BlueCross BlueShield
Federal Employee Program

IVIG (intravenous immunoglobulin)

Asceniv, Alyglo, Bivigam, Flebogamma, Gammagard, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following documented indications:

1. Primary immunodeficiency disease (PID) with **ONE** of the following:
    a. Hypogammaglobulinemia, IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency with **ALL** of the following:
        i. Documented history of recurrent bacterial and viral infections
        ii. Impaired antibody response to pneumococcal vaccine
        iii. **ONE** of the following pre-treatment laboratory findings:
            1) Hypogammaglobulinemia: IgG < 500 mg/dL or $\underline{\geq}$ 2 SD below the mean for age
            2) Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
            3) Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
            4) IgG subclass deficiency: IgG1, IgG2, or IgG3 $\underline{\geq}$ 2 SD below the mean for the age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/ low IgA levels
            5) Specific antibody deficiency: normal IgG, IgA and IgM levels

    b. SCID (severe combined immunodeficiency disease) or Agammaglobulinemia with **ONE** of the following
        i. Confirmed diagnosis by genetic or molecular testing
        ii. Pretreatment IgG level < 200mg/dL
        iii. Absence or very low number of T cells (CD3 T cells < 300/microliter) or presence of maternal T cells in the circulation (SCID only)

    c. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia

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(or other non SCID combined immunodeficiency) with **ALL** of the following:

i. Confirmed diagnosis by genetic or molecular testing
ii. Documented history of recurrent bacterial and viral infections
iii. Impaired antibody response to pneumococcal vaccine

d. CVID (common variable immunodeficiency disease) with **ALL** of the following:
   i. Age 4 years and older
   ii. Documented history of recurrent bacterial and viral infections
   iii. Impaired antibody response to pneumococcal vaccine
   iv. Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy, etc.)
   v. Pretreatment IgG level < 500mg/dL or ≥ 2 SD below the mean for the age

2. Idiopathic thrombocytopenic purpura (ITP)
   a. Newly diagnosed ITP (diagnosed with in the past 3 months) must have **ONE** of the following:
      i. Children (<18 years of age) with **ONE** of the following:
         1) Significant bleeding symptoms (mucosal bleeding or moderate /severe bleeding)
         2) High risk for bleeding
         3) Rapid increase in platelets is required (e.g., surgery or procedure)

      ii. Adults (≥ 18 years of age) with **ONE** of the following:
         1) Platelet count < 30,000/mcL
         2) Platelet count < 50,000/mcL and significant bleeding symptoms , high risk for bleeding or rapid increase in platelets is required

      AND the following:
         1) Corticosteroid therapy is contraindicated and IVIG will be used alone or IVIG will be used in combination with corticosteroid therapy

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b. Chronic/persistent ITP (> 3 months from diagnosis)

AND ONE of the following:

i. Platelet count < 30,000/mcL
ii. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required

AND the following:

i. Relapse after previous response to IVIG or inadequate treatment response, intolerance or contraindication to corticosteroid therapy

c. ITP unresponsive to first-line therapy

AND ONE of the following:

i. Platelet count < 30,000/mcL
ii. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required

AND the following:

i. Relapse after previous response to IVIG or inadequate treatment response, intolerance or contraindication to corticosteroid therapy

d. Adults with refractory ITP after splenectomy must have **ONE** of the following:

i. Platelet count < 30,000/mcL
ii. Significant bleeding symptoms

e. ITP in pregnant women

3. B-cell chronic lymphocytic leukemia with **ALL** of the following:
   a. IVIG is prescribed for prophylaxis of bacterial and viral infections
   b. Documented history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization
   c. Pretreatment serum IgG level < 500 mg/dL

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4. Kawasaki syndrome

5. Prophylaxis of bacterial and viral infections in Bone Marrow Transplantation (BMT) / Hematopoietic Stem Cell Transplantation (HSCT) recipients with **ALL** of the following:
    a. IVIG is prescribed for prophylaxis of bacterial and viral infections
    b. **ONE** of the following:
        i. IVIG is requested within the first 100 days post-transplant
        ii. Pretreatment serum IgG level < 400 mg/dL

6. Peripheral blood progenitor cell (PBPC) collection

7. Umbilical Cord Stem Cell Transplantation

8. Prophylaxis of bacterial and viral infections in HIV-Infected pediatric patients with **ALL** of the following:
    a. Patient is ≤ 12 years of age
    b. Patient is using as **ONE** of the following:
        i. Primary prophylaxis:
            1) Pretreatment serum IgG level < 400 mg/dL
        ii. Secondary prophylaxis:
            1) Documented recurrent bacterial and viral infections (> 2 serious infections in a year)
            2) **NOT** able to take combination antiretroviral therapy
            3) Antibiotic prophylaxis **NOT** effective

9. Polymyositis or Dermatomyositis with **ALL** of the following:
    a. Documented clinical features of diagnosis (e.g., elevated muscle enzymes, muscle biopsy, supportive diagnostic tests)
    b. Inadequate response, intolerance, or contraindication to first–line treatments (corticosteroids or immunosuppressants)

10. Inclusion-body myositis

11. Guillain-Barre syndrome (GBS) with **ALL** of the following:
    a. Physical mobility is severely affected such that patient requires an aid to walk

