL; OR
   b) Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding*, or rapid increase in platelets is required*; AND
   c) Relapse after previous response to IVIG or inadequate response/intolerance/contraindication to corticosteroid.
3. Adults with refractory ITP after splenectomy:
   a) Platelet count < 30,000/mcL; OR
   b) Significant bleeding symptoms.
4. ITP in pregnant women: authorization through delivery may be granted to pregnant women with ITP if any one or more of the following:
   a) Any bleeding during pregnancy
   b) Platelet count less than $30x10^9$/L at any time during pregnancy
   c) Platelet count less than $50x10^9$/L prior to delivery; AND
5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
6. **Dosage allowed/Quantity limit:** Please see dosage and administration information in individual drug package insert.

*The member's risk factor(s) for bleeding (see Appendix A) or reason requiring a rapid increase in platelets must be provided.

If all the above requirements are met, the medication will be approved for 1 month.

For **reauthorization**:
1. Medication will not be reauthorized for continuous use.

Kawasaki Syndrome

For **initial** authorization:
1. Medication is prescribed by or in consultation with a pediatric cardiologist or rheumatologist; AND
2. Member has a documented diagnosis of Kawasaki Syndrome; AND
3. Member is experiencing fever, significant elevation of inflammatory markers (i.e., CRP or ESR), and/or coronary artery abnormality; AND
4. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
5. **Dosage allowed/Quantity limit:** 2g/kg as a single dose. If fever recurs or persists after at least 36 hours, a second dose may be given.

If all the above requirements are met, the medication will be approved for 1 month.

For **reauthorization**:
1. Medication will not be reauthorized for continuous use.

Lambert-Eaton Myasthenic Syndrome (LEMS)

For **initial** authorization:
1. Medication must be prescribed by or in consultation with a neurologist or oncologist; AND
2. Member has a diagnosis of LEMS as confirmed by at least one of the following:
   a) Repetitive nerve stimulation (RNS) study abnormalities
   b) Positive P/Q type anti-voltage gated calcium channel (VGCC) antibody assay; AND
3. Member has progressive proximal muscle weakness; AND
4. Member has tried and failed amifampridine (Firdapse or Ruzurgi) or pyridostigmine; AND
5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
6. **Dosage allowed/Quantity limit:** Consult clinical literature. Consider 2g/kg given over 2 to 5 days, every 8 weeks.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must document significant improvement in muscle strength and maintenance of improvement since initiation of IVIG therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Multifocal Motor Neuropathy

For **initial** authorization:
1. Medication is prescribed by or in consultation with a neurologist; AND
2. Member has a diagnosis of MMN as evidenced by BOTH of the following:
   a) Progressive, focal, asymmetric limb weakness with motor involvement of at least 2 nerves for more than one month, and
   b) No objective sensory abnormalities (e.g., normal sensory nerve conduction study); AND
3. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
4. **Dosage allowed/Quantity limit:** 0.5-2.4 g/kg/month IV in adults (per Gammagard liquid)

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Member has improved muscle strength and disability since initiation of IVIG therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Myasthenia Gravis

For **initial** authorization:
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of myasthenia gravis and meets one of the following:
   a) For short term use: Member has impending or manifest myasthenic crisis with signs of significant respiratory or bulbar dysfunction and potential airway compromise; OR
   b) For maintenance:
      i) Member has severe, refractory myasthenia gravis that is unchanged or worse after corticosteroids and at least 2 other immunosuppressive therapies (e.g., azathioprine [first line], cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) for an adequate duration, with persistent symptoms or side effects that limit functioning; AND
      ii) Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND
4. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
5. **Dosage allowed/Quantity limit:** Consult clinical literature. Consider a daily dose of 0.4 g/kg x 5 days or 1g/kg x 2 days.

If all the above requirements are met, the medication will be approved for 1 month (1 course) for crisis episode (as defined in 2a) or 12 months for maintenance use (as defined in 2b).

For **reauthorization**:
1. Member must meet initial criteria; AND
2. Chart notes must document clinically significant improvement of muscle weakness with treatment.

If all the above requirements are met, the medication will be approved for an additional 1 month for crisis episode (as defined in 2a) or 6 months for maintenance use (as defined in 2b).

