Immunoglobulins Therapy Medication and/or Infusion Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	Email:	

Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name: *(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.				
Address:	City:	State:	ZIP:		
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:	Office Contact Name:	Phone:			

Specialty *(Check one):* ☐ **Oncologist** ☐ **Hematologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other
☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: ☐ **Asceniv** ☐ **Bivigam** ☐ **Cutaquig** ☐ **Cuvitru** ☐ **Flebogamma DIF** ☐ **Hizentra** ☐ **HyQvia** ☐ **GamaSTAN**
☐ **Gammagard Liquid** ☐ **Gammagard S/D** ☐ **Gammaked** ☐ **Gammaplex** ☐ **Gamunex-C** ☐ **Octagam**
☐ **Panzyga** ☐ **Privigen** ☐ **Xembify**

Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

For All Requests (Exception GamaSTAN) (clinical documentation required for all requests):

☐ Yes ☐ No Has the patient received immunoglobulin therapy for a requested indication within the last 3 months?
☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?
→ ☐ Yes ☐ No Is this request to continue previously established treatment with the requested medication?
→ Please explain: ☐ This is a new therapy request (patient has not received requested medication in the last 6 months)
☐ This is a request for a different brand immune globulin product that the patient has not received previously
→ Please select the continuation request:
☐ This is a continuation of an existing treatment
☐ This is a continuation request, however a gap in therapy of greater than 8 weeks has occurred
☐ Yes ☐ No Does the patient have laboratory confirmed autoantibodies to immunoglobulin A?
☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?
☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?
☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?
→ Please provide a description of the behavioral issue or impairment: _____

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G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
→ Please provide a description of the condition:
☐ Cardiovascular: _____
☐ Respiratory: _____
☐ Renal: _____

For Initiation requests (Exception GamaSTAN) (clinical documentation required for all requests):

☐ **Acquired red cell aplasia**

☐ **Acute disseminated encephalomyelitis**
☐ Yes ☐ No Has the patient had an insufficient response to intravenous corticosteroid treatment?

☐ **Autoimmune hemolytic anemia**
Which type of autoimmune hemolytic anemia does the patient have? ☐ warm type ☐ cold type ☐ other
☐ Yes ☐ No Has the patient tried corticosteroids with inadequate response?
→ ☐ Yes ☐ No Has the patient had a splenectomy with inadequate response?
→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids or splenectomy?

☐ **Autoimmune mucocutaneous blistering diseases**
Please select which applies to the patient: ☐ Bullous pemphigoid ☐ Epidermolysis bullosa acquisita ☐ Pemphigus vulgaris ☐ Mucous membrane pemphigoid ☐ Pemphigus foliaceus ☐ Other, please explain: _____
☐ Yes ☐ No Has the diagnosis been proven by biopsy and confirmed by pathology report?
☐ Yes ☐ No Is the condition rapidly progressing, extensive, or debilitating?
☐ Yes ☐ No Has the patient failed or experienced significant complications (e.g., diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents)?

☐ **Autoimmune neutropenia**
☐ Yes ☐ No Is treatment with G-CSF (granulocyte colony stimulating factor) an appropriate option? Examples of G-CSF include Fulphila, Granix, Leukine, Neulasta, Neupogen, Udenyca, Zarxio.

☐ **B-cell chronic lymphocytic leukemia (CLL)**
Please provide the patient's pre-treatment IgG level: _____
☐ Yes ☐ No Is IG prescribed for prophylaxis of bacterial infections?
☐ Yes ☐ No Does the patient have a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization?

☐ **Birdshot retinochoroidopathy**
☐ Yes ☐ No Has the patient tried immunosuppressant therapy (e.g., corticosteroids, cyclosporine) with inadequate response?

☐ **BK virus associated nephropathy**

☐ **Bone marrow transplant/hematopoietic stem cell transplant recipient**
☐ Yes ☐ No Will therapy be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic), septecemia and other infections (e.g., cytomegalovirus {CMV}, recurrent bacterial infections)?
☐ Yes ☐ No Has the patient received a bone marrow/hematopoietic stem cell transplant within the past 100 days?
→ Please provide the patient's pre-treatment IgG level: _____

☐ **CAR-T therapy related hypogammaglobulinemia**
Please provide the patient's IgG level: _____
☐ Yes ☐ No Has the patient received treatment with CAR-T therapy (e.g., tisagenlecleucel [Kymriah] or axicabtagene ciloleucel [Yescarta]?