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b. IVIG therapy will be initiated within 2 weeks of symptom onset

12. Fetal alloimmune thrombocytopenia (F/NAIT)

13. Myasthenia gravis with **ONE** of the following:
    a. Worsening weakness includes an increase in any of the following symptoms:
        i. Diplopia
        ii. Ptosis
        iii. Blurred vision
        iv. Dysarthria
        v. Dysphagia
        vi. Difficulty chewing
        vii. Impaired respiratory status
        viii. Fatigue
        ix. Limb weakness
    b. Pre-operative management

14. Multiple sclerosis

15. Multifocal motor neuropathy (MMN) with **ALL** of the following:
    a. Weakness without objective sensory loss in 2 or more nerves
    b. Electrodiagnostic studies are consistent with motor conduction block
    c. Normal sensory nerve conduction studies

16. Secondary immunosuppression associated with hematological malignancy with **ALL** of the following:
    a. Hypogammaglobulinemia: IgG < 500 mg/dL or $\underline{\geq}$ 2 SD below the mean for age
    b. Documented history of recurrent bacterial and viral infections
    c. Impaired antibody response to pneumococcal vaccine

17. Chronic inflammatory demyelinating polyneuropathy (CIDP) with **ALL** of the following:
    a. Moderate to severe functional disability
    b. Electrodiagnostic studies are consistent with multifocal demyelinating

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abnormalities

18. Autoimmune encephalitis
    a. Confirmation of diagnosis with **TWO** of the following tests:
        i. Neuroimaging
        ii. Electroencephalography (EEG)
        iii. Lumbar puncture
        iv. Serologic testing

19. Lambert-Eaton myasthenic syndrome (LEMS)

20. Parvovirus B 19-induced pure red cell aplasia (PRCA)

21. Stiff-person syndrome with **ALL** of the following:
    a. Inadequate treatment response, intolerance, or contraindication to first–line treatments (benzodiazepine or baclofen)

22. End-stage renal disease (ESRD)
    a. Used to improve the chances of successful kidney transplantation

AND ONE of the following for **ALL** indications:
a. Monitor patients carefully for signs and symptoms of thrombosis both at the time of infusion and after infusion
b. Patients or caregivers have been instructed on how to monitor for signs and symptoms of thrombosis when self-administering the medication

AND the following for **ALL** indications:
a. **NO** concurrent therapy with another IVIG / SCIG product

Prior - Approval Limits
Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

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    b. SCID (severe combined immunodeficiency disease) or Agammaglobulinemia
    c. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non SCID combined immunodeficiency)
    d. CVID (common variable Immunodeficiency disease)
        i. Age 4 years and older

    AND ALL of the following:
    a. Reduction in frequency of bacterial and viral infections has been documented since initiation
    b. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication)
    c. The prescriber will re-evaluate the dose of the IVIG and reconsider a dose adjustment

2. Idiopathic thrombocytopenic purpura (ITP)

3. B-cell chronic lymphocytic leukemia
    a. Reduction in frequency of bacterial and viral infections has been documented since initiation

4. Kawasaki syndrome

5. Prophylaxis of bacterial and viral infections in Bone Marrow Transplantation (BMT) / Hematopoietic Stem Cell Transplantation (HSCT) recipients
    a. Reduction in frequency of bacterial and viral infections has been documented since initiation

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8. Prophylaxis of bacterial and viral infections in HIV-Infected pediatric patients
    a. Patient is ≤ 12 years of age
    b. Reduction in frequency of bacterial and viral infections has been documented since initiation

9. Polymyositis or dermatomyositis
    a. Significant improvement in disability and maintenance of improvement since initiation

10. Inclusion-body myositis

11. Guillain-Barre Syndrome (GBS)

12. Fetal alloimmune thrombocytopenia (F/NAIT)

13. Myasthenia gravis

14. Multiple sclerosis

15. Multifocal motor neuropathy (MMN)
    a. Significant improvement in disability and maintenance of improvement since initiation

16. Secondary immunosuppression associated with hematological malignancy
    a. Documented reduction in frequency of bacterial and viral infections since initiation

17. Chronic inflammatory demyelinating polyneuropathy (CIDP) with **ALL** of the following:
    a. Significant improvement in disability and maintenance of improvement since initiation
    b. IVIG is being used at the lowest effective dose and frequency
    c. Chronic stable patients have been tapered and/or treatment withdrawn to determine whether continued treatment is necessary

18. Autoimmune encephalitis
    a. Improvement in disability and maintenance of improvement since

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initiation confirmed by neurological exam

19. Lambert-Eaton syndrome (LEMS)

20. Parvovirus B 19-induced pure red cell aplasia (PRCA)

21. Stiff-person syndrome

22. End-stage renal disease (ESRD)
    a. Used to improve the chances of successful kidney transplantation

AND ONE of the following for **ALL** indications:
a. Monitor patients carefully for signs and symptoms of thrombosis both at the time of infusion and after infusion
b. Patients or caregivers have been instructed on how to monitor for signs and symptoms of thrombosis when self-administering the medication

AND the following for **ALL** indications:
a. **NO** concurrent therapy with another IVIG / SCIG product

Prior – Approval *Renewal* Limits
Same as above