1230 US Highway 11
Gouverneur, NY 13642
Phone: 1-877-635-9545
Prior Authorization Fax: 1-844-712-8129

Immune Globulins Prior Authorization Request Form (Page 1 of 6)

Member Information (required)

Member Name:		
Insurance ID#:		
Date of Birth:		
Street Address:		
City:	State:	Zip:
Phone:		

Provider Information (required)

Provider Name:		
NPI#:	Specialty:	
Office Phone:		
Office Fax:		
Office Street Address:		
City:	State:	Zip:

Medication Information (required)

Medication Name:	Strength:	Dosage Form:
❑ Check if requesting **brand**	Directions for Use:	
❑ Check if request is for **continuation of therapy**		

Clinical Information (required)

Select the requested medication below:

❑ Bivigam	❑ Flebogamma	❑ Gammagard S/D	❑ Hizentra
❑ Carimune NF	❑ Flebogamma DIF	❑ Gammaked	❑ HyQvia
❑ Cuvitru	❑ Gamastan S/D	❑ Gammaplex	❑ Octagram
❑ Cytogam	❑ Gammagard Liquid	❑ Gamunex-C	❑ Privigen

Select the diagnosis below:

- ❑ Acquired (pure) red cell aplasia (PRCA)
- ❑ Autoimmune blistering disease
- ❑ B-cell chronic lymphocytic leukemia (CLL)
- ❑ Bone marrow transplantation
- ❑ Chronic inflammatory demyelinating polyneuropathy (CIDP)
- ❑ Cytomegalovirus (CMV) (Cytogam only)
- ❑ Guillain-Barre syndrome
- ❑ Fetal alloimmune thrombocytopenia
- ❑ Hemolytic disease of the newborn with established hyperbilirubinemia
- ❑ Hepatitis A (Gamastan S/D only)
- ❑ HIV infection
- ❑ Idiopathic thrombocytopenic purpura (ITP)
- ❑ Inflammatory myopathies (dermatomyositis and polymyositis)
- ❑ Kawasaki disease
- ❑ Lambert-Eaton myasthenic syndrome
- ❑ Measles (Gamastan S/D only)
- ❑ Multifocal motor neuropathy
- ❑ Multiple myeloma
- ❑ Myasthenia gravis exacerbation
- ❑ Post-transfusion purpura
- ❑ Primary immunodeficiency disease/syndrome
  - ❑ Common variable immunodeficiency
  - ❑ Congenital agammaglobulinemia (X-linked or autosomal recessive)
  - ❑ Severe combined immunodeficiencies
  - ❑ Wiskott-Aldrich syndrome
- ❑ Relapsing-remitting multiple sclerosis
- ❑ Rubella (Gamastan S/D only)
- ❑ Solid organ transplant
- ❑ Stiff-person syndrome
- ❑ Varicella (Gamastan S/D only)
- ❑ Other diagnosis:_____ICD-10 Code(s): _____

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Clinical Information:

Will immune globulin (Ig) be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis? ❑ **Yes** ❑ **No**

Is immune globulin being used intravenously? ❑ **Yes** ❑ **No**

Does the patient have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)? ❑ **Yes** ❑ **No**

For Privigen requests: Does the patient have hyperprolinemia? ❑ **Yes** ❑ **No**

For Octagam requests: Does the patient have an allergy to corn? ❑ **Yes** ❑ **No**

For Gammaplex requests:

Does the patient have hereditary intolerance to fructose? ❑ **Yes** ❑ **No**

Is the patient an infant for whom sucrose or fructose tolerance has not been established? ❑ **Yes** ❑ **No**

Is immune globulin therapy prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.)? ❑ **Yes** ❑ **No**

For acquired (pure) red cell aplasia, also answer the following:

Does the patient have acquired (pure) red cell aplasia (PRCA) that is immunologic? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to a corticosteroid? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to an immunosuppressant (i.e., cyclophosphamide, cyclosporine)? ❑ **Yes** ❑ **No**

Does the patient have viral PRCA caused by parvovirus B19? ❑ **Yes** ❑ **No**

For autoimmune blistering disease, also answer the following:

Does the patient have history of failure, contraindication, or intolerance to a corticosteroid? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to an immunosuppressant (i.e., cyclophosphamide, Dapsone, methotrexate, azathioprine, or mycophenolate mofetil)? ❑ **Yes** ❑ **No**

For B-cell chronic lymphocytic leukemia (CLL), also answer the following:

Does the patient have documented hypogammaglobulinemia (an immune globulin (IgG) level less than 500 mg/dL)? ❑ **Yes** ❑ **No**

Does the patient have a history of recurrent bacterial infections associated with B-cell CLL? ❑ **Yes** ❑ **No**

For bone marrow transplantation, answer the following:

Does the patient have confirmed allogeneic bone marrow transplant within the last 100 days? ❑ **Yes** ❑ **No**

Does the patient have severe hypogammaglobulinemia (an immune globulin level (IgG) level less than 400 mg/dL)? ❑ **Yes** ❑ **No**