☐ **Chronic inflammatory demyelinating polyneuropathy (CIDP)**
☐ Yes ☐ No Is the disease course progressive or relapsing/remitting for 2 months or longer?
☐ Yes ☐ No Does the patient have moderate to severe functional disability?
☐ Yes ☐ No Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis?

☐ **Churg-Strauss Syndrome**
☐ Yes ☐ No Does the patient have severe, active disease?
☐ Yes ☐ No Will immune globulin be used as adjunctive therapy?
☐ Yes ☐ No Has the patient experienced failure, intolerance, or is contraindicated to other interventions?

☐ **Dermatomyositis** OR ☐ **Polymyositis**
Please select clinical features the patient exhibits (select all that apply): ☐ Proximal muscle weakness (upper or lower extremity and trunk)
☐ Elevated serum creatine kinase (CK) or aldolase level ☐ Muscle pain on grasping or spontaneous pain ☐ Non-destructive arthritis or arthralgias
☐ Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
☐ Positive for anti-synthetase antibodies (e.g., anti-Jo-1, also called histadyl tRNA synthetase)
☐ Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method)
☐ Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen)
☐ The patient does not exhibit clinical features
☐ Yes ☐ No Were standard first-line (corticosteroids) and second-line (immunosuppressants) treatments tried but were unsuccessful or not tolerated?
→ ☐ Yes ☐ No Is the patient unable to receive standard first-line and second-line therapy because of a contraindication or other clinical reason?

☐ **Enteroviral meningoencephalitis**
☐ Yes ☐ No Is the patient's condition severe?

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Guillain-Barre Syndrome (GBS)**
- ☐ Yes ☐ No Does the patient have severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)?
- ☐ Yes ☐ No Did the onset of neurologic symptoms occur less than 4 weeks from the anticipated start of immunoglobulin therapy?

☐ **Hemophagocytic lymphohistiocytosis (HLH)** OR ☐ **Macrophage activation syndrome (MAS)**

Please provide the patient's total IgG level: _____ (Please provide a copy of the laboratory report with the pre-treatment IgG level)

- ☐ Yes ☐ No Is the patient's total IgG level less than 400mg/dL?
  - → ☐ Yes ☐ No Is the IgG level two standard deviations below the mean for age?

☐ **Human immunodeficiency virus (HIV) infection**

For a **pediatric** patient:

- ☐ Yes ☐ No Is the requested drug being prescribed for prophylaxis of bacterial infections?
  - → ☐ Yes ☐ No Is the requested drug being prescribed for treatment of thrombocytopenia associated with HIV?
    - → Please provide the patient's pre-treatment IgG level: _____
  - ☐ Yes ☐ No Has the patient had 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent?
    - → ☐ Yes ☐ No Does the patient have HIV-associated thrombocytopenia despite anti-retroviral therapy?
      - → Please provided the patient's T4 cell count: _____
        For T4 cell count less than 200/mm^3 or unknown:
        - ☐ Yes ☐ No Does the patient live in an area where measles is highly prevalent?
        - ☐ Yes ☐ No Has the patient failed to develop an antibody response after two doses of measles, mumps, and rubella live virus vaccine?
        - ☐ Yes ☐ No Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?
- → Please indicate whether IG will be used for primary or secondary prophylaxis:
  - ☐ primary prophylaxis
    - → Please provide the patient's pre-treatment IgG level: _____
  - ☐ secondary prophylaxis
    - → ☐ Yes ☐ No Does the patient have a history of recurrent bacterial infections (>2 serious bacterial infections in a 1-year period)?
  - ☐ other prophylaxis
    - ☐ Yes ☐ No Has the patient failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine?
    - ☐ Yes ☐ No Is this request for a single dose of immune globulin for a patient who has been exposed to measles?
    - ☐ Yes ☐ No Does the patient live in an area where measles is highly prevalent?
      - → ☐ Yes ☐ No Has the patient failed to develop an antibody response after two doses of measles, mumps, and rubella live virus vaccine?
    - ☐ Yes ☐ No Does the patient have chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy?

