Medical Policy:

IVIG – IMMUNE GLOBULINS (immunoglobulin) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.86	March 17, 2025	

Length of Authorization

1. Initial and renewal authorization periods vary by specific covered indication.
2. The initial authorization will be provided up to 6 months unless otherwise specified and may be renewed.

Dosing Limits [Medical Benefit]

A. Max Units (per dose and over time):

Indication	Billable Units	Max Units Per # days (unless otherwise specified)
PID and Supportive Care after Rethymic transplant	180	21
IgG Subclass Deficiency	90	14
CIDP	Load: 460	5
	Maintenance: 230	21

Immune thrombocytopenia/ITP	460	28
FAIT	230	7
Kawasaki's Disease (*Pediatric Patients only*)	260	2 doses only
Multifocal Motor Neuropathy	460	28
CLL/MM	90	21
ALL	90	21
HIV (Pediatric Patients only)	47	28
Guillain-Barre	460	5 (*for two courses only)*
Myasthenia Gravis	460	28
Auto-immune blistering diseases	460	28
Allogeneic Bone Marrow or Stem Cell Transplant	Load: 120	7 (for 90 days)
	Maintenance: 120	21
Dermatomyositis/Polymyositis	460	28
Complications of transplanted solid organ *(kidney, liver, lung, heart and pancreas transplants)*	460	28
Stiff Person Syndrome	460	28
Toxic shock syndrome	460	5 *(for one cycle only)*
NAIT	20	2 doses only
Management of Immune Checkpoint Inhibitor Related Toxicity	460	5 *(for one cycle only)*
Management of CAR T-Cell-Related Toxicity	120	28

Guideline

I. Initial Approval Criteria

****For Medicare members: IVIG- please refer to our separate LCD/NCD Medicare criteria**

Intravenous Immune Globulins may be considered medically necessary if one of the below conditions are met **AND** use is consistent with the medical necessity criteria that follows:

The following indications require IVIG to be requested by one of the following specialists:

1. **Primary immunodeficiency (PID) and Chronic lymphocytic leukemia**
   - Allergist/Immunologist, Hematologist/Oncologist, or Infectious Disease Specialist
2. **Idiopathic thrombocytopenia purpura (ITP)**
   - Hematologist/Oncologist
3. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Guillain-Barre Syndrome (Acute inflammatory polyneuropathy), Multifocal Motor Neuropathy, Myasthenia Gravis, and Relapsing-Remitting Multiple Sclerosis**
   - Neurologist
4. **Dermatomyositis/Polymyositis**

- Dermatologist or Rheumatologist

Coverage is provided in the following conditions:

Primary immunodeficiency (PID) †

Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [***list not all inclusive***]

1. Patient's IgG level is < 200 mg/dL **OR** both of the following
   a. Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
      i. Four or more ear infections within 1 year
      ii. Two or more serious sinus infections within 1 year
      iii. Two or more months of antibiotics with little effect
      iv. Two or more pneumonias within 1 year
      v. Recurrent or deep skin or organ abscesses
      vi. Persistent thrush in the mouth or fungal infections on the skin
      vii. Need for intravenous antibiotics to clear infections
      viii. Two or more deep-seated infections including septicemia
      ix. Family history of PID; ; **AND**
   b. The patient has a deficiency in producing antibodies in response to vaccination; **AND**
      i. Titers were drawn before challenging with vaccination; **AND**
      ii. Titers were drawn between 4 and 8 weeks of vaccination

IgG Subclass Deficiency ‡

1. Patient has an IgG level < 400 mg/dL; **AND**
2. Patient has a history of recurrent infections; **AND**
3. Patient is receiving prophylactic antibiotic therapy

Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP) †

For acute ITP

1. To manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30 X 10^9/L); **OR**
2. To increase platelet counts prior to invasive surgical procedures such as splenectomy. (Platelets less than 100 X 10^9/L); **OR**
3. Patient has severe thrombocytopenia (platelet counts less than 20 X 10^9/L) and is considered to be at risk for intracerebral hemorrhage

Note: Authorization is valid for 1 month only and cannot be renewed

Chronic Immune Thrombocytopenia (CIT):

1. The patient is at increased risk for bleeding as indicated by a platelet count less than 30 X 10^9/L; **AND**
2. History of failure, contraindication, or intolerance to corticosteroids; **AND**
3. Duration of illness > 6 months; **AND**
4. Member age ≥ 2 years

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) †

1. Patient's disease course is progressive or relapsing and remitting for 2 months or longer; **AND**
2. Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
3. Electrodiagnostic testing indicating demyelination; **AND**
    a. Partial motor conduction block in at least two motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
    b. Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
    c. Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
    d. Reduced motor conduction velocity in at least 2 motor nerves; **OR**
    e. Prolonged distal motor latency in at least 2 motor nerves; **OR**
    f. Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
    g. Prolonged F wave latency in at least 2 motor nerves; **AND**
4. Refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; **AND**
5. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Note: Initial authorization is valid for 3 months

