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|---|---|
| **Policy:** | **Immune Globulin - Intravenous Utilization Management Medical Policy**<br>• Alyglo™ (immune globulin intravenous solution-stwk – GC Biopharma)<br>• Asceniv™ (immune globulin intravenous solution-sira – ADMA Biologics)<br>• Bivigam® (immune globulin intravenous solution – AMDA Biologics)<br>• Flebogamma® DIF (immune globulin intravenous solution – Grifols)<br>• Gammagard Liquid (immune globulin solution – Takeda)<br>• Gammagard Liquid ERC® (immune globulin solution – Baxalta [Takeda])<br>• Gammagard S/D < 1 mcg/mL in 5% solution (immune globulin intravenous solution – Takeda)<br>• Gammaked™ (immune globulin solution caprylate/chromatography purified – Kedrion)<br>• Gammaplex® (immune globulin intravenous solution – BPL)<br>• Gamunex®-C (immune globulin solution caprylate/chromatography purified – Grifols)<br>• Octagam® (immune globulin intravenous solution – Octapharma)<br>• Panzyga® (immune globulin intravenous solution-ifas – Octapharma/Pfizer)<br>• Privigen® (immune globulin intravenous solution – CSL Behring)<br>• Qivigy® (immune globulin intravenous solution-kthm – Kedrion)<br>• Yimmugo® (immune globulin intravenous solution-dira – Biotest (Grifols) |
| **DATE:** | 09/16/2026 |
| **Applicable Lines of Business:** | Medicare Advantage - Medical |
| **Applicable States:** | CGS J15 – Ohio, Kentucky |
| **Applicable NCDs, LCDs, and/or LCAs** | NCD 250.3, L35891, A56779, L38268, A57160 |

## SUMMARY OF EVIDENCE

Immune globulin intravenous (IVIG) products are concentrated human immunoglobulins, primarily immunoglobulin G (IgG).

All of these products (except Octagam 10%) are FDA-approved for replacement therapy in patients with **primary immune deficiencies** due to defects in humoral immunity. The following indications are FDA approved:

- **B-cell chronic lymphocytic leukemia (CLL)**, for prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent infections.[6,18,21]
- **Chronic inflammatory demyelinating polyneuropathy (CIDP)**, to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.[5,7,9,12,15,67]
- **Dermatomyositis (or polymyositis)**. Octagam 10% is indicated for the treatment of dermatomyositis in adults.[11] Patients with dermatomyositis treated with Octagam were under treatment with corticosteroids and/or maximally two immune-suppressants OR patients had previous failure or intolerance with a corticosteroid and at least one additional immunosuppressive drug.[33]
- **Idiopathic (immune) thrombocytopenic purpura (ITP)**, acute and chronic, when a rapid rise in platelet count is needed to prevent and/or control bleeding or to allow a patient with ITP to undergo surgery.[2,6-9,11,12,15,23-25]


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- **Kawasaki disease** in pediatric patients for the prevention of coronary artery aneurysm.[6,26] The American Heart Association and the American Academy of Pediatrics recommend initial therapy with 2 g of IVIG per kg as a single intravenous (IV) dose given over 10 to 12 hours.[26] The dose can be repeated if needed.
- **Multifocal motor neuropathy** in adults as maintenance therapy to improve muscle strength and disability.[5]
- **Primary humoral immune deficiency (PID)**, for replacement therapy, including but not limited to the humoral immune defect in the following conditions: common variable immunodeficiency, X-linked agammaglobulinemia [congenital agammaglobulinemia], Wiskott-Aldrich Syndrome, and severe combined immunodeficiencies.[1-3,5-10,12,15,16,25,53,80,84,85] Gammagard Liquid 10%, Gammaked, Gamunex-C, and Gammagard Liquid ERC may be administered via IV or subcutaneous infusion for primary immunodeficiency.[5,7,9,84] IVIG is also indicated for measles prophylaxis in individuals with PID who have been exposed to measles or who are at high risk of measles exposure.[3,7-10,12,13,17,25,45,80,84,85] Inborn errors of immunity includes all congenital disorders that primarily affect immune function, including primary immunodeficiencies.[99]

IVIG is prepared from pooled plasma collected from a large number of human donors.[1-3,5-12,15,16,25] The donors in a typical pool of plasma have a wide range of antibodies against infectious agents. These products have IgG subclasses similar to that found in normal humans. Asceniv contains not only antibodies which satisfy the requirement to treat patients with PID, it also has elevated levels of respiratory syncytial virus (RSV) antibodies.[19]

IVIG also is used for many off-label indications. Much of the evidence for clinical effectiveness of IVIG is anecdotal (i.e., case reports, open series, or cohort studies). Some conditions have been studied in controlled trials. Usually, IVIG is indicated only if standard approaches have failed, become intolerable, or are contraindicated.

- **Antibody-mediated rejection (ABMR) in transplantation:** Current strategies for treatment of antibody-mediated rejection include plasmapheresis, IVIG, and T-cell or B-cell-depleting agents.[75] Although there are no controlled trials regarding the most appropriate treatments, the benefits of immune globulin have been well described and has been used as the standard-of-care (along with plasmapheresis) in multiple studies.[18,76] Clinical practice guidelines (2009 Kidney Disease: Improving Global Outcomes) recommends a combination of corticosteroids, plasmapheresis, IVIG, anti-CD20 antibody, and lymphocyte-depleting antibody for antibody-mediated rejection.[76,77] As in desensitization therapy, much of the information for IVIG use is in patients with kidney transplants, but the same principles apply to transplantation of other organs and tissues. Immune globulin has been used in lung transplant patients to treat ABMR[20,44,78] and a scientific statement from the American Heart Association states that primary therapy for ABMR in patients with heart transplants may include IVIG, plasmapheresis, high-dose corticosteroids, and anti-lymphocyte antibodies.[36]
- **Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid [cicatricial pemphigoid], and epidermolysis bullosa acquisita):** Conventional therapy (a systemic corticosteroid and an immunosuppressive agent) is started at the same time or before IVIG. Many case reports and uncontrolled case series suggest benefit of IVIG in patients with recalcitrant disease or in those with contraindications to conventional therapy.[28-30] International expert recommendations for the management of pemphigus note that first-line treatment includes corticosteroids and anti-CD20 monoclonal antibodies. First-line corticosteroid-sparing agents include azathioprine and mycophenolate mofetil, and other corticosteroid-sparing agents including IVIG.[2]


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- **Aquaporin-4 Immunoglobulin Antibodies (AQP4-IgG)-positive Neuromyelitis Optica Spectrum Disorder (NMOSD):** NMOSD is an inflammatory disorder of the central nervous system characterized by severe, immune-mediated demyelination and axonal damage.[32] The range of NMOSD has expanded to include patients with aquaporin-4 (AQP4) antibody positivity who have single or recurrent attacks of optic neuritis, myelitis, or brainstem syndromes. Antibodies against AQP4 are present in the majority of NMOSD patients.[52] The loss of AQP4 expression leads to loss of nervous system cells and neuron damage. Products recommended for long-term management of the condition include rituximab, azathioprine, mycophenolate, and therapeutic antibodies, such as Soliris® (eculizumab intravenous infusion), Ultomiris® (ravulizumab-cwvz intravenous infusion), Uplizna® (inebilizumab-cdon intravenous infusion), and Enspryng® (satralizumab-mwge subcutaneous injection). IVIG is recommended in children or in case of contraindications to other long-term therapies.[52]
- **Coronavirus Disease-2019 (COVID-19)-Associated Multisystem Inflammatory Syndrome in Children (MIS-C):** MIS-C is a rare, but serious complication that may begin weeks after being infected with the virus that causes COVID-19. Patients diagnosed with MIS-C should be hospitalized. Treatment generally involves IVIG and steroids, both of which treat the overactive immune response.[94] American College of Rheumatology guidelines in MIS-C (2022) state that in select patients with mild disease or contraindications to glucocorticoids, IVIG alone may be appropriate as first-line treatment for MIS-C.[95]
- **Cytomegalovirus (CMV) pneumonitis or pneumonia in patients with cancer or transplant-related infection:** For CMV pneumonia, therapy generally consists of antivirals (e.g., ganciclovir, foscarnet). The National Comprehensive Cancer Network (NCCN) guidelines on prevention and treatment of cancer-related infections (version 1.2025 – June 20, 2025) lists IVIG as an adjunctive therapy for CMV pneumonitis.[31]
- **Desensitization therapy prior to and immediately after transplantation:** Most of the information on use of IVIG for desensitization is in patients with kidney transplantation but many of the same principles apply to transplantation of other organs and tissues.[34,35] Current protocols include using low-dose IVIG with plasma exchange or high-dose IVIG with or without B-cell depletions with rituximab.[18]
- **Evan's syndrome:** Is a rare autoimmune conditions generally characterized by simultaneous or sequential occurrence of ITP and autoimmune hemolytic anemia.[87] IVIG is not generally administered as chronic or maintenance therapy, it serves as a short-term adjunctive intervention to achieve rapid disease control. Treatment is extrapolated from dosing used for ITP.
- **Guillain Barré syndrome (GBS):** The American Academy of Neurology recommends IVIG in patients who require aid to walk within 2 or 4 weeks from the onset of neuropathic symptoms.[37] The European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of GBS (2023) recommends IVIG or plasma exchange in patients for up to 4 weeks after onset of weakness.[38] For patients who are > 4 weeks of onset and are still deteriorating, other diagnoses should be considered. The guidelines additionally note that observational data indicates that a repeated course of IVIG can be effective in case of treatment-related fluctuation.
- **Hematologic neoplasm-associated hypogammaglobulinemia or hypogammaglobulinemia after B-cell targeted therapies (secondary immunodeficiency):** Clinical guidelines for immunoglobulin use by the National Health Service-England note secondary antibody deficiency can be hypogammaglobinemia associated with therapeutic monoclonals targeted at B-cells and plasma cells, non-Hodgkin's lymphoma, CLL, multiple myeloma, or other relevant B-cell malignancies.[27] NCCN guidelines regarding management of chimeric antigen receptor (CAR)-T cell-related toxicities (version 2.2026 – November 11, 2025) recommends that after anti-CD19 CAR-T cell therapy, IVIG replacement should be considered for patients with serum IgG levels < 400 to 600 mg/dL and serious or recurrent infections.[73] NCCN drug compendia also notes IVIG


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should be administered during therapy with inotuzumab ozogamicin, blinatumomab, or tisagenlecluecel until B-cell recovery.[86] European guidelines note that IgG replacement in the first 3 months after CAR-T therapy is considered routine for children due to immunological maturity.[81]