For an **adult** patient:

- ☐ Yes ☐ No Is the requested drug being prescribed for treatment of thrombocytopenia associated with HIV?
- ☐ Yes ☐ No Does the patient have significant bleeding?

Please provide the patient's platelet count: _____ /mcL

- ☐ Yes ☐ No Is the patient Rh-positive?
  - → ☐ Yes ☐ No Has the patient failed treatment with RhIG?

☐ **Hyperimmunoglobulinemia E Syndrome**
- ☐ Yes ☐ No Does the patient have severe eczema?

☐ **Immune thrombocytopenic purpura (ITP)**
- ☐ Yes ☐ No Is the patient a pregnant woman? If yes, please provide estimated date of delivery: ____/____/____
  - → Please select which of the following applies to the patient:
    - ☐ <u>The patient is an adult with refractory ITP after splenectomy:</u>
      Please select the current pretreatment platelet count:
      - ☐ Less than 30,000/mcL (30 x 10^9/L)
      - ☐ Greater than 30,000/mcL (30 x 10^9/L)
        - → ☐ Yes ☐ No Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?

      <u>For Newly diagnosed, previously treated, chronic or persistent or ITP unresponsive to first line treatment:</u>
      - ☐ Yes ☐ No Does the patient have significant bleeding symptoms (e.g., mucosal bleeding or other moderate to severe bleeding)?
      - ☐ Yes ☐ No Is the patient at high risk for bleeding or does the patient require a rapid increase in platelets?
        - → Please indicate the risk factors:
          - ☐ Comorbidity (e.g., peptic ulcer disease or hypertension)
          - ☐ Undergoing a medical or dental procedure where blood loss is anticipated
          - ☐ Mandated anticoagulation therapy
          - ☐ Profession or lifestyle predisposes the patient to trauma (e.g., construction worker, fireman, professional athlete)
          - ☐ Other, please explain: _____

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G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

☐ Newly diagnosed ITP (diagnosed within the past 3 months) OR ☐ Previously untreated ITP (initial therapy)
- ☐ newly diagnosed children
- ☐ newly diagnosed adults:
  - → Please indicate the patient's current pretreatment platelet count:
    - ☐ Less than 30,000/mcL (30 x 10^9/L)
      - → Please select the prescribed regimen:
        - ☐ IG monotherapy
          - → ☐ Yes ☐ No Is corticosteroid therapy contraindicated?
        - ☐ IG in combination with corticosteroid
        - ☐ Other
    - ☐ 30,000 to less than 100,000/mcL (30 x 10^9 to < 100 x 10^9/L)
    - ☐ Greater than or equal to 100,000/mcL (100 x 10^9/L)

☐ Chronic or persistent ITP (≥ 3 months from diagnosis) OR ☐ ITP unresponsive to first-line treatment:

Please indicate the current pretreatment platelet count:
- ☐ Less than 30,000/mcL (30 x 10^9/L)
  - → ☐ Yes ☐ No Does the patient have relapsed ITP after a previous response to IG therapy?
  - ☐ Yes ☐ No Does the patient have a history of inadequate response, intolerance or a contraindication to corticosteroid or anti-D therapy?
- ☐ 30,000 to less than 100,000/mcL (30 x 10^9 to < 100 x 10^9/L)
- ☐ Greater than or equal to 100,000/mcL (100 x 10^9/L)

☐ Other classification of ITP

☐ **Immune checkpoint inhibitor related toxicity**
- ☐ Yes ☐ No Has the patient experienced a moderate or severe adverse event to a PD-1 inhibitor (e.g., pembrolizumab, nivolumab) or PD-L1 inhibitor (e.g., atezolizumab, avelumab, durvalumab)?
- ☐ Yes ☐ No Is the offending drug being temporarily held or has it been discontinued permanently?