Guillain-Barre Syndrome (Acute inflammatory polyneuropathy) ‡

1. Disease is severe (i.e., patient requires assistance to ambulate); **AND**
2. Onset of symptoms are recent (i.e., less than 1 month); **AND**
3. Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
4. Patient diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; **AND**
5. Approval will be granted for a maximum of 2 rounds of therapy within 6 weeks of onset

Note: Authorization is valid for 2 months only and cannot be renewed

Multifocal Motor Neuropathy †

1. Patient has progressive, focal, asymmetric weakness (without sensory symptoms) for > 1 month; **AND**
2. Complete or partial conduction block or abnormal temporal dispersion conduction must be present in at least 2 motor nerves **AND**
3. Patient has normal sensory nerve conduction on all nerves tested; **AND**
4. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Note: Initial authorization is valid for 3 months

HIV infected children: Bacterial control or prevention †‡

1. Patient < 13 years of age; **AND**
2. Patient's IgG level is less than 400 mg/dL

Myasthenia Gravis ‡

1. Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
2. Patient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
3. Patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); **AND**
4. Patient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.)

Note: Authorization is valid for 1 course per month and it can be renewed

Dermatomyositis †/Polymyositis ‡

1. Patient has severe active disease; **AND**
2. Patient has proximal weakness in all upper and/or lower limbs; **AND**
3. Diagnosis has been confirmed by muscle biopsy; **AND**
4. Patient has failed a trial of corticosteroids (i.e., prednisone); **AND**
5. Patient has failed a trial of an immunosuppressant (e.g., methotrexate, azathioprine, etc.); **AND**
6. Patient will be on combination therapy with corticosteroids or other immunosuppressants; **AND**
7. Patient has a documented baseline physical exam and muscular strength/function

Note: Initial authorization is valid for 3 months

Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant ‡

Coverage is provided for one or more of the following (list not all-inclusive):

1. Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation
2. Treatment of antibody-mediated rejection of solid organ transplantation
3. Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus)

Stiff-Person Syndrome ‡

1. Patient has anti-glutamic acid decarboxylase (GAD) antibodies; **AND**
2. Patient has failed > 2 of the following treatments: benzodiazepines (e.g., diazepam, clonazepam, alprazolam, lorazepam, oxazepam, temazepam, etc.), anti-spasticity agents (e.g., baclofen, tizanidine, etc.) or anti-epileptics (e.g., gabapentin, valproate, tiagabine, levetiracetam, etc.); **AND**
3. Patient has a documented baseline on physical exam

Allogeneic Bone Marrow or Stem Cell Transplant † ‡

1. Used for prevention of acute Graft-Versus-Host-Disease (aGVHD) or infection; **AND**
2. Patient's bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; **AND**
3. Patient's IgG level is less than 400 mg/dL

Note: Initial authorization is valid for 3 months

Kawasaki's disease (Pediatric) †

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

Fetal alloimmune thrombocytopenia (FAIT) ‡

1. Patient has a history of one or more of the following:
    a. Previous FAIT pregnancy
    b. Family history of the disease
    c. Screening reveals platelet alloantibodies

Note: Authorization is valid through the delivery date only and cannot be renewed

Neonatal Alloimmune Thrombocytopenia ‡

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

Auto-immune Mucocutaneous Blistering Diseases ‡

1. Patient has been diagnosed with one of the following:
    a. Pemphigus vulgaris
    b. Pemphigus foliaceus
    c. Bullous Pemphigoid
    d. Mucous Membrane Pemphigoid (a.k.a. Cicatricial Pemphigoid)
    e. Epidermolysis bullosa aquisita
    f. Pemphigus gestationis (Herpes gestationis)
    g. Linear IgA dermatosis; **AND**
2. Patient has severe disease that is extensive and debilitating; **AND**
3. Diagnosis has been confirmed by biopsy; **AND**
4. Patient's disease is progressive; **AND**
5. Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); **AND**
6. Patient has a documented baseline on physical exam

Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL) ‡

1. Used for prevention of infection; **AND**
2. Patient's IgG level is less than 400 mg/dL

Acquired Immune Deficiency secondary to Chronic lymphocytic leukemia † or Multiple Myeloma † ‡

1. Patient's IgG level is <200 mg/dL **OR**
2. Patient has an IgG level < 500 mg/dL; AND
    a. Patient has recurrent sinopulmonary infections requiring IV antibiotics or hospitalization; **OR**
3. Patient meets both of the following:
    a. Patient has a history of multiple hard to treat infections as indicated by at least one of the following:
        i. Four or more ear infections within 1 year
        ii. Two or more serious sinus infections within 1 year

iii. Two or more months of antibiotics with little effect
iv. Two or more pneumonias within 1 year
v. Recurrent, deep skin or organ abscesses
vi. Persistent thrush in the mouth or fungal infections on the skin
vii. Need for intravenous antibiotics to clear infections
viii. Two or more deep-seated infections including septicemia; **AND**

b. The patient has a deficiency in producing antibodies in response to vaccination; **AND**
   i. Titers were drawn before challenging with vaccination; **AND**
   ii. Titers were drawn between 4 and 8 weeks of vaccination

