Immune Globulin *(IVIG)*, injection, for IV use

PA Criteria	Criteria Details
Description	Immune globulin (IVIG) is an infusion of immune-supporting antibodies from human donor plasma. It is used to treat a wide variety of disease, including primary and secondary immunodeficiency states and hematologic and autoimmune disorders. Brand Names for IVIG: • **Alyglo** • **Asceniv** • **Bivigam** • **Flebogamma DIF** • **Gammagard** • **Gammaked** • **Gammaplex** • **Gamunex-C** • **Octagam** • **Panzyga** • **Privigen** • **Qivigy** • **Yimmugo** Subcutaneous immune globulin (SCIG) is NOT included in this criteria for Part B Prior Authorization.
Covered Uses (FDA approved indication)	See table below

Drug Name	FDA-Approved Indication
Alyglo	Treatment of primary humoral immunodeficiency (PI) (see Appendix) in adults.
Asceniv	Treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).
Bivigam	Treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years old.
Flebogamma DIF	Treatment of: • primary (inherited) immunodeficiency (PI) in adults and pediatric patients ≥ 2 years old. • chronic primary immune thrombocytopenia (ITP) age ≥ 2 years old.

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Drug Name	FDA-Approved Indication
Gammagard	Treatment of primary immunodeficiency (PI) in adults and pediatric patients ≥ 2 years old. Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL). Prevention and/or control of bleeding in adult chronic idiopathic thrombocytopenic purpura (ITP) patients. Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients. Maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy (MMN). Therapy to improve neuromuscular disability and impairment in adults with chronic inflammatory demyelinating polyneuropathy (CIDP). **Limitations:** • **Safety and effectiveness has not been studied in IVIG-naive patients with CIDP** • **Gammagard maintenance therapy in CIDP has not been studied beyond 6 months**
Gammaked	Treatment of: • primary humoral immunodeficiency (PI) in patients ≥ 2 years old • idiopathic thrombocytopenic purpura (ITP) in adults and children. • chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.
Gammaplex	Treatment of: • primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years old. • chronic immune thrombocytopenic purpura (ITP).
Gamunex-C	Treatment of: • primary humoral immunodeficiency (PI) in adults and pediatric patients ≥ 2 years old. • idiopathic thrombocytopenic purpura (ITP) in adults and children • chronic inflammatory demyelinating Polyneuropathy (CIDP) in adults.
Octagam	Treatment of: • primary humoral immunodeficiency (PI). • chronic immune thrombocytopenic purpura (ITP) in adults. • dermatomyositis in adults.

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Drug Name	FDA-Approved Indication
Panzyga	Treatment of: • primary humoral immunodeficiency in patients ≥ 2 years old. • chronic immune thrombocytopenia (ITP) in adults. • chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.
Privigen	Treatment of: • primary humoral immunodeficiency (PI). • chronic immune thrombocytopenic purpura (ITP) in patients ≥ 15 years old. • chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. **Limitations: Privigen maintenance therapy in CIDP has not been studied beyond six months.**
Qivigy	Treatment of primary humoral immunodeficiency (PI) in adults.
Yimmugo	Treatment of primary humoral immunodeficiency (PI) in patients ≥ 2 years old.
OFF Label IVIG indications approved by CMS (See LCD 34314)	Idiopathic Thrombocytopenia Purpura (ITP) in Pregnancy Neurological Disorders: • Myasthenia Gravis • Guillain-Barre Syndrome • Polymyositis • Multiple Myeloma • Multifocal Motor Neuropathy (MMN) • Dermatomyositis • Lambert-Eaton myasthenic syndrome • CIDP variants Other Disorders: • Kawasaki Disease (Mucocutaneous Lymph Node Syndrome) • Chronic lymphocytic leukemia (CLL) • Bone Marrow/Stem Cell Transplantation • Pediatric human immunodeficiency (HIV) • Transplantation rejection (kidney, stem cell or heart) antibody-mediated • Desensitization for a pre-kidney or pre-heart transplantation • Autoimmune retinopathy (limited to three months unless there is improvement on therapy)

