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Please note: All information below is required to process this request.

Mon-Fri: 5am to 10pm Pacific / Sat: 6am to 3pm Pacific

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

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Member Information <small>(required)</small>			Provider Information <small>(required)</small>		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:		Specialty:
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:
Medication Information <small>(required)</small>					
Medication Name:			Strength:		Dosage Form:
<input type="checkbox"/> Check if requesting <b>brand</b>			Directions for Use:		
<input type="checkbox"/> Check if request is for <b>continuation of therapy</b>					
Clinical Information <small>(required)</small>					
<b>Select the requested medication below:</b>					
<input type="checkbox"/> Bivigam	<input type="checkbox"/> Cytogam	<input type="checkbox"/> Gamastan S/D	<input type="checkbox"/> Gammaked	<input type="checkbox"/> Hizentra	<input type="checkbox"/> Panzyga
<input type="checkbox"/> Carimune NF	<input type="checkbox"/> Flebogamma	<input type="checkbox"/> Gammagard Liquid	<input type="checkbox"/> Gammaplex	<input type="checkbox"/> HyQvia	<input type="checkbox"/> Privigen
<input type="checkbox"/> Cuvitru	<input type="checkbox"/> Flebogamma DIF	<input type="checkbox"/> Gammagard S/D	<input type="checkbox"/> Gamunex-C	<input type="checkbox"/> Octagam	
<b>Select the diagnosis below:</b>					
<input type="checkbox"/> Acquired (pure) red cell aplasia (PRCA)			<input type="checkbox"/> Measles (Gamastan S/D only)		
<input type="checkbox"/> Autoimmune blistering disease			<input type="checkbox"/> Multifocal motor neuropathy		
<input type="checkbox"/> B-cell chronic lymphocytic leukemia (CLL)			<input type="checkbox"/> Multiple myeloma		
<input type="checkbox"/> Bone marrow transplantation			<input type="checkbox"/> Myasthenia gravis exacerbation		
<input type="checkbox"/> Chronic inflammatory demyelinating polyneuropathy (CIDP)			<input type="checkbox"/> Post-transfusion purpura		
<input type="checkbox"/> Cytomegalovirus (CMV) (Cytogam only)			<input type="checkbox"/> Primary immunodeficiency syndrome		
<input type="checkbox"/> Fetal alloimmune thrombocytopenia			<input type="checkbox"/> Common variable immunodeficiency		
<input type="checkbox"/> Guillain-Barre syndrome			<input type="checkbox"/> Congenital agammaglobulinemia (X-linked or autosomal recessive)		
<input type="checkbox"/> Hemolytic disease of the newborn with established hyperbilirubinemia			<input type="checkbox"/> Severe combined immunodeficiencies		
<input type="checkbox"/> Hepatitis A (Gamastan S/D only)			<input type="checkbox"/> Wiskott-Aldrich syndrome		
<input type="checkbox"/> Human immunodeficiency virus (HIV) infection			<input type="checkbox"/> Relapsing-remitting multiple sclerosis		
<input type="checkbox"/> Idiopathic thrombocytopenic purpura (ITP)			<input type="checkbox"/> Rubella (Gamastan S/D only)		
<input type="checkbox"/> Inflammatory myopathies (dermatomyositis and polymyositis)			<input type="checkbox"/> Solid organ transplant		
<input type="checkbox"/> Kawasaki disease			<input type="checkbox"/> Stiff-person syndrome		
<input type="checkbox"/> Lambert-Eaton myasthenic syndrome			<input type="checkbox"/> Varicella (Gamastan S/D only)		
<input type="checkbox"/> Other diagnosis: _____			ICD-10 Code(s): _____		

This document and others if attached contain information that is privileged, confidential and/or may contain protected health information (PHI). The Provider named above is required to safeguard PHI by applicable law. The information in this document is for the sole use of OptumRx. Proper consent to disclose PHI between these parties has been obtained. If you received this document by mistake, please know that sharing, copying, distributing or using information in this document is against the law. **If you are not the intended recipient, please notify the sender immediately.**

Office use only: ImmuneGlobulins\_CMS\_2019Feb-W



## Immune Globulins Prior Authorization Request Form (Page 2 of 6)

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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

Select the route of administration of the immune globulin being requested:

- Intravenous (IV)       Subcutaneous (SQ)

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 Hizentra or 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 primary immunodeficiency syndrome, also answer the following:

Does the patient have primary immunodeficiency syndrome (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, and D81.9)?  Yes  No

Will the requested medication be administered in the patient's home?  Yes  No

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

If "yes" to the above question, is the infusion pump paid for by Medicare?  Yes  No

Is the patient in a long-term care facility?  Yes  No

Select if the patient has clinically significant functional deficiency of humoral immunity as evidenced by the following:

- Documented failure to produce antibodies to specific antigens  
 History of significant recurrent infections