Note: other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis

Toxic Shock Syndrome ‡

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

Management of Immune-Checkpoint-Inhibitor Related Toxicity ‡

1. Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, retifanlimab, etc.); **AND**
2. Patient has one of the following toxicities related to their immunotherapy:
   1. Severe (G3) or life-threatening (G4) bullous dermatitis as an adjunct to rituximab
   2. Stevens-Johnson syndrome (SJS)
   3. Toxic epidermal necrolysis (TEN)
   4. Severe (G3-4) myasthenia gravis
   5. Demyelinating disease (optic neuritis, transverse myelitis, acute demyelinating encephalomyelitis)
   6. Myocarditis as further intervention if no improvement within 24-48 hours of starting pulse-dose methylprednisolone
   7. Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-dose methylprednisolone
   8. Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids
   9. Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone
   10. Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present
   11. Moderate, severe, or life-threatening steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids

Management of CAR T-Cell-Related Toxicity ‡

1. Patient has been receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**

a. Used for the management of G4 cytokine release syndrome (CRS) that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); **OR**

b. Patient has hypogammaglobulinemia as confirmed by serum IgG levels <600 mg/dL and serious or recurrent infections; **OR**

2. Patient has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); **AND**

    a. Used for the management of G4 cytokine release syndrome (CRS) that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); **OR**

    b. Patient has hypogammaglobulinemia as confirmed by serum IgG levels <400 mg/dL; **OR**

3. Used as prophylactic therapy prior to receiving treatment with anti-CD19 or BCMA-targeted CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, ciltacabtagene autoleucel, etc.); **AND**

    a. Patient has hypogammaglobulinemia as confirmed by serum IgG levels ≤400 mg/dL and serious, persistent, or recurrent bacterial infections

Supportive Care after Rethymic transplant ‡

1. Used as immunoglobulin replacement therapy in pediatric patients with congenital athymia after surgical implantation of Rethymic; OR
2. Used as re-initiation of treatment 2 months after stopping immunoglobulin replacement therapy in pediatric patients who have an IgG trough level lower than normal range for age

PANDAS/PANS

As per Massachusetts DOI Bulletin 2021-06, coverage for the following indication will be covered for Massachusetts residents under the Commercial line of business, starting 1/1/2022:

1. Treatment of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS).

*For Reference Use Only				
Brand Name/ Formulation	**FDA Indication**	**Contraindications**	**Product Specs**	**Comments**
Asceniv (liquid)	PID ((≥12 yo)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA:** ≤200 mcg/Ml **Osmolality**: 370 to 510 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Alyglo 10%	PID (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA:** ≤100 mcg/mL **Osmolality:** N/A **Stabilizer:** Glycine	
Bivigam 10% (liquid)	PID (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: ≤200 mcg/mL **Osmolality**: 370 to 510 mOsm/kg	

			Stabilizer: glycine	
Flebogamma 5% (liquid)	PID (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <50 mcg/mL **Osmolarity**: 240 to 370 mOsm/kg **Stabilizer**: sorbitol	
Flebogamma 10% (liquid)	PID (peds ≥2) cITP (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <32 mcg/mL **Osmolarity**: 240 to 370 mOsm/L **Stabilizer**: sorbitol	
Gammagard 10% (liquid)	PID (peds ≥2) MMN (adults) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 37 mcg/mL **Osmolality**: 240 to 300 mOsm/kg **Stabilizer**: glycine	May be used SC (see policy for criteria
Gammagard S/D 5% (lyophilized)	PID (peds ≥2) cITP (adult) CLL Kawasaki *(peds)*	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA:** ≤2.2 mcg/mL **Osmolality:** 636 mOsm/L **Stabilizer:** glycine	Contains some sugar (20mg/mL when prepared)
Gammaked 10% (liquid)	PID (peds ≥2) aITP or cITP (peds/adults) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 46 mcg/mL **Osmolality**: 258 mOsm/kg **Stabilizer**: glycine	May be used SC (see policy for criteria
Gammaplex 5% (liquid)	PID (peds ≥2) cITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Fructose intolerance	**IgA**: <10 mcg/mL **Osmolality**: 420 to 500 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Gammaplex 10% (liquid)	PID (peds >2) cITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <20 mcg/mL **Osmolality**: 280 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Gamunex-C (liquid)	PID (peds ≥2) aITP or cITP (peds/adults) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 46 mcg/mL **Osmolality**: 258 mOsm/kg **Stabilizer**: glycine	May be used SC (see policy for criteria
Octagam 5% (liquid)	PID (peds≥6)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Corn allergy	**IgA:** ≤100 mcg/mL **Osmolality:** 310 to 380 mOsm/kg **Stabilizer:** maltose	
Octagam 10% (liquid)	cITP (adults) Dermatomyositis (adult)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 106 mcg/mL **Osmolality**: 310 to 380 mOsm/kg **Stabilizer**: maltose	
Panzyga 10% (liquid)	PID (peds ≥2) cITP (adults) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA:** ≤100 mcg/mL **Osmolality:** 240 to 310 mOsm/kg **Stabilizer:** glycine	
Privigen 10% (liquid)	PID (peds >3) cITP (ped ≥15) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Hyperprolinemia	**IgA**: ≤25 mcg/mL **Osmolality**: 320 mOsm/kg **Stabilizer**: L-proline	
Yimmugo 10% (liquid)	PID (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA:** ≤300 mcg/mL **Osmolality:** 280 to 380 mOsm/kg **Stabilizer:** N/A	Does not contain carbohydrate stabilizers (e.g., sucrose, maltose) or preservatives

