

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Immune globulin (IVIG and SCIG):</b> <b>Intravenous (IVIG):</b> Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen, Yimmugo, Gammagard Liquid ERC, Qivigy <b>Subcutaneous (SCIG):</b> Cutaquig, Cuvitru, Hizentra, HyQvia, Xembify
<b>BENEFIT TYPE</b>	Medical
<b>STATUS</b>	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
4. **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).
6. **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).
5. **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.
3. **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.
5. **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  $30 \times 10^9/L$  at any time during pregnancy
  - c) Platelet count less than  $50 \times 10^9/L$  prior to delivery.
5. **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.
4. **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.
5. **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).
3. **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:

1. Medication is prescribed by or in consultation with a neurologist; AND
2. 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
3. **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).
5. **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 ( $<0.05 \times 10^9/L$ ) 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<sup>3</sup>) 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<sup>3</sup>); 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/ $\mu$ L), 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; ANDImpaired vaccine response.

**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).
5. **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. Member is 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).
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 allogeneic BMT/HSCT recipient; AND
2. IVIG is prescribed for prophylaxis of bacterial infections; AND
3. Member has a pretreatment serum IgG < 400 mg/dL
4. **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.
6. **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:

1. Member has had or is scheduled for a kidney transplant; AND
2. Medication must be prescribed by or in consultation with a nephrologist or transplant specialist; AND
3. Medication is being used for prevention of antibody-mediated acute humoral rejection in sensitized patients prior to a kidney transplant; OR
4. Medication is being used for treatment of antibody-mediated acute humoral rejection after a kidney transplant; AND
5. **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**:

6. 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	<p>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.</p> <p><u>Myasthenia Gravis</u>: 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.</p> <p><u>Parvovirus B19-induced PRCA</u>: 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.</p> <p><u>Stiff person syndrome</u>: 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.</p> <p><u>Kawasaki syndrome</u>: Added reference (previously none). Added specialist. Added dosing information.</p> <p><u>LEMS</u>: 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.</p> <p><u>GBS</u>: 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.</p> <p><u>CIDP</u>: 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.</p> <p><u>MMN</u>: Added reference. Added specialist. Added example dosing. Rephrased renewal criteria. Amended diagnostic criteria.</p> <p><u>DM/PM</u>: 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.</p>
03/15/2023	<p>Transferred to new template. Updated/added references.</p> <p><u>Autoimmune bullous diseases</u>: 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.</p> <p><u>CIDP</u>: 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.</p>

	<p><u>DM/PM</u>: Added dermatomyositis dosing per Octagam 10% label. Added MMF to examples list. Specified having active disease.</p> <p><u>GBS</u>: Added “bilateral weakness of limbs” to diagnosis. Added additional reasons to start therapy in addition to being unable to walk independently.</p> <p><u>ITP</u>: 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 &gt;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.</p> <p><u>Kawasaki</u>: Removed pediatrician as specialist and added rheumatologist. Added that the member has fever, elevated inflammatory markers, or CAA.</p> <p><u>HIV</u>: Specified increase IgG could be used as improvement in renewal criteria.</p> <p><u>BMT/HSCT</u>: 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.</p>
<b>02/01/2024</b>	<p>Updated references. Removed billing code appendix. Removed Carimune NF from policy (discontinued). Added Alyglo to policy (new product).</p> <p><u>CIDP</u>: Added Panzyga, HyQvia, Gammagard liquid to product list.</p> <p><u>DM/PM</u>: In reauth, changed “IVIG” to “IG.”</p> <p><u>GBS</u>: #4 changed “IVIG” to “IG.”</p> <p><u>PID</u>: 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.</p> <p><u>Prophylaxis of bacterial infections in B-cell CLL</u>: replaced sinopulmonary recurrent infections with bacterial infections, adding that reauthorization criteria must be documented in chart notes, adding diagnosis, and adding specialist.</p> <p><u>Kidney transplant</u>: 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.</p>
<b>06/26/2024</b>	Added Yimmugo to policy.
<b>07/15/2025</b>	Added Gammagard Liquid ERC to policy.
<b>11/13/2025</b>	Added Qivigy to policy. ODM approved on 01/28/26.