- **Hematopoietic cell transplantation (HCT) to prevent infections:** HCT is defined as transplantation of any blood- or marrow-derived hematopoietic stem cells, regardless of transplant type (i.e., allogeneic or autologous) or cell source (i.e., bone marrow, peripheral blood, or umbilical cord blood). With regard to IVIG, guidelines recommend IVIG for prevention or preemptive treatment of specific infections in HCT recipients.[39] In adult or adolescent HCT recipients (allogeneic or autologous), IVIG is used to prevent infections in those with severe hypogammaglobulinemia (i.e., serum IgG < 400 mg/dL) during the first 100 days after HCT. In pediatric patients, IVIG is indicated in those with an allogeneic HCT if hypogammaglobulinemia is severe during the first 100 days after HCT. For prevention of infections beyond 100 days post-HCT (allogeneic or autologous), IVIG is recommended in recipients with severe hypogammaglobulinemia (i.e., serum IgG < 400 mg/dL). Guidelines from the American Society for Blood and Marrow Transplantation make recommendations for IVIG dosing in HCT recipients to prevent infectious complications.[39] During the first 100 days after HCT, the dose in adults and adolescents is 0.5 g/kg per week. The IVIG dose should be individualized to maintain trough (pre-dose) serum IgG > 400 to 500 mg/dL. The dose in allogeneic pediatric HCT patients is 0.4 g/kg per month, adjusted to keep IgG > 400 mg/dL. Higher and more frequent dosing may be necessary in patients for prevention of early disease after HCT because the half-life of IVIG is reduced to between 1 to 10 days in this population. Dosing for > 100 days post-HCT is 0.5 g/kg given every 3 to 4 weeks. The dose is not adjusted using serum IgG level in patients with multiple myeloma or malignant macroglobulinemia. NCCN guidelines on HCT (version 3.2025 – September 24, 2025) states there may be subsets of patients where prophylactic immune globulin replacement may be considered, such as recipients of an umbilical cord blood transplant, in patients undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency, and in patients with chronic graft versus host disease with recurrent sinopulmonary infections.[82]
- **Human immunodeficiency virus (HIV)- or Hepatitis C-associated thrombocytopenia:** Secondary ITP can occur in patients with HIV infection.[23,24] It can also occur in patients with Hepatitis C. The American Society of Hematology (ASH) guidelines for ITP recommend initial treatment with corticosteroids, IVIG, or Rh0(D) immune globulin for patients with secondary ITP due to HIV. ASH also recommends IVIG for secondary ITP associated with Hepatitis C.[23,24]
- **HIV-infected infants and children to prevent recurrent infections:** IVIG is recommended to prevent serious bacterial infections in HIV-infected children who have hypogammaglobulinemia (IgG < 400 mg/dL).[40] Clinicians providing care for adolescents are advised to use the US Department of Health and Human Services Adult and Adolescent HIV-guideline for the care of post-pubertal adolescents (sexual maturity rating [SMR] four and five) and to use the pediatric guideline for guidance on the care of adolescents at SMR 3 or lower.[40]
- **Immune-Mediated Necrotizing Myopathy:** Muscle weakness is the predominant clinical feature and sometimes severely affects the lower limbs.[56] Pharyngeal muscles may also be affected and dysphagia is common. Serum creatine kinase (CK) is also high. The CK value can widely vary but is often well above 1,000 IU/L.[62] Myositis-specific antibodies are often detected (e.g., anti-HMGCR antibodies, anti-SRP antibodies). Muscle imaging and biopsy can also be useful to confirm the diagnosis. International consensus guidelines recommend IVIG as a second-line agent for anti-HMGCR to avoid long-term disability.[63] For patients with anti-HMGCR monotherapy with IVIG has also been used.[62]
- **Immunotherapy-related toxicities associated with checkpoint inhibitor therapy:** NCCN guidelines for the management of immunotherapy-related toxicities (version 2.2024 – October 25, 2024) recommends IVIG for the management of suspected myocarditis/pericarditis/large vessel


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vasculitis, severe pneumonitis after 48 hours of methylprednisolone therapy, severe myasthenia gravis, encephalitis, moderate or severe GBS, demyelinating disease, myositis, bullous dermatitis, and Stevens-Johnson syndrome/toxic epidermal necrolysis.[73] The American Society of Clinical Oncology also has practice guidelines on the management of immune-related adverse events in patients treated with checkpoint inhibitor therapy.[74] These practice guidelines note that corticosteroids may be administered for toxicities and refractory or severe cases may require other immunosuppressive therapies or IVIG.

- **Lambert-Eaton Myasthenic Syndrome:** Limited, but moderate- to high-quality evidence from randomized controlled trials have shown that 3,4-diaminopyridine or IVIG was associated with improved muscle strength score and compounded muscle action potential amplitudes. IVIG may be used as an alternative in patients who do not respond or do not tolerate other therapies.[18]
- **Multiple myeloma:** Patients with multiple myeloma are often functionally hypogammaglobulinemic with total immunoglobulin production being elevated, but the repertoire of antibody production restricted.[31] The NCCN guidelines on multiple myeloma (version 3.2026 – November 3, 2025) recommends immune globulin replacement with CAR-T cell and bispecific antibody therapies, based on clinical context.[42] NCCN also notes replacement can be considered for IgG < 400 mg/dL and recurrent life-threatening infections, making sure to consider the portion of IgG that is clonal. NCCN guidelines on CAR-T cell therapy toxicities notes that immune globulin replacement during CAR-T cell therapy in patients with multiple myeloma is not guided by the presence of infections.[73]
- **Multiple sclerosis, acute severe exacerbation or relapses:** Medication options for relapse management include high dose corticosteroids, intramuscular adrenocorticotrophic hormone, plasmapheresis, and IVIG. IVIG is sometimes used to treat relapses that do not respond to corticosteroids.[43] During pregnancy, relapses severe enough to require treatment can be safely managed with a short-term course of corticosteroids after the first trimester. Methylprednisolone is the preferred agent because it is metabolized before crossing the placenta.[43]
- **Myasthenia gravis:** Recommendations from an international consensus guidance statement for management of adult or juvenile myasthenia gravis include the use of IVIG in some patients.[65] An update to these guidelines provides new recommendations for methotrexate, rituximab, and eculizumab intravenous infusion (Soliris®, biosimilars).[98] The international consensus guidance statement for myasthenia gravis[65] recommends an initial dose of 2 g/kg given in divided doses over 2 to 5 days. For maintenance therapy, the recommended dose is 0.4 to 1 g/kg given every 4 weeks; an attempt to decrease frequency can be made over time. If additional treatment is required, the dose should be adjusted based on the response.
- **Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD):** International MOGAD Panel proposed criteria reports the central nervous system demyelinating features of this condition include optic neuritis (most common feature), acute disseminated encephalomyelitis (with or without optic neuritis), transverse myelitis, and other less common presentations.[69] Serological evidence of myelin oligodendrocyte glycoprotein (MOG)-IgG is also seen. MOGAD can present as an acute attack and relapses of attacks; a diagnosis of multiple sclerosis should be excluded. Disease flares in MOGAD are generally treated with high dose corticosteroids.[70] A typical dose used for IVIG is 0.4 g/kg/day for 5 days. Maintenance therapy is generally offered in patients who have had two or more attacked; however, exceptions are noted in cases to prevent further disability.[70] For maintenance infusions, a loading dose of 0.4 g/kg/day for 5 days can be given, followed by treatment every 4 weeks with a dose of 0.4 g/kg to 2 g/kg.
- **Neonatal Isoimmune Hemolytic Disease (Hemolytic Disease of the Fetus and Newborn), Acute Treatment:** Neonatal isoimmune hemolytic disease occurs when maternal IgG antibodies cross the placenta and destroy fetal red blood cells, leading to fetal/neonatal anemia and hyperbilirubinemia.[88] IVIG (0.5 to 1 g/kg) may be provided when total serum bilirubin (TSB)


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reaches or exceeds escalation of care threshold. The use of IVIG during escalation of care may reduce hemolysis and stabilize or reduce TSB concentrations, preventing the need for exchange transfusion. IVIG may be considered in patients who have not initially responded to phototherapy when the TSB is rising or it is within 2 to 3 mg/dL of the exchange level.[89]

- **Opsoclonus-Myoclonus-Ataxia Syndrome (OMAS):** OMAS is a rare immune-mediated neurological disorder; it occurs in three main contexts: paraneoplastic (most commonly neuroblastoma in children), post-infectious, and idiopathic. Various regimens have been used including dexamethasone, adrenocorticotropic hormone, and IVIG.[96] IVIG may be given as a dose of 2 g/kg over 2 to 5 days followed by 1 to 2 g/kg every 4 weeks.
- **Passive immunization for measles (post-exposure prophylaxis):** When administered within 6 days of exposure, immune globulin (IG) can prevent or modify measles in patients who are nonimmune.[13] IG therapy is not indicated in persons who have received one dose of measles-containing vaccine at ≥ 12 months, unless the patient is severely immunocompromised. The Advisory Committee on Immunization Practices (ACIP) recommends the use of IG therapy for post-exposure prophylaxis of measles in the following patients who are at risk for severe disease and complication from measles: infants < 12 months of age, pregnant women without evidence of measles immunity, and severely immunocompromised persons.[13] For infants < 12 months of age, intramuscular IG is used; infants 6 through 11 months of age can receive measles, mumps, and rubella vaccine instead of IG if given within 72 hours of exposure. IVIG is used for pregnant women and severely immunocompromised patients. ACIP recommends 400 mg/kg as an IV infusion.[13] The American College of Obstetricians and Gynecologists Practice Advisory on pregnant patients during a measles outbreak (2024, last updated May 2025) recommends pregnant patients with suspected measles exposure, but without immunity (or those who cannot readily show evidence of immunity), should receive IVIG 400 mg/kg within 6 days of exposure.[4] It additionally states that infants born to pregnant patients with suspected or confirmed measles should be given postexposure prophylaxis with IVIG, as the mother with measles can be infectious for up to days after the rash appears.
- **Parvovirus B19 infection and pure red blood cell aplasia, immunologic subtype:** In immunosuppressed patients lacking neutralizing antibodies, IVIG has been useful for the treatment of persistent B19 infection.[49] The guidelines from the American Society of Transplantation Infectious Diseases Community of Practice state that IVIG is frequently used for the treatment of solid organ transplant recipients with symptomatic parvovirus B19 infection.[66] A Canadian expert panel of hematologists recommend prednisone followed by cyclophosphamide or cyclosporine as first-line therapy for immunologic type pure red blood cell aplasia.[22] The panel considers IVIG a reasonable second-line option for this serious condition. Recent reviews note that 200 to 400 mg/kg/day for 5 to 10 days is considered the recommended treatment course.[79]
- **Post-exposure prophylaxis for varicella OR treatment or post-exposure prophylaxis for tetanus:** Children infected with HIV who lack evidence of immunity to varicella or who have severe immune suppression should receive VariZIG® (human varicella-zoster immune globulin for intramuscular administration)®.[40,41] An alternative to varicella-zoster immune globulin for passive immunization is oral valacyclovir or acyclovir beginning 7 days after exposure, and if this is not available, IVIG administered once within 10 days after exposure.[41] VariZIG is indicated for post-exposure prophylaxis in high risk individuals.[47] The dose is 400 mg/kg given once.[40,41,46] Per the Centers for Disease Control and Prevention, if tetanus immune globulin is not available, clinicians can use immune globulin at a dose of 200 to 400 mg/kg.[48]
- **Post-Transfusion Purpura, Acute Treatment:** Post-transfusion purpura is a rare but serious transfusion-associated complication. It is characterized by thrombocytopenia developing within 2 weeks of tranfusion.[91] IVIG is considered the treatment of choice for this condition. Recommended doses are 400 to 500 mg/kg/day for 1 to 10 days or 1-2 g/kg/day for 2 to 5 days.


