Fax completed form to: (855) 840-1678
If this is an URGENT request, please call (800) 882-4462
(800.88.CIGNA)

IVIG (Intravenous Immune Globulin)
SCIG (Subcutaneous Immune Globulin)

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Ordering Physician Phone:			* Patient Name:		
Office Contact and Phone:			* Cigna ID:	* Date of Birth:	
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

Urgency:
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Medication requested:

Intravenous:
- ☐ Carimune
- ☐ Flebogamma
- ☐ Gammagard liquid 10%
- ☐ Gammagard S-D
- ☐ Gammaked
- ☐ Gammaplex
- ☐ Gamunex
- ☐ Gamunex-C
- ☐ Octagam
- ☐ Panzyga
- ☐ Privigen

Subcutaneous:
- ☐ Cutaquig
- ☐ Cuvitru
- ☐ Gammagard liquid 10%
- ☐ Gammaked
- ☐ Gamunex C
- ☐ Hizentra
- ☐ Hyqvia

J-Code: ICD10:

Requested dose _____ GRAMS given every day X _____ day(s) every _____ weeks
Dose _____ grams/kg
Patient's current weight _____ KG
Duration of therapy_____

Where will this medication be obtained?
☐ Accredo Specialty Pharmacy *(Cigna's nationally preferred specialty pharmacy)*
☐ Physician's office stock
☐ Hospital - Outpatient
☐ Other (please specify):

Where will this medication be administered?
☐ Home
☐ MD Office
☐ Hospital Inpatient
☐ Hospital Outpatient
☐ Ambulatory Infusion Center
☐ Other (please specify):

Facility and/or doctor dispensing and administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Is this infusion occurring in a facility affiliated with hospital outpatient setting? Yes ☐ No ☐
If yes- Is this patient a candidate for re-direction to an alternate setting after 1-2 infusions (such as AIS, MDO, home) with assistance of a Specialty Care Option Case Manager? Yes ☐ No ☐
NOTE: Per some Cigna plans, infusion of medication MUST occur in the lowest cost, medically appropriate setting.

Is the requested medication for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient? ☐ Yes ☐ No

DIAGNOSIS: _____ **Please answer additional questions listed on the following pages.**

Diagnoses are grouped by condition type (Primary immunodeficiency, Secondary immunodeficiency, Transplantation, Hematology, Neurology, Rheumatology, Infectious disease, Dermatology)

Notice: Please be sure to complete this form in its entirety. Missing information makes it difficult to approve requests and creates a longer processing time.

1. PRIMARY IMMUNODEFICIENCY

Which of the following applies to your patient:

☐ new start on IvIg ☐ new start on ScIg

NEW STARTS: must provide all information requested below

☐ continuation of therapy with IvIg, **NEW TO Cigna/precertification now required****

☐ continuation of therapy with ScIg, **NEW TO Cigna/precertification now required****

☐ continuation of therapy with IvIg***

☐ continuation of therapy with ScIg***

****documentation must be provided of current IgG level, and response to therapy, IN ADDITION to the information requested below.**

*****documentation must only be provided of current IgG level and response to therapy.**

☐ **Hypogammaglobulinemia (including Common Variable Immunodeficiency [CVID]) – documentation must be provided for ALL of the following:**

1. immunologic evaluation, including documented serum IgG below the lower limits of normal of the laboratory's reported value on at least **TWO** occasions
2. lack of protective antibody titers (tetanus and diphtheria or HiB) measured 3–4 weeks after immunization
3. impaired antibody response ****see below**
4. recurrent infection *****see below**

☐ **IgG subclass deficiency – documentation must be provided for ALL of the following:**

1. 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
2. impaired antibody response ****see below**
3. recurrent infection *****see below**

☐ **Specific antibody deficiency (SAD)- documentation must be provided for ALL the following:**

1. immunologic evaluation, including documented normal serum IgG, IgG subclass, IgA, and IgM
2. normal responses to protein antigens (tetanus and diphtheria toxoid) measured 3–4 weeks after immunization
3. impaired antibody response ****see below**
4. recurrent infection (ALL of the following):
   - history of severe and recurrent bacterial sinopulmonary infections despite documentation of vaccination with Prevnar 7 or Prevnar 13 AND failure/inadequate response, contraindication, or intolerance to prophylactic antibiotic therapy
   - evidence of management of underlying conditions such as asthma or allergic rhinitis that may predispose to recurrent infections where applicable
   - supporting diagnostic imaging and/or laboratory results where applicable

**** Impaired Antibody Response- as documented by Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) measured 4/8 weeks after vaccination as defined by:**

1. (if age < 6 years) < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype)
2. (if age ≥ 6 years) < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype)

***** Recurrent Infection- as documented by ALL the following:**

1. history or recurrent bacterial sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy
2. evidence of management of underlying conditions such as asthma or allergic rhinitis that may predispose the patient to recurrent infections where applicable
3. supporting diagnostic imaging and/or laboratory results where applicable