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

References:

1. Bivigam [package insert]. Boca Raton, FL: Biotest Pharmaceuticals Corporation; 2023.
2. Flebogamma 10% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; January 2016.
3. Flebogamma 5% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; April 2015.
4. Gammagard Liquid [package insert]. Takeda Pharmaceuticals U.S.A., Inc.; 2024.
5. Gammagard S/D [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.
6. Gammagard S/D IgA less than 1 mcg/mL [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; September 2013.
7. Gammaked [package insert]. Fort Lee, NJ: Kedrion Biopharma, Inc.; September 2013.
8. Gammaplex [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; July 2015.
9. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; July 2014.
10. Octagam 10% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; 2022.
11. Octagam 5% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; October 2014.
12. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; November 2013.
13. Cuvitru [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2016.
14. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; October 2016.
15. HyQvia [package insert]. Takeda Pharmaceuticals U.S.A., Inc.; 2024.
16. Xembify [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics LLC; July 2019.
17. Cutaquig [prescribing information]. Paramus, NJ: Octapharma USA, Inc.; 2021.
18. Panzyga [prescribing information]. Paramus, NJ: Octapharma USA, Inc.; 2021.
19. Asceniv [prescribing information]. Boca Raton, FL: ADMA Biologics; April 2019.
20. Alyglo [prescribing information]. GC Biopharma Corp.; 2023.
21. Yimmugo [prescribing information]. Biotest AG; 2024.
22. Gammagard Liquid ERC [prescribing information]. Takeda Pharmaceuticals U.S.A., Inc.; 2025.
23. Qivigy [prescribing information]. Kedrion S.p.A.; 2025.
24. Amagai M, Ikeda S, Shimizu H, et al. A randomized double-blind trial of intravenous immunoglobulin for pemphigus. *J Am Acad Dermatol* 2009; 60(4):595-603.
25. Kirtschig G, Middleton P, Bennett C, Murrell DF, Wojnarowska F, Khumalo NP. Interventions for bullous pemphigoid. *Cochrane Database of Systematic Reviews* 2010, Issue 10. Art. No.: CD002292.
26. Orange JS, Hossny EM, Weiler CR, et al. Use of intravenous immunoglobulin in human disease: a review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma, and Immunology. *J Allergy Clin Immunol.* 2006;417(4 Suppl):S525-553.
27. Panel on Opportunistic Infections in Children with and Exposed to HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Children with and Exposed to HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/pediatric-opportunistic-infection>. Accessed March 22, 2023.
28. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplant recipients: a global perspective. *Biol Blood Marrow Transplant.* 2009;15(10):1143-1238.
29. Feasby T, Banwell B, Bernstead T, et al. Guidelines on the use of intravenous immune globulin for neurologic conditions. *Transfus Med Rev.* 2007;21(2):S57-S107.
30. Donofrio PD, Berger A, Brannagan TH 3rd, et al. Consensus statement: the use of intravenous immunoglobulin in the treatment of neuromuscular conditions report of the AANEM ad hoc committee. *Muscle Nerve.* 2009;40(5):890-900.
31. Elovaara I, Apostolski S, van Doorn P, et al. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases: EFNS task force on the use of intravenous immunoglobulin in treatment of neurological diseases. *Eur J Neurol.* 2008;15(9):893-908.
32. Patwa HS, Chaudhry V, Katzberg H, et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2012;78(13):1009-1015.
33. Anderson D, Kaiser A, Blanchette V, et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. *Transfus Med Rev.* 2007;21(2):S9-S56.

