Immunoglobulin Therapy (Medical Policy II-51) Pre-authorization (PA) Request Form

Please review the medical policy review criteria on providers.bluecrossmn.com criteria prior to submission.

Effective May 1, 2019, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) providers are required to use the Availity® Provider Portal to submit preservice prior authorization requests. **Faxes and phone calls for these requests will no longer be accepted by Blue Cross.** Please complete the clinical sections on this form and attach it to your request at **Availity.com** to ensure a timely review.

Providers outside of Minnesota without electronic access can fax this form, along with clinical records to support the request, to (651) 662-2810.

Patient Information

☐ **Request for Urgent Review:** By checking this box, I certify that applying the standard review time may seriously jeopardize the life or health of the member or the member's ability to regain maximum function per Federal definition of "Urgent".

Member ID: _____ Group number: _____

Member name: _____ Date of birth: ___ /___ /_____

Member address: _____

Member city/state/ZIP: _____

Member phone: _____

Servicing Provider Information

Contact person: _____ Phone: _____

Servicing provider name: _____

Servicing provider ID/NPI number: _____

Servicing provider address: _____

City/state/ZIP: _____

Servicing provider phone: _____ Servicing provider fax _____

Inpatient/outpatient facility name: _____ Facility ID:_____

Ordering Provider Information

Ordering provider name: _____

Ordering provider ID/NPI number: _____

Ordering provider address: _____

City/state/ZIP: _____

Ordering provider phone: _____ Ordering provider fax: _____

Services/Procedurs/ Items Requested

HCPC/CPT Code(s)	HCPC/CPT Code(s) Description	ICD-10 Diagnosis Code(s)	Start Date mm/dd/yy	End Date mm/dd/yy

Requested Drug Dosing / Frequency	Place of Service	Drug Administration
	☐ Office/Clinic ☐ Infusion Center ☐ Home ☐ Other _____	☐ Self-Administration ☐ Health Professional to Administer If yes – > Buy and Bill? ☐ Yes ☐ No
		Route of Administration:
		☐ Intravenous ☐ Subcutaneous

Site of Care

For commercial and Medicaid health plan members, please select at least ONE of the following criteria that was met*

- ☐ Age < 18 years
- ☐ First dose OR <60 days from the first dose
- ☐ Reinitiating therapy after not being on therapy for ≥6 months
- ☐ Nearest non-hospital outpatient facility with infusion or injection capabilities is >30 miles from patient's home AND patient is not eligible for home infusion
- ☐ Changing IVIG or SCIG products
- ☐ Immunoglobulin A (IgA) deficiency with anti-IgA antibodies
- ☐ History of a severe adverse event with prior infusion or injection therapy (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure)
- ☐ History of adverse events with prior infusion or injection therapy (e.g., hypersensitivity or allergic reactions), which have not been successfully managed through standard premedications or infusion rate adjustments
- ☐ Comorbidity or medical condition that increases the risk of an adverse event, including but not limited to the following:
  - Cardiopulmonary conditions
  - Inability to safely tolerate intravenous volume loads, including unstable renal function
  - Difficult or unstable vascular access
- ☐ Physical or cognitive impairment such that infusion or injection in a non-hospital outpatient setting would present an unnecessary health risk
- ☐ Concurrent treatment with medications that require a higher level of monitoring (e.g., intravenous cytotoxic chemotherapy, blood products)

*If IVIG or SCIG is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of care MUST be submitted, including documentation for one or more of the site of care criteria provided in the table above. When the above criteria for the hospital outpatient setting are not met, a non-hospital outpatient setting (i.e. physician's office, infusion center, or home) should be used.

Initial Request

Below and on the following pages, please select the indication(s) being treated with the drug and answer all corresponding questions.

