Subject: **Intravenous and Subcutaneous Immunoglobulin***

Effective Date: **April 29, 2003**

Department(s): **Utilization Management**

Policy: The use of intravenous and subcutaneous immunoglobulin is reimbursable under Plans administered by QualCare, Inc. when condition-specific criteria in the procedure section below are met.

Objective: To provide proper and consistent reimbursement for and to ensure appropriate utilization of a specific therapeutic agent.

Procedure:

Initial authorization is for 6 months unless specified otherwise within the individual criteria listed below by indication. Initial requests are subject to medical director review.

Subcutaneous immune globulin, when specific criteria are met, is reimbursable **only** for primary immunodeficiency disorders (hypo- g, IGG subclass deficiency, specific antibody deficiency[SAD], agammaglobulinemia, transient hypogammaglobulinemia of infancy, extremely low B-cell count, hypergammaglobulinemia E syndrome, or a recognized genetic defect supporting a primary immunodeficiency diagnosis).
A reauthorization for 6 months (up to 12 months for primary immunodeficiency disorders) is approvable when **all** of the following criteria are met:

- The condition under treatment has not fully resolved and the treatment has not exceeded any applicable duration listed below.
- There continues to be a sustained beneficial response to immune globulin as evidenced by treatment notes or a clinical narrative detailing progress to date and the expected frequency and duration of proposed treatment going forward.
- Where clinically appropriate, titration has occurred to the minimum dose and frequency to achieve sustained clinical effect.

A. Intravenous Immune Globulin -Specific Criteria by Medical Condition

I. Primary Immunodeficiency

Condition	Criteria for Use
Hypogammaglobulinemia (including Common Variable Immunodeficiency [CVID]) ICD-9 279.06 ICD-10 D83.0, D83.2-D83.9	**ALL of the following are met:** • **Immunologic evaluation including** documented serum IgG below the lower limits of normal of the laboratory's reported value on at least two occasions • **Impaired Antibody Response (EITHER of the following):** o Lack of protective antibody titers (tetanus and diphtheria or HiB) measured 3–4 weeks after immunization o Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by **EITHER** of the following: □Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) □Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) **Recurrent Infection (ALL of the following):** o History of recurrent bacterial

	sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy o Evidence of management of underlying conditions such as asthma or allergic rhinitis that may predispose to recurrent infections where applicable o Supporting diagnostic imaging and/or laboratory results where applicable
IgG subclass deficiency ICD-9 279.03 ICD-10 D80.3	**ALL of the following are met:** • **Immunologic evaluation** including documented normal total serum IgG with one or more subclasses, excluding isolated subclass IgG4, below the lower limits of normal of the laboratory's reported value on at least two occasions • **Impaired Antibody Response** – Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by **EITHER** of the following: o Age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) o Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) • **Recurrent Infection (ALL of the following)** o History of recurrent bacterial sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy o Evidence of management of underlying conditions such as asthma or allergic rhinitis that may predispose to recurrent infections where applicable o Supporting diagnostic imaging and/or laboratory results where applicable
Selected Specific Primary Immunodeficiency Disorders	**ONE of the following criteria is met:** • **Agammaglobulinemia** defined as serum IgG < 200 mg/dl • **Extremely low (< 2%) or absent B cell**

ICD-9 279.00, 279.09, 279.11 279.12, 279.2, 288.1 ICD-10 D71, D80.0, D80.1, D80.7,D81.0-D81.9, D82.0, D82.1	**count** (CD19+) • **Documentation of a recognized genetic defect** supporting diagnosis (see Appendix 1, Appendix 2, and Appendix 3) • **Transient hypogammaglobulinemia of infancy** with serum immunoglobulins below the age-specific normal range and **BOTH** of the following: o Evidence of recurrent bacterial sinopulmonary infections requiring antibiotic therapy (IVIG is only used for up to six months before re-evaluating the need for continued treatment) o Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination defined as < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) • **Hyperimmunoglobulinemia E syndrome** as evidenced by: O elevated serum IgE level, the presence of staphylococcus-binding IgE, eosinophilia, and recurrent lung and/or skin infections (abscess, chronic eczematous dermatitis) **AND** o Impaired Antibody Response (EITHER of the following): ❖ Lack of protective antibody titers (tetanus and diphtheria or HiB) measured 3–4 weeks after immunization ❖ Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by **EITHER** of the following: Age < 6 years, < 50% of serotypes are protective (i.e., ≥