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- **Rasmussen Encephalitis:** Rasmussen encephalitis is a rare, progressive autoimmune disorder characterized by unilateral hemispheric inflammation that can lead to epilepsy, progressive hemiparesis, and cognitive decline. IVIG is commonly used as first-line therapy, although no universally standardized treatment exists.[97]
- **Red Blood Cell Alloantibodies During Pregnancy:** The clinical practice guidelines for the management of pregnancy alloimmunized to red blood cell antigens (2025) recommends the use of IVIG in patients with a documented antigen-positive fetus and a history of either fetal anemia or a fetal loss due to HDFN before 24 weeks' gestation age in a previous pregnancy.[90]
- **Stiff-Person Syndrome (Moersch-Woltman Syndrome):** Per the European Federation of Neurological Societies, IVIG should be reserved for patients who have no symptomatic relief after the use of diazepam and/or baclofen and have severe disability in carrying out daily activities.[83]
- **Thrombocytopenia, feto-neonatal alloimmune:** Antenatal therapy with IVIG administered to the mother is effective in increasing fetal platelet counts in neonatal alloimmune thrombocytopenia.[50,51] First-line therapy for newborns with fetal/neonatal alloimmune thrombocytopenia is antigen-negative compatible platelets; IVIG is adjunctive therapy.
- **Toxic Shock Syndrome, Acute Treatment:** Per the Red Book® (2026), IVIG can be strongly considered for toxic shock syndrome if the patient is moderately to severely ill, although its use is supported by limited data.[93]
- **Warm Type Autoimmune Hemolytic Anemia:** First-line therapy for warm autoimmune hemolytic anemia is prednisone or rituximab.[92] Patients with severe hemolysis may not maintain satisfactory hemoglobulin. IVIG and plasma exchange can be a bridging therapy and alternatives such as immunosuppression can also be considered.

## ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of IVIG products Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. If the prescriber is switching between IVIG products and a case has already been approved by a clinician, a new approval may be entered without another clinical review. The new approval should only be extended for the remaining doses and duration which were granted on the original review. The indication (or diagnosis code) and dosing need to be the same as the original review. If the indication or dosing is different, a new clinical review would need to be completed. If the client is using the *Immune Globulin – Intravenous Medical Step Management Policy* in tandem with this Utilization Management policy, the new approval may be entered without another clinical review for a preferred product only.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and


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coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

*Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.*

*Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.*

*Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.*

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of IVIG products is recommended in those who meet one of the following criteria.

### FDA-Approved Indications

**1. Primary Immunodeficiencies. ^**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 1 year if the patient meets ONE of the following (i, ii, iii or iv):
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. IC-ISGP


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**i.** The patient has a diagnosis of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia due to the absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, severe combined immunodeficiency (SCID), Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a primary immune deficiency which has been confirmed by genetic or molecular testing; [IC-ISGP] OR
Note: Molecular testing is a type of genetic testing.

**ii.** The patient has a diagnosis of common variable immunodeficiency (CVID) and meets ONE of the following (1 or 2):
- **1)** The patient meets BOTH of the following (a and b):
  - **a.** The patient's pretreatment IgG level is below the normal range (age-adjusted and according to the normal reference range for the reporting laboratory); AND
  - **b.** The patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); OR
- **2)** The patient meets ALL of the following (a, b, and c):
  - **a.** The patient's pretreatment IgG level is within the normal range (age-adjusted and according to the normal reference range for the reporting laboratory); AND
  - **b.** The patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); AND
  - **c.** The patient has recurrent infections; OR

**iii.** The patient has a diagnosis of other immunodeficiencies with significant hypogammaglobulinemia and meets ALL of the following (1, 2 and 3): [IC-EC]
- **(1)** The patient's pretreatment IgG level is below the normal range (age-adjusted and according to the normal reference range for the reporting laboratory); [IC-EC] AND
- **(2)** The patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); [IC-EC] AND
- **(3)** The patient has recurrent infections; [IC-EC] OR

**iv.** The patient has an IgG subclass deficiency, selective antibody deficiency (SAD), or another confirmed primary immunodeficiency and meets the following criteria (1 and 2): [IC-EC]
- **(1)** The patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); [IC-EC] AND
- **(2)** The patient has recurrent infections; [IC-EC] OR

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has been diagnosed with a primary immunodeficiency and, according to the prescriber, is continuing to receive benefit from the product. [IC-ISGP]
Note: Examples of continued benefit with the product includes increased IgG levels or prevention and/or controlling of infections.

**Dosing.** Approve the following dosing regimens (A, B, C, or D):
**A)** An initial loading dose of 1 g/kg given intravenously one time; OR
**B)** 0.2 g/kg to 0.8 g/kg given intravenously once every 3 to 4 weeks; OR
**C)** The dose and interval between doses has been adjusted based on clinical response as determined by the prescriber; OR
**D)** Patients with primary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.


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**2. B-Cell Chronic Lymphocytic Leukemia (CLL) for Prevention of Infections.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 4 months if the patient meets the following (i or ii):
- **i.** The patient has an immunoglobulin G (IgG) level < 600 mg/dL (6.0 g/L); OR
- **ii.** The patient has a history of recurrent infections; OR

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient having a positive response to therapy according to the prescriber. [IC-ISGP]
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level or a decrease in the number of infections.

**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** 0.2 g/kg to 0.8 g/kg given intravenously every 3 to 4 weeks; OR
**B)** The dose and interval have been adjusted to maintain a trough (pre-dose) IgG level of greater than 500 mg/dL.

**3. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 3 months if electrodiagnostic studies support the diagnosis of CIDP.
**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has a clinically significant improvement in neurologic symptoms as determined by the prescriber. [IC-ISGP]
Note: Examples of improvement in neurologic symptoms include improvement in disability; nerve conduction study results improved or stabilized; physical examination show improvement in neurological symptoms, strength (e.g., grip strength), and sensation.

**Dosing.** Approve the following dosing regimens (A, B, or C):
**A)** An initial loading dose of 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days; OR
**B)** A maintenance dose of 1 g/kg given intravenously in divided doses over 1 to 4 consecutive days given every 3 weeks; OR
**C)** The dose and interval are adjusted according to clinical response with a maximum dose per treatment course of 2 g/kg.

**4. Dermatomyositis or Polymyositis.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial therapy. Approve for 6 months if the patient meets the following (i, ii and iii):
- **i.** Prior to starting any therapy, the patient meets one of the following (a or b):
  - **a.** Patient has or had an elevated creatinine kinase (CK) level, according to the prescriber; OR
  - **b.** Other measures support the diagnosis, according to the prescriber, including, but not limited to, skin manifestations, myositis autoantibody testing, muscle biopsy results, electromyographic (EMG) findings; [IC-ISGP] AND
- **ii.** The patient has tried a systemic corticosteroid OR a corticosteroid is contraindicated according to the prescriber; AND


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**iii.** The patient has tried a nonsteroidal immunosuppressive agent OR a nonsteroidal immunosuppressive agent is contraindicated according to the prescriber.
Note: Examples of nonsteroidal immunosuppressive agents include azathioprine, methotrexate, cyclosporine, cyclophosphamide, and mycophenolate mofetil.

**B)** Patients Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy according to the prescriber. [IC-ISGP]
Note: Examples of a response to therapy includes improved muscle strength, improved neuromuscular symptoms, and improved functional ability.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days every 4 weeks; OR
**B)** 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days every 2 to 3 weeks.

**5. Immune Thrombocytopenia (ITP). ^**

*Note: The diagnosis of Immune Thrombocytopenia (ITP) encompasses previous nomenclature, such as Idiopathic Thrombocytopenia, Idiopathic Thrombocytopenic Purpura, Immune Thrombocytopenic Purpura.*

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A, B, C, D or E):
**A)** Initial Therapy: Adults ≥ 18 years of age: Approve for 3 months if the patient meets ONE of the following (i, ii, or iii):
**i.** The patient has tried a systemic corticosteroid (e.g., prednisone); OR
**ii.** There is an urgent need to increase the platelet count quickly; OR
**iii.** A systemic corticosteroid is contraindicated according to the prescriber.
**B)** Initial Therapy: Children and adolescents (< 18 years of age): Approve for 3 months.
**C)** Initial Therapy: To increase platelet counts before surgical procedures or dental procedures: Approve for 1 month.
**D)** Initial Therapy: Pregnant patients: Approve for 6 months.
**E)** Patient is Currently Receiving Immune Globulin OR Requires Retreatment with Immune Globulin: Approve for 1 year if the patient is responding to therapy OR if the patient has previously responded to therapy, according to the prescriber. [IC-ISGP]
Note: Examples of responding to therapy include increased platelet counts, absence of significant bleeding, or preventing hemorrhage/ensuring an adequate platelet count in order for delivery in pregnant patients.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** Up to 1 g/kg on 2 consecutive days OR up to 0.4 g/kg on 5 consecutive days (up to a total of 2 g per kg per treatment course); OR
**B)** The dose and interval between doses has been adjusted according to the platelet count and/or to prevent significant bleeding as determined by the prescriber.

**6. Kawasaki Disease (Mucocutaneous Lymph Node Syndrome). ^**

**Criteria**. Approve for 3 months.


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**Dosing.** Approve up to 2 g/kg given intravenously as a single dose or over multiple consecutive days. The dose may be repeated if needed.

**7. Multifocal Motor Neuropathy (MMN). ^**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A)** Initial Therapy: Approve for 6 months if the diagnosis is supported by weakness without sensory abnormalities, upper motor neuron signs, or marked bulbar involvement and meets one of the following (i, ii, or iii): [IC-ISGP]
- **i.** The diagnosis is supported by nerve conduction studies that demonstrate motor conduction block or probable motor conduction block; [IC-ISGP] OR
- **ii.** The prescriber has determined the patient has multifocal motor neuropathy without conduction block; [IC-ISGP] OR
- **iii.** The diagnosis is supported by a motor nerve biopsy or by a magnetic resonance imaging (MRI) neurography. [IC-ISGP]

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has improvement in neurologic symptoms as determined by the prescriber.
Note: Examples of improvement in neurologic symptoms include improvement in disability; grip strength improvement (measured with dynamometer); physical examination show improvement in neurological symptoms and strength.