– All intravenous immunoglobulins are derived from human plasma. – Products with higher IgA content pose a greater risk for anaphylactic reactions, especially in patients with IgA deficiencies. – All products may predispose patients to nephrotoxicity especially those with sugar-based or proline-based stabilizers. To lower risks, lower concentration products and infusions rates should be used as well as using products with osmolality/osmolarity that is near physiologic range (around 300 mOsm/kg or mOsm/L). – Premedications (e.g., acetaminophen, antihistamine, etc.) are recommended to reduce the risk of infusion related reactions.
Adapted from: - *Professional Resource, Comparison of IVIG Products. Pharmacist's Letter/Prescriber's Letter. December 2016.* - *Product package inserts* - *Characteristics of Immunoglobulin Products Used to Treat Primary Immunodeficiencies (PI). Immune Deficiency Foundation. April 2020*

II. RENEWAL CRITERIA

Note: unless otherwise specified, renewal authorizations are provided for 1 year

Coverage can be renewed based upon the following criteria:

1. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: renal dysfunction and acute renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions/transfusion-related acute lung injury (TRALI), hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, volume overload, etc.; **AND**
2. BUN and serum creatinine have been obtained within the last 6 months and the concentration and rate of infusion have been adjusted accordingly; **AND**
3. Patient meets the disease-specific criteria identified below:

Primary Immunodeficiency (PID)

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection

IgG Subclass Deficiency

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection; **AND**
2. Continued treatment is necessary to decrease the risk of infection

Chronic Immune Thrombocytopenia/ITP

1. Disease response as indicated by the achievement and maintenance of a platelet count of at least 30 X 10^9/L and at least doubling the baseline platelet count

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP)

1. Acute ITP:
   a. May not be renewed
2. Chronic ITP:

a. Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 109/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy

1. Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

1. May not be renewed

Multifocal Motor Neuropathy

1. Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

HIV infected children: Bacterial control or prevention

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection; **AND**
2. Patient continues to be at an increased risk of infection necessitating continued therapy necessitating continued therapy as evidenced by an IgG level < 400 mg/dL

Myasthenia Gravis

1. May not be renewed

Dermatomyositis/Polymyositis

1. Patient had an improvement from baseline on physical exam and/or muscular strength and function

Note: Renewal authorizations are provided for 6 months

Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection; **AND**
2. Patient continues to be at an increased risk of infection necessitating continued therapy

Stiff Person Syndrome

1. Documented improvement from baseline on physical exam

Allogeneic Bone Marrow or Stem Cell Transplant

1. Patient continues to be at an increased risk of infection necessitating continued therapy as evidenced by an IgG level <400 mg/dL

Note: Renewal authorizations are provided for 3 months

Kawaski's Disease

1. May not be renewed

Fetal Alloimmune Thrombocytopenia (FAIT)

1. Authorization is valid through the delivery date only cannot be renewed

Neonatal Alloimmune Thrombocytopenia

1. May not be renewed

Auto-Immune Mucocutaneous Blistering Diseases

1. Documented improvement from baseline on physical exam

Note: Renewal authorizations are provided for 6 months

Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia or Multiple Myeloma

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection; **AND**
2. Patient continues to be at an increased risk of infection necessitating continued therapy

Acquired Immune Deficiency Secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL), or Multiple Myeloma (MM)

1. Disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection; **AND**
2. Continued treatment is necessary to decrease the risk of infection

Toxic Shock Syndrome

1. May not be renewed

Management of Immune Checkpoint Inhibitor related Toxicity ‡

1. May not be renewed.

Note: Renewal authorizations are provided for 6 months where applicable

Management of CAR T-Cell-Related Toxicity

1. Patient has received treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); AND
    a. Patient has serum IgG levels <600 mg/dl
2. Patient has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); **AND**
    a. Patient has serum IgG levels <400 mg/dL

Supportive Care after Rethymic transplant

1. Renewals for use as initial immunoglobulin replacement therapy will be authorized until all of the following criteria are met:
    a. Patient is no longer on immunosuppression (at least 10% of CD3+ T cells are naïve in phenotype); **AND**
    b. Patient is at least 9 months post-treatment; **AND**
    c. Patient's phytohemagglutinin (PHA) response within normal limits; **OR**
2. Renewals for use as re-initiation of treatment after stopping immunoglobulin replacement therapy for patients with an IgG trough level lower than normal range will be continued for 1 year before being retested using the above guidelines

Dosing Recommendations:

1. Patient's dose should be reduced to the lowest necessary to maintain benefit for their condition. Patients who are stable, or who have reached the maximum therapeutic response, should have a trial of dose reduction (e.g., 25-50% reduction in dose every 3 months).
2. Patients who have tolerated dose reduction and continue to show sustained improvement (i.e. remission) should have a trial of treatment discontinuation; with the following exceptions:
    a. PID would be excluded from a trial of discontinuation
    b. HIV-infected children should show satisfactory control of the underlying disease [e.g., undetectable viral load, CD4 counts elevated above 200 or >15% (ages 9 months – 5 years) on antiretroviral therapy, etc.]
    c. Solid organ transplant, CLL, and MM patients should not be at an increased risk of infection