	1.3 mcg/mL per serotype) OR Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype)
Specific antibody deficiency (SAD) ICD-9 279.09 ICD-10 D89.89*	**ALL of the following criteria are met:** • **Immunological evaluation** including documented normal serum IgG, IgA, and IgM • **BOTH of the following:** o Normal responses to protein antigens (tetanus and diphtheria toxoid) measured 3-4 weeks after immunization o Documentation of administration of Prevnar (PCV 7, PCV 13) • **Inadequate responsiveness** to pneumococcal polysaccharide vaccine (Pneumovax® 23) 4–8 weeks after vaccination as defined by EITHER of the following: o age < 6 years, < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) o age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) • **Recurrent Infection (ALL of the following):** o history of severe and recurrent bacterial sinopulmonary infections despite Prevnar 7 or Prevnar 13 vaccination and use of prophylactic antibiotic therapy o evidence of management of underlying conditions such as asthma or allergic rhinitis that may predispose to recurrent infections where applicable o supporting diagnostic imaging and/or laboratory results

II. Secondary Immunodeficiency

Condition	Criteria for Use
Acquired immunosuppression ICD-9 279.00, 279.2, 948.1-948.99 ICD-10 D81.9	Prevention of infection in individuals meeting **ALL** of the following: • Presence of hypogammaglobulinemia (serum IgG < 400 mg/dL) • Immunosuppression is attributed to **ONE** of the following: o Major surgery (e.g., cardiac transplant) o Hematologic malignancy o Extensive burns o Collagen-vascular disease • Recurrent sinopulmonary infection or history of serious bacterial infection(s)
B-cell Chronic Lymphocytic Leukemia (CLL) ICD-9 204.10-204.12 ICD-10 C91.10-C91.12	Treatment when **BOTH** of the following are met: • Serum IgG less than 500 mg/dL • Recurrent sinopulmonary infection or history of serious bacterial infection(s)
HIV-infected children ICD-9 042 ICD-10 B20	**ONE of the following criteria is met:** • Primary prophylaxis of bacterial infections when hypogammaglobulinemia (serum IgG < 400 mg/dL) is present • Secondary prophylaxis of frequent recurrent serious bacterial infections (e.g., > 2 serious bacterial infections in a 1-year period despite combination ART) when antibiotic prophylaxis is not effective
Multiple Myeloma ICD-9 203.01, 203.02 ICD-10 C90.01, C90.02	Treatment when recurrent sinopulmonary infection or history of serious bacterial infection(s)

III. Transplantation

Condition	Criteria for Use
Hematopoietic cell transplant (HCT) ICD-9 V42.81 ICD-10 Z48.290, Z94.81	Prevention of infection in HCT recipients (e.g., stem cell or bone marrow transplantation) with hypogammaglobulinemia (serum IgG < 400 mg/dL) and **EITHER** of the following: • Within the first 100 days after transplant • After 100 days and evidence of recurrent infections OR evidence of graft-versus-host-disease (GVHD)
Solid organ transplants ICD-9 ICD-10	Treatment for either of the following: • Desensitization for highly-allosensitized transplant candidates (i.e., PRA > 50%) o Authorization for a maximum dose of 2 grams/kg monthly for 4 consecutive months. Additional infusions at 12 months and 24 months may be authorized if the individual has not undergone transplantation. • Antibody-mediated rejection (AMR) o 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.
Graft–versus-host disease ICD-9 279.50-275.53 **ICD-10** D89.810-D89.813	Refractory to steroids and hypogammaglobulinemia (per reporting laboratory reference range) is present.