**Dosing.** Approve the following dosing regimens (A or B):

**A)** Therapy is initiated with 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days; OR

**B)** One of the following maintenance dosing regimen is used (i, ii or iii):
- **i.** 0.5 g/kg to 2.4 g/kg given intravenously every month; OR
- **ii.** 1 g/kg given intravenously every 2 to 4 weeks; OR
- **iii.** 2 g/kg given intravenously every 1 to 2 months.

**Other Uses with Supportive Evidence**

**8. Antibody-Mediated Rejection (ABMR) in Transplant. @**

**Criteria.** Approve for 1 year.

Dosing. Approve the following dosing regimens (A or B):

**A)** Up to 2 g/kg as an intravenous infusion (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 days]); OR

**B)** The dosage is based on a transplant center's protocol.

**9. Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita). ^**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):


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**A)** Initial Therapy: Approve for 6 months if the patient meets ONE of the following (i, ii, iii or iv):
- **i.** The patient has tried a systemic corticosteroid OR a corticosteroid is contraindicated according to the prescriber; [IC-ISGP] OR
- **ii.** The patient has tried a nonsteroidal immunosuppressive agent OR a nonsteroidal immunosuppressive agent is contraindicated according to the prescriber; [IC-ISGP] OR
  Note: Examples of nonsteroidal immunosuppressive agents include azathioprine, cyclophosphamide, dapsone, methotrexate, cyclosporine, mycophenolate mofetil, and tacrolimus.
- **iii.** The patient has rapid, debilitating, progressive disease, that cannot be controlled with a systemic corticosteroid and a nonsteroidal immunosuppressive agent; [IC-ISGP] OR
- **iv.** The disease is so serious that there is inadequate time for therapy with a systemic corticosteroid and a nonsteroidal immunosuppressive agent to have a rapid enough effect. [IC-ISGP]

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has responded to therapy according to the prescriber. [IC-ISGP]
Note: Examples of response to therapy can include healing of previous lesions or fewer new lesions.

**Dosing.** Approve the following dosing regimens (A, B, or C):
**A)** 2 g/kg per cycle given intravenously every 3 to 4 weeks. This dose is divided over 2, 3, or 5 consecutive days; OR
**B)** In patient with aggressive ocular disease, such as ocular cicatricial pemphigoid, 2 g/kg given intravenously may be given every 2 weeks in divided doses over 2, 3, or 5 consecutive days; OR
**C)** The frequency is gradually being slowly decreased as the lesions resolve and heal.

**10. Aquaporin-4 Immunoglobulin Antibodies (AQP4-IgG)-Positive Neuromyelitis Optica Spectrum Disorder (NMOSD). @**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient has the presence of at least one core clinical feature of NMOSD, according to the prescriber; AND
  Note: Examples of core clinical features of NMOSD include optic neuritis, acute myelitis, acute brainstem syndrome.
- **ii.** The diagnosis was confirmed by a positive blood serum test for AQP4-IgG; AND
  Note: Detection in cerebral spinal fluid would also satisfy this requirement.
- **iii.** Patient is using the requested medication for attack prevention AND meets ONE of the following (a or b):
  - **a)** Patient is < 18 years of age; OR
  - **b)** According to the prescriber, the patient has tried or has a contraindication to one other therapy for this condition; AND
    Note: Examples of other therapies for this condition include azathioprine, mycophenolate mofetil, rituximab, Enspryng (satralizumab subcutaneous injection), Soliris (eculizumab intravenous injection), Ultomiris (ravulizumab intravenous injection), Uplizna (inebilizumab intravenous injection).

**B)** Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy, according to the prescriber.


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Note: Examples of a response to therapy includes reduction in relapse rate, reduction in symptoms, slowing in the progression of symptoms.

**Dosing.** Approve up to 2 g/kg per month administered intravenously (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 days]).

**11. Coronavirus Disease-2019 (COVID-19)-Associated Multisystem Inflammatory Syndrome in Children (MIS-C).** @

**Criteria.** Approve for 1 month if the patient meets ALL of the following (A, B, C, and D):
**A)** Patient is < 21 years of age; AND
**B)** Patient meets ONE of the following (i or ii):
- **i.** Positive for current or recent COVID infection by molecular (PCR), antigen (ELISA) laboratory methods or serology results; OR
- **ii.** COVID exposure within 60 days prior to hospitalization; AND

**C)** Patient has ALL of the following symptoms and laboratory findings (i, ii, and iii):
- **i.** Fever (> 100.4°F for ≥ 24 hours, or report of subjective fever lasting ≥ 24 hours); AND
- **ii.** Laboratory evidence of inflammation including, but not limited to, at least ONE of the following: elevated C-reactive protein, erythrocyte sedimentation rate, fibrinogen, procalcitonin, D-dimer, ferritin, lactate dehydrogenase, interleukin-6, or neutrophils, or reduced lymphocytes or albumin levels; AND
- **iii.** Evidence of clinically severe illness that requires hospitalization with multisystem (i.e., > 2 organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic, or neurological); AND

**D)** Other causes have been excluded.

**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** Up to 2 g/kg administered intravenously given one time; OR
**B)** Up to 1 g/kg administered intravenously per day for 2 doses.

**12. Cytomegalovirus Pneumonitis or Pneumonia in Patients with Cancer or Transplant-Related Infection.** @

**Criteria.** Approve for 2 months.

**Dosing.** Approve 400 mg/kg given intravenously every other day for 3 to 5 doses.

**13. Desensitization Therapy Prior to and Immediately after Transplantation.** @

**Criteria.** Approve for 1 year.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** Up to 2 g/kg per month administered intravenously (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 days]); OR
**B)** The dosage is based on a transplant center's protocol.


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**14. Evan's syndrome.** @

**Criteria.** Approve for 3 months if the patient meets ONE of the following (A or B):
**A)** Adult ≥ 18 years of age: Patient meets ONE of the following (i, ii, or iii):
- **i.** Patient has tried or is currently receiving a systemic corticosteroid; OR
  Note: Examples of systemic corticosteroids include prednisone or prednisolone.
- **ii.** There is an urgent need to increase blood counts quickly (e.g., severe bleeding); OR
- **iii.** A systemic corticosteroid is contraindicated according to the prescriber; OR

**B)** Patient is < 18 Years of Age. Approve.

**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** Up to 500 mg/kg/day administered intravenously for 4 days; OR
**B)** Up to 1 g/kg/day administered intravenously for 2 days.

**15. Guillain Barre Syndrome.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 1 month (this is to provide one course of therapy) if the patient meets one of the following (i or ii):
- **i.** IVIG is initiated within 2 weeks and no longer than 4 weeks of onset of neuropathic symptoms; IC-ISGP OR
  Note: Examples of neuropathic symptoms include weakness, inability to stand or walk without assistance, and respiratory or bulbar weakness.
- **ii.** The patient has had a relapse (treatment related fluctuation), but had an initial response to IVIG. IC-ISGP

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 month (this is to provide one course of therapy).

**Dosing.** Approve 2 g/kg administered intravenously in divided doses over 2 to 5 days.

**16. Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-cell Targeted Therapies (Secondary Immunodeficiency [SID]).** ^ *Note: This includes hypogammaglobulinemia with non-neutropenic infection induced by rituximab in combination with cytotoxic chemotherapy.*

Note: Some 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), Blincyto (blinatumomab intravenous infusion).

Note: Refer to B-Cell Chronic Lymphocytic Leukemia (CLL) for Prevention of Infections and Multiple Myeloma for diagnosis-specific criteria.


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**Criteria.** Approve for 6 months if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve if the patient meets ONE of the following (i or ii):
- **i.** Patient meets BOTH of the following (a and b):
  - **a)** The patient has an immunoglobulin G (IgG) level of < 600 mg/dL (6.0 g/L) [excluding paraprotein]; [IC-ISGP] AND
  - **b)** The patient has recurrent or severe infections or there is a high risk of infection, according to the prescriber; OR [IC-ISGP]
- **ii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient is < 18 years of age; [IC-EC] AND
  - **b)** Patient will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy or other B-Cell targeted therapy; [IC-EC] OR
    Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion).
    Note: Examples of other B-Cell targeted therapy includes: Besponsa (inotuzumab ozogamicin intravenous infusion), Blincyto (blinatumomab intravenous infusion).

**B)** Patients Currently Receiving Immune Globulin: Approve if the patient is having a positive response to therapy according to the prescriber. [IC-ISGP]
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level or a decrease in the number of infections.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** 0.2 g/kg to 0.8 g/kg given intravenously once every 3 to 4 weeks; OR
**B)** The dose and interval between doses has been adjusted based on clinical response as determined by the prescriber.

## 17. Hematopoietic Cell Transplantation (HCT) to Prevent Infection. ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A, B, C or D):
**A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii):
- **i.** The patient is ≥ 20 years of age; AND
- **ii.** The requested medication is being used to prevent the risk of acute graft vs host disease (GVHD), associated interstitial pneumonia (infectious or idiopathic), and infections (e.g., cytomegalovirus infections [CMV], varicella-zoster virus infection, and recurrent bacterial infection) after allogenic hematopoetic stem cell transplantation (HSCT) in the first 100 days after transplantation; OR

**B)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient has had a HCT within the previous year; [IC-EC] AND
- **ii.** Patient has an immunoglobulin G (IgG) level < 600 mg/dL (6.0 g/L) OR the patient has multiple myeloma or malignant macroglobulinemia; [IC-EC] AND
- **iii.** According to the prescriber, the patient has a significant risk of having frequent and/or severe infections; [IC-EC] OR

**C)** Initial Therapy. Approve for 3 months if the patient meets ONE of the following (i, ii, or iii):
- **i.** Patient is a recipient of an umbilical cord blood transplant; [IC-EC] OR
- **ii.** Patient is undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency; [IC-EC] OR
- **iii.** Patient with chronic graft versus host disease with recurrent sinopulmonary infections; [IC-EC] OR


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**D)** Patient is Currently Receiving Immune Globulin. Approve for 6 months if the patient is having a positive response to therapy according to the prescriber. IC-EC
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level, controlling the number of infections, or a decrease in the number of infections.

