CareSource

PHARMACY POLICY STATEMENT **North Carolina 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
BILLING CODE	See Appendix C at end of document.
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required QUANTITY LIMIT— Dosing should be based on ideal body weight (IBW) or adjusted body weight (adjBW) rather than actual/total body weight (TBW).
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Immune Globulin will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AUTOIMMUNE BULLOUS DISEASE

For **initial** authorization:

1. Member has contraindications to, failure of (refractory to), or significant side effects from systemic corticosteroids or immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil); AND
2. Member has dermatologic condition, as indicated by **one** or more 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.
3. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
2. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect is provided with chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

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:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 6 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; AND
3. Symptoms of motor weakness and/or sensory disturbances have been present for at least 2 months; AND
4. Member has moderate to severe functional disability because of symptoms; AND
5. Electrodiagnostic studies must show evidence of demyelination in at least 2 nerves (e.g. reduced nerve conduction velocities, conduction block, abnormal temporal dispersion); AND
6. Member must meet at least one of the following:
   a) Trial and failure of or contraindication to a steroid regimen for at least 12 weeks (e.g. daily oral prednisone, monthly oral dexamethasone, IV methylprednisolone)
   b) Rapidly progressive disease
   c) Pure motor CIDP (no sensory symptoms, e.g. numbness, tingling, prickling).
7. **Dosage allowed:** See dosing information in individual drug package insert (Gammaked, Gamunex-C, Privigen, Hizentra).

If member meets all the requirements listed above, the medication will be approved for 3 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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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 or has contraindications to first line treatment with a corticosteroid (e.g. prednisone), and/or with a non-steroid immunosuppressant (e.g. azathioprine, methotrexate, cyclosporine) for at least 4 weeks.
4. **Dosage allowed:** Consult clinical literature. For example, 2g/kg IV over 2-5 days.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member has significantly improved muscle strength sustained since initiation of IVIG therapy.

If member meets all the reauthorization requirements above, 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:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, 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 diagnosis of Guillain-Barre Syndrome; AND
3. Physical mobility is severely affected such that member requires an aid to walk; AND
4. IVIG therapy will be initiated within 2 weeks of symptom onset.
5. **Dosage allowed:** Consult clinical literature. For example, 0.4g/kg/day x 5 days in adults.

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

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IDIOPATHIC THROMBOCYTOPENIC PURPURA (IMMUNE THROMBOCYTOPENIA)

For **initial** authorization:

1. Initial therapy (Member diagnosed with ITP within the past 3 months):
   a) Children (< 18 years of age):
      i) Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding); OR
      ii) High risk for bleeding* (see Appendix A); OR
      iii) Rapid increase in platelets is required* (e.g., surgery or procedure);
   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 and IVIG will be used alone or IVIG will be used in combination with corticosteroid therapy.
2. Chronic/persistent ITP (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy (i.e., corticosteroids):
   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 or anti-D therapy.
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 10,000/mm^3 ($10x10^9$/L) at any time during pregnancy;
   c) Platelet count between 10,000/mm^3 ($10x10^9$/L) and 30,000/mm^3 ($30x10^9$/L) in second or third trimester.
5. **Dosage allowed:** 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 member meets all the requirements listed above, the medication will be approved for 1 months for initial therapy, or for 6 months for chronic/persistent ITP or for adults with refractory ITP after splenectomy.

For **reauthorization**:

1. Medication will not be reauthorized for continuous use.

KAWASAKI SYNDROME

For **initial** authorization:

1. Medication is prescribed by a pediatric cardiologist or pediatrician experienced with diagnosing and treating Kawasaki Syndrome; AND
2. Member has a diagnosis of Kawasaki Syndrome.
3. **Dosage allowed:** 2g/kg as a single dose. If fever recurs or persists after at least 36 hours, a second dose may be given.

If member meets all the requirements listed above, the medication will be approved for 1 month.

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

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:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, the medication will be approved for 12 months.