- **Please attach all relevant clinical documentation that supports information selected in the form, including laboratory results with serum immunoglobulin levels and the age-adjusted reference ranges for the laboratory performing the tests when applicable.**
- **If applicable, please, also attach supporting documentation for drug intolerance, contraindications or hypersensitivity.**

☐ **Acquired Hypogammaglobulinemia and/or Significant and Recurrent Infections Associated with:**

- ☐ **B-Cell Chronic Lymphocyctic Leukemia**
- ☐ **Multiple Myeloma**
- ☐ **Post – CD20 Therapy**
- ☐ **Waldenstrom's Macroglobulinemia (Lymphoplasmacytic Lymphoma**
- ☐ **Post-CD19-directed CAR-T Cell Therapy**

☐ **Acute Inflammatory Demyelinating Polyneuropathy (Guillain-Barre Syndrome)**

☐ **Neonatal Alloimmune Thrombocytopenia (NAIT)/ Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT)**

☐ **Autoimmune Mucocutaneous Blistering Disease:**

- ☐ **Bullous Pemphigoid**
- ☐ **Bullous Systemic Lupus Erythematosus**
- ☐ **Epidermolysis Bullosa Acquisita**
- ☐ **Mucous Membrane Pemphigoid**
- ☐ **Pemphigus Foliaceus**
- ☐ **Pemphigus Vulgaris**

Does the patient have severe, progressive disease? ☐ Yes ☐ No

Has the patient tried any conventional agents to treat the diagnosis? (check all that apply) ☐ Yes ☐ No

☐ Azathioprine ☐ Corticosteroids ☐ Cyclophosphamide ☐ Other: _____

☐ **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

☐ **Dermatomyositis:**

Has the patient tried any conventional agents to treat the diagnosis? (check all that apply) ☐ Yes ☐ No

☐ Prednisone ☐ Immunosuppressant ☐ Other: _____

☐ **Hemolytic Disease of the Fetus and Newborn (Erythroblastosis Fetalis)**

☐ **HIV-Associated Thrombocytopenia**

☐ **Idiopathic Thrombocytopenic Purpura (ITP)**

☐ **Immune Checkpoint Inhibitor Related Toxicity**

Does the patient have one of the following toxicities related to immunotherapy? ☐ Yes ☐ No

- ☐ Severe or life-threatening bullous dermatitis when used as an adjunct to rituximab;
- ☐ Stevens-Johnson syndrome (SJS);
- ☐ Toxic epidermal necrolysis (TEN);
- ☐ Severe myasthenia gravis;
- ☐ Transverse myelitis;
- ☐ Myocarditis refractory to 24-48 hours of pulse-dose methylprednisolone therapy;
- ☐ Moderate or severe Guillain-Barre Syndrome or severe peripheral neuropathy toxicity used in combination with pulse-dose methylprednisolone;
- ☐ Moderate pneumonitis refractory to 48-72 hours of corticosteroids or severe pneumonitis refractory to 48 hours of methylprednisolone therapy;
- ☐ Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present;
- ☐ Moderate or severe steroid-refractory myalgias;
- ☐ Moderate, severe, or life-threatening steroid-refractory myositis

Is the patient currently receiving therapy with an immune checkpoint inhibitor? ☐ Yes ☐ No

☐ **Kawasaki Disease (Mucocutaneous Lymph Node Syndrome)**

☐ **Lambert-Eaton Myasthenic Syndrome (LEMS)**

Initial Request (continued)

☐ **Multifocal Motor Neuropathy in Patients with Conduction Block and Anti-GM1 Antibodies**

☐ **Myasthenia Gravis:**

Does the patient have myasthenic crisis (i.e., acute episode of respiratory muscle weakness)? ☐ Yes ☐ No

Does the patient have chronic debilitating disease despite treatment with cholinesterase inhibitors, or complications from or failure of steroids and/or azathioprine? ☐ Yes ☐ No

☐ **Pediatric acute onset neuropsychiatric syndrome (PANS)/Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)**

Does the patient have a diagnosis not otherwise explained by another known neurologic or medical disorder? ☐ Yes ☐ No

Is the patient free of strep infections and other treatable infections? ☐ Yes ☐ No

Does laboratory testing confirm that patient is not IgA deficient? ☐ Yes ☐ No

☐ **Pediatric Human Immunodeficiency Virus (HIV) Infection with Hypogammaglobulinemia**

☐ **Polymyositis:**

Has the patient tried any conventional agents to treat the diagnosis? (check all that apply) ☐ Yes ☐ No

☐ Prednisone ☐ Immunosuppressant ☐ Other: _____

☐ **Post-Hematopoietic Stem-Cell Transplantation, for Treatment of Related Immunodeficiencies**

