



Immunoglobulin (Ig) Therapy (Including Intravenous [IVIG] and Subcutaneous Ig [SCIG])

Number: RX504.003

Effective Date: 03-01-2023

Coverage:

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and acceptable standards of medical practice. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

NOTE 1: A form is available for optional use to assist in requesting review for consideration of coverage of Immunoglobulin Therapy. The form is available on the Provider / Forms page of the applicable Blue Cross Blue Shield web site, i.e., BCBSIL.com, BCBSNM.com, BCBSOK.com, BCBSTX.com, or BCBSMT.com.

| | |
|--|--|
| <p>Intravenous Immune Globulin (IVIG) may be considered medically necessary for the following U.S. Food and Drug Administration (FDA) labeled indications when the listed criteria are met.</p> | |
| <u>INDICATIONS:</u> | <u>CRITERIA:</u> |
| Bone marrow transplant (BMT) | <p>1) To prevent risk of infection in the first 100 days post-transplant; OR</p> <p>2) After 100 days post-transplant with serum IgG < 400 mg/dL.</p> |
| Human immunodeficiency virus (HIV) infected children | <p>Children who meet ANY of the following criteria:</p> <p>1) Hypogammaglobulinemia, serum IgG concentration less than 700 mg/dL; OR</p> <p>2) Recurrent serious bacterial infections, defined as two or more major infections such as bacteremia, meningitis, or pneumonia in a one-year period; OR</p> <p>3) Failure to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine; OR</p> |

| | |
|--|--|
| | <p>4) Living in areas with high measles prevalence and have no antibody response after two doses of measles, mumps, and rubella virus vaccine live;OR</p> <p>5) Exposed to measles (single dose of IVIG); OR</p> <p>6) Chronic bronchiectasis, poorly responsive to standard therapy.</p> |
| HIV-associated Thrombocytopenia | <p>1) Significant bleeding in thrombocytopenic patients or platelet count less than 20,000/μl; AND</p> <p>2) Failure of Rh-immune globulin (RhIg) in Rh-positive patients.</p> |
| Chronic Lymphocytic Leukemia (CLL) | <p>Patients with hypogammaglobulinemia (IgG level less than 700 mg/dL), AND</p> <p>1) One severe bacterial infection within preceding six months, or two or more bacterial infections in one year; OR</p> <p>2) Evidence of specific antibody deficiency.</p> |
| Chronic inflammatory demyelinating polyneuropathy (CIDP) | <p>Used either alone or following therapeutic plasma exchange to prolong its effect.</p> <p>NOTE 1: For established diagnostic criteria for CIDP see the Description section.</p> |
| Kawasaki disease (Mucocutaneous Lymph Node Syndrome [MCLS]) | No criteria |
| Multifocal motor neuropathy | No criteria |
| <p>Primary humoral immunodeficiencies including, but not limited to:</p> <ul style="list-style-type: none"> • Congenital agammaglobulinemia (X-linked agammaglobulinemia), • Hypogammaglobulinemia, • Common variable immunodeficiency (CVID), • X-linked immunodeficiency, • Severe combined immunodeficiency (e.g., | <p>When ANY of the following criteria are met:</p> <p>1) Agammaglobulinemia:</p> <p>a) Total IgG < 200 mg/dL, or</p> <p>b) Infants with BTK gene and/or absence of B lymphocytes;</p> <p>OR</p> <p>2) Persistent hypogammaglobulinemia:</p> <p>a) Total IgG < 700 mg/dL, AND</p> <p>b) Recurrent bacterial infections, AND</p> <p>c) Lack of response to protein or polysaccharide antigens (inability to make IgG antibody against EITHER diphtheria and tetanus toxoids, OR</p> |