Please select which of the following adverse events the patient experienced: ☐ pneumonitis ☐ myasthenia gravis ☐ peripheral neuropathy ☐ encephalitis ☐ transverse myelitis ☐ severe inflammatory arthritis ☐ myocarditis ☐ bullous dermatitis ☐ Guillain-Barre syndrome ☐ steroid-refractory myalgias or myositis ☐ Stevens-Johnson syndrome, toxic epidermal necrolysis ☐other

☐ **Isoimmune hemolytic disease of newborn**

☐ **Kawasaki syndrome (pediatric)**

☐ **Lambert-Eaton myasthenic syndrome**
- ☐ Yes ☐ No Has the diagnosis been confirmed by neurophysiology studies (e.g., electromyography) or a positive anti- P/Q type voltage-gated calcium channel antibody test?
  - → Please select: ☐ neurophysiology studies ☐ positive anti- P/Q type voltage-gated calcium channel antibody test
- ☐ Yes ☐ No Has the patient tried an anticholinesterase (e.g., pyridostigmine) but it was unsuccessful or not tolerated?
- ☐ Yes ☐ No Has the patient tried amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) but it was unsuccessful or not tolerated?
- ☐ Yes ☐ No Does the patient have severe weakness?
  - → ☐ Yes ☐ No Is there difficulty with venous access for plasmapheresis?

☐ **Measles**
- ☐ Yes ☐ No Is the patient susceptible and exposed to measles less than 6 days prior to this request?
- ☐ Yes ☐ No Is this request for postexposure to prevent or modify symptoms of measles (rubeola)?

☐ **Multifocal motor neuropathy**
- ☐ Yes ☐ No Has the patient experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in 2 or more nerves for at least 1 month?
- ☐ Yes ☐ No Were electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS]) performed to confirm the diagnosis?

☐ **Multiple Myeloma**
- ☐ Yes ☐ No Does the patient have recurrent, serious infections despite the use of prophylactic antibiotics?

☐ **Myasthenia Gravis**

Please indicate the primary reason for IG is being prescribed:
- ☐ Refractory myasthenia gravis
  - → ☐ Yes ☐ No Has the patient tried and failed 2 or more standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab)?
- ☐ Acute exacerbation/crisis
  - → ☐ Yes ☐ No Does the patient have severe swallowing difficulty and/or respiratory failure?
    - → ☐ Yes ☐ No Does the patient have weakness with an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, or limb weakness?
- ☐ Worsening weakness
  - → ☐ Yes ☐ No Does the patient have weakness with an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, or limb weakness?
- ☐ Pre-operative management (e.g., prior to thymectomy)
- ☐ Other, please explain: _____

☐ **Neonatal Alloimmune Thrombocytopenia (NAIT) (also known as Fetal Alloimmune Thrombocytopenia or FAIT)**

☐ **Neonatal Hemochromatosis**
- ☐ Yes ☐ No Is the patient currently pregnant?
  - → ☐ Yes ☐ No Does the patient have a history of pregnancy ending in documented neonatal hemochromatosis?

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☐ **Opsoclonus-myoclonus**
- ☐ Yes ☐ No Does the patient have paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma?
  - → ☐ Yes ☐ No Does the patient have refractory opsoclonus-myoclonus?
  - ☐ Yes ☐ No Is immune globulin being used as last-resort treatment?

☐ **Parvovirus B19-induced pure red cell aplasia (PRCA)**
- ☐ Yes ☐ No Does the patient have severe, refractory anemia associated with bone marrow suppression?
- ☐ Yes ☐ No Does the patient have parvovirus B19 viremia?

☐ **Post-transfusion purpura**

☐ **Primary immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome)**
- ☐ Yes ☐ No Does the patient have a history of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal infections)?
- ☐ Yes ☐ No Was the immune globulin therapy initiated in the hospital setting?

For the patient of 2 years of age or older:
- ☐ Yes ☐ No Has the patient demonstrated an impaired antibody response to vaccination with a pneumococcal polysaccharide vaccine?

Please indicate the specific immunodeficiency disorder:

☐ Common variable immunodeficiency (CVID)
- → ☐ Yes ☐ No Have other causes of immune deficiency been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy)?
  - Please provide the patient's pre-treatment IgG level: _____
  - For pre-treatment IgG level greater than or equal to 500 mg/dL:
    - ☐ Yes ☐ No Is the patient's pretreatment IgG level ≥ 2 SD below the mean for age?