IV. Hematologic

Condition	Criteria for Use
Anemia related to chronic parvovirus B19 infection ICD-9 079.83 ICD-10 B34.3	Treatment when there is a severe refractory anemia and evidence of viremia
Evan's syndrome ICD-9 287.32 ICD-10 D69.41	Treatment when there is failure, contraindication, or intolerance to available alternative therapies (i.e., azathioprine, cyclophosphamide, cyclosporine or prednisone)
Fetal Alloimmune Thrombocytopenia (FAIT) ICD-9 776.1 ICD-10 D69.59, P61.0	Treatment when **ALL** of the following: • Documentation of maternal antibodies to paternal platelet antigen • **ONE** of the following: o Previous pregnancy complicated by FAIT o Fetal blood sampling documents thrombocytopenia
Hepatitis C-associated Thrombocytopenia ICD-9 287.5 ICD-10 D69.59	Treatment for **ANY** of the following: • Clinically significant bleeding associated with thrombocytopenia • Preoperative treatment prior to a major surgical procedure (e.g., splenectomy) • Receiving antiviral treatment for hepatitis C infection or treatment is contraindicated
HIV-associated Thrombocytopenia ICD-9 287.5 ICD-10 D69.9	Treatment for **ANY** of the following: • Clinically significant bleeding* associated with thrombocytopenia • Preoperative treatment prior to a major surgical procedure (e.g., splenectomy) • Receiving treatment for HIV infection with antiretroviral therapy AND failure, contraindication, or intolerance to corticosteroids

Immune (Idiopathic) Thrombocytopenia – Adult ICD-9 287.31 ICD-10 D69.3	Platelet count < 30,000/mm3 and **ONE** of the following are met: • Clinical need to rapidly increase the platelet count (examples include, but are not limited to: active bleeding, prior to major surgical procedure, risk of cerebral hemorrhage) • Not a candidate for splenectomy or experienced relapse post-splenectomy AND failure, contraindication, or intolerance to ALL of the following: o Corticosteroids o Thrombopoietin receptor agonists (eltrombopag [Promacta®] or romiplostim [Nplate®]) o Rituximab (Rituxan®)
Immune (Idiopathic) Thrombocytopenia – Pediatric ICD-9 287.31 ICD-10 D69.3	**ONE of the following are met:** • Clinical need to rapidly increase the platelet count (examples include, but are not limited to: active bleeding, prior to major surgical procedure, risk of cerebral hemorrhage) • Prevention of bleeding during the first 12 months of persistent disease if responsive to previous treatment with IVIG
Immune Thrombocytopenia (ITP) in pregnancy ICD-9 287.31 ICD-10 D69.3	Treatment when **ALL** of the following are met: • Diagnosis of thrombocytopenia • Failure, contraindication, or intolerance to corticosteroids OR clinical need to rapidly increase the platelet count
Neonatal iso-immune hemolytic disease in conjunction with phototherapy ICD-9 773.0-773.2 ICD-10 P55.0-P55.9	Acute treatment only
Post-transfusion purpura	Acute treatment only

ICD-9 287.41 ICD-10 D69.51	
Warm type autoimmune hemolytic anemia (characterized by predominance of IgG antibodies as opposed to cold type that is predominated by IgM antibodies) ICD-9 283.0 ICD-10 D59.1	Treatment when there is failure, contraindication, or intolerance to available alternative therapies (i.e., azathioprine, cyclophosphamide, cyclosporine, prednisone, plasmapheresis, or splenectomy)

V. Neurologic

Condition	Criteria for Use
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), including Multifocal Acquired Demyelinating Sensory and Motor Neuropathy (MADSAM) (Lewis-Sumner Syndrome) ICD-9 357.81,357.89 ICD-10 G68.81, G61.89,	**For initial authorization**: Treatment when **ALL** of the following **required** elements are met: • Progressive or relapsing motor and/or sensory symptoms of more than one limb **AND** hyporeflexia or areflexia in affected limbs present for at least 2 months • Electrophysiologic findings indicate demyelinating neuropathy (3 of the following 4 criteria are met per the American Academy of Neurology): o Partial conduction block* of ≥ 1 motor nerve o Reduced conduction velocity* of ≥ 2 motor nerves o Prolonged distal latency* of ≥ 2 motor nerves Prolonged F-wave latencies* of ≥ 2 motor nerves or the absence of F waves • Other causes of demyelinating neuropathy have been excluded (from the European Federation of Neurological Societies and the Peripheral Nerve Society): o Borrelia burgdorferi infection (Lyme disease),