| | |
|--|---|
| <p>X-SCID, jak3, ZAP70, ADA, PNP, RAG defects, Ataxia Telangiectasia, DiGeorge syndrome),</p> <ul style="list-style-type: none"> • Wiskott-Aldrich syndrome, • Hyper IgM Syndrome. | <p>pneumococcal polysaccharide vaccine, OR both) (See criteria in “Testing Table” below);</p> <p>NOTE 2: Hypogammaglobulinemia associated with cancer must meet criteria above.</p> |
| <p>Selective IgG subclass deficiency</p> | <p>1) Selective IgG subclass deficiency:</p> <p>a) Deficiency of one or more IgG subclasses to levels less than two standard deviations below the age-specific mean, assessed on at least two occasions while the patient is free of infections; AND</p> <p>b) Unexplained recurrent or persistent severe bacterial infections despite adequate treatment; AND</p> <p>c) Demonstrated inability to mount an adequate response to protein and polysaccharide antigens (inability to make IgG antibody against EITHER diphtheria and tetanus toxoids, OR pneumococcal polysaccharide vaccine, OR both) (See criteria in “Testing Table” below).</p> <p>NOTE 3: The physician should consider discontinuing IVIG if the number and/or severity of infections have not been reduced, because not all persons with selective IgG subclass deficiencies benefit from IVIG.</p> |
| <p>Specific Antibody Deficiency (SAD)</p> | <p>1) Normal total IgG levels, with:</p> <p>a) Evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g., recurrent otitis media, bronchiectasis, recurrent infections requiring IV antibiotics, multiple antibiotic hypersensitivities, chronic or recurrent sinusitis) despite aggressive management and treatment with antibiotics, AND</p> <p>b) Severe polysaccharide nonresponsiveness (See criteria in “Testing Table” below).</p> |
| <p>Idiopathic Thrombocytopenia purpura (ITP)</p> | <ul style="list-style-type: none"> • Acute, Severe Idiopathic Thrombocytopenia purpura (ITP) with platelet counts below 30,000/mm; OR |

- Chronic ITP; in patients with at least 6 months' duration of disease, and with persistent thrombocytopenia, despite treatment with corticosteroids and splenectomy.

NOTE 4: Acute, severe ITP may be defined by the following parameters:

- Acute ITP with major bleeding, e.g., life-threatening bleeding and/or clinically important mucocutaneous bleeding,
- Acute ITP with severe thrombocytopenia and at high risk for bleeding complications,
- Acute ITP with severe thrombocytopenia and a slow or inadequate response to corticosteroids, or
- Acute ITP with severe thrombocytopenia and a predictable risk of bleeding in the future (e.g., a procedure or surgery with a high bleeding risk).

Testing Table-For Initiation of IVIG Therapy

NOTE 5: Testing applies ONLY to:

--Primary humoral immunodeficiencies (as noted above)

--Selective IgG Subclass Deficiency

--Specific antibody deficiency (SAD)

Serum antibody titers to tetanus and/or diphtheria

- Obtain serum antibody titer prior to immunization with diphtheria and/or tetanus vaccine, and then again three to four weeks after immunization.
- An inadequate response is defined as less than a fourfold rise in antibody titer and lack of protective antibody level (as defined by laboratory performing the assay).

OR

Serum antibody titers to pneumococcus

- Obtain serum antibody titer prior to immunization, and then again three to six weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (Pneumovax 23).

- An inadequate antibody response is defined as failure to generate a protective antibody titer (defined as specific IgG concentration greater than 1.3 mcg/ml) AND failure to increase the baseline titer at least 2-fold.
- A failed overall challenge test (with Pneumovax 23) is failure in 12 or more serotypes (50% or more) in a child under 6 years of age or failure in 7 or more serotypes (30% or more) in patients age 6 years or older.