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

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

Has the patient had failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Has the patient had 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:

Has the patient had failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Has the patient had 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 infection(s) 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 documented severe hypogammaglobulinemia (an immune globulin [IgG] level less than 400 mg/dL)?  Yes  No

## Immune Globulins Prior Authorization Request Form (Page 3 of 6)

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**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)

Is there documentation the patient has had a positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]?  Yes  No

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

**For cytomegalovirus (CMV), answer the following:** For Cytogam requests only

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

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 Guillain-Barre syndrome, also answer the following:**

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

Does the patient have onset of 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)

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

**For hepatitis A, answer the following:** For Gamastan S/D requests only

Is Gamastan S/D being administered intramuscularly?  Yes  No

Will immune globulin (Ig) be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis?  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

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 human immunodeficiency virus (HIV) infection, also answer the following:**

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

Does the patient have active bleeding or a platelet count less than  $10 \times 10^9/L$ ?  Yes  No

Select if the patient has functional antibody deficiency as demonstrated by the following:

- Poor specific antibody titers
- Recurrent bacterial infections

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

Has the patient had failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Document the patient's platelet count: \_\_\_\_\_ cells/mm<sup>3</sup> or /L (circle one)

## Immune Globulins Prior Authorization Request Form (Page 4 of 6)

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

Select if the patient has one of the following diagnoses:

- Dermatomyositis       Polymyositis

Has the patient had history of failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Has the patient had history of failure, contraindication, or intolerance to an immunosuppressant (i.e., azathioprine, cyclophosphamide, cyclosporine A, methotrexate, or tacrolimus)?  Yes  No

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

Is there documentation the patient has been titrated 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:

Has the patient had history of failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Has the patient had 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)

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

### For measles, answer the following: For Gamastan S/D requests only

Is Gamastan S/D being administered intramuscularly?  Yes  No

Will immune globulin (Ig) be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis?  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

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)

Is there documentation the patient has had a positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]?  Yes  No

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

### 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 crises?  Yes  No

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

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

Has the patient had failure, contraindication, or intolerance to a corticosteroid?  Yes  No

Has the patient had failure, contraindication, or intolerance to an immunosuppressant (i.e., azathioprine, cyclophosphamide, cyclosporine, or mycophenolate mofetil)?  Yes  No

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

Is immune globulin therapy prescribed by a neurologist?  Yes  No

## Immune Globulins Prior Authorization Request Form (Page 5 of 6)

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### For relapsing-remitting multiple sclerosis, answer the following:

Is there documentation the patient has 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 had trial and failure, contraindication, or intolerance to the following agents:

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Aubagio (teriflunomide)               | <input type="checkbox"/> Extavia (interferon beta-1b)     | <input type="checkbox"/> Rebif (interferon beta-1a)    |
| <input type="checkbox"/> Avonex (interferon beta-1a)           | <input type="checkbox"/> Gilenya (fingolimod)             | <input type="checkbox"/> Tecfidera (dimethyl fumarate) |
| <input type="checkbox"/> Betaseron (interferon beta-1b)        | <input type="checkbox"/> Lemtrada (alemtuzumab)           | <input type="checkbox"/> Tysabri (natalizumab)         |
| <input type="checkbox"/> Copaxone/Glatopa (glatiramer acetate) | <input type="checkbox"/> Plegridy (peginterferon beta-1a) | <input type="checkbox"/> Zinbryta (daclizumab)         |

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

Select if the prescriber maintains and provides chart documentation of the patient's evaluation, including the following:

- Findings of interval examination including neurological deficits incurred
- Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS])

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

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

### For rubella, answer the following: For Gamastan S/D requests only

Is Gamastan S/D being administered intramuscularly?  Yes  No

Will immune globulin (Ig) be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis?  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

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) being 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

Has the patient had failure, contraindication, or intolerance to standard therapies?  Yes  No

### For stiff-person syndrome, also answer the following:

Has the patient had failure, contraindication, or intolerance to at least two standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants)?  Yes  No

Has the patient had history of failure, contraindication, or intolerance to GABAergic medication (e.g., baclofen)?  Yes  No

Has the patient had 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)

Is there documentation the patient has been titrated to the minimum dose and frequency needed to maintain a sustained clinical effect?  Yes  No

### For varicella, answer the following: For Gamastan S/D requests only

Is Gamastan S/D being administered intramuscularly?  Yes  No

Will immune globulin (Ig) be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis?  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

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

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

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### Reauthorization:

If this is a reauthorization for non-oncology requests, 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 Hizentra or 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?

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Please note:

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

If the patient is not able to meet the above standard prior authorization requirements, please call 1-800-711-4555.

For urgent or expedited requests please call 1-800-711-4555.

This form may be used for non-urgent requests and faxed to 1-800-527-0531.