

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 ≥ 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 ≥ 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 ≥ 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
6. Peripheral blood progenitor cell (PBPC) collection
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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

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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