Intravenous Immune Globulin may be considered medically necessary *when standard intervention, treatment, and/or therapy has failed, become intolerable, and/or is contraindicated* for ANY of the following off-label indications when the listed criteria are met.

| <u>INDICATIONS:</u> | <u>CRITERIA:</u> |
|--|---|
| Acute inflammatory demyelinating polyneuropathy, including Guillain-Barré syndrome | Patients who have one or more of the following: <ul style="list-style-type: none"> • Rapid deterioration with acute symptoms for less than two weeks; OR • Rapidly deteriorating ability to ambulate; OR • Unable to ambulate independently for ten meters; OR • Deteriorating pulmonary function tests. <p>NOTE 6: IVIG is given as an equivalent alternative to plasma exchange in children and adults. (CAUTION - this is not the same as chronic fatigue syndrome. Refer to the listing of conditions that are considered experimental, investigational, and/or unproven.)</p> |
| Acute lymphoblastic leukemia (ALL) | Only for patients with hypogammaglobulinemia (IgG level less than 700 mg/dL), AND <ul style="list-style-type: none"> • One severe bacterial infection within preceding six months, or two or more bacterial infections in one year; OR • Evidence of specific antibody deficiency. |
| Catastrophic Antiphospholipid Syndrome (CAPS) | <ul style="list-style-type: none"> • Patients who have developed widespread thrombotic disease with organ damage, AND • Used in combination with anticoagulation and glucocorticoid therapy, AND • One course of therapy at dose limit of 2 g/kg in divided doses over 2 to 5 days. |
| Autoimmune hemolytic anemia | Refractory to corticosteroids or splenectomy. |

| | |
|--|--|
| Autoimmune mucocutaneous blistering diseases (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid [a.k.a., cicatricial pemphigoid], epidermolysis bullosa acquisita) | <p>Diagnosis has been confirmed by biopsy and pathology report, AND</p> <ul style="list-style-type: none"> • Patient either has failed, has contraindications to, or has experienced significant complications from conventional therapy; OR • Patient's disease is aggressively progressing, extensive, or debilitating such that clinical response would not be rapid enough with conventional treatment alone and IVIG will be given along with conventional treatment until conventional treatment takes effect. |
| Autoimmune neutropenia | Non-responsive to other treatment modalities or those treatments are contraindicated. |
| Hyperimmunoglobulin E (HIE) syndrome (Job's syndrome, Hyper IgE syndrome) | No criteria |
| Infections, neonates | High-risk, preterm, low-birth-weight neonates, as prophylaxis and/or treatment adjunct. |
| Inflammatory myopathies, Refractory inflammatory myopathies (e.g., polymyositis, dermatomyositis) | Corticosteroid-resistant patients or patients in whom corticosteroids are contraindicated. |
| Lambert-Eaton myasthenic syndrome (LEMS) | Not controlled by anticholinesterases and diaminopyridine. |
| Limbic encephalitis in a child | For documented diagnosis. |
| Multiple Myeloma | <ul style="list-style-type: none"> • "Plateau Phase" (more than three months since diagnosis); AND • IgG level <700 mg/dL; AND <ol style="list-style-type: none"> 1. Two or more significant infections in last year or a single life-threatening infection; OR 2. Evidence of specific antibody deficiency. |
| Multiple Sclerosis (MS) | <ul style="list-style-type: none"> • <u>Severe manifestations of relapsing-remitting type only</u>, AND |

| | |
|---|--|
| | <ul style="list-style-type: none"> • Other therapy (e.g., interferon beta, glatiramer) has failed, become intolerable, and/or is contraindicated. <p>(CAUTION - this is not the same as chronic- [primary- or secondary-] progressive multiple sclerosis. Refer to the listing of conditions that are considered experimental, investigational, and/or unproven.)</p> |
| Myasthenia gravis (MG) | <ul style="list-style-type: none"> • Acute severe decompensation when other treatments have been unsuccessful or are contraindicated; OR • Myasthenia crisis (i.e., an acute episode of respiratory muscle weakness) in patients with contraindications to plasma exchange; OR • Chronic debilitating disease in spite of treatment with cholinesterase inhibitors, and/or complications from or failure of steroids and/or azathioprine, OR • Periodical use to maintain remission in patients with MG that is not well controlled despite the use of chronic immunomodulating drugs. <p>NOTE 7: For myasthenia crisis, IVIG is administered over 2-5 days.</p> |
| Neonatal alloimmune thrombocytopenia, severe | <p>When other interventions have failed or are contraindicated.</p> <p>(CAUTION - this is not the same as non-immune thrombocytopenia. Refer to the listing of conditions that are considered experimental, investigational, and/or unproven.)</p> |
| Neuromyelitis optica | No criteria |
| Fetal-Neonatal Alloimmune Thrombocytopenia (F/NAIT) | <ul style="list-style-type: none"> • Pregnant women with a previously affected pregnancy; OR • Pregnant women with a familial history of F/NAIT, or those found on screening to have platelet alloantibodies. <p>NOTE 8: Timing of IVIG should be based on the severity of fetal thrombocytopenia, determined by cordocentesis, generally around 20-30 weeks.</p> |
| Hemolytic disease of the fetus and newborn (aka erythroblastosis fetalis) | No criteria |