**Dosing.** Approve ONE of the following dosing regimens (A, B, C, or D):
**A)** During the first 100 days after HCT, the patient meets ONE of the following (i or ii):
- **i.** Adults and adolescents: 0.5 g/kg per week given intravenously and the dose is adjusted to maintain trough (pre-dose) serum IgG greater than 400 mg/dL; OR
- **ii.** Pediatric patient with allogeneic HCT: 0.4 g/kg per month given intravenously and the dose is adjusted to keep IgG greater than 400 mg/dL; OR

**B)** Greater than 100 days post-HCT, the dose is 0.5 g/kg given intravenously every 3 to 4 weeks, and the dose is adjusted to keep IgG greater than 400 mg/dL; OR
**C)** 0.2 g/kg to 0.8 g/kg given intravenously every 3 to 4 weeks; OR
**D)** The dosage is based on a transplant center's protocol.

**18. Human Immunodeficiency Virus (HIV)- or Hepatitis C-Associated Thrombocytopenia.** @

**Criteria.** Approve for 1 month if the patient is receiving antiviral therapy.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** Up to 2 g/kg given intravenously in divided doses over 2 to 5 days; OR
**B)** Up to 1 g/kg one time given intravenously up to once weekly.

**19. Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Infections.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 6 months if the patient meets the following (i and ii):
- **i.** The patient is < 18 years of age; IC-EC AND
- **ii.** The patient has ONE of the following (a, b, or c):
  - **a.** Hypogammaglobulinemia (i.e., IgG < 400 mg/dL [4.0 g/L]); OR
  - **b.** Functional antibody deficiency is demonstrated by poor specific antibody titers (that is, the patient does not develop specific antibody responses against protein and polysaccharide antigens); IC-EC OR
  - **c.** Functional antibody deficiency is demonstrated by the patient having recurrent (two or more per year), serious infections (e.g., bacteremia, meningitis, pneumonia) despite administration of combination antiretroviral therapy (cART) and appropriate antimicrobial prophylaxis. IC-EC

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the frequency and/or severity of infections have decreased according to the prescriber. IC-ISGP

**Dosing.** Approve the following dosing regimens (A or B):
**A)** The dose is 0.4 g/kg given intravenously infusion every 2 to 4 weeks; OR
**B)** The dose and interval are adjusted according to clinical effectiveness.


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Note: Examples of adjusting according to clinical effectiveness may include the need to increase the dose or frequency based on frequency or severity of infections, hospitalizations, days of school or work missed, failure to thrive.

**20. Immune-Mediated Necrotizing Myopathy.** @

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Also known as necrotizing autoimmune myopathy.
**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient has muscle weakness; AND
- **ii.** Patient has or had an elevated creatine kinase (CK) level above 1,000 IU/L; AND
- **iii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has myositis-associated autoantibodies; OR
    Note: Examples of myositis-associated autoantibodies include anti-SRP autoantibodies, anti-HMGCR autoantibodies.
  - **b)** Patient has an electromyography, muscle magnetic resonance imaging, or muscle biopsy which, according to the prescriber, supports the given diagnosis; AND
- **iv.** Patient meets ONE of the following (a, b, c, or d):
  - **a)** Patient has tried a systemic corticosteroid; OR
  - **b)** Corticosteroids are contraindicated, according to the prescriber; OR
  - **c)** Patient has tried one of rituximab, methotrexate, mycophenolate, or tacrolimus; OR
  - **d)** Patient has anti-HMGCR autoantibodies.

**B)** Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy, according to the prescriber.
Note: Examples of a response to therapy includes improved muscle strength, improved functional ability, CK decrease.

**Dosing.** Approve up to 2 g/kg per month administered intravenously (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 days]).

**21. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy.** @

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

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 1 month if the patient meets the following criteria (i, ii or iii):
- i. The patient has tried a systemic corticosteroid and has not adequately responded to therapy; OR
  Note: Examples of systemic corticosteroids include prednisone, methylprednisolone.
- ii. IVIG is being started with a systemic corticosteroid; OR
- iii. A corticosteroid is contraindicated, per the prescriber.

**B)** Patients Currently Receiving Immune Globulin: Approve for 6 months if the patient is having a positive response to therapy, as determined by the prescriber, and the prescriber has determined extended therapy is required.


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**Dosing.** Approve the following dosing regimens (A, B, or C):
**A)** Up to 0.4 g/kg given intravenously daily for 5 days; OR
**B)** Up to 2 g/kg given intravenously over 2 to 5 days; OR
**C)** The dose and interval between doses has been adjusted based on clinical response as determined by the prescriber.

**22. Lambert-Eaton Myasthenic Syndrome (LEMS). @**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 1 month (to allow for one course of therapy) if the patient meets the following (i and ii):
- **i.** The patient is having refractory weakness after symptomatic treatment of LEMS with an amifampridine product (e.g., Firdapse, Ruzurgi), guanidine, or pyridostigmine; AND
- **ii.** The patient meets ONE of the following (a or b):
  - **a.** The patient has paraneoplastic LEMS; OR
  - **b.** The patient has non-paraneoplastic LEMS AND has tried a systemic corticosteroid (e.g., prednisone) or another nonsteroidal immunosuppressive agent (e.g., azathioprine), or has a contraindication to corticosteroids and/or nonsteroidal immunosuppressive agents, according to the prescriber.

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has a response or continued effectiveness, according to the prescriber.
Note: Examples of a response to therapy include improved muscle strength or other clinical response.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** Up to 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days; OR
**B)** Maintenance therapy every 4 weeks with up to 2 g/kg with the dose being adjusted based on clinical symptoms.

**23. Multiple Myeloma. ^**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy. Approve for 6 months if the patient meets one of the following (i, ii, iii or iv):
- **i.** The patient has, or is at risk of, severe recurrent infections according to the prescriber; OR
- **ii.** The patient will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy, bispecific antibody therapy, or other B-Cell targeted therapy; [IC-EC] OR
  Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel infusion).
  Note: Examples of bispecific antibody therapy or other B-Cell targeted therapy includes: Elrexfio (elranatamab-bcmm subcutaneous injection), Tecvayli (teclistamab-cqyv subcutaneous injection), Talvey (talquetamab-tgvs subcutaneous injection).
- **iii.** The patient meets ALL of the following (a, b, and c):[81]
  - **a.** The patient is in the plateau phase of the disease; AND
  - **b.** The patient has a serum IgG level < 600 mg/dL; AND
  - **c.** The patient has a history of one documented, serious bacterial infection requiring IV antibiotic therapy in the previous six months; OR


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**iv.** The patient has failed to mount an appropriate IgG humoral response to pneumococcal vaccine.[81]

**B)** Patients Currently Receiving Immune Globulin. Approve for 1 year.

**Dosing.** Approve 0.2 g/kg to 0.8 g/kg given intravenously every 3 to 4 weeks.

**24. Multiple Sclerosis (MS), Acute Severe Exacerbation or Relapses.** ^

**Criteria.** Approve for 1 month (this is to provide one course of therapy) if the patient meets ONE of the following criteria (A or B):

**A)** The patient has either not responded to OR has had a significant adverse reaction with systemic corticosteroids (e.g., methylprednisolone sodium succinate injection) OR plasma exchange; IC-ISGP
OR
(Note: A trial of Acthar® H.P. gel [repository corticotropin injection; adrenocorticotropic hormone, ACTH] would also count toward meeting this requirement.)

**B)** A systemic corticosteroid is contraindicated, according to the prescriber. IC-ISGP

**Dosing.** Approve the following dosing regimens (A or B):

**A)** A single 1 g/kg given intravenously ; OR

**B)** 0.4 g/kg per day IV infusion for 5 consecutive days.

**25. Myasthenia Gravis.** ^

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A, B, C, D or E):

**A)** Patient with myasthenic crisis or impending myasthenic crisis: Approve 30 days; OR

**B)** Initial Therapy for Short-Term (Acute) Use: Approve for 5 days (to allow for one course of therapy) if the patient meets ONE of the following conditions (i, ii, iii, or iv):

**i.** The patient has an exacerbation of myasthenia gravis; OR

**ii.** The patient requires stabilization of myasthenia gravis before surgery; OR

**iii.** The patient has been started on a nonsteroidal immunosuppressive drug and is waiting for full effect; IC-EC OR
Note: Examples of nonsteroidal immunosuppressive drugs include azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, or tacrolimus.

**iv.** The patient is starting therapy with a corticosteroid and IVIG is being given to prevent or minimize exacerbations. IC-EC

**C)** Patient is Cuurrently Receiving Immune Globulin Short-Term (Acute) Use. Approve for 5 days (to allow for one course of therapy).

**D)** Initial Therapy for Maintenance: Approve for 1 year if the patient meets ONE of the following criteria (i or ii):

**i.** Patient meets ONE of the following (a or b): IC-EC

**a)** Patient has tried at least ONE of the following medications for myasthenia gravis: a complement inhibitor, a neonatal Fc receptor blocker, or a CD19-directed monoclonal antibody; IC-EC OR
Note: Examples of complement inhibitors include eculizumab intravenous infusion (Soliris, biosimilars), Ultomiris (ravulizumab-cwvz intravenous infusion), Zilbrysq


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(zilucoplan subcutaneous injection). Examples of neonatal Fc receptor blockers include Imaavy (nipocalimab-aahu intravenous infusion), Rystiggo (rozanolixizumab-noli subcutaneous infusion), Vyvgart (efgartigimod alfa intravenous infusion), Vyvgart Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc subcutaneous injection). An example of CD19-directed monoclonal antibody is Uplizna (inebilizumab-cdon intravenous infusion).

**b)** According to the prescriber, complement inhibitors, neonatal Fc receptor blockers, and CD19-directed monoclonal antibodies are NOT clinically appropriate for the patient; [IC-EC] OR

**ii.** Patient meets ALL of the following (a, b and c):

**a)** Patient has failed to respond to, or has intolerable side effects to acetylcholinesterase inhibitors; AND

**b)** Patient is either refractory to corticosteroids over a 6 week period, has been unable to successfully taper corticosteroids below moderately high doses, or has developed severe side effects due to steroid therapy; AND

**c)** Patient has failed at least one immunosuppressive agent (e.g., azathiprime, methotrexate, cyclophosphamide, cyclosporine); OR

**E)** Patients Currently Receiving Immune Globulin for Maintenance Therapy: Approve for 1 year if the patient is responding according to the prescriber. [IC-ISGP]
Note: Examples of responding to therapy include improvement in weakness (bulbar, limb, or respiratory), improvement with ocular symptoms.

**Dosing.** Approve the following dosing regimens (A, B, or C):

**A)** Crisis or Short-term use: 2 g/kg given intravenously in divided doses over 2 to 5 consecutive days; OR

**B)** Maintenance therapy: 0.4 g/kg to 1 g/kg given intravenously every 4 weeks; OR

**C)** The dose and interval between doses has been adjusted based on clinical response as determined by the prescriber.

## 26. Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD). @

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):

**i.** Patient has a clinical demyelinating event, according to the prescriber; AND
Note: Examples of a clinical demyelinating event includes, but is not limited to, optic neuritis, acute disseminated encephalomyelitis, traverse myelitis.