☐ Hypogammaglobulinemia (unspecified) or other predominant antibody deficiency disorder
- → Please provide the patient's pre-treatment IgG level: _____
- For pre-treatment IgG level greater than or equal to 500 mg/dL:
  - ☐ Yes ☐ No Is the patient's pretreatment IgG level ≥ 2 SD below the mean for age?

☐ IgG subclass deficiency
- → ☐ Yes ☐ No Does the patient have low levels of any IgG subclasses?
  - → Please select the subclass: ☐ IgG1 ☐ IgG2 ☐ IgG3 ☐ Other
- ☐ Yes ☐ No Was the IgG subclass level ≥ 2 SD below the mean for age measured on at least 2 different occasions?
- ☐ Yes ☐ No Does the patient have normal pre-treatment total IgG levels, normal IgM levels and normal/low IgA levels?

☐ Selective IgA deficiency
- → Please indicate the patient's pre-treatment IgA level: _____
- ☐ Yes ☐ No Does the patient have normal pre-treatment IgG and IgM levels?

☐ Selective IgM deficiency
- → Please indicate the patient's pre-treatment IgM level: _____
- ☐ Yes ☐ No Does the patient have normal pre-treatment IgG and IgA levels?

☐ Severe combined immunodeficiency (SCID)
- → ☐ Yes ☐ No Was the diagnosis confirmed by molecular or genetic testing?
  - → Please indicate the patient's pre-treatment IgG level: _____
  - For pre-treatment IgG greater than or equal to 200 mg/dL:
    - ☐ Yes ☐ No Are maternal T-cells present in the circulation?
      - → Please indicate the patient's CD3 T-cell count: _____

☐ Other non-SCID combined immunodeficiency disorder
- → ☐ Yes ☐ No Was the diagnosis confirmed by molecular or genetic testing?

☐ Congenital agammaglobulinemia (e.g., X-linked or autosomal recessive agammaglobulinemia)
- → ☐ Yes ☐ No Was the diagnosis confirmed by molecular or genetic testing?
  - → Please indicate the patient's pre-treatment IgG level: _____

☐ Specific antibody deficiency
- → ☐ Yes ☐ No Does the patient have normal pre-treatment IgG, IgA, and IgM levels?

☐ Other immunodeficiency disorder/none of the above

☐ **Rasmussen encephalitis**
- ☐ Yes ☐ No Did the patient try anti-epileptic drugs with no improvement in symptoms?
- ☐ Yes ☐ No Did the patient try corticosteroids with no improvement in symptoms?

☐ **Secondary Immunosuppression Due to Surgery, Malignancy, Burns, Collagen-Vascular Diseases**

Please select which of the following applies to the patient:
- ☐ Major surgery associated secondary immunosuppression ☐ Hematologic malignancy associated secondary immunosuppression
- ☐ Major burns associated secondary immunosuppression ☐ Collagen-vascular disease associated secondary immunosuppression

Please indicate the patient's pre-treatment IgG level: _____
- ☐ Yes ☐ No Is immune globulin being requested to prevent or modify recurrent bacterial or viral infections?

☐ **Solid organ transplantation**
- ☐ Yes ☐ No Is immune globulin being prescribed for solid organ transplantation in an allosensitized patient?
  - → ☐ Yes ☐ No Is the patient undergoing renal transplantation from a live donor with ABO incompatibility or positive cross match?

☐ **Stiff person syndrome**
- ☐ Yes ☐ No Has the diagnosis been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing?
- ☐ Yes ☐ No Has the patient received first-line treatment with benzodiazepines and/or baclofen and experienced an inadequate response?

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☐ **Systemic lupus erythematosus (SLE)**
- ☐ Yes ☐ No Does the patient have severe, active disease?
- ☐ Yes ☐ No Has the patient experienced inadequate response, intolerance, or have a contraindication to first line therapy?
- ☐ Yes ☐ No Has the patient experienced inadequate response, intolerance, or have a contraindication to second line therapy?

☐ **Tetanus treatment and prophylaxis**
- ☐ Yes ☐ No Is this request for treatment or postexposure prophylaxis of tetanus as an alternative when tetanus immune globulin (TIG) is unavailable?

☐ **Toxic epidermal necrolysis** OR ☐ **Steven-Johnson Syndrome**
- ☐ Yes ☐ No Is the patient's case severe?