III. Dosage/Administration

Dosing should be calculated using adjusted body weight if one or more of the following criteria are met:

1. Patient's body mass index (BMI) is 30 kg/m^2 or more; **OR**
2. Patient's actual body weight is 20% higher than his or her ideal body weight (IBW)

Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5-gram increment in adult patients):

Dosing formulas
BMI = 703 x (weight in pounds/height in inches^2)

IBW (kg) for males = 50 + [2.3 (height in inches – 60)]
IBW (kg) for females = 45.5 + [2.3 x (height in inches – 60)]
Adjusted body weight = IBW + 0.5 (actual body weight – IBW)

This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

Indication	Dose
PID	200 to 800 mg/kg every 21 to 28 days
IgG Subclass Deficiency	300 to 400 mg/kg every 14 days
CIDP	2 g/kg divided over 2-5 days initially, then 1 g/kg administered in 1-2 infusions every 21 days
ITP	2 g/kg divided over 5 days or 1 g/kg once daily for 2 consecutive days in a 28-day cycle
FAIT	1 g/kg/week until delivery
Kawasaki's Disease (Pediatric Patients)	1 g/kg to 2 g/kg x 1 dose, may be repeated once if needed
Multifocal Motor Neuropathy	Up to 2 g/kg divided over 5 days in a 28-day cycle
Acquired immune deficiency: CLL, SLL, MM and ALL	400 mg/kg every 3 to 4 weeks
Pediatric HIV	400 mg/kg every 2 to 4 weeks
Guillain-Barre	2 g/kg divided over 5 days x 1 course. May be repeated once within 6 weeks of onset if needed
Myasthenia Gravis	1-2 g/kg divided as either 0.5 g/kg daily x 2 days or 0.4 g/kg daily x 5 days x 1 course
Auto-immune blistering diseases	Up to 2 g/kg divided over 5 days in a 28-day cycle
Dermatomyositis/Polymyositis	2 g/kg divided over 2 to 5 days in a 28-day cycle
Allogenic Bone Marrow or Stem Cell Transplant	500 mg/kg once weekly x 90 days, then 500 mg/kg every 3 to 4 weeks
Complications of transplanted solid organ: (kidney, liver, lung, heart, pancreas) and bone marrow transplant	2 g/kg divided over 5 days in a 28-day cycle
Stiff Person syndrome	2 g/kg divided over 5 days in a 28-day cycle
Toxic shock syndrome	2 g/kg divided over 5 days x 1 course

Indication	Dose
Neonatal Alloimmune Thrombocytopenia	1 g/kg x 1 dose, may be repeated once if needed
Management of Immune Checkpoint Inhibitor Related Toxicity	2 g/kg divided over 5 days x 1 course
Management of CAR T-Cell Related Toxicity	400-500 mg/kg every 28 days
**Dosing for IVIG is highly variable depending on numerous patient specific factors, indication(s), and the specific product selected. For specific dosing regimens refer to current prescribing literature.*	

IV. Limitations/Exclusions

Immune Globulins (immunoglobulin) is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes and Applicable NDCs:

Drug	Manufacturer	J-Code C-Code	1 Billable Unit Equivalent	IgG (grams) per SDV	NDC
Asceniv	ADMA Biologics	J1554	500 mg	5	69800-0250-XX
			500 mg		
Alyglo	GC Biopharma	J1552	500mg	5,10,20	61476-0104-XX
Bivigam	ADMA Biologics	J1556	500 mg	5	59730-6502-XX
				10	59730-6503-XX
Flebogamma 10% DIF	Instituto Grifols, S.A.	J1572	500 mg	5, 10, 20	61953-0005-XX
Flebogamma 5% DIF				0.5, 2.5, 5, 10, 20	61953-0004-XX
Gamunex-C	Grifols Therapeutics	J1561	500 mg	1, 2.5, 5, 10, 20, 40	13533-0800-XX
Gammagard Liquid	Baxalta	J1569	500 mg	1, 2.5, 5, 10, 20, 30	00944-2700-XX
Gammagard S/D	Baxalta	J1566	500 mg	5	00944-2656-XX
				10	00944-2658-XX

Gammaked	Grifols Therapeutics	J1561	500 mg	1, 2.5, 5, 10, 20	76125-0900-XX
Gammaplex 5%	Bio Products Laboratory	J1557	500 mg	5, 10, 20	64208-8234-XX
Gammaplex 10%				5, 10, 20	64208-8235-XX
Octagam 10%	Octapharma USA Inc	J1568	500 mg	2, 5, 10, 20	68982-0850-XX
Octagam 5%				1, 2.5, 5, 10, 25	68982-0840-XX
Privigen	CSL Behring LLC	J1459	500 mg	5	44206-0436-XX
				10	44206-0437-XX
				20	44206-0438-XX
				40	44206-0439-XX
Panzyga	Octapharma USA Inc	J1576	500mg	1, 2.5, 5, 10, 20, 30	68982-0820-XX
Yimmugo	Biotest AG	J1599	N/A	5,10,20	83372-0605-XX
Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg	Pfizer U.S.	J1576	500mg	1, 2.5, 5, 10, 20, 30	00069-1011-XX 00069-1109-XX 00069-1224-XX 00069-1312-XX 00069-1415-XX 0006-1558-XX 68982-0822-XX