For chronic inflammatory demyelinating polyneuropathy (CIDP), also answer the following:

Does the patient have progressive symptoms that have been present for at least 2 months? ❑ **Yes** ❑ **No**

Does the patient have symptomatic polyradiculoneuropathy as indicated by progressive or relapsing **motor** or **sensory** impairment of more than one limb? ❑ **Yes** ❑ **No**

Select if the following electrophysiologic findings are present:

- ❑ Partial conduction block of 1 or more motor nerve
- ❑ Reduced conduction velocity of 2 or more motor nerves
- ❑ Prolonged distal latency of 2 or more motor nerves
- ❑ Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]? ❑ **Yes** ❑ **No**

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For cytomegalovirus (CMV), answer the following:

Does the patient require prophylaxis for CMV infection following kidney, liver, heart lung, or pancreas transplantation? ❑ **Yes** ❑ **No**

Is the patient CMV-seronegative? ❑ **Yes** ❑ **No**

Is the organ donor CMV-seronegative? ❑ **Yes** ❑ **No**

For liver, heart, kidney, lung, or pancreas transplantation, will the patient receive concomitant therapy with ganciclovir or valganciclovir, unless the patient has a hypersensitivity or intolerance, or therapy is deemed inappropriate? ❑ **Yes** ❑ **No**

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For Guillain-Barre syndrome, also answer the following:

Does the patient have severe disease and requires aid to walk? ❑ **Yes** ❑ **No**

Does the patient have neuropathic symptoms within the last four weeks? ❑ **Yes** ❑ **No**

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For Hepatitis A, also answer the following:

Is Gamastan S/D being used as prophylaxis before or soon after exposure to Hepatitis A? ❑ **Yes** ❑ **No**

Does the patient have clinical manifestations of hepatitis A? ❑ **Yes** ❑ **No**

If *"yes"* to the above question, did exposure to hepatitis A occur more than 2 weeks previously? ❑ **Yes** ❑ **No**

For HIV infection, also answer the following:

Does the patient have hypogammaglobulinemia (an immune globulin level (IgG) level less than 400 mg/dL)? ❑ **Yes** ❑ **No**

Does the patient have active bleeding or a platelet count less than 10 x 109/L? ❑ **Yes** ❑ **No**

Does the patient have functional antibody deficiency as demonstrated by poor specific antibody titers or recurrent bacterial infections? ❑ **Yes** ❑ **No**

For idiopathic thrombocytopenic purpura (ITP), also answer the following:

Does the patient have history of failure, contraindication, or intolerance to a corticosteroid? ❑ **Yes** ❑ **No**

Document the platelet count:_____cells/mm^3

For inflammatory myopathies (dermatomyositis and polymyositis), also answer the following:

Select if the patient has one of the following diagnoses:

❑ Dermatomyositis
❑ Polymyositis

Does the patient have history of failure, contraindication, or intolerance to a corticosteroid? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to an immunosuppressant (i.e., azathioprine, cyclophosphamide, cyclosporine A, methotrexate)? ❑ **Yes** ❑ **No**

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For Lambert-Eaton myasthenic syndrome (LEMS), also answer the following:

Does the patient have history of failure, contraindication, or intolerance to a corticosteroid? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to an immunosuppressant (e.g., azathioprine)? ❑ **Yes** ❑ **No**

Will concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, be used for long-term management of LEMS? ❑ **Yes** ❑ **No**

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For measles, also answer the following:

Has the patient been exposed to measles fewer than 6 days previously? ❑ **Yes** ❑ **No**

Is the patient receiving the measles vaccine at the same time with Gamastan S/D therapy? ❑ **Yes** ❑ **No**

For multifocal motor neuropathy, also answer the following:

Does the patient have weakness with slowly progressive or stepwise progressive course over at least one month? ❑ **Yes** ❑ **No**

Does the patient have asymmetric involvement of two or more nerves? ❑ **Yes** ❑ **No**

Does the patient have absence of both motor neuron signs and bulbar signs? ❑ **Yes** ❑ **No**

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]? ❑ **Yes** ❑ **No**

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

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For multiple myeloma, also answer the following:

Does the patient have multiple myeloma in plateau phase? ❑ **Yes** ❑ **No**

Does the patient have hypogammaglobulinemia? ❑ **Yes** ❑ **No**

For myasthenia gravis exacerbation, also answer the following:

Does the patient have generalized myasthenia gravis? ❑ **Yes** ❑ **No**

Does the patient have severe exacerbations or myasthenic crisis? ❑ **Yes** ❑ **No**

Select if the patient has evidence of myasthenic exacerbation, as defined by the following symptom(s) in the last month:

- ❑ Acute respiratory failure
- ❑ Difficulty swallowing
- ❑ Major functional disability responsible for the discontinuation of physical activity

Will concomitant immunomodulator therapy (e.g., azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil), unless contraindicated, be used for long-term management of myasthenia gravis? ❑ **Yes** ❑ **No**

Is immune globulin therapy prescribed by a neurologist? ❑ **Yes** ❑ **No**

For primary immunodeficiency disease/syndrome, also answer the following:

Does the patient have primary immunodeficiency disease/syndrome (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2; ICD-10 codes D80.0, D80.5, D83.8, D83.9, D83.0, D83.2, D82.0, D81.0, D81.1, D81.2, D81.89, D81.6, D81.7, D81.9)? ❑ **Yes** ❑ **No**

Will the requested medication be administered in the patient's home (not including facility providing skilled nursing care)? ❑ **Yes** ❑ **No**

For subcutaneous administration (SCIG), is the requested medication being administered using an infusion pump? ❑ **Yes** ❑ **No**

Was the infusion pump paid for by Medicare? ❑ **Yes** ❑ **No**

Is the patient in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)? ❑ **Yes** ❑ **No**

Does the patient have clinically significant functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens or history of significant recurrent infections? ❑ **Yes** ❑ **No**

Has the patient had an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis? ❑ **Yes** ❑ **No**

Does the patient lack an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine)? ❑ **Yes** ❑ **No**

For relapsing-remitting multiple sclerosis, answer the following:

Does the patient have documentation of a multiple sclerosis exacerbation or progression (worsening) of clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy? ❑ **Yes** ❑ **No**

Select if the patient has failure, contraindication, or intolerance to the following agents:

- ❑ Aubagio (teriflunomide)
- ❑ Avonex (interferon beta-1a)
- ❑ Betaseron (interferon beta-1b)
- ❑ Copaxone (glatiramer acetate)
- ❑ Extavia (interferon beta-1b)
- ❑ Gilenya (fingolimod)
- ❑ Rebif (interferon beta-1a)
- ❑ Tecfidera (dimethyl fumarate)
- ❑ Tysabri (natalizumab)

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the prescriber maintain and provide chart documentation of the patient's evaluation, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Score (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]? ❑ **Yes** ❑ **No**

Does the patient have stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)? ❑ **Yes** ❑ **No**

Does the patient have documentation of decreased number of relapses since starting immune globulin therapy? ❑ **Yes** ❑ **No**

Does the patient's diagnosis continue to be a relapsing-remitting form of MS (RRMS)? ❑ **Yes** ❑ **No**

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For Rubella, also answer the following:

Is the patient a pregnant woman who has been exposed or is susceptible to Rubella? ❑ **Yes** ❑ **No**

Is the patient considering a therapeutic abortion? ❑ **Yes** ❑ **No**

For solid organ transplant, also answer the following:

Is intravenous immune globulin (IVIG) used for CMV prophylaxis? ❑ **Yes** ❑ **No**

Is the patient a kidney transplant recipient? ❑ **Yes** ❑ **No**

Does the patient have donor specific antibodies? ❑ **Yes** ❑ **No**

Does the patient have steroid-resistant rejection? ❑ **Yes** ❑ **No**

Does the patient have failure, contraindication, or intolerance to standard therapies? ❑ **Yes** ❑ **No**

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For stiff-person syndrome, also answer the following:

Does the patient have history of failure, contraindication, or intolerance to at least two standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants)? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to GABAergic medication (e.g., baclofen)? ❑ **Yes** ❑ **No**

Does the patient have history of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids)? ❑ **Yes** ❑ **No**

Reauthorization: *(please note, questions in the "Reauthorization" section at the end of this form may also apply)*

Does the patient have documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect? ❑ **Yes** ❑ **No**

For varicella, also answer the following:

Does the patient require passive immunization against varicella? ❑ **Yes** ❑ **No**

Is the patient immunocompromised? ❑ **Yes** ❑ **No**

Is the varicella zoster immune globulin (human) vaccine available? ❑ **Yes** ❑ **No**

Reauthorization:

If this is a reauthorization request, answer the following questions:

Has the patient experienced an objective improvement on immune globulin therapy? ❑ **Yes** ❑ **No**

Will immune globulin (Ig) be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy? ❑ **Yes** ❑ **No**

Does the patient have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)? ❑ **Yes** ❑ **No**

For Privigen requests: does the patient have hyperprolinemia? ❑ **Yes** ❑ **No**

For Octagam requests: does the patient have an allergy to corn? ❑ **Yes** ❑ **No**

For Gammaplex requests:

Does the patient have hereditary intolerance to fructose? ❑ **Yes** ❑ **No**

Is the patient an infant for whom sucrose or fructose tolerance has not been established? ❑ **Yes** ❑ **No**

Is immune globulin therapy prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.)? ❑ **Yes** ❑ **No**

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

Please note: This request may be denied unless all required information is received.

Please fax this form to 1-844-712-8129 to initiate a prior authorization review for the member and medication above.

Please note: plan benefits may limit or exclude coverage of specific medications including those requested on this form.

<Continued on next page>

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I certify, to the best of my knowledge, the statements and information provided on this form are factual and correct.

Provider/Representative (and Title): _____ **Date:** _____

PROACT INTERNAL USE ONLY:					
Clinical Review Decision					
	Approved, through				
	Denied (documentation attached, if necessary)				
Tracking:					
1st Attempt		2nd Attempt		Letter Mailed:	