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Drug Name	FDA-Approved Indication
	• Antiviral prophylaxis or post-exposure prophylaxis against viruses when SCIG is unavailable **(subQ preferred)** » HIV » Primary immunodeficiencies » Bone marrow transplantation » Hepatitis A » Measles » Rubella » Varicella **See LCD 34314 for specific approval criteria required for each.**

Dosing and Administration

Drug Name		Dosing Regimen
Alyglo		**1st infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Double infusion rate every 30 minutes (if tolerated) up to 8 mg/kg/min **2nd infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 2 mg/kg/min • Double infusion rate every 15 minutes (if tolerated) up to 8 mg/kg/min
Asceniv		300-800 mg/kg IV Q21-28 days; infusion rate 0.5 mg/kg/min for first 15 minutes • Increase rate gradually every 15 minutes (if tolerated) up to 8 mg/kg/min
Bivigam		300-800 mg/kg IV Q21-28 days; infusion rate 0.5 mg/kg/min for first 10 minutes • Increase rate every 20 minutes (if tolerated) by 0.8 mg/kg/min up to 6 mg/kg/min
Flebogamma DIF	5%	**PI:** 300-600 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase rate gradually up to 5 mg/kg/min
	10%	**PI:** 300-600 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Increase rate gradually if tolerated up to 8 mg/kg/min **ITP:** 1 g/kg IV daily for two consecutive days; infusion rate: 1 mg/kg/min • Increase rate gradually if tolerated up to 8 mg/kg/min
Gammagard		300-600 mg/kg IV Q21-28 days; infusion rate: 0.8 mg/kg/min • Increase rate every 30 minutes (if tolerated) up to 8 mg/kg/min
Gammaked		300-600 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Increase rate gradually if tolerated up to 8 mg/kg/min
Gammaplex	5%	**PI:** 300-800 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase rate every 15 minutes (if tolerated) up to 4 mg/kg/min **ITP:** 1 g/kg IV daily for two consecutive days; infusion rate: 0.5 mg/kg/min • Increase rate every 15 minutes (if tolerated) up to 4 mg/kg/min
	10%	**PI:** 300-800 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase rate every 15 minutes (if tolerated) up to 8 mg/kg/min **ITP:** 1 g/kg IV daily for two consecutive days; infusion rate: 0.5 mg/kg/min • Increase rate every 15 minutes (if tolerated) up to 8 mg/kg/min

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Drug Name	Dosing Regimen	
Gamunex-C	**PI:** 300-600 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min **ITP:** 2 g/kg IV q21 days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min **CIDP:** 2 g/kg IV loading dose + 1 g/kg IV maintenance dose Q21 days • LD infusion rate: 2 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min	
Octagam	5%	**PI:** 300-600 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase rate gradually (if tolerated) up to 3.33 mg/kg/min
	10%	**Chronic ITP:** 2 g/kg IV daily for two consecutive days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 12 mg/kg/min Dermatomyositis: 2 g/kg IV daily for two-five consecutive days Q28 days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 4 mg/kg/min
Panzyga	**PI:** 300-600 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 14 mg/kg/min **Chronic ITP in Adults:** 2 g/kg IV daily for two consecutive doses; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min **CIDP in Adults:** Loading Dose: 1 g/kg IV daily for two consecutive doses; infusion rate: 1 mg/kg/min Maintenance: 1-2 g/kg IV every three weeks divided into two doses given over two consecutive days; infusion rate: 1 mg/kg/min • Increase rate gradually (if tolerated) up to 12 mg/kg/min	
Privigen	**PI:** 200-800 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min **ITP:** 1 g/kg IV daily for two consecutive days; infusion rate: 0.5 mg/kg/min • Increase rate gradually (if tolerated) up to 4 mg/kg/min **CIDP:** Loading dose: 2 g/kg in divided doses over two-five consecutive days • LD infusion rate: 0.5 mg/kg/min Maintenance: 1 g/kg IV daily over one-two consecutive days Q21 days; infusion rate: 0.5 mg/kg/min • Increase rate gradually (if tolerated) up to 8 mg/kg/min	

