

DR.002.H Intravenous Immune Globulin (IVIG)

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Thank you for being a valued provider for members in one or more of our health plans: Jefferson Health Plans Medicare Advantage, Jefferson Health Plans Individual and Family Plans, Jefferson Health Plans CHIP, and/or Jefferson Health Plans EverWell (our Medicaid plan).

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans lines of business.

POLICY STATEMENT

We consider Intravenous Immune Globulin (IVIG) medically necessary when used to treat its approved FDA labeled indications AND all the prior authorization criteria listed in the policy are met.

OFF-LABEL USE

Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the Medical Staff will be predicated on the appropriateness of treatment and full consideration of medical necessity. For off label use Medical Directors will review scientific literature and local practice patterns. Medical Directors will review all the documentation provided to assure that:

1. The diagnosis of the disorder is reasonably certain and based on a thorough history and examination and appropriate laboratory testing (such as electromyography (EMG), spinal fluid tests, serum tests, and biopsy findings).
2. Previous treatment failures are documented (when applicable).

3. The requested dose and interval of administration are consistent with recommendations in peer-reviewed literature and professional guidelines for the requested indication.
4. Once treatment is initiated, there is adequate documentation of improvement for continued treatment to be medically necessary. An objective quantitative assessment to monitor progress is required, when applicable.
5. Depending on the diagnosis and clinical circumstances, an attempt is made to decrease/wean the dosage when improvement has occurred. An attempt to stop the IVIG infusion when clinically appropriate for the diagnosis is made if improvement is sustained with dosage reduction. If improvement does not occur with IVIG, continued infusion may not be considered medically necessary (this does not apply to persons with primary immune deficiency diseases).

Off-Labeled use includes the following (not an all-inclusive list):

- Auto immune mucocutaneous blistering diseases.
- Dermatomyositis.
- Fetal/neonatal alloimmune thrombocytopenia (FAIT).
- Guillain-Barre syndrome (GBS).
- Lambert-Eaton myasthenic syndrome.
- Multifocal motor neuropathy.
- Myasthenia gravis.
- Parvovirus B19-induced pure red cell aplasia (PRCA).
- Polymyositis.
- Prophylaxis of bacterial and viral infection in pediatric human immunodeficiency virus (HIV) infection.
- Prophylaxis of bacterial and viral infections in bone marrow transplant.
- (BMT)/hematopoietic stem cell transplant (HSCT) recipients.
- Relapsing-Remitting Multiple Sclerosis (not primary or secondary progressive).
- Stiff-person syndrome.
- Toxic Shock Syndrome.

The use of IVIG or Subcutaneous Immune Globulin (SCIG) is considered experimental, investigational, or unproven for any of the following indications: (this may not be all-inclusive):

- Hashimoto encephalopathy
- Inclusion body myositis (IBM)

- Lyme neuropathy
- Neonatal sepsis
- Pediatric acute-onset neuropsychiatric syndrome (PANS) and Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS), Primary progressive multiple sclerosis (MS) and secondary progressive MS, acute MS exacerbations, or clinically isolated syndrome, recurrent pregnancy loss.

FDA APPROVED INDICATIONS

(FDA APPROVED INDICATIONS MAY VARY BY PRODUCT)

- Ascenive™
- Atgam®
- Bivigam®
- Carimune NF®
- Cutaquig®
- Flebogamma®
- Gammagard Liquid®
- Gammagard S/D®
- Gammaked®
- Gammaplex®
- Gamunex-C®
- HyQuia®
- Octagam®
- Panzyga®
- Privigen®
- Thymoglobulin®

PRIOR AUTHORIZATION CRITERIA

CRITERIA REFERENCE BY MEDICAL CONDITION

- I. Dermatology
- II. Hematology
- III. Infectious Disease
- IV. Neurology
- V. Primary Immunodeficiency Disorder (PID)
- VI. Rheumatology

- VII. Secondary Immunodeficiency
- VIII. Transplant

I. Primary Immunodeficiency Disorder

Therapy is considered medically necessary under the following conditions:

- *Hypogammaglobulinemia* (including Common Variable Immunodeficiency [CVID])
 - Labs confirming IgG below the normal reference range on at least two occasions.
 - Impaired antibody response to pneumococcal polysaccharide vaccine *or* tetanus and diphtheria *or* HiB.
 - Recurrent serious bacterial infections that require multiple or extended courses of antibiotics.
- *IgG Subclass Deficiency*
 - Labs confirming IgG for at least one subclass (excluding subclass IgG4) below the normal reference range on at least two occasions.
 - Impaired antibody response to pneumococcal polysaccharide vaccine.
 - Recurrent serious bacterial infections that require multiple or extended courses of antibiotics.
 - Documentation that underlying conditions (such as asthma, allergic rhinitis) are controlled.
- *Primary Immunodeficiency Disorders* (other indications)
 - Diagnosis confirmed by genetic or molecular testing (if applicable), *and (the following not applicable for patients < 2 years old)*.
 - History of recurrent bacterial infections (such as pneumonia, otitis media, sinusitis, sepsis, gastrointestinal, *and*

- Impaired antibody response to pneumococcal polysaccharide vaccine (not required for children younger than 2 years of age and members with severe PIDD and very low IGG levels, who generally have poor immunological response to antigens).
- Specific Antibody Deficiency (SAD)
 - Labs confirming normal IgG, IgG subclass, IgA and IgM levels.
 - Normal response to proteins (tetanus and diphtheria toxoid)
 - Impaired antibody response to pneumococcal polysaccharide vaccine
 - Recurrent serious bacterial infections
 - Documentation that underlying conditions (such as asthma, allergic rhinitis) are controlled.

II. Secondary Immunodeficiency

- *Acquired Immunodeficiency* due to hematologic malignancy, major surgery (such as heart transplant), extensive burns, collagen-vascular disease.
 - Labs confirming hypogammaglobulinemia (IgG < 400 mg/dL).
 - Recurrent sinopulmonary infection or serious bacterial infection(s).
- *B-cell Chronic Lymphocytic Leukemia (CLL)*
 - Labs confirming IgG < 500 mg/dL.
 - Recurrent sinopulmonary infection or serious bacterial infection(s).
- *HIV-infection in Pediatrics*
 - Primary prophylaxis of bacterial infections.
 - Labs confirming hypogammaglobulinemia (IgG < 400 mg/dL).

- Secondary prophylaxis when the following are met:
 - Documentation that patient is on effective antiretroviral therapy.
- *Multiple Myeloma*
 - Recurrent serious bacterial infections.
 - Failure of antibiotic prophylaxis.

III. Infectious Disease

- Toxic Shock Syndrome (staphylococcal or streptococcal)
 - Persistent oliguria with pulmonary edema.
 - Refractory to aggressive treatment.
 - Undrainable focus.

IV. Transplant

- Kidney Transplant
 - Refractory BK viremia in kidney transplant
- Solid organ transplant
 - Refractory CMV Viremia
 - When being used as desensitization therapy prior to and immediately after transplant *OR*
 - When being used for antibody-mediated rejection (AMR)
- Hematopoietic Cell Transplant (HCT)
 - Labs confirming hypogammaglobulinemia (IgG < 400 mg/dL)
AND one of the following:
 - a. Transplant less than 100 days ago *or*
 - b. Transplant after 100 days with recurrent infections
 - c. Transplant after 100 days with evidence of graft-versus-host-disease

V. Hematology

- Parvovirus B19-induced pure red cell aplasia (PRCA)
 - Severe refractory anemia
 - Evidence of parvovirus viremia

- **Fetal Alloimmune Thrombocytopenia (FAIT)**
 - Confirmation of maternal antibodies to paternal platelet antigen *AND one of the following*
 - Previous FAIT pregnancy *OR*
 - Fetal blood confirms thrombocytopenia.
- **Immune (idiopathic) Thrombocytopenia (ITP) in Adults with Platelet count < 30,000/mm₃ a one of the following:**
 - Clinical need to rapidly replenish platelet count (such as in the setting of acute bleeding, prior to major surgery, risk of cerebral hemorrhage)
 - Not a candidate for splenectomy, or is status-post splenectomy *AND*
 - Failure, contraindication, or intolerance to *all* the following:
 - Corticosteroids.
 - Thrombopoietin receptor agonists (such as eltrombopag or romiplostim).
 - Rituximab.
- **Immune (idiopathic) Thrombocytopenia (ITP) in Pediatrics**
 - Clinical need to rapidly replenish platelet count (such as in the setting of acute bleeding, prior to major surgery, risk of cerebral hemorrhage) *OR*
 - Prevention of bleeding during the first 12 months of persistent disease.
- **Immune (idiopathic) Thrombocytopenia (ITP) in Pregnancy**
 - Diagnosis of thrombocytopenia *AND*
 - Failure, contraindication, or intolerance to corticosteroids *OR*
 - Clinical need to rapidly replenish platelet count (such as in the setting of acute bleeding, prior to major surgery, risk of cerebral hemorrhage).

VI. Neurology

- **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**
 - Progressive or relapsing and remitting symptoms for two months or longer *AND*
 - Present in more than one limb.

- Hyporeflexia or areflexia in affected limbs.
 - Electrophysiologic findings indicate demyelinating neuropathy (*at least 3 of the following*)
 - Partial conduction block of ≥ 1 motor nerve.
 - Reduced conduction velocity of ≥ 2 motor nerves.
 - Prolonged distal latency of ≥ 2 motor nerves.
 - Prolonged F-wave latencies of ≥ 2 motor nerves or the absence of F waves.
 - The following causes of demyelinating neuropathy have been excluded (*from the European Federation of Neurological Societies and the Peripheral Nerve Society*):
 - *Borrelia burgdorferi* infection (Lyme disease).
 - Diphtheria, drug, or toxin exposure probably to have caused the neuropathy.
 - Hereditary demyelinating neuropathy.
 - Prominent sphincter disturbance.
 - Diagnosis of multifocal motor neuropathy.
 - IgM monoclonal gammopathy with high titer antibodies to myelin-associated glycoprotein.
 - Other causes for demyelinating neuropathy include POEMS syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy, PNS lymphoma and amyloidosis.
- **Guillain-Barre Syndrome (GBS)**
 - The symptoms began less than 6 weeks ago.
 - Severe disease requiring assistance to ambulate.
 - **Lambert-Eaton Myasthenic Syndrome**
 - Failure, contraindication, or intolerance to symptomatic therapies (acetylcholinesterase inhibitors such as Mestinon and immunosuppressants such as prednisone, azathioprine).
 - **Multifocal Motor Neuropathy (MMN)**
 - Diagnosis of definite or probable MMN supported by nerve conduction studies showing focal demyelination and conduction block in motor nerves and normal sensory nerves.
 - Findings rule out other conditions that may not respond to IVIG treatment.
 - **Myasthenia Gravis (acute)**

- In the setting of acute crisis (approve up to 5 days).
 - In the setting of thymectomy (prior to and acutely for post-operative period).
 - When initiating immunosuppressive treatment.
- **Myasthenia Gravis (refractory, up to 12-month approval)**
 - Failure, contraindication, or intolerance to pyridostigmine, *AND*
 - Failure, contraindication, or intolerance to corticosteroid maintenance treatment, *AND*
 - Failure, contraindication, or intolerance to (at least one of the following) azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, tacrolimus.
 - Confirmation of failure or contraindication to thymectomy.
- **Relapsing-Remitting Multiple Sclerosis (RRMS)**
 - Failure of *TWO* formulary products indicated for the treatment RRMS.
- **Stiff-Person Syndrome**
 - Confirmation of anti-glutamic acid decarboxylase (GAD) antibodies.
 - Failure of at least two of the following from different classes: Benzodiazepines, Baclofen, Gabapentin, Valproate, levetiracetam, Clonidine, Tizanidine.

VII. Rheumatology

- **Dermatomyositis or Polymyositis**
 - Diagnosis confirmed by muscle biopsy.
 - Failure of corticosteroids.
 - Failure of at least two other immunosuppressants (such as azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.
 - Acute and profound muscular weakness.
- **Kawasaki Disease**
 - For the prevention of coronary artery aneurysms at the time of diagnosis.

VIII. Dermatology

- Auto-immune Mucocutaneous Blistering disease (such as bullous pemphigoid, epidermolysis bullosa acquisita, mucus membrane pemphigoid (or cicatricial pemphigoid)) [not to be approved as maintenance therapy, *approvable up to 6 consecutive months*]
 - In the setting of severe disease that is extensive and debilitating.
 - Failure, contraindication, or intolerance to standard therapy (such as azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, tacrolimus).
- Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN)
 - Approvable for acute treatment.

INITIAL AUTHORIZATION is up to 6 months unless otherwise noted within specific criteria by indication.

AUTHORIZATION FOR RENEWAL is up to 6 months (up to 12 months for PID and refractory mg).

DOSAGE AND ADMINISTRATION

Per package labeling.

RISK FACTORS/SIDE EFFECTS

Per package labeling.

MONITORING

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury). Monitor patients with known risk factors for thrombotic events.

BLACK BOX WARNING

Thrombosis, renal dysfunction, acute renal failure, osmotic nephrosis, anaphylaxis, and death may occur with intravenous immune globulin.

CLINICAL EVIDENCE

N/A

BACKGROUND

Intravenous immunoglobulin (IVIG) is a blood-derived therapy containing immunoglobulins (antibodies) used to treat an array of disorders, including primary and secondary immune deficiency states and various autoimmune and inflammatory disorders.

IVIG provides a board spectrum of IgG antibodies that can opsonize pathogens and neutralize bacterial toxins and viruses. Its exact mechanism of action has not been fully elucidated, but is believed to work through multiple immunomodulatory effects.

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT® is a registered trademark of the American Medical Association.

CPT Code	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

HCPSC Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1552	Injection, immune globulin (Alyglo), 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, non-lyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (100 mg immune globulin
J1576	Injection, immune globulin (Panzyga®), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1577	Injection, immune globulin (Qivigy), 100 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg

ICD-10 Codes	Description
N/A	

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Jefferson Health Plans EverWell and Jefferson Health Plans CHIP products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2026 Annual Review. Revisions made to Dosage and Administration, Side Effects and Risk Factor Sections. Additions to Background section. CPT codes and HCPCS codes added. References updated.	H	08/19/2026
2025 Annual Review. HCPCS codes added.	G	08/21/2025
2024 Annual review. J1551 (Cutaquig) & J1575 (HyQuia®) were added to the coding table.	F	9/18/2024
2023 Annual review. Prior authorization criteria were reformatted. Minor revisions to the dosing and monitoring sections. J1576 was added to the coding table.	E	11/16/2023
2022 Annual review. Added: Asceniv® and PANZYGA® J1599 was added to the coding table. Policy formatting revised	D	02/22/2023

Summary	Version	Version Date
2021 Annual review. Primary inherited immunodeficiency (PID) broken out into multiple sections. Additional specialists were added. J1554 added to coding table.	C	07/01/2021
2020 Annual policy review. Updated policy language to include additional prior authorization criteria.	B	08/01/2020
2019 Annual policy review. Coding table added. No changes to policy language.	A	07/15/2018
New Policy	A	07/15/2019

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7. Gammaked® [prescribing information]. Kedrion Biopharma. 2016 Sept. Revised 2020 January.
8. Gammaplex® [prescribing information]. Bio Products Laboratory Ltd. Revised 2024 May.
9. Gamunex-C® [prescribing information]. Grifols Therapeutics, Inc. 2017 Mar. Revised 2020 Jan.

10. Octagam® [prescribing information]. Octapharma USA Inc. 2013 Oct. Revised 2022 April.
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