**ii.** The diagnosis was confirmed by a positive blood serum test which was positive for myelin oligodendrocyte glycoprotein (MOG)-Immune globulin G (IgG); AND
Note: Detection in cerebral spinal fluid would also satisfy this requirement.

**iii.** Patient meets ONE of the following (a or b):

**a)** Patient is using the requested medication for the treatment of acute attacks AND meets ONE of the following [(1) or (2)]:

**(1)** Patient has tried a systemic corticosteroid; OR

**(2)** Corticosteroids are contraindicated, according to the prescriber; OR

**b)** Patient is using the requested medication for attack prevention AND meets ONE of the following [(1) or (2)]:

**(1)** Patient has tried a nonsteroidal immunosuppressant; OR

**(2)** Nonsteroidal immunosuppressants are contraindicated, according to the prescriber.


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**B)** Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy, according to the prescriber.
Note: Examples of a response to therapy includes a reduction in relapse rate, slowing of disability, slowing in the progression of symptoms.

**Dosing.** Approve up to 2 g/kg per month administered intravenously (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 days]).

**27. Neonatal Isoimmune Hemolytic Disease (Hemolytic Disease of the Fetus and Newborn), Acute Treatment.** @
Note: Also could see the diagnosis Red Blood Cell Alloantibodies During Pregnancy.

**Criteria.** Approve for 1 month if the patient's total serum bilirubin is rising despite intensive phototherapy OR is within 3 mg/dL of the exchange transfusion threshold.

**Dosing.** Approve 0.5 g/kg/dose to 1 g/kg/dose administered intravenously; may repeat dose if necessary.

**28. Opsoclonus-Myoclonus-Ataxia Syndrome.** @

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 6 months.
**B)** Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy, according to the prescriber.
Note: Examples of response to therapy can include improvement of stance and gait, arm or hand function, opsoclonus, mood or behavior, or speech.

**Dosing.** Approve the following dosing regimen: Up to 2 g/kg over 2 to 5 days followed by 1 to 2 g/kg every 4 weeks.

**29. Passive Immunization for Measles (Post-Exposure Prophylaxis).** @

Note: For patients with primary immune deficiency, see criteria for PID.

**Criteria.** Approve for 1 day (to allow for a single dose) if the patient meets ONE of the following (A, B or C):
**A)** The patient is pregnant and meets the following (i and ii):
- **i.** The patient has been exposed to measles; AND
- **ii.** The patient cannot readily show they have evidence of immunity against measles (e.g., the patient does not have a history of the disease or age-appropriate vaccination); OR

**B)** Infants born to pregnant patients with suspected or confirmed measles; OR
**C)** The patient meets ALL of the following (i and ii):
- **i.** The patient is immunocompromised; AND
- **ii.** The patient has been exposed to measles.


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**Dosing.** Approve the following dosing regimen: 0.4 g/kg intravenously administered one time.

**30. Post-Exposure Prophylaxis for Varicella OR Treatment or Post-Exposure Prophylaxis for Tetanus.** @

**Criteria.** Approve for 1 day (to allow for a single dose) if the patient meets ONE of the following (A or B):
**A)** For Varicella post-exposure, Varicella immune globulin is not available or cannot be administered; OR
**B)** For Tetanus treatment or post-exposure, Tetanus Immune globulin is not available.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** 0.4 g/kg given intravenously one time; OR
**B)** 0.2 to 0.4 g/kg given intravenously one time

**31. Parvovirus B19 Infection.**@

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 2 months if the patient has an immunodeficiency condition. Note: Examples of an immunodeficiency condition include patients with HIV infection, solid organ transplants (e.g., renal, liver), chemotherapy for hematologic malignancy.
**B)** Patients Currently Receiving Immune Globulin: Approve for 6 months.

**Dosing.** Approve the following dosing regimens (A, B, C, or D):
**A)** 2 g/kg given intravenously over a period of 2 to 5 consecutive days; OR
**B)** 0.4 g/kg to 0.5 g/kg given intravenously daily for 5 days; OR
**C)** 0.4 g/kg given intravenously once every 4 weeks; OR
**D)** 0.2 g/kg to 0.4 g/kg given intravenously daily for 5 to 10 days.

**32. Post-Transfusion Purpura, Acute Treatment.** @

**Criteria.** Approve for 1 month.

**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** Up to 2 g/kg/day administered intravenously over either 2 or 5 days; OR
**B)** Up to 500 mg/kg/day administered intravenously for 1 to 10 days.

**33. Pure Red Blood Cell Aplasia (PRCA), Immunologic Subtype.** @


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**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 1 month if the patient meets ALL of the following criteria (i and ii):
- **i.** The patient has tried a systemic corticosteroid (e.g., prednisone); AND
- **ii.** The patient has tried either cyclophosphamide OR cyclosporine.

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 month if the patient has responded with an increase in hemoglobin and reticulocytosis, according to the prescriber.

**Dosing.** Approve 0.5 g/kg given intravenously for 4 weeks.

## 34. Rasmussen Encephalitis. @

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 6 months if the patient meets ONE of the following (i or ii):
- **i.** As determined by the prescriber, clinical features, an electroencephalogram, AND magnetic resonance imaging support the diagnosis of Rasmussen encephalitis; OR
- **ii.** As determined by the prescriber, two of the three features 1) clinical features, 2) magnetic resonance imaging, or 3) histopathology support the diagnosis of Rasmussen encephalitis; OR

**B)** Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has responded to therapy, according to the prescriber.
Note: Examples of response to therapy can include improvement or stabilization of seizure frequency or motor deficits.

**Dosing.** Approve the following dosing regimen: Up to 2 g/kg administered intravenously over 2 to 5 days per treatment cycle.

## 35. Red Blood Cell Alloantibodies During Pregnancy. @

**Criteria.** Approve for the duration of the pregnancy if the patient meets ONE of the following (A or B):
**A)** Patient meets BOTH of the following (i and ii):
- **i.** Patient has a clinically significant maternal red blood cell alloantibody (e.g., anti-D, anti-Kell, anti-c, or other clinically significant antigen); AND
- **ii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient has an antigen-positive fetus or a fetus presumed to be antigen-positive: AND
  - **b)** Patient meets ONE of the following (1 or 2):
    - **(1)** Patient has a history of a pregnancy or child with fetal anemia requiring intrauterine transfusion; OR
    - **(2)** Patient experienced dyrops fetalis or fetal loss due to hemolytic disease of the fetus and newborn in a previous pregnancy; OR

**B)** Patient has already been started on immune globulin therapy for the condition.

**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** Up to 2 g/kg administered intravenously once weekly; OR
**B)** Up to 2 g/kg per cycle administered intravenously over two consecutive days every 3 weeks


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**36. Stiff-Person Syndrome (Moersch-Woltman Syndrome). ^**

**Criteria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy: Approve for 3 months if the patient meets both of the following (i and ii):
- **i.** IVIG is prescribed by or in consultation with a neurologist or other physician who is competent in the diagnosis of Stiff-Person Syndrome; AND
- **ii.** The patient has tried a benzodiazepine (e.g., diazepam) OR baclofen; IC-EC OR
- **iii.** The patient has contraindications to both a benzodiazepine AND baclofen according to the prescriber. IC-EC

**B)** Patients Currently Receiving Immune Globulin: Approve for 1 year if the patient has responded to therapy according to the prescriber. IC-ISGP
Note: Examples of response to therapy includes reduced stiffness or frequency of spasms, ability to walk unassisted.

**Dosing.** Approve the following dosing regimens (A or B):
**A)** 2 g/kg given intravenously over a period of 2 to 5 consecutive days every month; OR
**B)** For maintenance therapy, the dose is adjusted to provide the minimum effective dosage of IVIG. Maximum dose is 2 g/kg given intravenously.

**37. Thrombocytopenia, Feto-neonatal Alloimmune. @**

**Criteria.** Approve for 6 months.

**Dosing.** Approve the following dosing regimens (A, B, C, or D):
**A)** For the mother: 1 g/kg given intravenously every week; OR
**B)** For the mother: 2 g/kg given intravenously every week; OR
**C)** For the mother: 1 g/kg given intravenously twice weekly; OR
**D)** For the newborn: 1 g/kg to 2 g/kg given intravenously dosed per the prescriber.

**38. Toxic Shock Syndrome, Acute Treatment. @**

**Criteria.** Approve for 1 month.

**Dosing.** Approve the following dosing regimen: Up to 1 g/kg on day 1, followed by up to 500 mg/kg once daily on days 2 and 3.

**39. Autoimmune Hemolytic Anemia. ^**

**Criteria.** Approve for 1 month if the patient meets one of the following conditions (A or B):
**A)** The patient has failed to respond to at least one other form of therapy (e.g., corticosteroids, immunosuppressive agents, cytotoxic agents, monoclonal antibodies such as rituximab, splenectomy); OR
**B)** The patient requires rapid cessation of hemolysis due to severe or life threatening manifestations of the condition.


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**Dosing.** Approve ONE of the following dosing regimens (A or B):
**A)** Up to 500 mg/kg/day administered intravenously for 4 days; OR
**B)** Up to 1 g/kg/day administered intravenously for 2 days.

**40. Autoimmune Neutropenia.** #

**Criteria.** Approve for 2 days (to allow for one course of therapy to be given over 1 to 2 consecutive days) if the patient meets both of the following (A and B):
**A)** The patient has an absolute neutrophil count less than 800/mm$^3$; AND
**B)** The patient has recurrent bacterial infections.

**Dosing.** [81] Approve doses up to 2 g/kg given over 1 to 2 days.
Since data is limited, other dosing regimens can be reviewed on a case-by-case basis.

**41. Chronic Graft versus Host Disease (GVHD).** #

**Criteria.** Approve for 6 months if the patient meets ALL of the following (A, B, C and D):
**A)** The patient has a confirmed diagnosis of chronic graft versus host disease (GVHD); AND
**B)** The patient has laboratory-proven hypogammaglobulinemia with an immunoglobulin G (IgG) level < 400 mg/dL (4.0 g/L); AND
**C)** The patient has had at least one acute infection requiring hospitalization and/or parenteral antibiotics; AND
**D)** The patient is at least 100 days post-transplant.