Parvovirus B19-Induced Pure Red Cell Aplasia (PRCA)

For **initial** authorization:
1. Medication is prescribed by or in consultation with a hematologist or infectious disease specialist; AND
2. Member is immunocompromised (e.g., HIV, cancer, transplant); AND
3. Member has severe anemia as evidenced by hemoglobin lab results (i.e., less than 8.0 g/dL); AND
4. Member has tested positive for parvovirus B19 (e.g., by PCR or bone marrow exam); AND
5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
6. **Dosage allowed/Quantity limit:** Consult clinical literature. For example: 2g/kg divided over 5 days (400mg/kg/day).

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Member is chronically infected with parvovirus B19; AND
2. Hemoglobin level improved from baseline; AND
3. Member relapsed when treatment was stopped.

If all the above requirements are met, the medication will be approved for an additional 3 months.

Primary Immunodeficiency

For **initial** authorization:
1. Medication is prescribed by or in consultation with an immunologist; AND
2. Member meets listed criteria for ONE of the following confirmed diagnoses with documentation:
   a) Severe combined immunodeficiency (SCID) including "leaky" SCID with one of the following:
      i) Engraftment of transplacentally acquired maternal T cells OR
      ii) Confirmation by genetic testing; AND
         (1) Very low T cells (<0.05 × 10^9/L) OR
         (2) At least 2 of the following:
            (a) Low T-cell number for age
            (b) Oligoclonal T cells
            (c) Abnormal TRECS OR <20% of CD4+ T cells are naive.
   b) X-Linked Agammaglobulinemia (XLA; Bruton agammaglobulinemia):
      i) Less than 2% CD19+ B cells; AND
      ii) Molecular confirmation (mutation in Btk, absent Btk mRNA, or absent Btk protein) OR ALL the following:
         (1) Low serum IgG, IgM, and IgA

(2) Onset of recurrent bacterial infections in the first 5 years of life
(3) Absent isohemagglutinins and /or poor response to vaccines.

c) Common variable immunodeficiency (CVID) with all of the following:
   i) At least 4 years of age; AND
   ii) Hypogammaglobulinemia (low IgG) according to the age-adjusted reference range; AND
   iii) Low IgA OR low IgM; AND
   iv) Impaired antibody response to pneumococcal polysaccharide vaccine OR IgG <100 mg/dL.
d) Wiskott-Aldrich Syndrome (WAS) with all of the following:
   i) Thrombocytopenia (less than 70,000 platelets/mm^3) and small platelet size; AND
   ii) WAS mutation and/or abnormal WAS protein expression.
e) Ataxia-telangiectasia (AT) with all of the following:
   i) History of recurrent infections despite antibiotic prophylaxis; AND
   ii) Mutations on both alleles of the ATM gene; AND
      (1) Progressive cerebellar ataxia OR
      (2) Increased radiation induced chromosomal breakage in cultured cells.
f) DiGeorge syndrome (DGS) with all of the following:
   i) History of recurrent infections despite antibiotic prophylaxis; AND
   ii) Reduced numbers of CD3+ T cells (less than 1500/mm^3); AND
   iii) Deletion of chromosome 22q11.2.
g) Hyper IgM with all of the following:
   i) Recurrent bacterial and opportunistic infections; AND
   ii) Molecularly confirmed activation-induced cytidine deaminase (AID) or uracil nucleoside glycosylase (UNG) antibody deficiency (HIM type 2 or 5) AND normal or increased serum IgM AND reduced IgG and IgA OR
   iii) X-linked hyper IgM (XHIM, HIM type 1) AND serum IgG concentration at least 2 SD below normal for age AND one of the following:
      (1) Mutation in the CD40L gene OR
      (2) Maternal cousins, uncles, or nephews with confirmed diagnosis of XHIM.
h) X-linked lymphoproliferative syndrome (XLP) with all of the following:
   i) Lymphoma
   ii) Hypogammaglobulinemia/ dysgammaglobulinemia
   iii) Infection
   iv) Mutation in SH2D1A gene.
i) Nuclear factor-κB (NEMO) deficiency with all of the following:
   i) Severe recurrent infections
   ii) Mutations in the IKBKG or IKBA gene.
j) Warts, hypogammaglobulinemia, immunodeficiency, myelokathexis (WHIM) syndrome with all of the following:
   i) Chronic neutropenia (absolute neutrophil count of less than 500/µL); AND
   ii) Myelokathexis (retention of senescent neutrophils in the bone marrow); AND
   iii) Mutation of CXCR4 gene OR
   iv) Two of the following: Chronic or recurrent warts, chronic lymphopenia (absolute lymphocyte count of less than 1500/µL), serum IgG at or below the normal range for age, a parent with neutropenia and warts.
k) Specific Antibody Deficiency (SAD) with all of the following:
   i) At least 2 years of age; AND