34. Picard C, Al-Herz W, Bousfiha A, et al. Primary immunodeficiency diseases: an update on the classification from the International Union of Immunological Societies Expert Committee for Primary Immunodeficiency. *J Clin Immunol*. 2015; 35(8):696-726.
35. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol*. 2015;136(5):1186-205.e1-78.
36. Orange JS, Ballow M, Stiehm ER, et al. Use and interpretation of diagnostic vaccination in primary immunodeficiency: a working group report of the Basic and Clinical Immunology Interest section of the American Academy of Allergy, Asthma and Immunology. *J Allergy Clin Immunol*. 2012;130:S1-S24.
37. Ameratunga R, Woon ST, Gillis D, Koopmans W, Steele R. New diagnostic criteria for common variable immune deficiency (CVID), which may assist with decisions to treat with intravenous or subcutaneous immunoglobulin. *Clin Exp Immunol*. 2013;174(2):203-11.
38. Immune Deficiency Foundation. About primary immunodeficiencies. Specific disease types. <http://primaryimmune.org/about-primary-immunodeficiencies/specific-disease-types/>. Accessed February 12, 2024.
39. Immune Deficiency Foundation. Diagnostic and Clinical Care Guidelines for Primary Immunodeficiency Diseases. 3rd edition. Towson, MD: Immune Deficiency Foundation; 2015. <http://primaryimmune.org/wpcontent/uploads/2015/03/2015-Diagnostic-and-Clinical-Care-Guidelines-for-PI.pdf>. Accessed November 8, 2017.
40. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society—first revision. *J Peripher Nerv Syst*. 2010;15(4):295-301. doi:10.1111/j.1529-8027.2010.00290.x
41. Dalakas MC. Inflammatory muscle diseases. *N Engl J Med*. 2015;372(18):1734-1747. doi:10.1056/NEJMra1402225
42. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011;117(16):4190-4207.
43. Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. *Blood*. 2010;115(2):168-186.
44. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790
45. Sussman J, Farrugia ME, Maddison P, Hill M, Leite MI, Hilton-Jones D. Myasthenia gravis: Association of British Neurologists' management guidelines. *Pract Neurol*. 2015;15(3):199-206. doi:10.1136/practneurol-2015-001126
46. Gajdos P, Chevret S, Toyka KV. Intravenous immunoglobulin for myasthenia gravis. *Cochrane Database Syst Rev*. 2012;12(12):CD002277. Published 2012 Dec 12. doi:10.1002/14651858.CD002277.pub4
47. Balasubramanian SK, Sadaps M, Thota S, et al. Rational management approach to pure red cell aplasia. *Haematologica*. 2018;103(2):221-230. doi:10.3324/haematol.2017.175810
48. Crabol Y, Terrier B, Rozenberg F, et al. Intravenous immunoglobulin therapy for pure red cell aplasia related to human parvovirus b19 infection: a retrospective study of 10 patients and review of the literature. *Clin Infect Dis*. 2013;56(7):968-977. doi:10.1093/cid/cis1046
49. Brown KE, Young NS. Parvovirus B19 infection and hematopoiesis. *Blood Rev*. 1995;9(3):176-182. doi:10.1016/0268-960x(95)90023-3
50. Dalakas MC. The role of IVIg in the treatment of patients with stiff person syndrome and other neurological diseases associated with anti-GAD antibodies. *J Neurol*. 2005;252 Suppl 1:119-125. doi:10.1007/s00415-005-1105-4
51. Dalakas MC, Fujii M, Li M, Lutfi B, Kyhos J, McElroy B. High-dose intravenous immune globulin for stiff-person syndrome. *N Engl J Med*. 2001;345(26):1870-1876. doi:10.1056/NEJMoa01167
52. McCrindle BW, Rowley AH, Newburger JW, et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association [published correction appears in *Circulation*. 2019 Jul 30;140(5):e181-e184]. *Circulation*. 2017;135(17):e927-e999. doi:10.1161/CIR.0000000000000484
53. Titulaer MJ, Lang B, Verschuuren JJ. Lambert-Eaton myasthenic syndrome: from clinical characteristics to therapeutic strategies. *Lancet Neurol*. 2011;10(12):1098-1107. doi:10.1016/S1474-4422(11)70245-9
54. Keogh M, Sedehizadeh S, Maddison P. Treatment for Lambert-Eaton myasthenic syndrome. *Cochrane Database Syst Rev*. 2011;2011(2):CD003279. Published 2011 Feb 16. doi:10.1002/14651858.CD003279.pub3
55. Willison HJ, Jacobs BC, van Doorn PA. Guillain-Barré syndrome. *Lancet*. 2016;388(10045):717-727. doi:10.1016/S0140-6736(16)00339-1
56. van Schaik IN, Brill V, van Geloven N, et al. Subcutaneous immunoglobulin for maintenance treatment in chronic inflammatory demyelinating polyneuropathy (PATH): a randomised, double-blind, placebo-controlled, phase 3 trial [published correction appears in *Lancet Neurol*. 2018 Jan;17(1):26] [published correction appears in *Lancet Neurol*. 2018 Aug;17(8):661]. *Lancet Neurol*. 2018;17(1):35-46. doi:10.1016/S1474-4422(17)30378-2