☐ **Toxic necrotizing fasciitis**
- ☐ Yes ☐ No Does the patient have toxic necrotizing fasciitis due to invasive group A streptococcal infection?

☐ **Toxic shock syndrome**
- ☐ Yes ☐ No Does the patient have toxic shock syndrome due to a staphylococcal or streptococcal infection?
- ☐ Yes ☐ No Is the infection refractory to several hours of aggressive therapy?
  - → ☐ Yes ☐ No Does the patient have an undrainable focus of infection?
    - → ☐ Yes ☐ No Does the patient have persistent oliguria with pulmonary edema?

☐ **Varicella**
- ☐ Yes ☐ No Is this request for treatment or postexposure prophylaxis of varicella in susceptible patients when varicella-zoster immune globulin (VZIG) is unavailable?

For GamaSTAN only (clinical documentation required for all requests):

☐ **Prophylaxis of hepatitis A**
- ☐ Yes ☐ No Was the patient exposed to hepatitis A virus within the past 2 weeks (e.g., household contact, sexual contact, childcare center or classroom contact with an infected person)?
  - → ☐ Yes ☐ No Is the patient at high risk for exposure to hepatitis A virus (examples of populations at high risk for hepatitis A are travelers to and workers in countries of high endemicity of infection and illicit drug users)?

☐ **Prophylaxis of measles (rubeola)**
- ☐ Yes ☐ No Was the patient exposed to measles within the past 6 days?
- ☐ Yes ☐ No Has the patient ever received the measles vaccine (e.g., MMR)?
- ☐ Yes ☐ No Has the patient ever had the measles?

☐ **Prophylaxis of rubella**
- ☐ Yes ☐ No Was the patient recently exposed to rubella?
- ☐ Yes ☐ No Is the patient currently pregnant?

☐ **Prophylaxis of varicella (chickenpox)**
- ☐ Yes ☐ No Was the patient exposed to varicella within the past 10 days?
- ☐ Yes ☐ No Is the patient at high risk for severe varicella (e.g., immunocompromised, newborn/infant, pregnant woman)?
- ☐ Yes ☐ No Is varicella zoster immune globulin (e.g., Varizig) currently not available?

For Continuation Requests (Exception GamaSTAN) (clinical documentation required for all requests):

☐ **B-cell chronic lymphocytic leukemia (CLL)** OR ☐ **Bone marrow transplant/hematopoietic stem cell transplant recipient** OR
☐ **Human immunodeficiency virus (HIV) infection (prophylaxis or thrombocytopenia)**
- ☐ Yes ☐ No Has the patient experienced a reduction in the frequency of bacterial infections since starting IG therapy?

☐ **Chronic inflammatory demyelinating polyneuropathy (CIDP)**
- ☐ Yes ☐ No Has the patient demonstrated significant improvement in disability and maintenance of improvement since starting IG therapy?
- ☐ Yes ☐ No Is IG being used at the lowest effective dose and frequency?

☐ **Dermatomyositis** OR ☐ **Polymyositis**
- ☐ Yes ☐ No Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?

☐ **Lambert-Eaton myasthenic syndrome**
- ☐ Yes ☐ No Has the patient experienced stability or improvement in symptoms relative to the natural course of LEMS?

☐ **Multifocal motor neuropathy**
- ☐ Yes ☐ No Has the patient demonstrated significant improvement in disability and/or maintenance of improvement since starting IG therapy?

☐ **Primary immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome)**
- ☐ Yes ☐ No Has the patient experienced a reduction in the frequency of bacterial infections since starting immune globulin therapy?
- ☐ Yes ☐ No Does the prescriber measure trough IgG levels at least once per year?
- ☐ Yes ☐ No Is the measure trough IgG level applicable for diagnosis?
- ☐ Yes ☐ No Is the most recent trough IgG level at or above the lower range of normal for age?
  - → ☐ Yes ☐ No Is this value applicable for diagnosis?
    - → ☐ Yes ☐ No Will the prescriber re-evaluate the dose of immune globulin and consider a dose adjustment (when clinically appropriate)?
      - → ☐ Yes ☐ No Is this applicable/not clinically appropriate?

H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required):* _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.