CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	**Immune globulin (IVIG and SCIG):** **Intravenous (IVIG**): Asceniv, Bivigam, Carimune NF, 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 or 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.

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). 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 IVIG 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. IVIG 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 $30x10^9$/L at any time during pregnancy
   c) Platelet count less than $50x10^9$/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:

Member must have one of the following diagnoses:

1. Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (e.g., X-linked or autosomal recessive agammaglobulinemia):
    a) Diagnosis confirmed by genetic or molecular testing; OR
    b) Pretreatment IgG level < 200 mg/dL; OR
    c) Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only);
2. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
    a) Diagnosis confirmed by genetic or molecular testing (if applicable); AND
    b) History of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal); AND
    c) Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix B);
3. Common variable immunodeficiency (CVID):
    a) Member is 4 years of age or older; AND
    b) Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy); AND
    c) Member's pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age; AND
    d) Member has a history of recurrent bacterial infections; AND
    e) Member has impaired antibody response to pneumococcal polysaccharide vaccine documented in chart notes (see Appendix B);
4. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
    a) Member has a history of recurrent bacterial infections; AND
    b) Member has impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix B)
    c) Member has ANY of the following pre-treatment laboratory findings:
        i) Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age;
        ii) Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels;
        iii) Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels;

iv) IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels;
v) Specific antibody deficiency: normal IgG, IgA and IgM levels;

5. Other predominant antibody deficiency disorders must meet a), b), and c) i) in section 4. above;
6. Other combined immunodeficiency must meet criteria in section 2. above.
7. Dosage allowed/Quantity limit: See dosage and administration information in individual drug package insert. Note: Gammagard Liquid, 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 12 months.

For **reauthorization**:
1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy; AND
2. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication); OR
3. The prescriber will re-evaluate the dose of IVIG and consider a dose adjustment (when appropriate).

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. 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. IVIG is prescribed for prophylaxis of bacterial infections; AND
2. Member has a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization; AND
3. Member has a pretreatment serum IgG level <500 mg/dL (Copy of laboratory report with pre-treatment serum IgG level must be provided with chart notes).
4. **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. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

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

Kidney Transplant

For **initial** authorization:

1. Medication is used for prophylaxis or treatment of acute kidney rejection in conjunction with concomitant immunosuppression (e.g., cyclosporine, mycophenolate mofetil, and corticosteroids).
2. **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 12 months.

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.

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: Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine
- Age 6 years and older: antibody levels are not ≥ 1.3 mcg/mL for at least 70% of serotypes in the vaccine
- Age 2 to 5 years: antibody levels are not ≥ 1.3 mcg/mL for at least 50% of serotypes in the vaccine
- Not established for children less than 2 years of age

Appendix C: Billing codes

Product	Code
Asceniv	J1554
Bivigam	J1556
Carimune NF	J1566
Flebogamma DIF	J1572
Gammagard liquid	J1569
Gammagard S/D	J1566
Gammaked	J1561
Gammaplex	J1557
Gamunex-C	J1561
Octagam	J1568
Panzyga	J1559
Privigen	J1459
Cutaquig	J1599
Cuvitru	J1555
Hizentra	J1559
HyQvia	J1575
Xembify	J1558

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1. Bivigam [package insert]. Boca Raton, FL: Biotest Pharmaceuticals Corporation; October 2013.
2. Carimune NF [package insert]. Kankakee, IL: CSL Behring LLC; May 2018.
3. Flebogamma 10% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; January 2016.
4. Flebogamma 5% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; April 2015.
5. Gammagard Liquid [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.
6. Gammagard S/D [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.
7. Gammagard S/D IgA less than 1 mcg/mL [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; September 2013.
8. Gammaked [package insert]. Fort Lee, NJ: Kedrion Biopharma, Inc.; September 2013.
9. Gammaplex [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; July 2015.
10. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; July 2014.
11. Octagam 10% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; 2022.
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13. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; November 2013.
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15. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; October 2016.
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21. 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.
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