57. Eftimov F, Winer JB, Vermeulen M, de Haan R, van Schaik IN. Intravenous immunoglobulin for chronic inflammatory demyelinating polyradiculoneuropathy. *Cochrane Database Syst Rev*. 2013;(12):CD001797. Published 2013 Dec 30. doi:10.1002/14651858.CD001797.pub3
58. Oaklander AL, Lunn MP, Hughes RA, van Schaik IN, Frost C, Chalk CH. Treatments for chronic inflammatory demyelinating polyradiculoneuropathy (CIDP): an overview of systematic reviews. *Cochrane Database Syst Rev*. 2017;1(1):CD010369. Published 2017 Jan 13. doi:10.1002/14651858.CD010369.pub2
59. Ryan M, Ryan SJ. Chronic inflammatory demyelinating polyneuropathy: considerations for diagnosis, management, and population health. *Am J Manag Care*. 2018;24(17 Suppl):S371-S379.
60. Hameed S, Cascella M. Multifocal Motor Neuropathy. [Updated 2021 Feb 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/cedarville.ohionet.org/books/NBK554524/>
61. Lundberg IE, Tjårlund A, Bottai M, et al. 2017 European League Against Rheumatism/American College of Rheumatology classification criteria for adult and juvenile idiopathic inflammatory myopathies and their major subgroups [published correction appears in *Ann Rheum Dis*. 2018 Sep;77(9):e64]. *Ann Rheum Dis*. 2017;76(12):1955-1964. doi:10.1136/annrheumdis-2017-211468
62. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in *Blood Adv*. 2020 Jan 28;4(2):252]. *Blood Adv*. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
63. Provan D, Arnold DM, Bussell JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv*. 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812
64. Egami S, Yamagami J, Amagai M. Autoimmune bullous skin diseases, pemphigus and pemphigoid. *J Allergy Clin Immunol*. 2020;145(4):1031-1047. doi:10.1016/j.jaci.2020.02.013
65. Harman KE, Black MM. High-dose intravenous immune globulin for the treatment of autoimmune blistering diseases: an evaluation of its use in 14 cases. *Br J Dermatol*. 1999;140(5):865-874. doi:10.1046/j.1365-2133.1999.02817.x
66. Murrell DF, Peña S, Joly P, et al. Diagnosis and management of pemphigus: Recommendations of an international panel of experts. *J Am Acad Dermatol*. 2020;82(3):575-585.e1. doi:10.1016/j.jaad.2018.02.021
67. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision [published correction appears in *Eur J Neurol*. 2022 Apr;29(4):1288]. *Eur J Neurol*. 2021;28(11):3556-3583. doi:10.1111/ene.14959
68. Oldroyd AGS, Lilleker JB, Amin T, et al. British Society for Rheumatology guideline on management of paediatric, adolescent and adult patients with idiopathic inflammatory myopathy. *Rheumatology (Oxford)*. 2022;61(5):1760-1768. doi:10.1093/rheumatology/keac115
69. Dalakas MC. Inflammatory myopathies: update on diagnosis, pathogenesis and therapies, and COVID-19-related implications. *Acta Myol*. 2020;39(4):289-301. Published 2020 Dec 1. doi:10.36185/2532-1900-03270. National Institute of Child Health and Human Development Intravenous Immunoglobulin Study Group. Intravenous immune globulin for the prevention of bacterial infections in children with symptomatic human immunodeficiency virus infection. *N Engl J Med*. 1991;325(2):73-80. doi:10.1056/NEJM199107113250201
70. Leonhard SE, Mandarakas MR, Gondim FAA, et al. Diagnosis and management of Guillain-Barré syndrome in ten steps. *Nat Rev Neurol*. 2019;15(11):671-683. doi:10.1038/s41582-019-0250-9
71. Gorelik M, Chung SA, Ardalán K, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Kawasaki Disease. *Arthritis Care Res (Hoboken)*. 2022;74(4):538-548. doi:10.1002/acr.24838
72. de Graef FN, Groot N, Ozen S, et al. European consensus-based recommendations for the diagnosis and treatment of Kawasaki disease - the SHARE initiative. *Rheumatology (Oxford)*. 2019;58(4):672-682. doi:10.1093/rheumatology/key344
73. Broderick C, Kobayashi S, Suto M, Ito S, Kobayashi T. Intravenous immunoglobulin for the treatment of Kawasaki disease. *Cochrane Database Syst Rev*. 2023;1(1):CD014884. Published 2023 Jan 25. doi:10.1002/14651858.CD014884.pub2
74. Dykewicz CA; Centers for Disease Control and Prevention (U.S.); Infectious Diseases Society of America; American Society of Blood and Marrow Transplantation. Summary of the Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients. *Clin Infect Dis*. 2001;33(2):139-144. doi:10.1086/321805
75. Centers for Disease Control and Prevention; Infectious Disease Society of America; American Society of Blood and Marrow Transplantation. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients [published correction appears in *MMWR Recomm Rep*. 2004 May 14;53(19):396]. *MMWR Recomm Rep*. 2000;49(RR-10):1-CE7.
76. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol*. 2017;139(3S):S1-S46. doi:10.1016/j.jaci.2016.09.023