☐ **Agammaglobulinemia – must provide documentation of serum IgG < 200 mg/dl**

☐ **B-cell disorder – must provide documentation of extremely low (< 2%) or absent B cell count (CD19+)**

☐ **Autosomal recessive agammaglobulinemia (ARA) – documentation must be provided for ALL of the following:**

1. recurrent sinopulmonary bacterial infections
2. extremely low or absent IgG, IgM and IgA
3. IGHM, CD79a, CD199b, BLNK, or LRRC8 gene impairment

☐ **Autosomal recessive hyperimmunoglobulin M syndrome (HIM) – documentation must be provided for ALL of the following:**

1. normal or elevated levels of serum IgM
2. low or absent IgG and IgA levels
3. AICDA or UNG gene impaired

☐ **Congenital Hypogammaglobulinemia- documentation must be provided for ALL of the following:**

1. late onset
2. inducible co-stimulator (ICOS) impaired

☐ **Congenital/X-linked agammaglobulinemia (XLA), Bruton's Disease -** must provide documentation of BTK gene impairment

☐ **Hyperimmunoglobulinemia E syndrome (HIES, Job syndrome)- documentation must be provided for ALL of the following:**

1. elevated serum IgE level
2. the presence of staphylococcus-binding IgE, eosinophilia, AND recurrent lung and/or skin infections (abscess, chronic eczematous dermatitis)
3. impaired antibody response- as documented by both of the following:
   a. lack of protective antibody titers (tetanus and diphtheria or HiB) measured 3–4 weeks after immunization
   b. inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax® 23) measured 4/8 weeks after vaccination as defined by:
      i. (if age < 6 years) < 50% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype)
      ii. (if age ≥ 6 years) < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype)

2. SECONDARY IMMUNODEFICIENCY

Which of the following applies to your patient:

☐ new start on IvIg **NEW STARTS: must provide all information requested below**

☐ continuation of therapy with IvIg, **NEW TO Cigna/precertification now required***

☐ continuation of therapy with IvIg**

***documentation must be provided of response to therapy, IN ADDITION to the information requested below.**

****documentation must only be provided of current IgG trough/level and response to therapy.**

☐ **Acquired immunosuppression - must provide documentation of ALL the following:**

1. serum IgG less than 400 mg/dL
2. immunosuppression is attributed to ONE of the following: major surgery (e.g., cardiac transplant), hematologic malignancy, collagen-vascular disease, or extensive burns
3. recurrent sinopulmonary infection history or serious bacterial infection(s)

☐ **B-cell CLL - must provide documentation to ALL of the following:**

1. serum IgG less than 500 mg/dL
2. recurrent sinopulmonary infection or history of serious bacterial infection(s)

☐ **Multiple Myeloma - must provide documentation of recurrent life-threatening infections or history of serious bacterial infection(s)**

☐ **HIV- infected children - must provide documentation of EITHER of the following:**

1. serum IgG < 400 mg/dL
2. frequent recurrent serious bacterial infections (e.g., more than 2 serious bacterial infections in a 1-year period despite combination ART) and antibiotic prophylaxis is not effective

3. TRANSPLANTATION

☐ **Hematopoietic cell transplant (HCT)- must provide documentation of ALL the following:**

1. date of transplant
2. serum IgG < 400 mg/dL
3. either within the first 100 days after transplant OR, if after 100 days, evidence of recurrent infections or graft-versus-host disease (GVHD)

☐ **Solid organ transplants – must provide documentation of both of the following:**

1. date of transplant
2. highly-allosensitized transplant candidate (i.e. PRA > 50%) OR antibody-mediated rejection (AMR)

4. HEMATOLOGY

*Examples of clinically significant bleeding include, not are not limited to, hematuria, gastrointestinal bleeding, significant mucous membrane bleeding

☐ **Immune (Idiopathic) Thrombocytopenia (ITP)-ADULT - must provide documentation of platelet count < 30,000/mm3 and ONE of the following:**

1. 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)
2. patient is not a candidate for splenectomy or has experienced relapse post-splenectomy AND failure, contraindication, or intolerance to ALL of the following:
    a. corticosteroids
    b. thrombopoietin receptor agonists (Promacta or Nplate)
    c. rituximab (Rituxan)

☐ **Immune (Idiopathic) Thrombocytopenia (ITP)-PEDIATRIC - must provide documentation of ONE of the following:**

1. 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)
2. prevention of bleeding during the first 12 months of persistent disease if responsive to previous treatment with IVIG

☐ **Chronic Immune Thrombocytopenia (ITP)- must provide documentation of ALL of the following:**

