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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Biologicals	**Original Policy Date:**	March 8, 2002
Subject:	IVIG	**Page:**	1 of 15

Last Review Date: June 16, 2022

IVIG (intravenous immunoglobulin)

Description

IVIG Immune Globulin – Asceniv, Bivigam, Flebogamma, Gammagard, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen

Background
Immune globulin products from human plasma were first used in the 1950s and 60s to treat immune deficiency. These initial preparations were given either intramuscularly or subcutaneously to avoid the severe shock-like reactions from intravenous administration. In the early 1980s chemical and enzymatic modifications of the pooled plasma provided a preparation suitable for intravenous administration. Intravenous immunoglobulin (IVIG) products are prepared from pooled donations exceeding 10,000 liters (1).

IVIG is used to treat various autoimmune, infectious, and idiopathic diseases (1).

Regulatory Status
The immune globulins addressed by this policy are FDA-approved for use in one or more of the following conditions: (2-12)

- Primary immune deficiency (PID)
- Acute and Chronic Thrombocytopenic Purpura (ITP)
- Prevention of bacterial and viral infections in patients with hypogammaglobulinemia and/or recurrent bacterial and viral infections associated with B-cell Chronic Lymphocytic Leukemia (CLL)
- Prevention of coronary artery aneurysms associated with Kawasaki syndrome
- Multifocal Motor Neuropathy (MMN)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Off-Label Use: (13-29)

1. Prophylaxis of bacterial and viral infections in pediatric human immunodeficiency virus (HIV) infection
2. Prophylaxis of bacterial and viral infections in bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT) recipients
3. Dermatomyositis
4. Polymyositis
5. Myasthenia gravis
6. Guillain-Barre syndrome
7. Lambert-Eaton myasthenic syndrome
8. Fetal/neonatal alloimmune thrombocytopenia
9. Parvovirus B19-induced pure red cell aplasia
10. Stiff-person syndrome

Use of immune globulin to treat immunosuppression secondary to hematological malignancy is supported by data from several clinical trials. This acquired hypogammaglobulinemia is thought to occur, in part, due to the use of therapies targeting B-cells, and due to the clonal proliferation of abnormal B-cells as part of the hematological malignancy's disease process. The decision to supplement with exogenous IVIG should be made after review of patient's physical history and IgG serum concentrations indicating hypogammaglobulinemia (serum IgG < 500 mg/dL or ≥ 2 standard deviations below the mean concentration for age) (1, 29).

There are various types of immune-mediated encephalopathy, including anti-NMDA encephalitis, VGKG-associated limbic encephalopathies, and Hu and Ma2-mediated encephalitis. These have been seen in patients both with cancer and cancer-free of all ages, notably in young adults and children. First-line treatment, showing moderate success, includes the use of IVIGs (14-15)

Immune globulin use is associated with increased risk of thrombosis, particularly in the elderly and patients with risk factors such as cardiovascular disease, hypercoagulopathy, those on estrogen therapy, and patients with central venous catheters. Patients should be monitored carefully for signs and symptoms of thrombosis both at the time of infusion and after infusion. For those patients who will be self-administering the medication, practitioners need to instruct the patients and caregivers on how to monitor for signs and symptoms of thrombosis. Thrombosis may occur regardless of the route of administration (2-12).

IVIG products have been associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, > 65 years of age, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs (2-12).

Other potential complications to monitor include the following (2-12):
Immunoglobulin A deficiency: People with this condition have the potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.

Aseptic meningitis syndrome (AMS): Rare occurrences of AMS have been reported in association with IVIG treatment. AMS usually begins within several hours to 2 days following IVIG treatment and is characterized by symptoms including severe headache, drowsiness, fever, photophobia, painful eye movements, muscle rigidity, nausea, and vomiting. AMS may occur more frequently in association with high-dose (2 g/kg) IVIG treatment. Discontinuation of IVIG treatment has resulted in remission of AMS within several days without sequelae.

Bleeding complications: Bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

Severe reactions: Severe reactions, such as anaphylaxis or angioneurotic edema, have been reported in association with IV immunoglobulins, even in patients not known to be sensitive to human immunoglobulins or blood products.

Related policies

Atgam, Cablivi, GamaSTAN, SCIG

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

IVIG may be considered **medically necessary** for treatment of the following conditions indicated below with the listed requirements.

IVIG may be considered **investigational** for all other indications.