☐ **Post-Organ Transplantation, for Treatment of Antibody-Mediated Rejection**

☐ **Post-Transfusion Purpura**

☐ **Pre-Solid Organ Transplantation, for Treatment of Patients at High Risk of Antibody-Mediated Rejection, Including Highly Sensitized Patients and Those Receiving an ABO Incompatible Organ**

☐ **Primary Humoral Immunodeficiency:**

- ☐ **Ataxia Telangiectasia (Louis-Bar syndrome)**
- ☐ **Common Variable Immune Deficiency (CVID)**
- ☐ **Congenital Agammaglobulinemia**
- ☐ **DiGeorge's Syndrome**
- ☐ **Hyper-IgE Syndrome**
- ☐ **Hyper-IgM Syndrome**
- ☐ **Nezelof Syndrome**
- ☐ **Primary Hypogammagloblulinemia**
- ☐ **IgG Subclass Deficiency**
- ☐ **Severe Combined Immune Deficiency (SCID)**
- ☐ **Wiskott-Aldrich Syndrome**
- ☐ **X-linked Agammaglobulinemia**
- ☐ **X-linked Immunodeficiency**
- ☐ **Other:** _____

Does the patient have agammaglobulinemia? ☐ Yes ☐ No

If yes, is the total serum IgG level <200 mg/dL? ☐ Yes* ☐ No

If yes, does the patient have an abnormal Bruton tyrosine kinase (BTK) gene or absence of the BTK protein? ☐ Yes* ☐ No

If yes, does the patient have an absence of B lymphocytes? ☐ Yes* ☐ No

Does the patient have hypogammagloblulinemia? ☐ Yes* ☐ No

If yes, does the patient have significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis)? ☐ Yes ☐ No

If yes, is the total serum IgG level <700 mg/dL ☐ Yes ☐ No

If yes, is the total serum IgG level at least 2 standard deviations below the normal age-adjusted mean? ☐ Yes ☐ No

If yes, are one or more serum IgG subclass levels at least 2 standard deviations below the normal age-adjusted mean in patients with normal levels of total serum IgG and IgM? ☐ Yes ☐ No

If yes, has the patient demonstrated an impaired response to immunization with protein antigens? ☐ Yes ☐ No

If yes, was the response less than a 4-fold rise in antibody titer? ☐ Yes ☐ No

If yes, has the patient demonstrated an impaired response to immunization with polysaccharide antigens? ☐ Yes ☐ No

If yes, was the response less than a 4-fold rise in antibody titer? ☐ Yes ☐ No

***Please attach lab report**

Initial Request (continued)	
	☐ **Pure Red Cell Aplasia Due to Parvovirus B19**
	☐ **Stiff-Person Syndrome (Moersch-Woltman Syndrome):** Has the patient tried any conventional agents to treat the diagnosis? (check all that apply) ☐ Yes ☐ No ☐ Baclofen ☐ Benzodiazepines ☐ Other: _____
	☐ **Toxic Epidermal Necrolysis (TEN)**
	☐ **Toxic Shock Syndrome Due to Staphylococcal or Streptococcal Infection:** Has the patient tried any conventional agents to treat the diagnosis? ☐ Yes ☐ No
	☐ **Warm Antibody Autoimmune Hemolytic Anemia** Has the patient tried any conventional agents to treat the diagnosis? (check all that apply) ☐ Yes ☐ No ☐ Corticosteroids ☐ Splenectomy ☐ Other: _____
	☐ **Other*** (please specify below)
	Has the patient been previously approved for immunoglobulin therapy through Blue Cross and Blue Shield of Minnesota's initial review process? ☐ Yes ☐ No Is the renewal request for the same indication previously approved? ☐ Yes ☐ No Has the patient shown positive clinical response (e.g., reduced number and/or severity of infections, decreased use/elimination of prophylactic antibiotics, functional improvement) while on immunoglobulin therapy? ☐ Yes* ☐ No **Please attach all relevant clinical documentation supporting positive clinical response.**

Please attach all relevant clinical documentation that supports information selected in the form.

Description / Additional Information:

Total Pages _____