1. duration greater than 6 months
2. no other concurrent illness/disease explaining thrombocytopenia
3. prior treatment with a reasonable course of corticosteroids or splenectomy
4. platelet count < 30,000/mm3 in children or < 20,000/mm3 in adults

☐ **HIV- associated thrombocytopenia- must provide documentation of ANY of the following:**

1. clinically significant bleeding* associated with thrombocytopenia
2. preoperative treatment prior to a major surgical procedure (e.g., splenectomy)
3. receiving treatment for HIV infection with antiretroviral therapy AND failure, contraindication, or intolerance to corticosteroids

☐ **Hepatitis C-associated thrombocytopenia - must provide documentation of ANY of the following:**

1. clinically significant bleeding* associated with thrombocytopenia
2. preoperative treatment prior to a major surgical procedure (e.g., splenectomy)
3. receiving antiviral treatment for hepatitis C infection or treatment is contraindicated

☐ **Fetal Alloimmune Thrombocytopenia (FAIT)- must provide documentation of ALL of the following:**

1. maternal antibodies to paternal platelet antigen
2. previous pregnancy complicated by FAIT or fetal blood sampling documents thrombocytopenia

☐ **Immune Thrombocytopenia (ITP) in pregnancy- must provide documentation of ALL of the following:**

1. diagnosis of thrombocytopenia
2. failure, contraindication, or intolerance to corticosteroids or clinical need to rapidly increase the platelet count

☐ **Warm type autoimmune hemolytic anemia- must provide documentation of ALL of the following:**

1. predominance of IgG antibodies
2. failure, contraindication, or intolerance to available alternative therapies (i.e. azathioprine, cyclophosphamide, cyclosporine, prednisone, plasmapheresis, or splenectomy)

5. NEUROLOGY

Which of the following applies to your patient:

☐ new start on IvIg **NEW STARTS: must provide all information requested below**

☐ continuation of therapy with IvIg, **NEW TO Cigna/precertification now required***

☐ continuation of therapy with IvIg**

***documentation must be provided of response to therapy, IN ADDITION to the information requested below.**

****documentation must only be provided of response to therapy.**

☐ **Chronic inflammatory demyelinating polyneuropathy (CIDP), including** m**ultifocal acquired demyelinating sensory and motor neuropathy (MADSAM) (Lewis Sumner Syndrome):**

ALL of the following **required** elements:

- 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 as documented by objective measurement
- electrophysiologic findings indicate demyelinating neuropathy (3 of the following 4 criteria are met per the American Academy of Neurology):
    - Partial conduction block** of ≥ 1 motor nerve
    - Reduced conduction velocity*** of ≥ 2 motor nerves
    - 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):
    - Borrelia burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy
    - Hereditary demyelinating neuropathy
    - Prominent sphincter disturbance
    - Diagnosis of multifocal motor neuropathy
    - IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein
    - Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy, PNS lymphoma and amyloidosis.
- When available, results of other pertinent testing to support diagnosis should be provided. This includes, but is not limited to, the following:
    - Cerebrospinal fluid (CSF) examination demonstrating elevated CSF protein with leukocyte count <10/mm3
    - MRI showing gadolinium enhancement and/or hypertrophy of the cauda equina, lumbosacral or cervical nerve roots, or the brachial or lumbosacral plexuses
    - Nerve biopsy showing unequivocal evidence of demyelination and/or remyelination by electron microscopy or teased fibre analysis

*** 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.*

***If continued therapy, documentation of the following must also be provided:**

1. significant improvement in clinical condition 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 of other similar, validated neurological scales
2. when applicable, a reduction in the level of sensory loss
3. any titration efforts since last renewal
4. updated test results (e.g., if NCV/EMG has been repeated)

☐ **Multifocal Motor Neuropathy (MMN) – must provide documentation of progressive symptoms present for at least 1 month and ONE of the following:**

1. diagnosis of **definite** multifocal motor neuropathy (as defined by American Association of Neuromuscular and Electrodiagnostic Medicine Consensus Criteria for the Diagnosis of Multifocal Motor Neuropathy) with documentation of **ALL** the following:
    a. weakness without objective sensory loss in the distribution of two or more named nerves. During the early stages of symptomatic weakness, the historical or physical finding of diffuse, symmetric weakness excludes multifocal motor neuropathy.
    b. definite conduction block is present in two or more nerves outside of common entrapment sites (median nerve at wrist; ulnar nerve at elbow or wrist; peroneal nerve at fibular head).
    c. normal sensory nerve conduction velocity across the same segments with demonstrated motor conduction block.
    d. normal results for sensory nerve conduction studies on all tested nerves, with a minimum of three nerves tested. The absence of each of the following upper motor neuron signs: spastic tone, clonus, extensor plantar response, and pseudobulbar palsy.