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; these require prior auth) or pyridostigmine.
5. **Dosage allowed:** Consult clinical literature. Consider 2g/kg given over 2 to 5 days, every 8 weeks.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

MULTIFOCAL MOTOR NEUROPATHY (MMN)

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:** Consult clinical literature. (Per Gammagard liquid: 0.5-2.4 g/kg/month IV in adults).

If member meets all the requirements listed above, the medication will be approved for 3 months.

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

If member meets all the reauthorization requirements above, 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:** Consult clinical literature. Consider a daily dose of 0.4 g/kg x 5 days or 1g/kg x 2 days.

If member meets the requirements listed above, 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 the reauthorization requirements above are met, the medication will be approved for 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:** Consult clinical literature. For example: 2g/kg divided over 5 days (400mg/kg/day).

If member meets all the requirements listed above, 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 the reauthorization requirements above 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:** Please 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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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PROPHYLAXIS OF BACTERIAL INFECTIONS IN BMT/HSCT RECIPIENTS

For **initial** authorization:

1. Member is BMT/HSCT recipient; AND
2. IVIG is prescribed for prophylaxis of bacterial infections; AND
3. Either of the following:
   a) IVIG is requested within the first 100 days post-transplant; OR
   b) Member has a pretreatment serum IgG < 400 mg/dL.
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy and documented in chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

PROPHYLAXIS OF BACTERIAL INFECTIONS IN HIV-INFECTED PEDIATRIC PATIENTS

For **initial** authorization:

1. Member with HIV infection and is 18 years of age or younger; AND
2. IVIG is prescribed for **primary** prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL; OR
3. IVIG is prescribed for **secondary** prophylaxis of bacterial infections with ALL of the following:
   a) History of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period);
   b) Member is not able to take combination antiretroviral therapy;
   c) Antibiotic prophylaxis was tried but was not effective (e.g., trimethoprim-sulfamethoxazole).
4. **Dosage allowed:** Please see dosage and administration information in individual drug package insert.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy and documented in chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 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:** Consult the clinical literature for guidance. A dose of 2 g/kg over 2-5 days has been commonly cited.

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

CareSource considers Immune Globulin not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

Acquired hemophilia	Myocarditis, acute
Adrenoleukodystrophy	Neonatal sepsis, prevention
Alzheimer's disease	Neonatal sepsis, treatment
Amyotrophic lateral sclerosis (ALS)	Ocular myasthenia
Antiphospholipid antibody syndrome (APS) in pregnancy	Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy
Asthma, non-steroid dependent	Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
Atopic dermatitis	POEMS syndrome
Autism spectrum disorders	Postinfectious cerebellar ataxia
Autoimmune liver disease	Postoperative sepsis
Autoimmune neutropenia	Pseudomembranous colitis
Campylobacter species-induced enteritis	Respiratory syncytial virus (RSV) lower respiratory tract infection
Cerebral infarctions with antiphospholipid antibodies	Rheumatic fever, acute
Chronic fatigue syndrome	Sjogren's syndrome
Demyelinative brain stem encephalitis	Spontaneous recurrent abortions, prevention
Demyelinating neuropathy associated with monoclonal IgM	Systemic lupus erythematosus
Dilated cardiomyopathy	Urticaria, chronic
HIV infection or prophylaxis	Vasculitides and antineutrophil antibody syndromes
HTLV-1-associated myelopathy	Routine prophylaxis of Measles, Varicella, and Rubella
Idiopathic dysautonomia, acute	Treatment of Measles, Varicella, and Rubella
Inclusion body myositis	
Isolated IgA deficiency	
Isolated IgG4 deficiency	
Lumbosacral or brachial plexitis	

DATE	ACTION/DESCRIPTION

11/15/2017	New policy for Immune Globulin created. Diagnoses associate with inpatient life-threatening 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.

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APPENDICES

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

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (e.g., construction worker, fireman, professional athlete)

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