PHARMACY POLICY STATEMENT
Indiana 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 **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
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. 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.

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.

i) Less than 4 years of age; AND
ii)

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).

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
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.

	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

	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

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