ICD-10 Diagnoses

Code	Description
A48.3	Toxic shock syndrome
B20	Human immunodeficiency virus (HIV) disease
B25.0	Cytomegaloviral pneumonitis
B25.1	Cytomegaloviral hepatitis
B25.2	Cytomegaloviral pancreatitis
B25.8	Other cytomegaloviral diseases
B25.9	Cytomegaloviral disease, unspecified
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck

C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C90.00	Multiple Myeloma not having achieved remission
C90.01	Multiple Myeloma in remission
C90.02	Multiple Myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.00	Acute lymphoblastic leukemia not having achieved remission
C90.01	Acute lymphoblastic leukemia, in remission
C90.02	Acute lymphoblastic leukemia, in relapse
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
D69.42	Congenital and hereditary thrombocytopenic purpura
D69.49	Other primary thrombocytopenia
D69.59	Other secondary thrombocytopenia
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	DiGeorge's syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D89.810	Acute graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease

D89.834	Cytokine release syndrome, grade 4
D89.839	Cytokine release syndrome, grade unspecified
G03.8	Meningitis due to other specified causes
G03.9	Meningitis, unspecified
G04.81	Other encephalitis and encephalomyelitis
G04.89	Other myelitis
G04.90	Encephalitis and encephalomyelitis, unspecified
G04.91	Myelitis, unspecified
G25.82	Stiff-man syndrome
G56.80	Other specified mononeuropathies of unspecified upper limb
G56.81	Other specified mononeuropathies of right upper limb
G56.82	Other specified mononeuropathies of left upper limb
G56.83	Other specified mononeuropathies of bilateral upper limbs
G56.90	Unspecified mononeuropathy of unspecified upper limb
G56.91	Unspecified mononeuropathy of right upper limb
G56.92	Unspecified mononeuropathy of left upper limb
G56.93	Unspecified mononeuropathy of bilateral upper limbs
G57.80	Other specified mononeuropathies of unspecified lower limb
G57.81	Other specified mononeuropathies of right lower limb
G57.82	Other specified mononeuropathies of left lower limb
G57.83	Other specified mononeuropathies of bilateral lower limbs
G57.90	Unspecified mononeuropathy of unspecified lower limb
G57.91	Unspecified mononeuropathy of right lower limb
G57.92	Unspecified mononeuropathy of left lower limb
G57.93	Unspecified mononeuropathy of bilateral lower limbs
G61.0	Guillain-Barre syndrome
G61.1	Serum neuropathy
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.82	Multifocal motor neuropathy
G61.89	Other inflammatory polyneuropathies
G61.9	Inflammatory polyneuropathy, unspecified
G62.89	Other specified polyneuropathies
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
H46.9	Unspecified optic neuritis
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
J70.2	Acute drug-induced interstitial lung disorders
J70.4	Drug-induced interstitial lung disorders, unspecified
L10.0	Pemphigus vulgaris
L10.2	Pemphigus foliaceous
L12.0	Bullous pemphigoid
L12.1	Cicatricial pemphigoid
L12.30	Acquired epidermolysis bullosa, unspecified

L12.31	Epidermolysis bullosa due to drug
L12.35	Other acquired epidermolysis bullosa
L12.5	Other acquired epidermolysis bullosa
L13.8	Other specified bullous disorders
L13.9	Bullous disorder, unspecified
L51.1	Stevens-Johnson syndrome
L51.2	Toxic epidermal necrolysis [Lyell
M30.3	Mucocutaneous lymph node syndrome [Kawasaki]
M33.00	Juvenile dermatomyositis, organ involvement unspecified
M33.01	Juvenile dermatomyositis with respiratory involvement
M33.02	Juvenile dermatomyositis with myopathy
M33.03	Juvenile dermatomyositis without myopathy
M33.09	Juvenile dermatomyositis with other organ involvement
M33.10	Other dermatomyositis, organ involvement unspecified
M33.11	Other dermatomyositis with respiratory involvement
M33.12	Other dermatomyositis with myopathy
M33.13	Other dermatomyositis without myopathy
M33.19	Other dermatomyositis with other organ involvement
M33.20	Polymyositis, organ involvement unspecified
M33.21	Polymyositis with respiratory involvement
M33.22	Polymyositis with myopathy
M33.29	Polymyositis with other organ involvement
M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified
M33.91	Dermatopolymyositis, unspecified with respiratory involvement
M33.92	Dermatopolymyositis, unspecified with myopathy
M33.93	Dermatopolymyositis, unspecified without myopathy
M33.99	Dermatopolymyositis, unspecified with other organ involvement
M36.0	Dermato(poly)myositis in neoplastic disease
M60.80	Other myositis, unspecified site
M60.811	Other myositis, right shoulder
M60.812	Other myositis, left shoulder
M60.819	Other myositis, unspecified shoulder
M60.821	Other myositis, right upper arm
M60.822	Other myositis, left upper arm
M60.829	Other myositis, unspecified upper arm
M60.831	Other myositis, right forearm
M60.832	Other myositis, left forearm
M60.839	Other myositis, unspecified forearm
M60.841	Other myositis, right hand
M60.842	Other myositis, left hand
M60.849	Other myositis, unspecified hand
M60.851	Other myositis, right thigh
M60.852	Other myositis, left thigh
M60.859	Other myositis, unspecified thigh
M60.861	Other myositis, right lower leg
M60.862	Other myositis, left lower leg