| | |
|--|--|
| Neonatal hemochromatosis | For treatment of high-risk pregnant women who have a history of previous pregnancy ending due to hemochromatosis, or an infant affected by hemochromatosis. |
| Post transfusion purpura severe | No criteria |
| Pure red cell aplasia | <ul style="list-style-type: none"> • With documented parvovirus B19 infection; OR • As salvage therapy for severe anemia refractory to first-line immunosuppressive therapy. |
| Solid organ transplant | <ul style="list-style-type: none"> • Prior to transplant for treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ; OR • Following transplant for treatment of antibody-mediated rejection. <p>NOTE 9: Initial authorization for a maximum dose of 2 grams/kg monthly for 3 months. Reauthorization for up to 3 months is dependent on documented beneficial clinical response.</p> |
| Stevens-Johnson Syndrome (SJS) / Toxic Epidermal Necrolysis (TEN) | For severe, acute case. |
| Stiff person syndrome (Moersch-Woltman syndrome) | <ul style="list-style-type: none"> • Anti-GAD antibody is present; AND • Other therapy has failed (i.e., benzodiazepines and/or baclofen, phenytoin, clonidine, tizanidine). |
| Systemic lupus erythematosus (SLE) | Patients with severe active illness for whom other interventions have been unsuccessful or intolerable. |
| Toxic shock syndrome or toxic necrotizing fasciitis due to streptococcal or staphylococcal organisms | <ul style="list-style-type: none"> • Infection is refractory to several hours of aggressive therapy; OR • Undrainable focus is present; OR • Patient has persistent oliguria with pulmonary edema. |
| Vasculitis syndromes | Patients with severe active illness for whom other interventions have been unsuccessful or intolerable. |
| Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections and | <ul style="list-style-type: none"> • Laboratory confirmation that the patient is <u>not</u> IgA deficient, AND • Documentation that the patient is free of strep infections and other treatable infections, AND |

Pediatric Acute Onset Neuropsychiatric Syndrome (PANDAS/PANS).

- One course of therapy at dose limit of 2 grams/kg of child's weight (1 gm/kg per day for 2 days).

Additional courses of IVIG therapy for moderate to severe PANDAS/PANS **are considered experimental, investigational and/or unproven.**

NOTE 10: It is recommended by the PANDAS Physicians Network (PPN) that antibiotics should be prescribed at treatment level dosages for 2 to 4 weeks before initiating IVIG.

NOTE 11: FOR ILLINOIS PLAN ONLY: Per Illinois state mandate the use of intravenous immunoglobulin (IVIG) is considered covered for the treatment of Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections and Pediatric Acute Onset Neuropsychiatric Syndrome (PANDAS/PANS) when consistent with the criteria outlined in this Medical Policy.

Subcutaneously administered immunoglobulin (SCIG) may be considered medically necessary as an alternative to intravenous Ig therapy when the criteria listed above are met.