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Drug Name	Dosing Regimen
Qivigy	**1st infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 1 mg/kg/min • Increase infusion rate every 30 minutes (if tolerated) up to 8 mg/kg/min **2nd infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 2 mg/kg/min • Increase infusion rate every 15 minutes (if tolerated) up to 8 mg/kg/min
Yimmugo	**1st infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase infusion rate every 30 minutes (if tolerated) up to 3 mg/kg/min **2nd infusion:** 300-800 mg/kg IV Q21-28 days; infusion rate: 0.5 mg/kg/min • Increase infusion rate gradually (if tolerated) up to 13 mg/kg/min

Billing and Coding Information

	10-digit NDC	11-digit NDC
Alyglo	5 g: 61476-104-05 10 g: 61476-104-10 20 g: 61476-104-20	5 g: 61476-0104-05 10 g: 61476-0104-10 20 g: 61476-0104-20
Asceniv	5 g: 69800-0250-1	5 g: 69800-0250-01
Bivigam	5 g: 69800-6502-1 10 g: 69800-6503-1	5 g: 69800-6502-01 10 g: 69800-6503-01
Flebogamma DIF	2.5 g: 61953-0004-2 5 g/50 mL: 61953-0005-1 5 g/100 mL: 61953-0004-3 10 g/100 mL: 61953-0005-2 10 g/200 mL: 61953-0004-4 20 g/200 mL: 61953-0005-3 20 g/400 mL: 61953-0004-5	2.5 g: 61953-0004-02 5 g/50 mL: 61953-0005-01 5 g/100 mL: 61953-0004-03 10 g/100 mL: 61953-0005-02 10 g/200 mL: 61953-0004-04 20 g/200 mL: 61953-0005-03 20 g/400 mL: 61953-0004-05
Gammagard	1 g: 0944-2700-02 2.5 g: 0944-2700-03 5 g: 0944-2700-04 10 g: 0944-2700-05 20 g: 0944-2700-06 30 g: 0944-2700-07	1 g: 00944-2700-02 2.5 g: 00944-2700-03 5 g: 00944-2700-04 10 g: 00944-2700-05 20 g: 00944-2700-06 30 g: 00944-2700-07
Gammaked	1 g: 76125-900-01 5 g: 76125-900-50 10 g: 76125-900-10 20 g: 76125-900-20	1 g: 76125-0900-01 5 g: 76125-0900-50 10 g: 76125-0900-10 20 g: 76125-0900-20
Gammaplex	5 g/50 mL: 64208-8235-5 5 g/100 mL: 64208-8234-6 10 g/100 mL: 64208-8235-6 10 g/200 mL: 64208-8234-7 20 g/200 mL: 64208-8235-7 20 g/400 mL: 64208-8234-8	5 g/50 mL: 64208-8235-05 5 g/100 mL: 64208-8234-06 10 g/100 mL: 64208-8235-06 10 g/200 mL: 64208-8234-07 20 g/200 mL: 64208-8235-07 20 g/400 mL: 64208-8234-08
Gamunex-C	1 g: 13533-800-12 2.5 g: 13533-800-15 5 g: 13533-800-20 10 g: 13533-800-71 20 g: 13533-800-24 40 g: 13533-800-40	1 g: 13533-0800-12 2.5 g: 13533-0800-15 5 g: 13533-0800-20 10 g: 13533-0800-71 20 g: 13533-0800-24 40 g: 13533-0800-40