77. European Society for Immunodeficiencies (ESID). Diagnostic criteria for PID. Available at <https://esid.org/Working-Parties/Clinical-Working-Party/Resources/Diagnostic-criteria-for-PID2>. Accessed February 5, 2024.
78. Dvorak CC, Haddad E, Heimall J, et al. The diagnosis of severe combined immunodeficiency (SCID): The Primary Immune Deficiency Treatment Consortium (PIDTC) 2022 Definitions. *J Allergy Clin Immunol*. 2023;151(2):539-546. doi:10.1016/j.jaci.2022.10.022
79. Bonilla FA, Barlan I, Chapel H, et al. International Consensus Document (ICON): Common Variable Immunodeficiency Disorders. *J Allergy Clin Immunol Pract*. 2016;4(1):38-59. doi:10.1016/j.jaip.2015.07.025
80. Picard C, Bobby Gaspar H, Al-Herz W, et al. International Union of Immunological Societies: 2017 Primary Immunodeficiency Diseases Committee Report on Inborn Errors of Immunity. *J Clin Immunol*. 2018;38(1):96-128. doi:10.1007/s10875-017-0464-9
81. Tangye SG, Al-Herz W, Bousfiha A, et al. Human Inborn Errors of Immunity: 2022 Update on the Classification from the International Union of Immunological Societies Expert Committee. *J Clin Immunol*. 2022;42(7):1473-1507. doi:10.1007/s10875-022-01289-3
82. National Blood Authority. Criteria for the clinical use of immunoglobulin in Australia (the Criteria). BloodSTAR v.3.11.0. Available from: <https://www.criteria.blood.gov.au/MedicalCondition/View/2685> (accessed 22 Feb 2024).
83. Justiz-Vaillant AA, Hoyte T, Davis N, et al. A Systematic Review of the Clinical Diagnosis of Transient Hypogammaglobulinemia of Infancy. *Children (Basel)*. 2023;10(8):1358. Published 2023 Aug 8. doi:10.3390/children10081358
84. Perez E, Bonilla FA, Orange JS, Ballou M. Specific Antibody Deficiency: Controversies in Diagnosis and Management [published correction appears in *Front Immunol*. 2018 Mar 15;9:450]. *Front Immunol*. 2017;8:586. Published 2017 May 22. doi:10.3389/fimmu.2017.00586
85. Mustillo PJ, Sullivan KE, Chinn IK, et al. Clinical Practice Guidelines for the Immunological Management of Chromosome 22q11.2 Deletion Syndrome and Other Defects in Thymic Development [published correction appears in *J Clin Immunol*. 2024 Jan 22;44(2):53]. *J Clin Immunol*. 2023;43(2):247-270. doi:10.1007/s10875-022-01418-y
86. AT Society. Ataxia-telangiectasia in children Guidance on diagnosis and clinical care. October 2014. Available from: [https://atsociety.org.uk/wp-content/uploads/2017/10/A-T\\_Clinical\\_Guidance\\_Document\\_Final.pdf](https://atsociety.org.uk/wp-content/uploads/2017/10/A-T_Clinical_Guidance_Document_Final.pdf). Accessed February 22, 2024.
87. Cooperative Group for the Study of Immunoglobulin in Chronic Lymphocytic Leukemia, Gale RP, Chapel HM, et al. Intravenous immunoglobulin for the prevention of infection in chronic lymphocytic leukemia. A randomized, controlled clinical trial. *N Engl J Med*. 1988;319(14):902-907. doi:10.1056/NEJM198810063191403
88. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2024). [https://www.nccn.org/professionals/physician\\_gls/pdf/cll.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf). Accessed February 7, 2024.
89. Shehata N, Palda VA, Meyer RM, et al. The use of immunoglobulin therapy for patients undergoing solid organ transplantation: an evidence-based practice guideline. *Transfus Med Rev*. 2010;24 Suppl 1:S7-S27. doi:10.1016/j.tmr.2009.09.010
90. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant*. 2009;9 Suppl 3:S1-S155. doi:10.1111/j.1600-6143.2009.02834.x.
91. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from [codes.ohio.gov](https://codes.ohio.gov).
92. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from [codes.ohio.gov](https://codes.ohio.gov).
93. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from [codes.ohio.gov](https://codes.ohio.gov).

Effective date: 04/01/2026

Revised date: 11/13/2025