Field Name	Field Description
Prior Authorization Group Description	**Immune Globulins**
Drugs	Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gamastan (IM) (Immune Globulin) Gamastan SD (IM) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin ****Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**All Requests:**

	• Documentation of diagnosis confirmed by a specialist
	• Member has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines
	• Member's height and weight are provided
	• Dosing will be calculated using ideal body weight (IBW), unless ONE of the following:
	  o If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight
	  o If the member's body mass index (BMI) is ≥30 kg/m^2 OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW)
	
	Primary Immunodeficiency*:
	• Patient's IgG level is provided and below normal for requested indication
	• Clinically significant deficiency of humoral immunity as evidenced by ONE of the following:
	  o Inability to produce an adequate immunologic response to specific antigens.
	  o History of recurrent infections despite prophylactic antibiotics
	• Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
	
	• If criteria is met, approve for 6 months.
	
	*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome
	
	Idiopathic Thrombocytopenic Purpura, acute and chronic:
	• Acute:
	  o Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids

	○ Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days • Chronic: ○ Duration of illness is greater than 12 months ○ Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis. ○ Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for up to 5 days. **Kawasaki disease:** • Immunoglobulin is being given with high dose aspirin unless contraindicated • Requested dose does not exceed a single 2g/kg dose • If criteria is met, approve for 1 dose **Chronic B-cell lymphocytic leukemia:** • The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL • Dose does not exceed 500mg/kg every 3-4 weeks • If criteria is met, approve for 3 months. **Bone marrow transplantation:** • The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL • Dose does not exceed 500mg/kg/wk for the first 100 days post- transplant • Dose does not exceed 500 mg//kg every 3-4 weeks 100 days after transplant • If criteria is met, approve for 3 months. **Pediatric HIV**: • Patient is < 13 years of age • Either patient's IgG level is < 400mg/dL or • If patient's IgG level is ≥ 400 mg/dL than significant

	deficiency of humoral immunity as evidenced by ONE of the following: o Inability to produce an adequate immunologic response to specific antigens. o History of recurrent bacterial infections despite prophylactic antibiotics • Dose does not exceed 400mg/kg/dose every 2-4 weeks • If criteria is met, approve for 3 months. **Multifocal motor neuropathy (MMN)**: • Duration of symptoms has been at least 1 month with disability. • Nerve conduction studies were completed to rule out other possible conditions and confirms the diagnosis of MMN. • Dose does not exceed 2g/kg/month administered over 2 to 5 days. • If criteria is met, approve for up to 5 days for 3 months. **Chronic inflammatory demyelinating polyneuropathy (CIDP):** • Duration of symptoms has been at least 2 months with disability. • Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions and confirms the diagnosis of CIDP. • Patient has tried and failed, or has a documented medical reason for not using, corticosteroids. o If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required • Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for up to 5 days for 3 months **Guillain-Barre syndrome:** • Patient has severe disease with the inability to walk without aid • Onset of symptoms within the last 4 weeks • Dose does not exceed 2g/kg administered over 2-5 days

	• If criteria is met, approve for up to 5 days.
	
	<u>Myasthenia Gravis:</u>
	• <u>Acute:</u>
	  o Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation
	  o Dose does not exceed 2 g/kg administered over 2-5 days
	  o If criteria is met, approve for up to 5 days
	• <u>Chronic:</u>
	  o Diagnosis of refractory generalized myasthenia gravis
	  o Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil)
	  o Dose does not exceed 2 g/kg/month administered over 2-5 days
	  o If criteria is met, approve for 3 months
	
	<u>Dermatomyositis (DM):</u>
	• One of the following:
	  o Bohan and Peter score of 3 (i.e. definite DM)
	  o Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
	• Patient does NOT have any of the following:
	  o Cancer (CA) associated myositis defined as myositis within 2 years of CA diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cure)
	  o Active malignancy
	  o Malignancy diagnosed within the previous 5 years
	  o Breast CA within the previous 10 years
	• For a diagnosis of DM, one of the following:
	  o Member has tried and failed, or has a documented medical reason for not using both of the following:
	  ▪ methotrexate (MTX) OR azathioprine
	  ▪ rituximab.
	  o Member has severe, life-threatening weakness or dysphagia
	• For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM):

Revision/Review Date 11/2024	○ Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil. • Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks. • If criteria is met, approve for up to 3 months. If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**