ii) Recurrent respiratory infections despite antibiotic prophylaxis; AND
iii) Impaired antibody response to pneumococcal polysaccharide vaccine; AND
iv) Normal IgA, IgM, total IgG, and IgG subclass levels.

l) Transient hypogammaglobulinemia of infancy (THI) with all of the following:
i) Less than 4 years of age; AND
ii) Recurrent viral and bacterial respiratory illnesses despite antibiotic prophylaxis; AND
iii) Hypogammaglobulinemia (low IgG) greater than two standard deviations below the mean for age.

m) IgG subclass deficiency (IGGSD) and all of the following:
i) Recurrent infections despite antibiotic prophylaxis; AND
ii) IgG1, IgG2, or IgG3 levels less than the fifth percentile assessed on at least 2 occasions, at least 1 month apart; AND
iii) Normal IgG (total), IgM, and IgA levels.

n) Hyper IgE syndrome (HIES) with all of the following:
i) Mutation of the STAT3 or DOCK8 gene; AND
ii) Recurrent sinopulmonary and skin infections; AND
iii) High serum IgE levels; AND
iv) Impaired vaccine response; AND

3. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).

3. Dosage allowed/Quantity limit: See dosage and administration information in individual drug package insert. Note: Gammagard Liquid, Gammagard Liquid ERC, Gamunex-C, and Gammaked may be administered intravenously or subcutaneously for primary immunodeficiency.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. An absence or reduction in the frequency of bacterial infections has been demonstrated since initiation of IG; AND
2. IgG trough levels are being monitored.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Stiff-Person Syndrome

For **initial** authorization:
1. Medication is prescribed by or in consultation with a neurologist; AND
2. Member has a diagnosis of stiff-person syndrome; AND
3. Member has anti-glutamic acid decarboxylase (GAD) antibodies; AND
4. Member has tried and failed both of the following first-line treatments (monotherapy or in combination) for an adequate dose and duration, unless contraindicated or not tolerated:
   a) Benzodiazepine (e.g., diazepam, clonazepam)
   b) Baclofen (An anticonvulsant is an acceptable alternative; for example, gabapentin, pregabalin, or valproate); AND
5. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).

6. Dosage allowed/Quantity limit: Consult the clinical literature for guidance. A dose of 2 g/kg over 2-5 days has been commonly cited.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must document reduced stiffness, improved gait, fewer falls, and/or improved function with activities of daily living; AND
2. Clinically significant or disabling symptoms return following an attempt to discontinue treatment.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients

For **initial** authorization:

1. Memberis 18 years of age or younger; AND
2. Member has a documented diagnosis of HIV infection; AND
3. Member meets one of the following:
   a) IVIG is prescribed for primary prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL; OR
   b) IVIG is prescribed for secondary prophylaxis of bacterial infections and member meets ALL of the following:
      i) Member has a history of recurrent bacterial infections (>2 serious bacterial infections in a 1-year period)
      ii) Member is not able to take combination antiretroviral therapy
      iii) Member has tried and failed antibiotic prophylaxis(e.g., trimethoprim-sulfamethoxazole); AND
4. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).

4. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example: IVIG 400 mg/kg every 2–4 weeks..

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show improvement of signs and symptoms of disease (ex. reduction in the frequency of bacterial infections or increased IgG)

If all the above requirements are met, the medication will be approved for an additional 6 months.

Prophylaxis of Bacterial Infections in BMT/HSCT Recipients

For **initial** authorization:

1. Member is an allogenic BMT/HSCT recipient; AND
2. IVIG is prescribed for prophylaxis of bacterial infections; AND
3. Member has a pretreatment serum IgG < 400 mg/dL; AND
4. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
5. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 500 mg/kg/dose IV every 3 to 4 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement of signs and symptoms of disease (ex. reduction in the frequency of bacterial infections or increase in serum IgG).

