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 (TTY:711)
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: ☐ **Alyglo** ☐ **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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☐ 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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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:

☐ The patient is an adult with refractory ITP after splenectomy:
- 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)?

For Newly diagnosed, previously treated, chronic or persistent or ITP unresponsive to first line treatment:
- ☐ 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 50,000/mcL (30 x 10^9/L to < 50 x 10^9/L)
    - ☐ Greater than or equal to 50,000/mcL (50 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 50,000/mcL (30 x 10^9/L to < 50 x 10^9/L)
- ☐ Greater than or equal to 50,000/mcL (50 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.