M60.869	Other myositis, unspecified lower leg
M60.871	Other myositis, right ankle and foot
M60.872	Other myositis, left ankle and foot
M60.879	Other myositis, unspecified ankle and foot
O26.40	Herpes gestationis, unspecified trimester
O26.41	Herpes gestationis, first trimester
O26.42	Herpes gestationis, second trimester
O26.43	Herpes gestationis, third trimester
O36.8210	Fetal anemia and thrombocytopenia, first trimester, not applicable or unspecified
O36.8211	Fetal anemia and thrombocytopenia, first trimester, fetus 1
O36.8212	Fetal anemia and thrombocytopenia, first trimester, fetus 2
O36.8213	Fetal anemia and thrombocytopenia, first trimester, fetus 3
O36.8214	Fetal anemia and thrombocytopenia, first trimester, fetus 4
O36.8215	Fetal anemia and thrombocytopenia, first trimester, fetus 5
O36.8219	Fetal anemia and thrombocytopenia, first trimester, other fetus
O36.8220	Fetal anemia and thrombocytopenia, second trimester, not applicable or unspecified
O36.8221	Fetal anemia and thrombocytopenia, second trimester, fetus 1
O36.8222	Fetal anemia and thrombocytopenia, second trimester, fetus 2
O36.8223	Fetal anemia and thrombocytopenia, second trimester, fetus 3
O36.8224	Fetal anemia and thrombocytopenia, second trimester, fetus 4
O36.8225	Fetal anemia and thrombocytopenia, second trimester, fetus 5
O36.8229	Fetal anemia and thrombocytopenia, second trimester, other fetus
O36.8230	Fetal anemia and thrombocytopenia, third trimester, not applicable or unspecified
O36.8231	Fetal anemia and thrombocytopenia, third trimester, fetus 1
O36.8232	Fetal anemia and thrombocytopenia, third trimester, fetus 2
O36.8233	Fetal anemia and thrombocytopenia, third trimester, fetus 3
O36.8234	Fetal anemia and thrombocytopenia, third trimester, fetus 4
O36.8235	Fetal anemia and thrombocytopenia, third trimester, fetus 5
O36.8239	Fetal anemia and thrombocytopenia, third trimester, other fetus
O36.8290	Fetal anemia and thrombocytopenia, unspecified trimester, not applicable or unspecified
O36.8291	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 1
P61.0	Transient neonatal thrombocytopenia
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XS	Complication of immune effector cellular therapy, sequela
T80.89XA	Other complications following infusion, transfusion and therapeutic injection, initial encounter
T80.89XS	Other complications following infusion, transfusion and therapeutic injection, sequela
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant

T86.20	Unspecified complication of heart transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.298	Other complications of heart transplant
T86.30	Unspecified complication of heart-lung transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.39	Other complications of heart-lung transplant
T86.40	Unspecified complication of liver transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.819	Unspecified complication of lung transplant
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
T86.899	Unspecified complication of other transplanted tissue
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.24	Encounter for aftercare following lung transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z48.290	Encounter for aftercare following bone marrow transplant
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.81	Bone marrow transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/17/2025	Updated Applicable Procedure Codes and Applicable NDCs, Max Units (per dose and over time) Updated *For Reference Use Only