If all the above requirements are met, the medication will be approved for an additional 6 months.

Prophylaxis of Bacterial Infections in B-Cell Chronic Lymphocytic Leukemia

For **initial** authorization:
1. Member has a diagnosis of B-cell chronic lymphocytic leukemia; AND
2. Medication is prescribed by or in consultation with an oncologist or infectious disease specialist; AND
3. IG is prescribed for prophylaxis of bacterial infections; AND
4. Member has a history of recurrent bacterial infections requiring intravenous antibiotics or hospitalization; AND
5. Chart notes must include documentation of a pretreatment serum IgG level <500 mg/dL; AND
6. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
7. **Dosage allowed/Quantity limit:** Please see dosage and administration information in individual drug package insert.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show a reduction in the frequency of bacterial infections from baseline.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Kidney Transplant

For **initial** authorization:
5. Member has had or is scheduled for a kidney transplant; AND
6. Medication must be prescribed by or in consultation with a nephrologist or transplant specialist; AND
7. Medication is being used for prevention of antibody-mediated acute humoral rejection in sensitized patients prior to a kidney transplant; OR
8. Medication is being used for treatment of antibody-mediated acute humoral rejection after a kidney transplant; AND
9. If the request is for a non-preferred product, the member has had a trial and failure of, or is unable to trial, a preferred IVIG or SCIG product (see appendix B).
10. **Dosage allowed/Quantity limit:** Consult clinical literature (off-label use). For example, 2 g/kg every month.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
11. Medication will not be reauthorized for continuous use.

CareSource considers immune globulin not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/15/2017	New policy for Immune Globulin created. Diagnoses associate with inpatient lifethreatening therapies were removed. Diagnoses of CIDP, Dermatomyositis or Polymyositis, ITP, MMN, Primary Immunodeficiency and Stiff-Person Syndrome got criteria. expanded. Diagnosis of Acquired red cell aplasia was revised to PRCA with criteria. Length of coverage and reauthorization length were added.
08/21/2019	New medication Xembify added to the list of subcutaneous immune globulins.
02/22/2021	Added Panzyga, Asceniv to product list. Removed Thymoglobulin. Added J codes for Cutaquig, Cuvitru and Xembify and moved list of billing codes to an appendix. Added general note about weight-based dosing. Myasthenia Gravis: Updated references. Added specialist requirement. Split between short- and long-term use; replaced short term criteria and created new criteria for long term. Refer to literature for dosing, not package insert; added common dose regimen. Added renewal criteria. Parvovirus B19-induced PRCA: Added references. Revised entire section. Refer to literature for dosing, not package insert. Added specialist requirement. Added that they must be immunocompromised. Added hemoglobin and viral confirmation. Reduced approval duration from 6 months to 3 months. Added renewal criteria. Stiff person syndrome: Added references. Added specialist requirement. Added GAD antibody requirement. Require 2 prior therapies. Refer to literature for dosing, not package insert. Added example dose. Reduced approval duration from 6 months to 3 months. Added renewal criteria. Kawasaki syndrome: Added reference (previously none). Added specialist. Added dosing information. LEMS: Added references. Added specialist requirement. Direct to literature for dosing rather than package insert. Added common dose. Added confirmation of diagnosis. Amended step drugs to more closely align with guidelines in literature. Added progressive proximal muscle weakness. Slightly revised the renewal criteria. Shortened initial auth duration from 12 months to 3 months. GBS: Added reference. Added specialist requirement. Refer to literature for dosing, not package insert. Added example dose. Shortened initial auth duration from 2 mo to 1 mo and added renewal criteria for additional month. CIDP: Added references. Added specialist requirement. Added drug names to dosing section for guidance. Added requirement for steroid unless rapidly progressive or pure motor. Removed CSF protein requirement; added main clinical diagnostic point (symptoms x 2 mo). Elaborated on electrodiagnostic studies. MMN: Added reference. Added specialist. Added example dosing. Rephrased renewal criteria. Amended diagnostic criteria. DM/PM: Added reference. Added specialists. Clarified diagnostic criteria. Rephrased standard therapies and added duration. Added example dose; refer to literature, not package insert. Rephrased renewal criteria.
03/15/2023	Transferred to new template. Updated/added references.