The use of **intravenous and/or subcutaneous immunoglobulin is considered experimental, investigational and/or unproven for any indication not listed above**, including but not limited to the following:

- Acquired Factor VIII inhibition;
- Acquired von Willebrand's syndrome;
- Acute disseminated encephalitis (ADEM);
- Acute myocarditis;
- Acute renal failure;
- Adrenoleukodystrophy;
- Alzheimer's disease;
- Amyotrophic lateral sclerosis (ALS or Lou Gehrig disease);
- Aplastic anemia;
- Asthma and inflammatory chest disease;
- Autism [see also medical policy PSY301.014, Autism Spectrum Disorders (ASD)];
- Autoimmune Autonomic Ganglionopathy (AAG);
- Behçet's syndrome;
- Burns;
- Chronic (primary or secondary) progressive multiple sclerosis;
- Chronic fatigue syndrome;
- Chronic sinusitis;
- Complex regional pain syndrome;
- Congenital heart block;
- Crohn's disease;

- Cystic fibrosis;
- Demyelinating optic neuritis;
- Diabetes mellitus;
- Diamond-Blackfan anemia;
- Endotoxemia;
- Epilepsy;
- Euthyroid ophthalmopathy;
- Fisher Syndrome;
- Hemolytic transfusion reaction (except post-transfusion purpura);
- Hemolytic uremic syndrome;
- Hemophagocytic syndrome;
- Inclusion-body myositis;
- Membranous nephropathy;
- Motor neuron syndromes;
- Multiple myeloma (except multiple myeloma with stable plateau phase disease who are at high risk of recurrent infections—see Off-Label indications above);
- Myelopathy, HTLV-1 associated;
- Nephrotic syndrome;
- Non-immune thrombocytopenia;
- Opsoclonus-myoclonus syndrome;
- Paraproteinemic neuropathy;
- Post-infectious sequelae;
- Post-polio syndrome;
- Progressive lumbosacral plexopathy;
- Rasmussen encephalitis (chronic focal encephalitis);
- Recent-onset dilated cardiomyopathy;
- Recurrent otitis media;
- Recurrent spontaneous abortion or recurrent pregnancy loss (not attributed to Catastrophic Antiphospholipid Syndrome (CAPS));
- Refractory recurrent pericarditis;
- Refractory rheumatoid arthritis, adult and juvenile;
- Sepsis in adult patients;
- Thrombotic thrombocytopenic purpura;
- Uveitis;
- Vasculitides (other than Kawasaki disease), including: vasculitis associated with anti-neutrophil cytoplasmic antibodies (ANCA; e.g., Wegener granulomatosis, polyarteritis nodosa), Goodpasture's syndrome, and vasculitis associated with other connective tissue diseases.

Length of Approval: 12 months

TARGET AGENTS

| Brand (generic) | GPI/NDC | HCPCS Code | Multisource Code |
|---------------------------------------|---|-------------------------------|-------------------------|
| Cutaquig 16.5% SCIG | | | |
| 1 gm | 19100020572021 | J1555 | M, N, O, or Y |
| 1.65 gm | 19100020572025 | J1555 | M, N, O, or Y |
| 2 gm | 19100020572030 | J1555 | M, N, O, or Y |
| 3.3 gm | 19100020572035 | J1555 | M, N, O, or Y |
| 4 gm | 19100020572040 | J1555 | M, N, O, or Y |
| 8 gm | 19100020572055 | J1555 | M, N, O, or Y |
| Cuvitru 20% SCIG | | | |
| 1 gm/5 mL | 19100020202050 NDC 00944285001 00944285002 | J1555, 90284 | M, N, O, or Y |
| 2 gm/10 mL | 19100020202054 NDC 00944285003 00944285004 | J1555, 90284 | M, N, O, or Y |
| 4 gm/20 mL | 19100020202058 NDC 00944285005 00944285006 | J1555, 90284 | M, N, O, or Y |
| 8 gm/40 mL | 19100020202062 NDC 00944285007 00944285008 | J1555, 90284 | M, N, O, or Y |
| 10 gm/50 mL | 19100020202065 NDC 00944285009 00944285010 | J1555, 90284 | M, N, O, or Y |
| Gammagard S/D 5% IVIG | | | |
| 5.0 gm | 19100020102120 NDC 00944265603 | J1566, J1569, J1599, 90283 | M, N, O, or Y |
| 10.0 gm | 19100020102130 NDC 00944265804 | J1566, J1569, J1599, 90283 | M, N, O, or Y |
| Gammagard Liquid 10% SCIG/IVIG | | | |
| 1 gm/10 mL | 19100020302060 NDC 00944270002 00944270008 | J1569, J1599, 90283,90284 | M, N, O, or Y |
| 2.5 gm/25 mL | 19100020302064 NDC 00944270003 00944270009 | J1569, J1599, 90283, 90284 | M, N, O, or Y |
| 5 gm/50 mL | 19100020302068 NDC 00944270004 00944270010 | J1569, J1599, 90283, 90284 | M, N, O, or Y |
| 10 gm/100 mL | 19100020302072 NDC 00944270005 00944270011 | J1569, J1599, 90283,90284 | M, N, O, or Y |
| 20 gm/200 mL | 19100020302076 NDC | J1569, J1599, 90283, 90284 | M, N, O, or Y |

