curative

Immune Globulins Prior Authorization

Drug(s) Applied:	Gamunex-C

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for a compendia-supported indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Primary Immunodeficiency** as indicated by chart notes within past 120 days
  1. ONE of the following:
     a) Total IgG less than 200mg/dL at baseline prior to immune globulin therapy **or**
     b) Patient has abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein **or**
     c) Patient has an absence of B lymphocytes **or**
     d) ALL of the following:
        (1) Patient has ONE of the following:
            (a) Selective IgG subclass deficiency [Defined as deficiency of 1 or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) by more than 2 standard deviations (SD) below age-specific mean, assessed on 2 separate occasions during infection free period] **and**
            (b) Specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses **and**
            (c) Hypogammaglobulinemia defined as total IgG less than 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy **and**
            (d) Another primary immunodeficiency [e.g., Common variable immunodeficiency (CVID), X-linked immunodeficiency, severe combined immunodeficiency (SCID), combined immunodeficiency syndromes (e.g., Ataxia Telangiectasia (A-T), DiGeorge syndrome, Wiskott-Aldrich Syndrome)] **and**
        (2) Patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (e.g., inability

to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both) **and**

(3) Patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with antibiotics **and**

2. Prescriber has submitted support of use of SCIG over preferred IVIG with ONE of the following after at least 6 months of consistent IVIG therapy:
    a) History of multiple upper respiratory symptoms or malaise during the week prior to the next infusion with the patient being adherent to an infusion schedule of every 3 or 4 weeks **or**
    b) IgG trough level is below the patient's individualized goal IgG trough level (e.g. IgG trough level > 500mg/dL) with the patient being adherent to an infusion schedule of every 3 or 4 weeks and no infections during the time the trough level was drawn **and**
3. Patient does NOT have any FDA labeled contraindications to the requested agent, including but not limited to IgA deficiency with antibodies against IgA and a history of hypersensitivity

Approval Duration: 12 months

B. Chronic inflammatory Demyelinating Polyneuropathy (CIDP) as indicated by chart notes within past 120 days

1. Patient has progressive symptoms present for at least 2 months **and**
2. Patient has progressive or relapsing motor sensory impairment of more than one limb **and**
3. Patient has electrodiagnostic findings indicating at least ONE of the following are present:
    a) Motor distal latency prolongation in 2 nerves
    b) Reduction of motor conduction velocity in 2 nerves
    c) Prolongation of F-wave latency in 2 nerves
    d) Absence of F-waves in at least 1 nerve
    e) Partial motor conduction block of at least 1motor nerve
    f) Abnormal temporal dispersion in at least 2 nerves
    g) Distal CMAP duration increase in at least 1 nerve **and**
4. Prescriber has submitted support of use of SCIG over preferred IVIG with ONE of the following after at least 6 months of consistent IVIG therapy:
    a) History of multiple upper respiratory symptoms or malaise during the

week prior to the next infusion with the patient being adherent to an infusion schedule of every 3 or 4 weeks **or**

b) IgG trough level is below the patient's individualized goal IgG trough level (e.g. IgG trough level > 500mg/dL) with the patient being adherent to an infusion schedule of every 3 or 4 weeks and no infections during the time the trough level was drawn **and**

5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., neurology) **and**
6. Patient does NOT have any FDA labeled contraindications to the requested agent

Approval Duration: 12 months

C. Dermatomyositis as indicated by chart notes within past 120 days

1. ONE of the following:
   a) Patient has tried and had an inadequate response to a conventional therapy (e.g. prednisone, azathioprine, mycophenolate) **or**
   b) Patient has an intolerance or FDA labeled contraindication to ALL conventional therapies (e.g. prednisone, azathioprine, mycophenolate) **and**
2. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology, immunology) **and**
3. Prescriber has submitted support of use of SCIG over preferred IVIG with ONE of the following after at least 6 months of consistent IVIG therapy:
   a) History of multiple upper respiratory symptoms or malaise during the week prior to the next infusion with the patient being adherent to an infusion schedule of every 3 or 4 weeks **or**
   b) IgG trough level is below the patient's individualized goal IgG trough level (e.g. IgG trough level > 500mg/dL) with the patient being adherent to an infusion schedule of every 3 or 4 weeks and no infections during the time the trough level was drawn **and**
4. Patient does NOT have any FDA labeled contraindications to the requested agent

Approval Duration: 12 months

D. Polymyositis as indicated by chart notes within past 120 days

1. ONE of the following:
   a) Patient has tried and had an inadequate response to a conventional therapy (e.g. prednisone, azathioprine, mycophenolate) **or**
   b) Patient has an intolerance or FDA labeled contraindication to ALL

conventional therapies (e.g. prednisone, azathioprine, mycophenolate) **and**

2. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g. immunology, rheumatology) **and**
3. Prescriber has submitted support of use of SCIG over preferred IVIG with ONE of the following after at least 6 months of consistent IVIG therapy:
    a) History of multiple upper respiratory symptoms or malaise during the week prior to the next infusion with the patient being adherent to an infusion schedule of every 3 or 4 weeks **or**
    b) IgG trough level is below the patient's individualized goal IgG trough level (e.g. IgG trough level > 500mg/dL) with the patient being adherent to an infusion schedule of every 3 or 4 weeks and no infections during the time the trough level was drawn **and**
4. Patient does NOT have any FDA labeled contraindications to the requested agent

Approval Duration: 12 months

II. Continued Therapy Criteria

A. All indications as indicated by chart notes within past 12 months

For Maryland Fully Insured groups only, chart notes not required.

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Chart notes indicate patient has been treated with multiple doses of the requested agent within the past 120 days and is a continuation of therapy (starting on samples is not approvable) **and**
3. If the patient has received more than 6 months of therapy, there is documented clinical benefit or disease stabilization since starting the requested agent (i.e., IgG level has improved from pre-treatment levels with the requested agent, reduction in the number and/or severity of difficult to treat infections) **and**
4. Patient does NOT have any FDA labeled contraindications to the requested agent

Approval Duration: 12 months

Policy Owned by: Curative PBM team