2. diagnosis of **probable** multifocal motor neuropathy (as defined by American Association of Neuromuscular and Electrodiagnostic Medicine Consensus Criteria for the Diagnosis of Multifocal Motor Neuropathy) with documentation of **ALL** the following:
    a. weakness without objective sensory loss in the distribution of two or more named nerves. During the initial weeks of symptomatic weakness, the presence of diffuse, symmetric weakness excludes multifocal motor neuropathy.
    b. the presence of either:
        i. Probable conduction block in two or more motor nerve segments that are not common entrapment sites
        ii. Definite conduction block in one motor nerve segment and probable conduction block in a different motor nerve segment, neither of which segments are common entrapment sites.
    c. normal sensory nerve conduction velocity across the same segments with demonstrated motor conduction block, when this segment is technically feasible for study (that is, this is not required for segments proximal to axilla or popliteal fossa).
    d. normal results for sensory nerve conduction studies on all tested nerves, with a minimum of three nerves tested.
    e. the absence of each of the following upper motor neuron signs: spastic tone, clonus, extensor plantar response, and pseudobulbar palsy.

☐ **Myasthenia gravis (MG)- must provide documentation of ALL the following:**

1. date of planned or past thymectomy
2. support of acute crisis, if applicable e.g. significant dysphagia, respiratory failure, inability to perform physical activity)
3. initiation of immunosuppressive treatment, if applicable.

*Please note that IvIg is not covered for maintenance therapy.

☐ **Relapsing-Remitting Multiple Sclerosis- must provide documentation of ALL the following:**

1. clinical records/labs/Xray supporting diagnosis of RRMS
2. current medications and treatment plan with initiation of IvIg, including use of IvIg as monotherapy
3. failure to TWO available standard medical therapies

☐ **Guillain-Barré syndrome (GBS) including acute inflammatory demyelinating polyneuropathy (AIDP) - must provide documentation of ALL the following:**

1. date of initial onset of symptoms
2. current medications and treatment plan with initiation of IvIg

☐ **Lambert-Eaton myasthenic syndrome (LEMS) - must provide documentation of current medications and treatment plan with initiation of IvIg**

☐ **Stiff Person Syndrome (Moersch-Woltmann Syndrome) - must provide documentation of ALL the following:**

1. anti-GAD antibody testing
2. failure to available standard medical therapy (e.g. diazepam, baclofen, phenytoin, clonidine, or tizanidine)

6. RHEUMATOLOGY

☐ **Dermatomyositis or Polymyositis- must provide documentation of ALL the following:**

1. biopsy results and date
2. failure of standard medical therapy (corticosteroids AND immunosuppressants) OR profound, rapidly progressive and/or potentially life threatening muscular weakness)
3. serum creatine kinase (CK) levels and dates taken
4. muscle strength scales and dates taken

☐ **Kawasaki disease- must provide documentation of ALL the following:**

1. date of initial onset of symptoms
2. current medications and treatment plan with initiation of IvIg

7. INFECTIOUS DISEASE

☐ **Staphylococcal or streptococcal toxic shock syndrome- must provide documentation of ALL the following:**

1. infection is refractory to aggressive treatment (include therapies tried)
2. presence of an undrainable focus
3. persistent oliguria with pulmonary edema

☐ **Measles Prophylaxis - must provide documentation of exposure to measles or living in a high-prevalence measles area AND supportive documentation for the following situations.**

1. Pregnant woman without evidence of measles immunity
2. Severe primary immunodeficiency
3. 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
4. Individual on treatment for acute lymphoblastic leukemia (ALL) within and until at least 6 months after completion of immunosuppressive chemotherapy
5. AIDS or HIV-infected persons either with severe immunosuppression defined as CD4 percent <15% (all ages) or CD4 count <200 lymphocytes/mm^3 (aged >5 years) or who have not received MMR vaccine since receiving effective antiretroviral therapy (ART)

☐ **Tetanus / Varicella- must provide documentation of unavailability of tetanus or varicella Immune Globulin**

8. DERMATOLOGY

☐ **Autoimmune mucocutaneous blistering diseases; such as: Bullous Pemphigoid, Epidermolysis Bullosa Acquisita, Pemphigoid (a.k.a., Cicatricial Pemphigoid), Pemphigus Foliaceus, Pemphigus Vulgaris- must provide documentation of ALL the following:**

1. failure, contraindication or intolerance of conventional therapy (corticosteroids, azathioprine, cyclophosphamide, mycophenolate mofetil)
2. rapidly progressive disease in which a clinical response cannot be affected quickly enough using conventional agents

OTHER

☐ **Other- must provide documentation and chart notes in support of this use-** _____

Which of the following applies to your patient:

☐ new start on IvIg
☐ new start on ScIg
☐ continuation of therapy with IvIg*
☐ continuation of therapy with ScIg*

***If continued therapy, documentation must also be provided of positive response to therapy (including labs, chart notes, etc.).**

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ **Date:**_____

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