G62.89	diphtheria, drug or toxin exposure probably to have caused the neuropathy o Hereditary demyelinating neuropathy o Prominent sphincter disturbance o Diagnosis of multifocal motor neuropathy o IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein o Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy, PNS lymphoma and amyloidosis. Definitions from the American Academy of Neurology • **Partial conduction block** is a drop of at least 20% in negative peak area or peak-to-peak amplitude and a change of < 15% in duration between proximal and distal site stimulation. • **Possible conduction block or temporal dispersion** is a drop of at least 20% in negative peak area or peak-to-peak amplitude and a change of at least 15% in duration between proximal and distal site stimulation. • **Reduced conduction velocity** is a velocity of < 80% of the lower limit of the normal range if the amplitude of the compound muscle action potential (CMAP) is > 80% of the lower limit of the normal range or < 70% of the lower limit if the CMAP amplitude is less than 80% of the lower limit. • **Prolonged distal latency** is more than 125% of the upper limit of the normal range if the CMAP amplitude is more than 80% of the lower limit of the normal range or more than 150% of the upper limit if the CMAP amplitude is less than 80% of the lower limit. • **Absent F wave or F-wave latency** is more than 125% of the upper limit if the CMAP amplitude is more than 80% of the lower limit or latency is more than 150% of the upper limit if

	the CMAP amplitude is less than 80% of the lower limit. **When available**, results of other pertinent testing to support diagnosis should be provided. This includes, but is not limited to, the following: o Cerebrospinal fluid (CSF) examination demonstrating elevated CSF protein with leukocyte count <10/mm3 o MRI showing gadolinium enhancement and/or hypertrophy of the cauda equina, lumbosacral or cervical nerve roots, or the brachial or lumbosacral plexuses o Nerve biopsy showing unequivocal evidence of demyelination and/or remyelination by electron microscopy or teased fibre analysis **For reauthorizations**, significant improvement in clinical condition has been documented by an objective measurement such as the inflammatory neuropathy cause and treatment group (INCAT) sensory sum score; assessment of grip strength via a hand-held dynamometer (e.g., Jamar, Vigorimeter); or Medical Research Council (MRC) scales or other similar, validated neurological scales **AND**, when applicable, a reduction in the level of sensory loss should be noted. (see Appendix 4) **For long-term treatment**, evidence that the dose has been periodically reduced or the treatment withdrawn, and the effects measured.
Guillain-Barré Syndrome (GBS) – including Acute Inflammatory Demyelinating Polyneuropathy (AIDP) ICD-9 357.0 ICD-10 G61.0	Acute treatment when **ALL** of the following criteria have been met: • Initial treatment within 4 weeks of the onset of symptoms • No concomitant use of plasmapheresis • Treatment may be repeated once but should not extend beyond 8 weeks from the onset of

	symptoms
Lambert-Eaton Myasthenic Syndrome (LEMS) ICD-9 358.1 ICD-10 G73.3	Treatment when there is failure, contraindication, or intolerance to other symptomatic therapies (e.g., acetylcholinesterase inhibitors such as mestinon and immunosuppressants such as prednisone, azathioprine)
Multifocal Motor Neuropathy (MMN) ICD-9 357.89 ICD-10 G61.82	Treatment when **BOTH** of the following are present: • Progressive symptoms present for at least 1 month • Diagnosis of definite or probable MMN as defined by the American Association of Neuromuscular and Electrodiagnostic Medicine (see Appendix 5)
Myasthenia Gravis ICD-9 358.81 ICD-10 G70.01	Treatment when **ANY** of the following is present: • Before planned thymectomy or during the post-operative period following thymectomy • During an acute crisis (e.g., significant dysphagia, respiratory failure, inability to perform physical activity) – duration of treatment should not exceed 5 days • During initiation of immunosuppressive treatment **Note:** IVIG for the treatment of myasthenia gravis is not covered as maintenance therapy.
Opsoclonus-Myoclonus-Ataxia Syndrome ICD-9 357.89 ICD-10 G61.89, G 62.89	Treatment when there is a documented diagnosis