	Autoimmune bullous diseases: Added specialist requirement, changed dosing section to refer to clinical lit rather than package inserts since it is off label and provided an example; reduced initial auth duration from 6 months to 4 months, specified improvement of blistering in renewal criteria or decreased steroid use. CIDP: Increased initial auth duration from 3 months to 4 months. Removed requirement for demyelination in at least 2 nerves since CIDP variants may not meet this; changed to just confirming diagnosis by electrodiagnostic testing in general. Changed "moderate to severe functional disability to "impairment of activities of daily living due to disabling symptoms." Added note SCIG is not recommended for initiation. DM/PM: Added dermatomyositis dosing per Octagam 10% label. Added MMF to examples list. Specified having active disease. GBS: Added "bilateral weakness of limbs" to diagnosis. Added additional reasons to start therapy in addition to being unable to walk independently. ITP: Added example of grade 3 or higher to moderate/severe bleeding. Added corticosteroid failure as option for newly dx'd peds. Added corticosteroid failure to the corticosteroid contraindication option for newly dx'd adults. Removed anti-D from persistent/chronic section. Amended platelet thresholds for maternal ITP. Added age >60 to appendix A and changed "comorbidity (e.g., peptic ulcer disease, hypertension)" to "comorbidities that predispose the patient to bleeding." Changed all initial auth durations to 1 month since it should not be used chronically. Kawasaki: Removed pediatrician as specialist and added rheumatologist. Added that the member has fever, elevated inflammatory markers, or CAA. HIV: Specified increase IgG could be used as improvement in renewal criteria. BMT/HSCT: Specified allogenic transplant requirement. Removed requirement for request needing to be within the first 100 days of transplant to be in line with guidelines. Changed dosing section to refer to clinical lit rather than package inserts since it is off label and provided an example. Specified increase IgG could be used as improvement in renewal criteria.
02/01/2024	Updated references. Removed billing code appendix. Removed Carimune NF from policy (discontinued). Added Alyglo to policy (new product). CIDP: Added Panzyga, HyQvia, Gammagard liquid to product list. DM/PM: In reauth, changed "IVIG" to "IG." GBS: #4 changed "IVIG" to "IG." PID: Removed appendix for impaired vaccine response levels. Added requirement for immunology specialist. Reduced initial auth duration from 12 months to 6 months. Simplified trough monitoring requirement for reauth. Changed reduction of infections to absence or reduction for reauth. Updated SCID criteria (PIDTC 2022). Created separate bullet and criteria for X-Linked Agammaglobulinemia (was grouped with SCID). Changed CVID criteria to align with ICON 2016 definition. Removed selective IgA deficiency and selective IgM deficiency (unlikely beneficial; Perez 2017); separated IGGSD, SAD. Separated WAS, DGS, AT. Removed "Other predominant antibody deficiency disorders" and "Other combined immunodeficiency" and added the most applicable of the specific disorders; added THI, Hyper-IgE, WHIM, NEMO, XLP, Hyper IgM. Prophylaxis of bacterial infections in B-cell CLL: replaced sinopulmonary recurrent infections with bacterial infections, adding that reauthorization criteria must be documented in chart notes, adding diagnosis, and adding specialist. Kidney transplant: removing consulting PI for dosing and adding consulting clinical literature with example off-label dosing, adding that medication cannot be reauthorized, adding that member has had or is scheduled for a kidney transplant,

	adding prescriber specialty, specifying type of treatment or prophylaxis that medication is being used for, removing that concomitant immunosuppressive therapy must be used.
06/26/2024	Added Yimmugo to policy.
07/15/2025	Added Gammagard Liquid ERC to policy.
11/13/2025	Added Qivigy to policy.
06/16/2026	Added trial and failure of preferred IVIG/SCIG product and appendix B.

APPENDICES

Appendix A: Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidities that predispose the patient to bleeding
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (e.g., construction worker, fireman, professional athlete)
- Age >60 years

Appendix B:

Preferred IVIG Product(s)	**Non-Preferred IVIG Product(s)**
Gammagard	Privigen Alyglo Yimmugo Asceniv Bivigam Gammaplex Gammaked Gamunex-C Gammagard S/D (discontinued) Carimune NF Octagam Flebogamma, Flebogamma DIF Panzyga

Preferred SCIG Product(s)	**Non-Preferred SCIG Product(s)**
Cutaquig Hizentra	Cuvitru Xembify Hyqvia

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