		Addition of Alyglo, Yimmugo to policy Addition to PID: Persistent thrush in the mouth or fungal infections on the skin and Family history of PID. Addition of IgG Subclass Deficiency ‡ along with criteria Updated: Dermatomyositis † (Φ for Octagam 10%) / Polymyositis ‡ - update from Must be used as part of combination therapy with other agents to "Patient will be on combination therapy with corticosteroids or other immunosuppressants" Updated" Stiff-Person Syndrome - Patient has failed at least 2 of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam. Now reads "Patient has failed > 2 of the following treatments: benzodiazepines (e.g., diazepam, clonazepam, alprazolam, lorazepam, oxazepam, temazepam, etc.), anti-spasticity agents (e.g., baclofen, tizanidine, etc.) or anti-epileptics (e.g., gabapentin, valproate, tiagabine, levetiracetam, etc.)" Updated: Acquired Immune Deficiency secondary to Chronic lymphocytic leukemia † or Multiple Myeloma † ‡ to read Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia † ‡ or Small Lymphocytic Lymphoma ‡. Additional criteria updates. Updated: Management of Immune-Checkpoint-Inhibitor Related Toxicity ‡. Removed transverse myelitis. Replaced with Demyelinating disease (optic neuritis, transverse myelitis, acute demyelinating encephalomyelitis) Updated: Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present. Now states "Encephalitis used in combination with high-dose methylprednisolone for severe or progressing symptoms" Additional update to now read Moderate, severe, or life-threatening steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids Updated criteria for: Management of CAR T-Cell-Related Toxicity ‡ Addition of Supportive Care after Rethymic transplant ‡ with criteria. Updated renewal criteria for newly added and existing indications
EmblemHealth & ConnectiCare	4/8/2024	Added Statement: **For Medicare members: IVIG- please refer to our separate LCD/NCD Medicare criteria
EmblemHealth & ConnectiCare	2/16/2024	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	6/23/2023	Annual Review: Dosage Limits chart: added "Management of CAR T-Cell-Related Toxicity" Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): Initial Criteria: Removed "4. Cerebrospinal fluid analysis indicates the following: a. CSF white cell count of <10 cells/mm3; AND b. CSF protein is elevated; AND" Multifocal Motor Neuropathy: Initial Criteria: Removed " Patient has progressive, multi-focal, weakness (without sensory symptoms); AND" replaced with "Patient has progressive, focal, asymmetric weakness (without sensory

		symptoms) for > 1 month; AND" Removed "Complete or partial conduction block or abnormal temporal dispersion conduction must be present in at least 2 nerves with accompanying normal sensory nerve conduction study across the same nerve that demonstrated the conduction block; AND" Replaced with "Complete or partial conduction block or abnormal temporal dispersion conduction must be present in at least 2 motor nerves AND" Added "Patient has normal sensory nerve conduction on all nerves tested; AND" Allogeneic Bone Marrow or Stem Cell Transplant: Initial Criteria: Removed "Patient's BMT was allogeneic; AND" and replaced with "Patient's BMT or hematopoietic stem cell (HSCT) transplant was allogeneic; AND" Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL): Initial Criteria: Removed "Patient age is less than 18 years old; AND"Management of Immune-Checkpoint-Inhibitor Related Toxicity: Initial Criteria: Removed a. "Myasthenia gravis refractory to high-dose corticosteroids b. Severe transverse myelitis c. Moderate or severe Guillain-Barre Syndrome or peripheral neuropathy toxicity used in combination with pulse-dose methylprednisolone d. Severe pneumonitis refractory to methylprednisolone after 48 hours of therapy e. Encephalitis used in combination with pulse-dose methylprednisolone" Replaced with "a. Severe (G3) or life-threatening (G4) bullous dermatitis as an adjunct to rituximab b.Stevens-Johnson syndrome (SJS) c. Toxic epidermal necrolysis (TEN) d. Severe (G3-4) myasthenia gravis e. Transverse myelitis f. Myocarditis as further intervention if no improvement within 24-48 hours of starting pulse-dose methylprednisolone g. Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-dose methylprednisolone h. Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids i. Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone j. Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present k. Moderate, severe, or life-threatening steroid-refractory myalgias or myositis" Removed Relapsing-Remitting Multiple Sclerosis Initial Criteria Added: Management of CAR T-Cell-Related Toxicity Initial Criteria and renewal criteria Removed Carimune from Reference chart Chronic Immune Thrombocytopenia/ITP Renewal Criteria Removed: "Disease response as indicated by the achievement and maintenance of a platelet count of at least 50 X 10^9/L as necessary to reduce the risk for bleeding" Replaced with "Disease response as indicated by the achievement and maintenance of a

		platelet count of at least 30 X 10^9/L and at least doubling the baseline platelet count" HIV Infected Children Renewal Criteria: Added "necessitating continued therapy as evidenced by an IgG level < 400 mg/dL"
EmblemHealth & ConnectiCare	7/22/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	4/7/2022	Removed Site of Service language. Refer to Site of Service policy effective 7/1/2022
EmblemHealth & ConnectiCare	7/22/2021	Added PANDAS/PANS coverage as per Massachusetts DOI Bulletin 2021-06 for Massachusetts residents under the Commercial line of business, starting 1/1/2022
EmblemHealth & ConnectiCare	7/2/2021	Updated Asceniv code to J1554
EmblemHealth & ConnectiCare	4/6/2021	Removed BUN/SCr requirement from criteria
EmblemHealth & ConnectiCare	1/1/2021	Added C-Code: C9072 Injection, immune globulin (Asceniv), 500 mg
EmblemHealth & ConnectiCare	9/11/2020	Removed the following statement from Renewal criteria: Patient continues to meet criteria identified in section I above;
EmblemHealth & ConnectiCare	02/06/2020	For myasthenia gravis indication, we changed the approval from 1 course per 28 days and cannot be renewed. To 1 course per 28 days and it can be renewed on a case-by-case basis (approved in Medical Policy Subcommittee on 02/06/2020).
EmblemHealth & ConnectiCare	01/26/2020	Added Asceniv J-code J1599 and applicable NDC
EmblemHealth & ConnectiCare	09/11/2019	Added Mandatory Site of Service, effective 04/01/2020 (Effected lines of business: Commercial and Healthcare Exchange). Other lines of business pending further review.

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