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	10-digit NDC	11-digit NDC
Octagam	1 g: 0069-8400-02 2 g: 0069-6002-02 2.5 g: 0069-8425-02 5 g/50 mL: 0069-6550-02 5 g/100 mL: 0069-8451-02 10 g/100 mL: 0069-6111-02 10 g/200 mL: 0069-8476-02 20 g: 0069-6237-02 30 g: 0069-6339-02	1 g: 00069-8400-02 2 g: 00069-6002-02 2.5 g: 00069-8425-02 5 g/50 mL: 00069-6550-02 5 g/100 mL: 00069-8451-02 10 g/100 mL: 00069-6111-02 10 g/200 mL: 00069-8476-02 20 g: 00069-6237-02 30 g: 00069-6339-02
Panzyga	1 g: 0069-1011-02 2.5 g: 0069-1109-02 5 g: 0069-1224-02 10 g: 0069-1312-02 20 g: 0069-1415-02 30 g: 0069-1558-02	1 g: 00069-1011-02 2.5 g: 00069-1109-02 5 g: 00069-1224-02 10 g: 00069-1312-02 20 g: 00069-1415-02 30 g: 00069-1558-02
Privigen	5 g: 44206-436-05 10 g: 44206-437-10 20 g: 44206-438-20 40 g: 44206-439-40	5 g: 44206-0436-05 10 g: 44206-0437-10 20 g: 44206-0438-20 40 g: 44206-0439-40
Qivigy	5 g: 76179-010-02 10 g: 76179-010-04	5 g: 76179-0010-02 10 g: 76179-0010-04
Yimmugo	5 g: 83372-605-01 10 g: 83372-605-11 20 g: 83372-605-21	5 g: 83372-0605-01 10 g: 83372-0605-11 20 g: 83372-0605-21

	HCPCS Code	Description
Alyglo	J1552	Injection, immune globulin, 500 mg
Asceniv	J1554	Injection, immune globulin, 500 mg
Bivigam	J1556	Injection, immune globulin, 500 mg
Flebogamma DIF	J1572	Injection, immune globulin, non-lyophilized, 500 mg
Gammagard	J1569	Injection, immune globulin, non-lyophilized, 500 mg
Gammaked	J1561	Injection, immune globulin, non-lyophilized, 500 mg
Gammaplex	J1557	Injection, immune globulin, non-lyophilized, 500 mg
Gamunex-C	J1561	Injection, immune globulin, non-lyophilized, 500 mg
Octagam	J1568	Injection, immune globulin, non-lyophilized, 500 mg
Panzyga	J1576	Injection, immune globulin, non-lyophilized, 500 mg
Privigen	J1459	Injection, immune globulin, non-lyophilized, 500 mg
Qivigy	J3590, C9399	Unclassified drugs or biologicals; unclassified biologics
Yimmugo	J1553	Injection, immune globulin, 100 mg

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	CPT Procedural Codes	Description
Alyglo	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Asceniv	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Bivigam	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Flebogamma DIF	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Gammagard	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Gammaked	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Gammaplex	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Gamunex-C	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Octagam	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Panzyga	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Privigen	96365 96366	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic IV infusion, add on
Qivigy	96365 96374	Ther/proph/diagnostic IV infusion initial Ther/proph/diagnostic injection IV push
Yimmugo	96365 96413	Ther/proph/diagnostic IV infusion initial Chemotherapy IV infusion one hour

Product Availability

Alyglo
- 5 g/50 mL
- 10 g/100 mL
- 20 g/200 mL

Asceniv
- 5 g/50 mL

Bivigam/Flebogamma DIF/Gammaplex/Octagam
- 5 g/50 mL
- 10 g/100 mL

Flebogamma DIF/Gammaplex
- 20 g/200 mL

	Flebogamma DIF/Gammaplex/Octagam • 5 g/100 mL • 10 g/200 mL Flebogamma DIF/Gammaplex/Octagam • 20 g/200 mL Flebogamma DIF/Octagam • 2.5 g/50 mL Gammagard Liquid • 30 g/300 mL Gammagard Liquid/Gammaked/Gamunex-C • 1 g/10 mL • 5 g/50 mL • 10 g/100 mL • 20 g/200 mL Gammagard Liquid/Gamunex-C • 2.5 g/25 mL Gammagard S/D Less IgA • 5 g • 10 g Gamunex-C • 40 g/400 mL Octagam • 2 g/200 mL • 30 g/300 mL Panzyga • 1 g/10 mL • 2.5 g/25 mL • 5 g/50 mL • 10 g/100 mL • 20 g/200 mL • 30 g/300 mL