**Dosing.** Approve the following dose: 0.5 g per kg IV infusion every 3 to 4 weeks, and the dose is adjusted to keep IgG greater than 400 mg/dL.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of immune globulin intravenous is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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## HISTORY

| Type of Revision | Summary of Changes | Date |
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| Policy created | New Medicare Advantage Medical Policy | 06/10/2020 |
| Policy revision | **Primary Immunodeficiencies (PID)**: Under Initial Therapy, added "or another confirmed primary immunodeficiency" under criterion c. For Continuation Therapy, moved examples receiving benefit from the product to a note and added the wording, according to the prescriber. Under the dosing section, removed examples for clinical response. For dosing with patients with PID and exposure to measles, added previous exposure or risk of future measles exposure and that the minimum dose has been determined by the prescriber. | 08/25/2020 |


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| | **B-Cell Chronic Lymphocytic Leukemia for Prevention of Bacterial Infections**: Added "having a positive response to therapy according to the prescriber" and placed current examples of a positive response as a note.<br><br>**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy**: For Continuation Therapy, moved examples of a clinically significant improvement to a note. Removed a neurologist or in consultation with a neurologist for continuation criteria.<br><br>**Idiopathic (Immune) Thrombocytopenic Purpura (ITP) or Immune Thrombocytopenia [IT] Acute and Chronic** was updated to Immune Thrombocytopenia (ITP). The following note was added: The diagnosis of Immune Thrombocytopenia (ITP) encompasses previous nomenclature, such as Idiopathic Thrombocytopenia, Idiopathic Thrombocytopenic Purpura, Immune Thrombocytopenic Purpura. Initial therapy criteria for adults ≥ 18 years of age was updated to have the patient try a systemic corticosteroid, or there is an urgent need to increase platelet count quickly, or if a systemic corticosteroid is contraindicated according to the prescriber. Initial therapy criteria for children and adolescents (< 18 years of age), to increase platelet counts before surgical procedures, and pregnant patients were updated to only include prescriber's specialty. Continuation Criteria: Added has responded to therapy according to the prescriber and examples of responding to therapy was moved to a note. Dosing criteria was updated to the following: Up to 1 g per kg on 2 consecutive day OR up to 0.4 g per kg on 5 consecutive day (up to a total of 2 g per kg per treatment course) OR the dose and interval between doses has been adjusted according to the platelet count and/or to prevent significant bleeding as determined by the prescriber.<br><br>**Kawasaki Disease**: Updating from a single dose to an approval for 3 months if prescribed by or in consultation with a pediatric cardiologist or pediatric infectious diseases physician.<br><br>**Multifocal Motor Neuropathy (MMN)**. For Continuation Therapy, moved examples of a clinically significant improvement to a note. Removed a neurologist or in consultation with a neurologist for continuation criteria.<br><br>**Antibody-Mediated Rejection (ABMR) in Solid Organ Transplantation (e.g., Kidney, Heart, Lung, Liver)** was updated to Antibody-Mediated Rejection (ABMR) in Transplantation. Dosing criteria was updated as up to 2 g per kg as an IV infusion (as a single dose or divided in smaller doses [e.g., 400 mg per kg daily for 5 day]) OR IVIG dosage is based on a transplant center's protocol.<br><br>**Autoimmune Mucocutaneous Blistering Diseases**. In the initial therapy criteria, examples of immunosuppressive agents were updated to notes. In the continuation criteria, examples of response to therapy were updated to notes.<br><br>**Cytomegalovirus (CMV) Interstitial Pneumonia in Patients with Cancer or Transplant-Related Infection** was updated to Cytomegalovirus (CMV) Pneumonia in Patients with Cancer or Transplant-Related Infection. | |


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| | **Dermatomyositis or Polymyositis**. In the initial therapy criteria, examples of immunosuppressive agents were updated to notes. In the continuation criteria, examples of response to therapy were updated to notes.<br><br>**Desensitization Therapy Prior to and Immediately after Solid Organ (Kidney, Heart, Lung, Liver, Intestinal) Transplantation** was updated to Desensitization Therapy Prior to and Immediately after Transplantation. Criteria was updated to approve for 1 year if IVIG is prescribed by or in consultation with a physician affiliated with a transplant center.<br><br>**Guillain Barre Syndrome (GBS).** Neuropathic symptoms were moved from criterion to a note.<br><br>**Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia after B-cell Targeted Therapies (Secondary Immunodeficieny [SID])**. Added IgG level in units of g/L. Continuation criteria: updated wording to having a positive response to therapy according to the prescriber and moved examples of a positive response to a note. In dosing criteria, updated 0.5 g to 0.6 g and added the following criteria: 0.2 to 0.8 g per kg once every 3 to 4 weeks or the dose and interval between doses has been adjusted based on clinical response as determined by the prescriber.<br><br>**Hematopoietic Cell Transplantation (HCT) to Prevent Bacterial Infection**. Added IgG level in units of g/L. Continuation criteria: updated wording to having a positive response to therapy according to the prescriber and moved examples of a positive response to a note. Dosing criteria- added criterion C. that the IVIG dosage is based on a transplant center's protocol.<br><br>**Human Immunodeficiency Virus (HIV)-Associated Thrombocytopenia**. Dosing section- added "up to" to both dosing criteria.<br><br>**Human Immunodeficiency Virus (HIV)-Infected Infants and Children to Prevent Recurrent Bacterial Infections**. Added IgG level in units of g/L. Dosing criteria- removed "between infusions" and added a note of examples of adjusting the dose according to clinical effectiveness.<br><br>**Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy**. Initial therapy criteria- moved examples of systemic corticosteroid therapy to a note. Broke criteria i and ii into i, ii, and iii for clarity. Dosing criteria: Added "up to" and "as an IV infusion" wording. Added criterion regarding the dose and interval between doses has been adjusted based on clinical response as determined by the prescriber.<br><br>**Lambert-Eaton Myasthenic Syndrome (LEMS).** Continuation criteria- moved examples of a response to therapy to a note. Dosing criteria- added the wording "up to" on criteria A).<br><br>**Multiple Sclerosis (MS), Post-Partum to Prevent Relapses**. Added Vumerity and Zeposia to examples of disease modifying therapy.<br><br>**Myasthenia Gravis**. Moved examples of immunosuppressive drugs to notes. Dosing criteria- added criterion regarding the dose and interval between doses | |


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| | has been adjusted based on clinical response as determined by the prescriber. Also added the wording "up to" on criterion B).<br><br>**Passive Immunization for Measles (Post-Exposure Prophylaxis).** Broke criteria B) into i, ii, and iii for clarity. Moved examples of severe immunocompromised status into a note.<br><br>**Pure Red Blood Cell Aplasia (PRCA) Secondary to Chronic [Persistent] Parvovirus B19**. Moved examples of chronic immunodeficiency conditions to a note.<br><br>**Stiff-Person Syndrome (Moersch-Woltman Syndrome)**. Continuation therapy – moved examples of response to therapy to a note.<br><br>**Thrombocytopenia, Feto-neonatal Alloimmune.** Dosing section- added the wording "dosed per prescriber" to criterion D). | |
| Policy revision | For continuation criteria, removed the wording "intravenous." | 09/3/2020 |
| Policy revision | Removed Carimune from the policy (obsolete).<br><br>**B-Cell Chronic Lymphocytic Leukemia for Prevention of Infections:** The descriptor of "bacterial" was removed from the condition of approval. Additionally, the descriptor of "bacterial" was removed from the criterion regarding recurrent infections. The Dosing was updated to be: "greater than 500 mg/dL" (previously was "about 500 mg/dL and up to 700 mg/dL").<br><br>**Dermatomyositis or Polymyositis:** This indication was moved from "Other Uses with Supportive Evidence" to an FDA-approved indication. Prior to starting therapy, a requirement for an elevated kinase level, according to the prescriber, was added, unless other measures support the diagnosis, including, but not limited to, skin manifestations, autoantibody testing, muscle biopsy results, electromyographic findings. Dosing that referred to monthly use was updated to be once every 4 weeks.<br><br>**Multifocal Motor Neuropathy:** The indication "Multifocal Motor Neuropathy (Treatment)" was changed as listed. A requirement was added that the diagnosis to be supported by weakness without sensory abnormalities, upper motor signs, or marked bulbar involvement. Additionally, a requirement was added for one of the following: the diagnosis is supported by nerve conduction studies that demonstrate motor conduction block or probable motor conduction block; the prescriber has determined the patient has multifocal motor neuropathy without conduction block; or the diagnosis is supported by a motor nerve biopsy or by a magnetic resonance imaging neurography.<br><br>**Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita):** In the Dosing, the word "initially" was removed (not needed).<br><br>**Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia after B-cell Targeted Therapies (Secondary Immunodeficiency [SID]):** Additional examples of chimeric antigen receptor T-cell therapy were added. The descriptor of "bacterial" was removed from the criterion regarding recurrent or severe infection. | 10/04/2021 |


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| | **Hematopoietic Cell Transplantation to Prevent Infection:** The indication "Hematopoietic Cell Transplantation to Prevent Bacterial Infection" was changed to as listed. Additionally, the descriptor of "bacterial" was removed from the criterion regarding frequent and/or severe infections. In Dosing, the phrase "greater than 400 to 500 mg per/dL" for serum IgG was updated to "greater than 400 mg/dL".<br><br>**Human Immunodeficiency Virus-Associated Thrombocytopenia:** For Dosing, the phrase "for platelet counts less than 20 x $10^9$/L or 20,000/µL to 30 x $10^9$/L or 30,000/µL per mm3 and this dose is repeated once weekly if needed" was changed to "up to once weekly."<br><br>**Human Immunodeficiency Virus Infected Infants and Children to Prevent Recurrent Infections:** The indication "Human Immunodeficiency Virus-Infected Infants and Children to Prevent Recurrent Bacterial Infections" was changed to as listed. Additionally, the word "bacterial" was removed from the criterion regarding recurrent, serious infections.<br><br>**Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** Added additional examples of checkpoint inhibitors.<br><br>**Multiple Myeloma:** The word "bacterial" was removed from the criterion regarding severe, recurrent infections.<br><br>**Multiple Sclerosis, Post-Partum to Prevent Relapses:** This condition and related criteria were removed.<br><br>**Myasthenia Gravis:** Approval criteria were clarified related to continuation of therapy in patients using immune globulin for short-term (acute) use. Examples of a response to therapy were added for continuation of treatment in patients receiving immune globulin for maintenance therapy. Dosing was changed to remove the wording "up to" for maintenance dosing.<br><br>**Passive Immunization for Measles (Post-Exposure Prophylaxis):** The requirement that the medication be given within 6 days of exposure was removed. The word "severely" was removed from the criterion related to immunocompromised patients. A note regarding examples of severely immunocompromised patients was removed. In Dosing, the wording "as soon as possible after exposure" was removed.<br><br>**Passive Immunization for Varicella (Chickenpox) [Post-Exposure Prophylaxis]:** The requirement that VariZIG is not available was updated to add "or it cannot be administered within 10 days of exposure". | |
| Policy revision | **Human Immunodeficiency Virus (HIV) - or Hepatitis C-Associated Thrombocytopenia.** The diagnosis Hepatitis C-Associated Thrombocytopenia was added to the policy. Criterion was updated from patient is receiving combination antiretroviral therapy to patient is receiving antiviral therapy. Criteria related to clinically significant bleeding complications according to the prescriber was removed.<br><br>**Multiple Myeloma.** Added the wording, "or is at risk of" to the criterion related to severe recurrent infections according to the prescriber. | 10/24/2022 |