| | | | |
|----------------------------------|---|-------------------------------|---------------|
| | 00944270006 00944270012 | | |
| 30 gm/300 mL | 19100020302080 NDC 00944270007 00944270013 | J1569, J1599, 90283, 90284 | M, N, O, or Y |
| Gammaked 10% SCIG/IVIG | | | |
| 1 gm/10 mL | 19100020302060 NDC 76125090001 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 5 gm/50 mL | 19100020302068 NDC 76125090050 76125090051 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 10 gm/100 mL | 19100020302072 NDC 76125090010 76125090011 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 20 gm/200 mL | 19100020302076 NDC 76125090020 76125090021 | J1561, 1599, 90283, 90284 | M, N, O, or Y |
| Gammaplex 5% Liquid IVIG | | | |
| 5 gm/100 mL | 19100020102038 NDC 64208823402 64208823406 | J1557, J1599, 90283 | M, N, O, or Y |
| 10 gm/200 mL | 19100020102042 NDC 64208823403 64208823407 | J1557, J1599, 90283 | M, N, O, or Y |
| 20 gm/400 mL | 19100020102044 NDC 64208823404 64208823408 | J1557 | M, N, O, or Y |
| Gammaplex 10% Liquid IVIG | | | |
| 5 gm/50 mL | 19100020102068 NDC 64208823501 64208823505 | J1557, J1599, 90283 | M, N, O, or Y |
| 10 gm/100 mL | 19100020102072 NDC 64208823502 64208823506 | J1557, J1599, 90283 | M, N, O, or Y |
| 20 gm/200 mL | 19100020102076 NDC 64208823503 64208823507 | J1557, J1599, 90283 | M, N, O, or Y |
| Gamunex-C 10% SCIG/IVIG | | | |
| 1 gm/10 mL | 19100020302060 NDC 13533080012 13533080013 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 2.5 gm/25 mL | 19100020302064 NDC 13533080015 | J1561, J1599, 90283, 90284 | M, N, O, or Y |