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	Privigen • 5 g/50 mL • 10 g/100 mL • 20 g/200 mL • 40 g/400 mL Qivigy • 5 g/50 mL • 10 g/100 mL Yimmugo • 5 g/50 mL • 10 g/100 mL • 20 g/200 mL
Contraindications	**ALL Brands:** • History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient with antibodies to IgA and a history of hypersensitivity *In addition to above:* **Gammaplex:** • Patients with hereditary intolerance to fructose, also in infants and neonates for whom sucrose or fructose tolerance has not been established. **Octagam:** • Patients with acute hypersensitivity reaction to corn. **Privigen:** • Hyperprolinemia (Privigen contains the stabilizer L-proline)
Recommended Medical Monitoring	**BLACK BOX WARNING: Thrombosis, Renal Dysfunction, and Acute Renal Failure** • **Thrombosis** may occur with IVIG products; risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors. • **Renal Dysfunction, acute renal failure**, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients. Renal Dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose. • For patients at risk of thrombosis, renal dysfunction or renal failure, administer IVIG at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. IVIG products may also be associated with: • Hypersensitivity reactions • Anaphylactic reactions • Hyperproteinemia • Increased serum viscosity

	• Hyponatremia or Pseudohyponatremia • Aseptic meningitis syndrome (AMS), especially with high doses or rapid infusion • Hemolysis • Transfusion-related lung injury (TRALI) • Risk of infections (human plasma product)
Approval Criteria	Target Agent(s) will be approved when **ALL** of the following are met: 1. Physician administered IV infusion; in-office or HOPD a. Cannot be self-administered 2. **ONE** of the following: a. The requested agent is eligibility for continuation of therapy and one of the following: i. The patient has been treated with multiple doses of the requested agent within the past 120 days, OR ii. The prescriber states the patient has been treated with the requested agent within the past 120 days AND is at risk if therapy is changed, OR b. **BOTH** of the following: i. **ONE** of the following: 1. If requesting IVIG, then ONE of the following: a. The patient has a diagnosis of primary immunodeficiency AND ONE of the following: i. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy OR ii. The patient has abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein OR iii. The patient has an absence of B lymphocytes OR iv. **ALL** of the following: 1. **ONE** of the following: a. The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) by more than 2 standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period] OR b. The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses OR c. The patient has hypogammaglobulinemia defined as total IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age at baseline prior to immune globulin therapy OR d. The patient has 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

Approval Criteria	v. The 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 vi. The 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 OR b. The patient has a diagnosis of primary immunodeficiency AND **ONE** of the following: i. The patient has hypogammaglobulinemia defined as total IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age at baseline prior to immune globulin therapy OR ii. The patient has history of recurrent bacterial infections requiring antibiotics and/or hospitalization OR c. The patient has a diagnosis of idiopathic thrombocytopenia purpura (ITP) and **ONE** of the following: i. Has tried and had an inadequate response to ONE conventional therapy (e.g., corticosteroids) for ITP OR ii. Has an intolerance or hypersensitivity to ONE conventional therapy (e.g., corticosteroids) OR iii. Has an FDA labeled contraindication to ALL conventional therapy (e.g., corticosteroids) OR d. The requested agent will be used for the prevention of bacterial infection in HIV-infected children AND **ALL** of the following: i. The patient is less than 13 years old AND ii. CD4 count is greater than 200/µL AND iii. The patient has hypogammaglobulinemia defined as total IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age at baseline prior to immune globulin therapy OR e. The patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) AND **ALL** of the following: i. The patient has progressive or relapsing symptoms present for at least two months AND ii. The patient has progressive or relapsing motor sensory impairment of more than one limb AND iii. The patient has electrodiagnostic findings indicating at least ONE of the following are present: 1. Motor distal latency prolongation in at least two motor nerves OR 2. Reduction of motor conduction velocity in at least two motor nerves OR 3. Prolongation of F-wave latency in at least two motor nerves OR 4. Absence of F-waves in at least two motor nerves plus one or more other criterion listed here in at least one other nerve OR 5. Partial motor conduction block in at least 2 motor nerves or one nerve plus one other criterion listed here except absence of F-waves OR

6. Abnormal temporal dispersion in at least two motor nerves OR
7. Distal CMAP duration prolongation in at least one motor nerve plus one other criterion listed here in at least one other nerve AND

iv. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or has consulted with a specialist in the area of the patient's diagnosis OR

f. The patient has a diagnosis of multifocal motor neuropathy AND **BOTH** of the following:

i. The diagnosis was confirmed by **ALL** of the following:

1. Weakness with slowly progressive or stepwise progressive course over at least 1 month AND
2. Asymmetric involvement of two or more nerves AND
3. Absence of upper motor neuron signs and bulbar signs AND

ii. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or has consulted with a specialist in the area of the patient's diagnosis OR

g. The patient has a diagnosis of Kawasaki disease OR

h. The patient has a diagnosis of Guillain-Barre syndrome OR

i. The requested agent will be used for prevention of infection or graft vs host disease following bone marrow transplantation AND the bone marrow transplant was within the last 100 days OR

j. The patient has a diagnosis of dermatomyositis and **BOTH** of the following:

i. The patient has **ONE** of the following:

1. Has tried and had an inadequate response to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] OR
2. Has an intolerance or hypersensitivity to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] OR
3. Has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) and immunosuppressants (e.g., azathioprine, mycophenolate)] AND

ii. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, immunologist), or has consulted with a specialist in the area of the patient's diagnosis OR

k. The patient has a diagnosis of polymyositis and **BOTH** of the following:

i. The patient has ONE of the following:

1. Has tried and had an inadequate response to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] OR
2. Has an intolerance or hypersensitivity ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] OR
3. Has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) and immunosuppressants (e.g., azathioprine, mycophenolate)] AND

<table>
<tr><td></td><td>
ii. The prescriber is a specialist in the area of the patient's diagnosis (e.g., immunologist, rheumatologist), or has consulted with a specialist in the area of the patient's diagnosis OR
l. The patient has another FDA labeled indication for the requested agent and route of administration OR
m. The patient has another indication that is supported in compendia for the requested agent and route of administration OR
c. The patient does NOT have any FDA labeled contraindications to the requested agent AND:
d. ONE of the following:
i. The requested dose does not exceed the maximum FDA labeled dose or the compendia supported dose for the requested indication OR
ii. There is support for therapy with the requested dose for the requested indication.
</td></tr>
<tr><td>Age Restriction</td><td>Product and condition specific; see approval criteria for age restriction details</td></tr>
<tr><td>Coverage Duration</td><td>
<table>
<tr><th>Indication</th><th>Length of Approval</th></tr>
<tr><td>Guillain-Barre Syndrome</td><td>3 months</td></tr>
<tr><td>Kawasaki disease</td><td>3 months</td></tr>
<tr><td>Prevention of infection following bone marrow transplant</td><td>3 months</td></tr>
<tr><td>Asceniv for ANY indication</td><td>6 months</td></tr>
<tr><td>Gammagard Liquid 10% or Privigen for CIDP</td><td>6 months</td></tr>
<tr><td>All other indications</td><td>12 months</td></tr>
</table>
Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
</td></tr>
<tr><td>Other Criteria (LCD, NCD, etc.)</td><td>Must follow LCD L34314 for Immune Globulin Intravenous (IVIG).</td></tr>
<tr><td>Misc Info, Appendix Etc.</td><td>None.</td></tr>
</table>

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/13/26	4/13/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26