Rasmussen Encephalitis ICD-9 323.81 ICD-10 G04.81	Treatment when there is failure to conventional therapy (corticosteroids, antiepileptic agents)
Relapsing-Remitting Multiple Sclerosis ICD-9 340 ICD-10 G35	Treatment as a single agent when there is failure to any **TWO** of the following products indicated for the treatment of relapsing-remitting multiple sclerosis: • Dimethyl fumarate (Tecfidera®)* • Fingolimod (Gilenya™)* • Glatiramer acetate (Copaxone®)* • Interferon beta-1a (Avonex® or Rebif®)* • Interferon beta-1b (Betaseron®, Extavia®)* • Natalizumab (Tysabri®)* • Teriflunomide (Aubagio®)* ** Please note: Individual plans may require prior authorization or pre-certification*
Stiff Person Syndrome (Moersch-Woltmann Syndrome) ICD-9 333.91 ICD-10 G25.82	Treatment when **BOTH** of the following are met: • Anti-GAD antibody testing performed • Failure to available standard medical therapy (e.g., diazepam, baclofen, phenytoin, clonidine, or tizanidine)

VI. Rheumatologic

Condition	Criteria for Use
Dermatomyositis or Polymyositis ICD-9 710.3, 710.4 ICD-10 M33.00-M33.19, M33.20-M33.29, M33.90-M33.99	Documented dermatomyositis or polymyositis established by biopsy AND Failure of standard medical therapy (i.e., corticosteroids AND immunosuppressants), OR When there is profound, rapidly progressive and/or potentially life threatening muscular weakness.

Kawasaki disease ICD-9 446.1 ICD-10 M30.3	Acute treatment when given in conjunction with aspirin within ten days of onset of symptoms
Churg-Strauss Syndrome(eosinophilic granulomatosis with polyangiitis) ICD-9 446.4 ICD-10 M30.1	With multi-organ involvement refractory to corticosteroids and cyclophosphamide(unless contraindicated)
Systemic Lupus Eryhtematosus with discoid lupus or subacute cutaneous lupus manifestations ICD-9 695.4 **ICD-10** L93.0, L93.1	When disease is severe and refractory to corticosteroids, while initiating other long-term treatment
Systemic Lupus Erythematosus Pneumonitis ICD-9 710.0 ICD-10 M32.13	When refractory to corticosteroids.

VII. Infectious Disease

Condition	Criteria for Use
Maternal-fetal transmission of HIV in women who are in their third trimester of pregnancy ICD-9 042 ICD-10 B20	When used in conjunction with antiretroviral treatment

Measles post-exposure prophylaxis ICD-9 V01.79 ICD-10 Z20.828	Prophylaxis when **ANY** of the following are met: • Pregnant women without evidence of measles immunity • Severe primary immunodeficiency • Individuals who have received a bone marrow transplant until at least 12 months after finishing all immunosuppressive treatment, or longer in individuals who have developed graft-versus-host disease • Individual on treatment for acute lymphoblastic leukemia (ALL) within and until at least 6 months after completion of immunosuppressive chemotherapy • Individuals with a diagnosis of AIDS or HIV-infected persons with severe immunosuppression defined as CD4 percent <15% (all ages) or CD4 count <200 lymphocytes/mm3 (aged >5 years) and those who have not received MMR vaccine since receiving effective antiretroviral therapy (ART)
Toxic Shock Syndrome (Staphylococcal or streptococcal) ICD-9 040.82 ICD-10 A48.3	Acute treatment for **ANY** of the following: • The infection is refractory to aggressive treatment • Presence of an undrainable focus • Persistent oliguria with pulmonary edema
Tetanus ICD-9 V07.3 ICD-10 Z29	Post-exposure prophylaxis or treatment when Tetanus Immune Globulin is unavailable
Varicella ICD-9 V01.71 ICD-10 Z20.820	Post-exposure prophylaxis when Varicella Immune Globulin is unavailable
Hepatitis A Prophylaxis ICD-9 V01.79 ICD-10 Z20.5	When vaccine or intramuscular immunoglobulin cannot be administered