| | | | |
|------------------------------|---|-------------------------------|---------------|
| | 13533080016 | | |
| 5 gm/50 mL | 19100020302068 NDC 13533080020 13533080021 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 10 gm/100 mL | 19100020302072 NDC 13533080071 13533080072 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 20 gm/200 mL | 19100020302076 NDC 13533080024 13533080025 | J1561, J1599, 90283, 90284 | M, N, O, or Y |
| 40 gm/400 mL | 19100020302084 NDC 13533080040 13533080041 | J1561, 1599, 90283, 90284 | M, N, O, or Y |
| Hizentra 20% SCIG | | | |
| 1 gm/5 mL | 19100020202050 NDC 44206045190 44206045101 | J1559, 90284 | M, N, O, or Y |
| 1 gm/5 mL prefilled syringe | 1910002020E520 NDC 44206045621 44206045694 | J1559, 90284 | M, N, O, or Y |
| 2 gm/10 mL | 19100020202054 NDC 44206045202 44206045291 | J1559, 90284 | M, N, O, or Y |
| 2 gm/10 mL prefilled syringe | 1910002020E530 NDC 44206045722 44206045795 | J1559,90284 | M, N, O, or Y |
| 4 gm/20 mL | 19100020202058 NDC 44206045404 44206045492 | J1559, 90284 | M, N, O, or Y |
| 4 gm/20 mL prefilled syringe | 1910002020E540 NDC 44206045824 44206045896 | J1559, 90284 | M, N, O, or Y |
| 10 gm/50 mL | 19100020202065 NDC 44206045510 44206045593 | J1559, 90284 | M, N, O, or Y |
| HyQvia 10% SCIG | | | |
| 2.5 gm/25 mL | 19990002356420 | J1575, 90284 | M, N, O, or Y |
| 5.0 gm/50 mL | 19990002356425 | J1575, 90284 | M, N, O, or Y |
| 10.0 gm/100 mL | 19990002356430 | J1575, 90284 | M, N, O, or Y |
| 20.0 gm/200 mL | 19990002356440 | J1575, 90284 | M, N, O, or Y |
| 30.0 gm/300 mL | 19990002356450 | J1575, 90284 | M, N, O, or Y |
| Octagam 5% IVIG | | | |
| 1 gm/20 mL | 19100020102030 NDC | J1568, J1599, 90283 | M, N, O, or Y |

| | | | |
|--------------------------|---|---------------------|---------------|
| | 68982084001 | | |
| 2.5 gm/50 mL | 19100020102034 NDC 68982084002 | J1568, J1599, 90283 | M, N, O, or Y |
| 5 gm/100 mL | 19100020102038 NDC 68982084003 | J1568, J1599, 90283 | M, N, O, or Y |
| 10 gm/200 mL | 19100020102042 NDC 68982084004 | J1568, J1599, 90283 | M, N, O, or Y |
| 25 gm/500 mL | 19100020102046 NDC 68982084005 | J1568, J1599, 90283 | M, N, O, or Y |
| Octagam 10% IVIG | | | |
| 2 gm/20 mL | 19100020102063 NDC 68982085001 | J1568, J1599, 90283 | M, N, O, or Y |
| 5 gm/50 mL | 19100020102068 NDC 68982085002 | J1568, J1599, 90283 | M, N, O, or Y |
| 10 gm/100 mL | 19100020102072 NDC 68982085003 | J1568, J1599, 90283 | M, N, O, or Y |
| 20 gm/200 mL | 19100020102076 NDC 68982085004 | J1568, J1599, 90283 | M, N, O, or Y |
| 30 gm/300 mL | 19100020102080 NDC 68982085005 | J1568, J1599, 90283 | M, N, O, or Y |
| Panzyga 10% IVIG | | | |
| 1 gm/10 mL | 19100020602020 | J1599, 90283 | M, N, O, or Y |
| 2.5 gm/25 mL | 19100020602025 | J1599, 90283 | M, N, O, or Y |
| 5 gm/50 mL | 19100020602030 | J1599, 90283 | M, N, O, or Y |
| 10 gm/100 mL | 19100020602035 | J1599, 90283 | M, N, O, or Y |
| 20 gm/200 mL | 19100020602040 | J1599, 90283 | M, N, O, or Y |
| 30 gm/300 mL | 19100020602045 | J1599, 90283 | M, N, O, or Y |
| Privigen 10% IVIG | | | |
| 5 gm/50 mL | 19100020102068 NDC 44206043605 44206043690 | J1459, J1599, 90283 | M, N, O, or Y |
| 10 gm/100 mL | 19100020102072 NDC 44206043710 44206043791 | J1459, J1599, 90283 | M, N, O, or Y |
| 20 gm/200 mL | 19100020102076 NDC 44206043820 44206043892 | J1459, J1599, 90283 | M, N, O, or Y |
| 40 gm/400 mL | 19100020102090 NDC 44206043940 44206043993 | J1459, J1599, 90283 | M, N, O, or Y |