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| | **Post-Exposure Prophylaxis for Varicella:** The diagnosis wording was previously Passive Immunization for Varicella (Chickenpox) [Post-Exposure Prophylaxis]. The following criteria were removed: 1) Patient has HIV; Patient is immune compromised; Patient is pregnant; 2) Patient does not have evidence of immunity to varicella. Also, Treatment or Post-Exposure Prophylaxis for Tetanus was added to the diagnosis with the following criterion: Tetanus Immune globulin is not available. Dosage of 0.2 to 0.4 g/kg intravenously one time was added.<br><br>**Parvovirus B19 Infection:** Diagnosis wording was previously Pure Red Blood Cell Aplasia (PRCA) Secondary to Chronic (Persistent) Parvovirus B19 Infection. The word "chronic" immunodeficiency condition was removed from initial therapy criteria. The criterion regarding "clinically significant anemia as determined by the prescriber" and "patient is transfusion dependent" was removed. Continuation of therapy criteria related to hemoglobin and relapse were removed from the criteria. Removed "(one course) for up to two courses" from the dosage 2g/kg given intravenously over a period of 2 to 5 consecutive days. | |
| Policy revision | **Cytomegalovirus Pneumonitis or Pneumonia in a Patient with Cancer or Transplant-Related Infection:** Added the wording pneumonitis; the diagnosis wording was previously Cytomegalovirus Pneumonia in a Patient with Cancer or Transplant-Related Infection.<br><br>**Multiple Myeloma:** The following option for approval was added in initial therapy as an alternative to existing criteria 1) Patient will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy OR bispecific antibody therapy. Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion). Note: Examples of bispecific antibody therapy includes: Elrexfio (elranatamab-bcmm subcutaneous injection), Tecvayli (teclistamab-cqyv subcutaneous injection), Talvey (talquetamab-tgvs subcutaneous injection).<br><br>**Parvovirus B19 Infection:** 0.2 g/kg to 0.4 g/kg given intravenously daily for 5 to 10 days was added as an alternative dosing regimen. | 11/27/2023 |
| Policy revision | **Alyglo was added to the policy** with the same criteria as all other immune globulin products.<br><br>**Chronic Inflammatory Demyelinating Polyneuropahy (CIDP) or Polyradiculoneurapthy**: Updated dosing from an initial loading dose of 2 g/kg given intravenously in divided doses over 2 to 4 days consecutive days to 2 to 5 days consecutive days. Updated dosing from a maintenance dose of 1 g/kg given intravenously over one day or divided into two doses of 0.5 g/kg given on 2 consecutive days to a maintenance dose of 1 g/kg given intravenously in divided doses over 1 to 4 consecutive days.<br><br>Revision based on review of commercial policy revision. | 02/27/2024 |
| Policy revision | **Immune Thrombocytopenia (ITP).** The duration of approval for initial therapy for adults and pediatric patients was changed from 1 year to 3 months. Criterion for patients requiring retreatment with immune globulin was added to the | 04/23/2024 |


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| | continuation criteria. Continuation criterion was also updated from "Patient has responded to therapy" to patient is responding to therapy OR the patient has previously responded to therapy.<br><br>**The following was added to the Policy Statement:**<br><br>If the client is using the IVIG MSM Policy in tandem with this UM policy, the new approval may be entered without another clinical review for a preferred product only.<br><br>Based on commercial policy revision | |
| Policy revision | **Yimmugo was added to the policy** with the same criteria as all other immune globulin products.<br><br>Revision based on commercial policy update | 08/02/2024 |
| Policy revision | **Primary Immunodeficiencies:** Added a note that molecular testing is a type of genetic testing.<br><br>**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy:** Added grip strength as an example of an improvement at physical examination.<br><br>**Aquaporin-4 Immunoglobulin Antibody (AQP4-IgG)-Positive Neuromyelitis Optica Spectrum Disorder (NMOSD); Immune-Mediated Necrotizing Myopathy; Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD):** These conditions of approval were added to the policy.<br><br>**Guillain Barre Syndrome:** For criterion 'patient currently receiving immune globulin', the wording "(this is to provide a second course) about 3 weeks after the first course" was removed.<br><br>**Passive Immunization for Measles (Post-Exposure Prophylaxis):** Patient does not have evidence of immunity to measles (i.e.,) was updated to Patient cannot readily show they have evidence of immunity against measles (e.g.,).<br><br>**Post-Exposure Prophylaxis for Varicella:** "within 10 days of exposure" was removed.<br><br>Revision based on revision to commercial policy. | 12/11/2024 |
| Policy review | No criteria changes<br>Review based on NCD/LCD/LCA surveillance review | 06/03/2025 |
| Policy revision | No criteria changes. Formatting and notation updates. | 06/11/2025 |
| Policy review | No criteria changes<br>Review based on NCD/LCD/LCA surveillance review | 10/24/2025 |
| Policy revision | **Gammagard Liquid ERC** and **Qivigy** were added to the policy with the same criteria as all other immune globulin products.<br><br>**B-Cell Chronic Lymphocytic Leukemia for Prevention of Infections**: Updating dosing to an expanded dose of 0.2 g/kg to 0.8 g/kg given intravenously | 12/19/2025 |


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| | every 3 to 4 weeks. Removing 0.4 g/kg given intravenously every 3 to 4 weeks and 0.3 g/kg to 0.5 g/kg given intravenously once monthly.<br><br>**Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-Cell Targeted Therapies (Secondary Immunodeficiency [SID])**: Added the wording "or treatment" to the indication. The following option for approval was added in initial therapy 1) Patient is < 18 years of age and will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy OR other B-cell targeted therapy. Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion). Note: Examples of other B-cell targeted therapy includes: Besponsa (inotuzumab ozogamicin intravenous infusion), Blincyto (blinatumomab intravenous infusion). Removed dosing option 0.4 g/kg to 0.6 g/kg given intravenously once a month (this dose is already covered by available dosing regimens).<br><br>**Hematopoietic Cell Transplantation (HCT) to Prevent Infection**: Updated wording of indication from Hematopoietic Stem Cell Transplantation to as listed. The following option for approval was added in initial therapy: Patient has had a HCT within the previous year, and Patient has an immunoglobulin G (IgG) level < 600 mg/dL (6.0 g/L) OR the patient has multiple myeloma or malignant macroglobulinemia, and According to the prescriber, the patient has a significant risk of having frequent and/or severe infections. The following option for approval was added in initial therapy: Patient is a recipient of an umbilical cord blood transplant; or patient is undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency; or patient with chronic graft versus host disease with recurrent sinopulmonary infections. Added criteria for patient currently receiving immune globulin if the patient is having a positive response to therapy according to the prescriber. Updated dosing.<br><br>**Multiple Myeloma**: Added the wording "or other B-Cell targeted therapy" in addition to CAR-T therapy and bispecific antibody therapy. Updated dosing from 0.4 g/kg to 0.5 g/kg given intravenously every 3 to 4 weeks to 0.2 g/kg to 0.8 g/kg given intravenously every 3 to 4 weeks.<br><br>**Passive Immunization for Measles (Post-Exposure Prophylaxis)**: The following option for approval was added: "Infants born to pregnant patients with suspected or confirmed measles." | |
| Policy revision | **Coronavirus Disease-2019 (COVID-19)-Associated Multisystem Inflammatory Syndrome in Children (MIS-C), Evan's syndrome, Neonatal Isoimmune Hemolytic Disease (Hemolytic Disease of the Fetus and Newborn), Acute Treatment, Opsoclonus-Myoclonus-Ataxia Syndrome, Post-Transfusion Purpura, Acute Treatment, Rasmussen Encephalitis, Red Blood Cell Alloantibodies During Pregnancy, Toxic Shock Syndrome, Acute Treatment:** These conditions of approval were added to the policy.<br><br>**Autoimmune Hemolytic Anemia: Dosing and approval duration was updated.** | 04/10/2026 |


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| Policy revision | **Dermatomyositis or Polymyositis**: Added "myositis" wording to autoantibody testing. Added the wording "nonsteroidal" to immunosuppressive agent criteria.<br><br>**Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrand Pemphigoid [Cicatricial Pemphigoid], and Epidermolysis Bullosa Acquisita)**: Added the wording "nonsteroidal" to immunosuppressive agent criteria.<br><br>**Guillain Barre Syndrome**: Added "this is to provide one course of therapy" to the continuation criterion.<br><br>Removed the word "Recurrent" from **Human Immunodeficiency Virus, to Prevent Recurrent Infections**.<br><br>**Lambert-Eaton Myasthenic Syndrome (LEMS)**: Added the wording "nonsteroidal" to the immunosuppressive agent criteria.<br><br>**Myasthenia Gravis**: Added approval criterion for patient with myasthenic crisis or impending myasthenic crisis. Added the wording "nonsteroidal" to the immunosuppressive agent criteria.<br><br>**Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)**: Added the wording "nonsteroidal" to the immunosuppressive agent criteria. | 06/09/2026 |
| Policy review | No criteria changes, CMS surveillance review | 07/09/2026 |
| Policy revision | **Primary Immunodeficiencies**: Removed requirement for common variable immunodeficiency (CVID) that patient has recurrent infections. Removed 'unspecified hypogammaglobulinemia' from the criteria. For the criterion, patient has an impaired antibody response (i.e., failure to produce antibodies to specific antigens), 'that is' (i.e.) was replaced with 'for example' (e.g.).<br><br>**Myasthenia Gravis**: The Initial Therapy for Maintenance criteria was updated. The following criteria were removed: patient has refractory myasthenia gravis, patient has tried an acetylcholinesterase inhibitor, and patient has tried an immunosuppressive therapy with at least one of the following agents: azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, tacrolimus AND has had an inadequate response. The following criteria were added: Patient has tried at least one of the following medications for myasthenia gravis: a complement inhibitor, a neonatal Fc receptor blocker, or a CD19-directed monoclonal antibody OR according to the prescriber, these therapies are not clinically appropriate for the patient. Examples of each class of medication were also added in a note; OR the patient failed to respond to, or has intolerable side effects to acetylcholinesterase inhibitors AND is either refractory to corticosteroids over a 6 week period, has been unable to successfully taper corticosteroids below moderately high doses, or has developed severe side effects due to steroid therapy AND has failed at least one immunosuppressive agent (e.g., azathiprime, methotrexate, cyclophosphamide, cyclosporine). | 09/16/2026 |


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