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 (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

   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 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:
   ii. Relapse after previous response to IVIG or inadequate 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

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. Member is ≤ 12 years of age
    b. Primary prophylaxis:
        i. Pretreatment serum IgG level < 400 mg/dL
    c. Secondary prophylaxis:
        i. Documented recurrent bacterial and viral infections (> 2 serious infections in a year)
        ii. **NOT** able to take combination antiretroviral therapy
        iii. 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
    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
    a. Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age

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 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 response, intolerance or contraindication to first–line treatments (benzodiazepine or baclofen)

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* Requirements

Diagnoses

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

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
    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. Documented reduction in frequency of bacterial and viral infections 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

7. Umbilical Cord Stem Cell Transplantation

8. Prophylaxis of bacterial and viral infections in HIV-Infected pediatric patients
    a. Member 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) with **ALL** of the following:
    a. Significant improvement in disability and maintenance of improvement since initiation

16. Secondary immunosuppression associated with hematological malignancy

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 initiation confirmed by neurological exam

19. Lambert-Eaton syndrome (LEMS)

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

21. Stiff-person Syndrome

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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

IVIG is used to provide immediate passive immunity after suspected exposure to an organism for which no active immunization exists or if there is inadequate time to develop active immunization, and as replacement therapy for patients with antibody deficiencies. The passive immunity imparted by IVIG is capable of attenuating or preventing infectious diseases or deleterious reactions from toxins, mycoplasma, parasites, bacteria, and viruses. The IVIG

products differ in the preparation method, viral inactivation steps, stabilizing agent, osmolality, and IgA content (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of IVIG while maintaining optimal therapeutic outcomes.

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Policy History

Date	Action

September 2008	FDA approved Gamunex for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) on 9/12/08. CIDP is approvable as off-label use for all Immune Globulins
March 2009	Added PrIVIGen to Immune Globulins and updated format.
November 2009	Off-label uses clarified; removed Gamimune, Gammar PIV, Venoglobulin-1 and Venoglobulin-S; all of which are no longer on the market.
April 2010	Line extension of Hizentra, FDA approved 3/4/2010, for the treatment of primary immunodeficiency (PI). Removed Polygam, Iveegam and Panglobulin which are no longer on the market. Added ICD-10 codes.
May 2010	Line extension of Gammaplex, FDA approved 12/11/2009, for primary humoral immunodeficiency.
September 2011	Line extension of Gamunex-C, FDA approved 10/14/2011, for primary immunodeficiency.
September 2011	Line extension of Gammaked, FDA approved 8/3/2011, for the treatment of primary humoral immunodeficiency disease (PI), idiopathic thrombocytopenic purpura (ITP) and chronic inflammatory demyelinating polyneuropathy (CIDP).
December 2012	Annual editorial review and update
February 2013	Line addition of BIVIGam
June 2013	Annual editorial review and reference update
June 2013	FDA: New Boxed Warning for Clot Risk with Immune Globulin, reference update
December 2013	Annual editorial review and reference update
February 2014	Revision to criteria requirements that self-administering patients are instructed to how to monitor for signs and symptoms of thrombosis.
September 2014	Line-addition of Octagam 10%. Reference update. Addition of HyQvia for all indications
November 2014	Addition of a line-extension of Gamunex-C 40/400ml
December 2014	Annual editorial review and reference update
March 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Addition of CVID (common variable Immunodeficiency disease) Policy code changed from 5.05.03 to 5.20.03
August 2016	Addition of Autoimmune encephalitis
October 2016	Transfer of Hizentra and Hyqvia from criteria to 5.20.08 Addition of all indication pre-requisites and new indications: Lambert-Eaton Myasthenic syndrome (LEMS), Parvovirus B 19-induced pure red cell aplasia (PRCA), Stiff-person Syndrome, Guillain-Barre Syndrome (GBS)
December 2016	Annual review
March 2017	Annual review

October 2017	Addition of initiation requirement for Autoimmune encephalitis with confirmation of diagnosis with TWO of the following tests: neuroimaging, electroencephalography (EEG), lumbar puncture, or serologic testing and renewal requirement of improvement in disability and maintenance of improvement since initiation confirmed by neurological exam Addition of NO concurrent therapy with another IVIG / SCIG product
December 2017	Annual review
January 2018	Change of Myasthenia gravis requirements from **ALL** to **ONE** of the following
March 2018	Annual review
October 2018	Addition of Panzyga
November 2018	Annual review and reference update. Carimune NF removed from market
June 2019	Annual review
September 2019	Annual review
December 2019	Addition of Asceniv
March 2020	Annual review
June 2021	Annual review and reference update
September 2021	Per FEP: changed “Neoplastic disease” indication to “Secondary immunosuppression associated with hematological malignancy” and added initiation requirement “Hypogammaglobulinemia: IgG < 500 mg/dL or $\underline{\geq}$ 2 SD below the mean for age”
December 2021	Annual review
June 2022	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.