VIII. Dermatologic

Condition	Criteria for Use
Autoimmune mucocutaneous blistering diseases; such as: • **Bullous Pemphigoid** • **Epidermolysis Bullosa Acquisita** • **Pemphigoid (a.k.a., Cicatricial Pemphigoid)** • **Pemphigus Foliaceus** • **Pemphigus Vulgaris** ICD-9 694.4, 694.5, 694.8 ICD-10 L10.0, L10.2, L12.0, l12.1, L12.30, L12.31, L12.35	Treatment when **EITHER** of the following criteria is met: • Failure, contraindication or intolerance of conventional therapy (corticosteroids, azathioprine, cyclophosphamide, mycophenolate mofetil) • Rapidly progressive disease in which a clinical response cannot be affected quickly enough using conventional agents. In these situations, IVIG therapy should be given along with conventional treatment(s) and the IVIG used only until conventional therapy takes effect **Note:** IVIG for the treatment of autoimmune mucocutaneous blistering disease is covered only for short-term therapy **(no longer than 6 consecutive months**) and not as a maintenance therapy
Stevens–Johnson Syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN) ICD-9 695.13-695.15 ICD-10 L51.1-L51.3	Acute treatment only.

IX. Other conditions

Condition	Criteria for Use
Gestational Alloimmune Liver Disease (GALD) and for prevention of GALD in a current	Treatment when there is a documented diagnosis **or** for prevention in the current pregnancy, when there is a history of a prior pregnancy resulting in an infant with GALD (dose is 1gm/kg weekly starting at week 18 until birth)

pregnancy ICD-9 ICD-10	
Scleromyxedema(Arndt-Gottron disease) ICD-9 701.8 ICD-10 L98.6	Treatment when there is a documented diagnosis.

B. The use of subcutaneous or intravenous immune globulin is NOT reimbursable for the following conditions as it is considered experimental, investigational or unproven (not an all-inclusive list):

1. Angioedema (ICD-9 277.6; ICD-10 D84.1)
2. Autism (ICD-9 299.0, 299.1; ICD-10 F84.0)
3. Autoimmune chronic urticaria (ICD-9 708.00; ICD-10 L50.9)
4. Clostridium dificile enterocolitis (ICD-(008.45; ICD-10 A04.7)
5. IGM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy(no specific ICD code)
6. Inclusion body myositis(ICD-9 729.1; ICD-10 M60.80-M60.9)
7. Neonatal sepsis (ICD-9 771.81; ICD-10 P36.0-P36.9)
8. Recurrent (at least two) spontaneous miscarriage/pregnancy loss (ICD-9 634.9, 646.33; ICD-10 O03.9, O26.20-O26.23)
9. Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci(PANDAS)(ICD-9 279.8; ICD-10 D89.89)
10. Pediatric acute-onset neuropsychiatric syndrome (PANS)(no specific ICD code)
11. Lyme neuropathy (no specific ICD codes)

C. FDA approved immune globulin products- (intravenous unless otherwise noted)

HCPCS Code	PRODUCT
J1459	Privigen, 500 mg
J1556	Bivigam, 500 mg
J1557	Gammaplex, 500 mg

J1559	Hizentra(immune globulin subcutaneous) 20% liquid
J1561	Gamunex, Gamunex-c, Gammaked, 500 mg (subcutaneous and intravenous)
J1566	Immune globulin, intravenous, lyophilized(powder), not otherwise specified, 500 mg
J1558	Octagam, 500 mg
J1569	Gammagard, 500 mg (subcutaneous and intravenous)
J1572	Flebogamma/ Flebogamma dif, 500 mg
J1575	HyQvia(immune globulin subcutaneous) 10% liquid, with hyaluronidase

D. Usual dosing-

Note -the frequency and amount of immunoglobulin therapy may vary from patient to patient. The proper dosing amount can be determined by monitoring clinical response.

For primary and secondary hypogammaglobulinemic (deficiency) conditions, the usual dose range is 0.3-0.6 Gm/Kg every 3 to 4 weeks. Typical dosing is 1Gm/Kg for for inflammatory and autoimmune disorders such as chronic immune thrombocytopenic purpura(ITP), CIDP(every 3 week maintenance dose after 2Gm/Kg load), Kawasaki disease(alternate regimen is 400Mg/Kg x 4 days), multifocal motor neuropathy(can range from 0.5 to 2.4 Gm/Kg per month according to clinical response).

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail