

Intravenous Immune Globulins

(Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard Liquid ERC, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen, Qivigy, Yimmugo)

When requesting Intravenous Immune Globulins (Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard Liquid ERC, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, Privigen, Qivigy, Yimmugo), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Intravenous Immune globulin (IVIG) injection is indicated for the treatment of:

- Primary humoral immunodeficiency including but not limited to: congenital agammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies
- Idiopathic thrombocytopenia purpura (ITP) to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery
- Chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse
- Multifocal motor neuropathy (MMN) to improve muscle strength and disability
- Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia
- Prevention of coronary artery aneurysms associated with Kawasaki syndrome
- Dermatomyositis or polymyositis

Approved Off-label Compendial Uses

- Secondary humoral immunodeficiency
- Antibody-mediated rejection in solid organ transplant
- Autoimmune mucocutaneous blistering disease
- Cytomegalovirus (CMV) interstitial pneumonia
- Guillain-Barre syndrome
- Human immunodeficiency virus (HIV) associated thrombocytopenia
- Hepatitis C associated thrombocytopenia

- Treatment or post-exposure prophylaxis for tetanus
- Myasthenia gravis
- Lambert-Eaton myasthenic syndrome
- Multiple sclerosis
- Stiff-person syndrome
- Multiple myeloma
- Pure red blood cell aplasia (PRCA)
- Post-exposure prophylaxis of measles
- Post-exposure prophylaxis of varicella
- Feto-neonatal alloimmune thrombocytopenia
- For desensitization therapy prior to and immediately after solid organ transplantation
- Immunotherapy-related toxicities associated with checkpoint inhibitor therapy
- Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)
- Immune-Mediated Necrotizing Myopathy
- Aquaporin-4 Immunoglobulin Antibodies (AQP4-IgG)-Positive Neuromyelitis Optica Spectrum Disorder (NMOSD)

Coverage Guidelines

Primary Humoral Immunodeficiency (PI)

The individual must meet the following criteria for initial authorization:

- Must have one of the following PI subtypes:
 - o Common variable immunodeficiency (CVID)
 - o X-linked agammaglobulinemia
 - o Congenital agammaglobulinemia
 - o Other agammaglobulinemia due to the absence of B-cells
 - o Severe combined immunodeficiency (SCID)
 - o Wiskott-Aldrich syndrome
 - o Hyper-Immunoglobulin M (IgM) syndromes
 - o IgG level lower than 250 mg/dL
 - o Ataxia telangiectasia
 - o DiGeorge syndrome
 - o Other combined immunodeficiencies with significant hypogammaglobulinemia
 - o Unspecified hypogammaglobulinemia
 - o IgG subclass deficiency
 - o Selective antibody deficiency (SAD)
 - o Other primary immune deficiency confirmed by genetic or molecular testing
- For CVID, unspecified hypogammaglobulinemia, or other combined immunodeficiencies with significant hypogammaglobulinemia indication, must meet both of the following criteria:
 - o The pretreatment total IgG level is below the normal range (age-related and according to the normal reference range for the reporting laboratory); AND
 - o Has an impaired antibody response (i.e., failure to produce antibodies to specific antigen) OR has recurrent infections.

- For IgG subclass deficiency, selective antibody deficiency (SAD), or another confirmed primary immunodeficiency must have an impaired antibody response (i.e., failure to produce antibodies to specific antigen) and recurrent infections;
- The requested product is prescribed by or in consultation with one of the following physician specialists: allergist, immunologist, otolaryngologist (ear, nose, and throat [ENT] physician), pulmonologist, or an infectious disease physician who treats patients with PI.

NOTE: An exception can be made for the impaired antibody response if, according to the prescriber, the delay caused by pre-vaccination and post-vaccination antibody measurement would be deleterious to the patient's health.

The individual must meet the following criterion for re-authorization:

- Has been diagnosed with a primary immunodeficiency and is continuing to receive benefit from the product (e.g., increased IgG levels, preventing or controlling infections).

Approval duration (initial and renewal): 12 months

Secondary Humoral Immunodeficiency:

Must have one of the following diseases/conditions:

- B-cell chronic lymphocytic leukemia
- Hematologic neoplasm-associated hypogammaglobulinemia
- Hypogammaglobulinemia after B-cell targeted therapies
- Post hematopoietic stem cell transplantation
- Human immunodeficiency virus (HIV) infection in pediatrics

B-Cell Chronic Lymphocytic Leukemia for Prevention of Infections

The individual must meet both of the following criteria for an initial authorization:

- Has an immunoglobulin G (IgG) level less than 600 mg/dL OR has a history of recurrent infections;
- The requested product is prescribed by or in consultation with an oncologist, hematologist, or infectious disease physician.

The individual must meet the following criterion for re-authorization:

- Is experiencing a positive response to therapy (e.g., maintaining an increased IgG trough level or a decrease in the number of infections).

Approval duration (initial): 4 months

Approval duration (renewal): 12 months

Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-cell Targeted Therapies

NOTE: Examples of B-cell targeted therapy are chimeric antigen receptor (CAR) T cell therapy (e.g., Kymriah [tisagenlecleucel injection], Abecma [idecabtagene vicleucel injection], Breyanzi [lisocabtagene maraleucel injection], Tecartus [brexucabtagene autoleucel injection], Yescarta [axicabtagene ciloleucel injection]), a rituximab product, Besponsa (inotuzumab ozogamicin injection, and Blincyto (blinatumomab injection).

The individual must meet one of the following criteria for an initial authorization:

- Meets all of the following:
 - o Has an immunoglobulin G (IgG) level less than 600 mg/dL;
 - o Has recurrent or severe infections or has high risk of infection;
 - o The requested product is prescribed by or in consultation with an oncologist, hematologist, infectious disease physician, or immunologist.
- Meets both of the following:
 - o Is less than 18 years of age;
 - o Will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy or other B-cell targeted therapy.

The individual must meet the following criterion for re-authorization:

- Is experiencing a positive response to therapy (e.g., maintaining an increased IgG trough level or a decrease in the number of infections).

Approval duration (initial and renewal): 6 months

Hematopoietic Cell Transplantation (HCT) to Prevent Infection

The individual must meet one of the following criteria for an initial authorization:

- Meets all of the following:
 - o Has had a HCT within the previous year;
 - o Has an immunoglobulin G (IgG) level less than 600 mg/dL OR has multiple myeloma or malignant macroglobulinemia;
 - o Has a significant risk of having frequent and/or severe infections;
 - o The requested product is prescribed by or in consultation with a hematologist, oncologist, or infectious disease physician; OR
- Is a recipient of an umbilical cord blood transplant; OR
- Is undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency; OR
- Has chronic graft versus host disease with recurrent sinopulmonary infections.

The individual must meet the following criterion for re-authorization:

- Is experiencing a positive response to therapy (e.g., maintaining an increased IgG trough level, controlling the number of infections, or a decrease in the number of infections).

Approval duration (initial): 3 months

Approval duration (renewal): 6 months

Human Immunodeficiency Virus (HIV)

The individual must meet the following criteria for an initial authorization:

- Is less than 18 years of age;
- Is receiving combination antiretroviral therapy;
- Meets one of the following:
 - o Has hypogammaglobulinemia (i.e., IgG less than 400 mg/dL); OR
 - o Functional antibody deficiency is demonstrated by poor specific antibody titers (i.e., does not develop specific antibody response against protein and polysaccharide antigens); OR

- o Functional antibody deficiency is demonstrated by having recurrent (2 or more per year) serious infections (e.g., bacteremia, meningitis, pneumonia) despite administration of combination antiretroviral therapy and appropriate antimicrobial prophylaxis;
- The requested product is prescribed by or in consultation with an infectious disease specialist or an immunologist.

The individual must meet the following criterion for re-authorization:

- The frequency and/or severity of infections have decreased.

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

The individual must meet both of the following criteria for an initial authorization:

- The requested product is prescribed by or in consultation with a neurologist;
- Electrodiagnostic studies support the diagnosis of CIDP.

The individual must meet the following criterion for re-authorization:

- Must have a clinically significant improvement in neurologic symptoms (e.g., improvement in disability, nerve conduction study results improved or stabilized, physical examination show improvement in neurological symptoms, strength [e.g., grip strength], and sensation).

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Immune Thrombocytopenia (ITP)

The individual must meet the following criteria for an initial authorization:

- Must meet one of the following criteria:
 - o Is pregnant; OR
 - o Is less than 18 years of age; OR
 - o The request product is being used to increase platelet count before surgical or dental procedures; OR
 - o Is 18 years of age or older and has tried a systemic corticosteroid (e.g., prednisone) unless contraindicated OR has an urgent need to increase the platelet count quickly.
- The requested product is prescribed by or in consultation with a hematologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., increased platelet counts, absence of significant bleeding, or preventing hemorrhage/ensuring adequate platelet count in order for delivery in pregnant patients) OR has previously responded to therapy.

Approval duration (pregnancy): 6 months

Approval duration (prior to surgical or dental procedures): 1 month

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Kawasaki Disease

The individual must meet the following criterion for authorization:

- The requested product is prescribed by or in consultation with a pediatric cardiologist or a pediatric infectious disease physician.

Approval duration: 3 months

Multifocal Motor Neuropathy (MMN)

The individual must meet both of the following criteria for an initial authorization:

- The diagnosis of MMN is supported by weakness without sensory abnormalities, upper motor neuron signs, or marked bulbar involvement and meets one of the following:
 - The diagnosis is supported by nerve conduction studies that demonstrate motor conduction block or probable motor conduction block; OR
 - Has MMN without conduction block; OR
 - The diagnosis is supported by a motor nerve biopsy or by a magnetic resonance imaging (MRI) neurography;
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Has improvement in neurologic symptoms (e.g., improvement in disability, grip strength improvement, physical examination shows improvement in neurological symptoms and strength).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Antibody-Mediated Rejection (ABMR) in Transplantation

The individual must meet the following criterion for authorization:

- The requested product is prescribed by or in consultation with a physician affiliated with a transplant center.

Approval duration: 12 months

Autoimmune Mucocutaneous Blistering Diseases (pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita)

The individual must meet the following criteria for an initial authorization:

- Must meet one of the following:
 - Has tried both a systemic corticosteroid and an immunosuppressive agent (e.g., azathioprine, cyclophosphamide, methotrexate, cyclosporine, mycophenolate, tacrolimus) unless contraindicated to both agents; OR
 - Has rapid, debilitating, progressive disease that cannot be controlled with a systemic corticosteroid and an immunosuppressive agent; OR

- o Has a serious disease that there is inadequate time for therapy with a systemic corticosteroid and an immunosuppressive agent to have a rapid enough effect;
- The requested product is prescribed by or in consultation with a dermatologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., healing of previous lesions or fewer new lesions).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Cytomegalovirus (CMV) Pneumonitis or Pneumonia

The individual must meet both of the following criteria for authorization:

- Has cancer or transplant-related infection;
- The requested product is prescribed by or in consultation with an oncologist, hematologist, or an infectious disease physician.

Approval duration: 2 months

Dermatomyositis or Polymyositis

The individual must meet all of the following criteria for an initial authorization:

- Prior to starting any therapy for this condition, must meet one of the following:
 - o Has or had an elevated creatine kinase (CK) level; OR
 - o Other measures support the diagnosis, including but not limited to, skin manifestations, autoantibody testing, muscle biopsy results, electromyographic (EMG) findings;
- Has tried a systemic corticosteroid unless contraindicated;
- Has tried an immunosuppressive agent (e.g., azathioprine, methotrexate, cyclosporine, cyclophosphamide, mycophenolate) unless contraindicated;
- The requested product is prescribed by or in consultation with a neurologist or a rheumatologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., improved muscle strength, neuromuscular symptoms, or functional ability).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Desensitization Therapy Prior to and Immediately after Solid Organ Transplantation

The individual must meet the following criterion for authorization:

- The requested product is prescribed by or in consultation with a physician affiliated with a transplant center.

Approval duration: 12 months

Guillain Barre Syndrome (GBS)

The individual must meet both of the following criteria for an initial authorization:

- Meets one of the following:
 - o The requested product will be initiated within 2 weeks and no longer than 4 weeks after onset of neuropathic symptoms (e.g., weakness, inability to stand or walk without assistance, respiratory or bulbar weakness); OR
 - o Has had a relapse but had an initial response to IVIG;
- The requested product is prescribed by or in consultation with a neurologist or a specialist with experience in diagnosing and treating patients with GBS.

Approval duration (initial and renewal): 1 month

Human Immunodeficiency Virus (HIV)- or Hepatitis C- Associated Thrombocytopenia

The individual must meet both of the following criteria for authorization:

- Is receiving antiviral therapy;
- The requested product is prescribed by or in consultation with an infectious disease specialist, a physician who specializes in the treatment of HIV infection, a gastroenterologist, hepatologist, or a liver transplant physician.

Approval duration: 1 month

Lambert-Eaton Myasthenic Syndrome (LEMS)

The individual must meet all of the following criteria for an initial authorization:

- Is having refractory weakness after symptomatic treatment of LEMS with an amifampridine product (e.g., Firdapse, Ruzurgi), guanidine, or pyridostigmine.
- Meets one of the following:
 - o Has paraneoplastic LEMS; OR
 - o Has non-paraneoplastic LEMS and has tried a systemic corticosteroid or another immunosuppressive agent unless contraindicated to corticosteroid and/or immunosuppressive agents
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Has shown a response to therapy (e.g., improved muscle strength, other clinical response) or continued effectiveness.

Approval duration (initial): 1 month

Approval duration (renewal): 12 months

Multiple Sclerosis (MS)

For acute severe exacerbation or relapses:

The individual must meet the following criteria for authorization:

- o Meets one of the following:
 - o Has not responded to or had a significant adverse reaction with systemic corticosteroids or plasma exchange; OR
 - o Has a contraindication to systemic corticosteroids;
- o Meets one of the following:
 - o Is already on maintenance therapy for MS or will be starting maintenance therapy for MS; OR
 - o Is pregnant or post-partum and maintenance therapy is not clinically appropriate;
- o The requested product is prescribed by or in consultation with a neurologist or physician who specializes in the treatment of MS.

Approval duration: 1 month

Multiple Myeloma

The individual must meet the following criteria for an initial authorization:

- Meets one of the following:
 - o Has or is at risk of severe, recurrent infections; OR
 - o Will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy, biospecific antibody therapy, or other B-cell targeted therapy;
- The requested product is prescribed by or in consultation with a hematologist, oncologist, or infectious disease specialist

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Myasthenia Gravis

For an initial authorization request for short-term (acute) use:

- o Has an exacerbation of myasthenia gravis; OR
- o Requires stabilization of myasthenia gravis before surgery; OR
- o Has started on an immunosuppressive drug (e.g., azathioprine, cyclosporine, cyclophosphamide, mycophenolate, methotrexate, tacrolimus) and is waiting for full effect; OR
- o Is starting therapy with a corticosteroid and IVIG is being given to prevent or minimize exacerbations; AND
- o The requested product is prescribed by or in consultation with a neurologist; OR
- o Continuation of therapy in patients using immune globulin for short-term (acute) use; (to allow for one course of therapy).

Approval duration: 5 days

For maintenance use:

The individual must meet all of the following criteria for an initial authorization:

- Has refractory myasthenia gravis;
- Has tried pyridostigmine;

- Has tried at least one of the following immunosuppressive agents and had an inadequate response: azathioprine, cyclosporine, cyclophosphamide, mycophenolate, methotrexate, tacrolimus;
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Is responding to IVIG therapy (e.g., improvement in weakness [bulbar, limb, or respiratory], improvement with ocular symptoms).

Approval duration (initial & renewal): 12 months

Stiff-Person Syndrome (Moersch-Woltman Syndrome)

The individual must meet both of the following criteria for an initial authorization:

- Has tried a benzodiazepine (e.g., diazepam) or baclofen OR has contraindication to both therapies;
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., reduced stiffness or frequency of spasms, ability to walk unassisted).

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Pure Red Blood Cell Aplasia (PRCA)

The individual must meet all of the following criteria for initial authorization:

- Has tried a systemic corticosteroid (e.g., prednisone);
- Has tried either cyclophosphamide or cyclosporine;
- The requested product is prescribed by or in consultation with one of the following specialist: an infectious disease specialist, immunologist, hematologist, or transplant specialist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy with an increase in hemoglobin and reticulocytosis.

Approval duration (initial and renewal): 1 month

Parvovirus B19 Infection

The individual must meet both of the following criteria for initial authorization:

- Has an immunodeficiency condition (e.g., HIV infection, solid organ transplant, chemotherapy for hematologic malignancy);
- The requested product is prescribed by or in consultation with one of the following specialists: an infectious disease specialist, immunologist, hematologist, or transplant specialist.

Approval duration (initial): 2 months

Approval duration (renewal): 6 months

Post-Exposure Prophylaxis for Varicella OR Treatment or Post-Exposure Prophylaxis for Tetanus

The individual must meet one of the following criteria for authorization:

- For Varicella post-exposure, Varicella immune globulin is not available OR it cannot be administered; OR
- For tetanus treatment or post-exposure, tetanus immune globulin is not available.

Approval duration: single dose

Passive Immunization for Measles (post-Exposure Prophylaxis)

The individual must meet one of the following criteria for authorization:

- Is immunocompromised and has been exposed to measles; OR
- Is pregnant and has been exposed to measles and cannot readily show the individual has evidence of immunity against measles (i.e., does not have a history of the disease or age-appropriate vaccination); OR
- Is an infant born to pregnant patient with suspected or confirmed measles.

Approval duration: single dose

Thrombocytopenia, Feto-neonatal Alloimmune

The individual must meet both of the following criteria for authorization:

- Is pregnant or newborn;
- The requested product is prescribed by or in consultation with a hematologist or an obstetrician.

Approval duration: 6 months

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)

The individual must meet all of the following criteria for an initial authorization:

- Has a clinical demyelinating event (e.g., optic neuritis, acute disseminated encephalomyelitis, transverse myelitis);
- The diagnosis was confirmed by a positive blood serum test with positive for myelin oligodendrocyte glycoprotein (MOG)-Immune globulin G (IgG);
- Meets one of the following:
 - o Is using the requested product for the treatment of acute attacks and has tried a systemic corticosteroid unless contraindicated; OR
 - o Is using the requested product for attack prevention and has tried an immunosuppressant unless contraindicated;
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., reduction in relapse rate, slowing of disability, slowing in the progression of symptoms).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy

Examples of checkpoint inhibitors are Keytruda (pembrolizumab injection), Opdivo (nivolumab injection), Yervoy (ipilimumab injection), Tecentriq (atezolizumab injection), Bavencio (avelumab injection), Imfinzi (durvalumab injection), Libtayo (cemiplimab injection), Jemperli (dostarlimab injection).

The individual must meet one of the following criteria for an initial authorization:

- Has tried a systemic corticosteroid (e.g., prednisone, methylprednisolone) and has not adequately responded to therapy; OR
- The requested product is being started with a systemic corticosteroid; OR
- A corticosteroid is contraindicated.

The individual must meet the following criterion for re-authorization:

- Is having a positive response to therapy and extended therapy is required.

Approval duration (initial): 1 month

Approval duration (renewal): 6 months

Aquaporin-4 Immunoglobulin Antibodies (AQP4-IgG)-Positive Neuromyelitis Optica Spectrum Disorder (NMOSD)

The individual must meet all of the following criteria for an initial authorization:

- Has the presence of at least one core clinical feature of NMOSD (e.g., optic neuritis, acute myelitis, acute brainstem syndrome);
- The diagnosis was confirmed by a positive blood serum test for AQP4-IgG; *Note: Detection in cerebral spinal fluid would also satisfy this requirement*
- Is using the requested product for attack prevention and meets one of the following:
 - Is less than 18 years of age; OR
 - Has tried or has a contraindication to one other therapy for this condition (e.g., azathioprine, mycophenolate mofetil, rituximab, eculizumab, Ultomiris, Uplizna).
- The requested product is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., reduction in relapse rate, reduction in symptoms, slowing in the progression of symptoms).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Immune-Mediated Necrotizing Myopathy

The individual must meet all of the following criteria for an initial authorization:

- Has muscle weakness;
- Has or had an elevated creatine kinase (CK) level above 1,000 IU/L;
- Meets one of the following:
 - Has myositis-associated autoantibodies (e.g., anti-SRP autoantibodies, anti-HMGCR autoantibodies); OR
 - Has an electromyography, muscle magnetic resonance imaging, or muscle biopsy that supports the given diagnosis;
- Meets one of the following:
 - Has tried a systemic corticosteroid; OR
 - Has a contraindication to corticosteroids; OR
 - Has tried rituximab, methotrexate, mycophenolate, or tacrolimus; OR
 - Has anti-HMGCR autoantibodies;
- The requested product is prescribed by or in consultation with a neurologist or rheumatologist.

The individual must meet the following criterion for re-authorization:

- Is responding to therapy (e.g., improved muscle strength, improved functional ability, CK decrease).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

Flebogamma/Octagam

Primary immunodeficiency (PI): The recommended dose is 300 to 600 mg/kg administered every 3 to 4 weeks.

Immune thrombocytopenia (ITP): The recommended dose is 1 g/kg administered intravenously daily for 2 consecutive days.

Gammagard Liquid

PI: The recommended dose is 300 to 600 mg/kg administered intravenously every 3 to 4 weeks.

Multifocal motor neuropathy (MMN): The recommended dose is 0.5 to 2.4 g/kg per month based on clinical response.

Gammagard S/D

PI: The recommended dose is 300 to 600 mg/kg administered every 3 to 4 weeks.

B-cell chronic lymphocytic leukemia: The recommended dose is 400 mg/kg every 3 to 4 weeks.

Kawasaki syndrome: The recommended dose is a single 1 g/kg or a dose of 400 mg/kg for 4 consecutive days beginning within seven days of the onset of fever.

ITP: The recommended dose is 1 g/kg. The need for additional doses can be determined by clinical response and platelet count. Up to three separate doses may be given on alternate days if required.

Gammaked/Gamunex-C

PI: The recommended dose is 300 to 600 mg/kg administered intravenously every 3 to 4 weeks.

ITP: The recommended dose is 2 g/kg, divided in two doses of 1 g/kg given intravenously on two consecutive days or into five doses of 0.4 g/kg given on five consecutive days.

Chronic inflammatory demyelinating polyneuropathy (CIDP): The recommended dose is loading dose 2 g/kg administered intravenously in divided doses over 2 to 5 consecutive days following with maintenance dose of 1 g/kg administered in divided doses over 1 to 4 consecutive days, every 3 weeks.

Gammaplex

PI: The recommended dose is 300 to 800 mg/kg administered intravenously every 3 to 4 weeks.

ITP: The recommended dose is 1 g/kg administered intravenously for 2 consecutive days.

Privigen

PI: The recommended dose is 200 to 800 mg/kg administered intravenously every 3 to 4 weeks.

ITP: The recommended dose is 1 g/kg administered intravenously for 2 consecutive days.

CIPD: The recommended dose is loading dose 2 g/kg administered intravenously in divided doses over 2 to 5 consecutive days following with maintenance dose of 1 g/kg administered in 1 to 2 infusions on consecutive days, every 3 weeks.

Panzyga

PI: The recommended dose is 300 to 600 mg/kg administered intravenously every 3 to 4 weeks.

ITP: The recommended dose is 1 g/kg administered intravenously on 2 consecutive days.

CIDP: The recommended loading dose is 1g/kg given on 2 consecutive days. Maintenance dose is 1-2 g/kg every 3 weeks divided in 2 doses given over 2 consecutive days.

Bivigam

PI: The recommended dose is 300 to 800 mg/kg administered every 3 to 4 weeks.

Asceniv

PI: The recommended dose is 300 to 800 mg/kg administered every 3 to 4 weeks.

Alyglo

PI: The recommended dose is 300 to 800 mg/kg administered every 3 to 4 weeks.

Yimmugo

PI: The recommended dose is 300 to 800 mg/kg administered every 3 to 4 weeks.

References

1. Bivigam® 10% intravenous solution [prescribing information]. Boca Raton, FL: ADMA Biologics; April 2025.
2. Murrell D, Pena S, Joly P, et al. Diagnosis and management of pemphigus: Recommendations of an international panel of experts. *J Am Acad Dermatol*. 2020;82(3):575-585.
3. Flebogamma® 5% DIF intravenous solution [prescribing information]. Los Angeles, CA: Grifols; August 2024.
4. American College of Obstetricians and Gynecologists Practice Advisory. Management of obstetric-gynecologic patients during a measles outbreak. March 2024. Last updated May 15, 2025. Available at: www.acog.com. Accessed on November 10, 2025.
5. Gammagard® Liquid 10% solution [prescribing information]. Cambridge, MA: Takeda; September 2024.
6. Gammagard® S/D IgA < 1 mcg/mL in a 5% intravenous solution [prescribing information]. Cambridge, MA: Takeda; February 2025.
7. Gammaked™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
8. Gammaplex® 5% intravenous solution [prescribing information]. Fort Lee, NJ: Kedrion (Bio Products Laboratory); July 2025.
9. Gamunex®-C 10% solution [prescribing information]. Research Triangle Park, NJ: Grifols; January 2020.
10. Octagam® 5% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
11. Octagam® 10% intravenous solution [prescribing information]. Paramus, NJ: Octapharma; April 2022.
12. Privigen® 10% intravenous solution [prescribing information]. Kankakee, IL: CSL Behring; May 2025.
13. McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2013;62:1-34.
14. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol*. 2015;136(5):1186-205.
15. Panzyga 10% intravenous solution [prescribing information]. New York, NY: Pfizer; April 2025.
16. Asceniv 10% intravenous solution [prescribing information]. Boca Raton, FL: ADMA Biologics; April 2025.
17. Bonilla FA, Barlan I, Chapel H, et al. International Consensus Document (ICON): Common variable immunodeficiency disorders. *J Allergy Clin Immunol Pract*. 2016;4(1):38-59.
18. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol*. 2017;139(3S):S1-S46.
19. Wasserman RL, Lumry W, Harris J, et al. Efficacy, safety, and pharmacokinetics of a new 10% liquid intravenous immunoglobulin containing high titer neutralizing antibody to RSV and other respiratory viruses in subjects with primary immunodeficiency disease. *J Clin Immunol*. 2016;36:590-599.
20. Otani S, Davis AK, Cantwell L, et al. Evolving experience of treating antibody-mediated rejection following lung transplantation. *Transpl Immunol*. 2014;31(2):75-80.
21. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2026 – October 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 10, 2025.
22. Anderson D, Ali K, Blanchette V, et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. *Transfus Med Rev*. 2007;21(2 Suppl 1):s9-56.
23. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829-3866.
24. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidenced-based practice guideline for immune thrombocytopenia. *Blood*. 2011;117:4190-4207.
25. Gammaplex 10% intravenous solution [prescribing information]. Fort Lee, NJ: Kedrion (Bio Products Laboratory); May 2024.
26. American Academy of Pediatrics. Kawasaki disease. In: Kimberlin DW, Banerjee R, Barnett ED, eds. Red Book; 2024 Report of the Committee on Infectious Diseases, 33rd Ed. American Academy of Pediatrics; 2024:522-529.
27. UK National Health Service. Commissioning position (2025). [NHS England » Clinical commissioning policy for the use of therapeutic immunoglobulin \(Ig\) England \(2025\)](https://www.nhs.uk/clinical-commissioning/policy-for-the-use-of-therapeutic-immunoglobulin-ig-en-gb/). Accessed on November 10, 2025.
28. Ahmed AR. Use of intravenous immunoglobulin therapy in autoimmune blistering diseases. *Int Immunopharmacol*. 2006;6(4):557-578.

29. Enk A, Hadaschik E, Eming R, et al. European guidelines on the use of high-dose intravenous immunoglobulin in dermatology. *J Dtsch Dermatol Ges*. 2017;15(2):228-241.
30. Gurean HM, Jeph S, Ahmed AR. Intravenous immunoglobulin therapy in autoimmune mucocutaneous blistering diseases: a review of the evidence for its efficacy and safety. *Am J Clin Dermatol*. 2010;11:315-326.
31. The NCCN Prevention and Treatment of Cancer-Related Infections Clinical Practice Guidelines in Oncology (version 1.2025 – June 20, 2025). © 2025 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. Accessed on November 10, 2025.
32. Glisson CC. UpToDate® 2025. Neuromyelitis optica spectrum disorder (NMOSD): Clinical features and diagnosis. Available at: www.uptodate.com. Accessed on November 10, 2025.
33. Aggarwal R, Charles-Schoeman C, Schessl J, et al. Prospective, double-blind, randomized, placebo-controlled, phase III study evaluating efficacy and safety of Octagam 10% in patients with dermatomyositis (ProDERM Study). *Medicine* (Baltimore). 2021;100(1):e23677.
34. Marfo K, Lu A, Ling M, Akalin E. Desensitization protocols and their outcome. *Clin J Am Soc Nephrol*. 2011;6:922-936.
35. Zachary AA, Leffell MS. Desensitization for solid organ and hematopoietic stem cell transplantation. *Immunol Rev*. 2014;258:183-207.
36. Colvin MM, Cook JL, Chang P, et al; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; American Heart Association Heart Failure and Transplantation Committee of the Council on Cardiopulmonary Critical Care, Perioperative and Resuscitation, et al. Antibody-mediated rejection in cardiac transplantation emerging knowledge in diagnosis and management: a scientific statement from the American Heart Association. *Circulation*. 2015;131:1608-1639.
37. Hughes RA, Wijidicks, EF, Barohn R, et al. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2003;61:736-740. Guideline Reaffirmed February 8, 2025.
38. Van Doorn PA, Van den Bergh PYK, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of Guillain-Barre syndrome. *Eur J Neurol*. 2023;30(12):3646-3674.
39. Tomblyn M, Chiller T, Einsele H, et al; Center for International Blood and Marrow Research; National Marrow Donor program; European Blood and Marrow Transplant Group; American Society of Blood and Marrow Transplantation; Canadian Blood and Marrow Transplant Group; Infectious Diseases Society of America; Society for Healthcare Epidemiology of America; Association of Medical Microbiology and Infectious Disease Canada; Centers for Disease Control and Prevention. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: A global perspective. *Biol Blood Marrow Transplant*. 2009;1:1143-1238.
40. Panel on Opportunistic Infections in Children with and Exposed to HIV. Guidelines for the prevention and treatment of opportunistic infections in children with and exposed to HIV. Department of Health and Human Services. Last review June 5, 2025. Available at: [Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children](#). Accessed on November 10, 2025.
41. American Academy of Pediatrics. Human Immunodeficiency Virus Infection. In: Kimberlin DW, Banerjee R, Barnett ED, eds. *Red Book®: 2024 Report of the Committee on Infectious Diseases*, 33rd Ed. American Academy of Pediatrics; 2024:489-503.
42. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2026 – November 3, 2025). © 2025 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. Accessed on November 10, 2025.
43. National Multiple Sclerosis Society. Relapse management. Available at: <http://www.nationalmssociety.org/For-Professionals/Clinical-Care/Managing-MS/Relapse-Management>. Accessed on November 10, 2025.
44. Hachem RR, Yusen RD, Meyers BF, et al. Anti-human leukocyte antigen antibodies and preemptive antibody-directed therapy after lung transplantation. *J Heart Lung Transplant*. 2010;29:973.
45. Lejeune A, Martin L, Santibanez S, et al. Postexposure prophylaxis with intravenous immunoglobulin G prevents infants from getting measles. *Acta Paediatr*. 2017;1066(1):174-177.
46. American Academy of Pediatrics. Varicella-Zoster Infections. In: Kimberlin DW, Banerjee R, Barnett ED, eds. *Red Book®: 2024 Report of the Committee on Infectious Diseases*, 33rd Ed. American Academy of Pediatrics; 2024:938-951.
47. VariZIG® for intramuscular injection [prescribing information]. Hoboken, NJ: Kamada; September 2022.
48. Centers for Disease Control and Prevention. Tetanus. Available at: [Clinical Care of Tetanus | Tetanus | CDC](#). Accessed on November 10, 2025.
49. Broliden K, Tolfyenstam T, Norbeck O. Clinical aspects of parvovirus B19 infection. *J Intern Med*. 2006;260:285-304.
50. Symington A, Paes B. Fetal and neonatal alloimmune thrombocytopenia: harvesting the evidence to develop a clinical approach to management. *Am J Perinatal*. 2011;28:137-144.
51. Townsley DM. Hematologic complications of pregnancy. *Semin Hematol*. 2013;50:222-231.
52. Kumpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. *J Neurol*. 2024;271:141-176.

53. Yimmugo® 10% intravenous solution [prescribing information]. Fort Lee, NJ. Kedrion(Biotest); July 2024.
54. From the Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2025. Available at: <https://ginasthma.org/>. Accessed on November 11, 2025.
55. Eichenfield LF, Ahluwalia J, Waldman A, et al. Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology Guidelines. *J Allergy Clin Immunol*. 2017;139(4S):S49-S57.
56. Allenbach Y, Mammen AL, Benveniste O, et al. 224th ENMC International Workshop: Clinico-sero-pathological classification of immune-mediated necrotizing myopathies. Zandvoort, The Netherlands, 14-16 October 2016. *Neuromuscul Disord*. 2018;28(1):87-99.
57. Goebel A, Baranowski A, Maurer K, et al. Intravenous immunoglobulin treatment of the complex regional pain syndrome: A randomized trial. *Ann Intern Med*. 2010;152:152-158.
58. Goebel A, Bisla J, Carganillo R, et al. Low-dose intravenous immunoglobulin treatment for long-standing complex regional pain syndrome: A randomized trial. *Ann Intern Med*. 2017;167(7):476-483.
59. Chrissafidou A, Malek M, Musch E. Experimental study on the use of intravenous immunoglobulin in patients with steroid-resistant Crohn's disease. *Gastroenterol*. 2007;45:605-608.
60. Balfour-Lynn IM, Mohan U, Bush A, Rosenthal M. Intravenous immunoglobulin for cystic fibrosis lung disease: a case series of 16 children. *Arch Dis Child*. 2004;89:315-319.
61. Relkin NR, Thomas RG, Rissman RA, et al. A phase 3 trial of IV immunoglobulin for Alzheimer disease. *Neurology*. 2017;88(18):1768-1775.
62. Christopher-Stine L. UpToDate® 2025. Clinical manifestations and diagnosis of immune-mediated necrotizing myopathy and Treatment of immune-mediated necrotizing myopathy. Available at: www.uptodate.com. Accessed on November 11, 2025.
63. Tavee J, Brannagan TH, Lenihan MW, et al. Updated consensus statement: Intravenous immunoglobulin in the treatment of neuromuscular disorders report of the AANEM ad hoc committee. *Muscle Nerve*. 2023;68(4):356-374.
64. Caro XJ, Winter EF, Dumas AJ. A subset of fibromyalgia patients have findings suggestive of chronic inflammatory demyelinating polyneuropathy and appear to respond to IVIG. *Rheumatology (Oxford)*. 2008;47:208-211.
65. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016;87(4):419-425.
66. Eid AJ, Ardura MI, AST Infectious Disease Community of Practice. Human parvovirus B19 in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019 Sep;33(9):e13535.
67. Van den Bergh PY, van Doorn PA, Hadden RD, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force – Second revision. *J Peripher Nerv Syst*. 2021 Sep;26(3):242-268.
68. Practice Committee of the American Society for Reproductive Medicine. The role of immunotherapy in in vitro fertilization: a guideline. *Fertil Steril*. 2018;110:387-400.
69. Banwell B, Bennett JL, Marignier R, et al. Diagnosis of myelin oligodendrocyte glycoprotein antibody-associated disease: International MOGAD Panel proposed criteria. *Lancet Neurol*. 2023;22:268-282.
70. Sechi E, Cacciaguerra L, Chen JJ, et al. Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD): A review of clinical and MRI features, diagnosis, and management. *Front Neurol*. 2022;13:885218.
71. Mcheik S, Peramo B, Quenby S, et al. ESHRE guideline: recurrent pregnancy loss: an update in 2022. *Hum Reprod Open*. 2023(1):hoad002. doi: 10.1093/hropen/hoad002.
72. The Practice Committee of the American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. *Fertil Steril*. 2012;95:1103-1111.
73. The NCCN guidelines on the management of CAR-T cell and lymphocyte engager-related toxicities (version 2.2026 – November 11, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 14, 2025.
74. Schneider BJ, Naidoo J, Santomasso BD, et al. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy: American Society of Clinical Oncology guideline update. *J Clin Oncol*. 2021;39(36):4073--4126.
75. Garces JC, Biusti S, Giusti S, et al. Antibody-mediated rejection: A review. *Ochsner J*. 2017;17(1):46-55.
76. Wan SS, Yin TD, Wyburn K, et al. The treatment of antibody-mediated rejection in kidney transplantation: An updated systematic review and meta-analysis. *Transplantation*. 2018;102(4):557-568.
77. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant*. 2009;9(Suppl 3):S1.
78. Witt CA, Gaut JP, Yusen RD, et al. Acute antibody-mediated rejection after lung transplantation. *J Heart Lung Transplant*. 2013;32:1034.
79. Ma Y, Man J, Niu J, et al. Progress of research on human parovirus B19 infection after renal transplantation. *Transplant Rev*. 2022;36(4):100730.
80. Alyglo™ 10% intravenous solution [prescribing information]. Teaneck, NJ: GC Biopharma; December 2023.
81. Hayden PJ, Roddie C, Prader P, et al. Management of adults and children receiving CAR T-cell therapy. 2021 best practice recommendations of the European Society for Blood and Marrow Transplantation and the Joint

Accreditation Committee of ISCT and EBMT and the European Haematology Association. *Ann Oncol.* 2022;33:259-75.

82. The NCCN guidelines on Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2025 – September 24, 2025). © 2025 National Comprehensive Cancer Network. Available at : <http://www.nccn.org>. Accessed on November 10, 2025.
83. Elovaar I, Apostolski S, Van Doorn P, et al. EFNS task force on the use of intravenous immunoglobulin in treatment of neurological diseases. *Eur J Neurol.* 2008;15:893-908.
84. Gammagard Liquid ERC 10% intravenous or subcutaneous solution [prescribing information]. Cambridge, MA: Takeda; June 2025.
85. Qivigy 10% intravenous solution [prescribing information]. Fort Lee, NJ: Kedrion; September 2025.
86. NCCN Drugs and Biologics Compendium. ® 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 14, 2025. Search term: Immune globulin.