POLICY Document for Intravenous Immune Globulin (IVIG)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 3: Initial Prior Authorization

Section 1: Site of Care

CareFirst Site of Care Criteria
Administration of Intravenous Immune Globulins

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

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT-HOSPITAL SETTING

This policy provides coverage for administration of Ig therapy in an outpatient hospital setting for 1 month when ANY of the following criteria are met:
A. The member is new to Ig therapy or is reinitiating therapy after not being on therapy for at least 6 months.
B. The member is switching to an Ig product that he/she has not received before.
C. The member has experienced a gap in Ig therapy for greater than 8 weeks.

This policy provides coverage for administration of infused Ig therapy in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:
A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member has developed IgA autoantibodies which increases the risk of infusion related reactions.
C. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
D. The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
E. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
F. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home
G. The member is less than 14 years of age.

For situations where administration of the Ig does not meet the criteria for outpatient hospital infusion, coverage for the Ig is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
B. Medical records supporting the member has developed IgA autoantibodies
C. Medical records supporting the member is medically unstable
D. Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
E. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
F. Records supporting alternative infusion sites are greater than 30 miles from the member's home.
G. Medical records supporting the member is new to therapy, switching to a new Ig product or has experience a gap in therapy

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

Intravenous Immune Globulin (IVIG):

Alyglo™, Asceniv™, Bivigam®, Flebogamma® DIF, Gammagard® Liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Octagam®, Panzyga®, and Privigen®

POLICY

III. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Primary immunodeficiency
   2. Idiopathic thrombocytopenic purpura (ITP)
   3. Chronic inflammatory demyelinating polyneuropathy (CIDP)
   4. Multifocal motor neuropathy
   5. Kawasaki syndrome
   6. B-cell chronic lymphocytic leukemia (CLL)
   7. Dermatomyositis

B. Compendial Uses
   1. Prophylaxis of bacterial infections in pediatric human immunodeficiency virus (HIV) infection
   2. Bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT)
   3. Polymyositis
   4. Myasthenia gravis
   5. Guillain-Barré syndrome
   6. Lambert-Eaton myasthenic syndrome
   7. Fetal/neonatal alloimmune thrombocytopenia

8. Parvovirus B19-induced pure red cell aplasia
9. Stiff-person syndrome
10. Management of immune checkpoint inhibitor-related toxicites
11. Acquired red cell aplasia
12. Acute disseminated encephalomyelitis
13. Autoimmune mucocutaneous blistering diseases
14. Autoimmune hemolytic anemia
15. Autoimmune neutropenia
16. Birdshot retinochoroidopathy
17. BK virus associated nephropathy
18. Churg-Strauss Syndrome
19. Enteroviral meningoencephalitis
20. Hematophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
21. Hemolytic disease of newborn
22. HIV-associated thrombocytopenia
23. Hyperimmunoglobulinemia E Syndrome
24. Hypogammaglobulinemia from chimeric antigen receptor T (CAR-T) therapy
25. Multiple myeloma
26. Neonatal hemochromatosis, prophylaxis
27. Opsoclonus-myoclonus
28. Paraneoplastic opsonus-myoclonus ataxia associated with neuroblastoma
29. Post-transfusion purpura
30. Rasmussen encephalitis
31. Renal transplantation from a live donor with ABO incompatibility or positive cross match
32. Secondary immunosuppression associated with major surgery, hematological malignancy, major burns, and collagen-vascular diseases
33. Solid organ transplantation, for allosensitized members
34. Toxic epidermal necrolysis and Stevens-Johnson syndrome
35. Toxic shock syndrome
36. Systemic lupus erythematosus (SLE)
37. Toxic necrotizing fasciitis due to group A streptococcus
38. Measles (Rubeola) prophylaxis
39. Tetanus treatment and prophylaxis
40. Varicella prophylaxis

All other indications are considered experimental/investigational and not medically necessary.

IV. DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. Primary immunodeficiency
   1. Diagnostic test results
      a. Copy of laboratory report with serum immunoglobulin levels: IgG, IgA, IgM, and IgG subclasses
      b. Vaccine response to pneumococcal polysaccharide vaccine (post-vaccination *Streptococcus pneumoniae* antibody titers)
      c. Pertinent genetic or molecular testing in members with a known genetic disorder
      d. Copy of laboratory report with lymphocyte subset enumeration by flow cytometry
   2. IgG trough level for those continuing with IG therapy

B. Myasthenia gravis
   1. Clinical records describing standard treatments tried and failed

C. Secondary hypogammaglobulinemia (e.g., CLL, BMT/HSCT recipients)
   1. Copy of laboratory report with pre-treatment serum IgG level

D. Chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN)

1. Pre-treatment electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS])

E. Dermatomyositis and polymyositis
   1. Clinical records describing standard treatments tried and failed
F. Lambert-Eaton Myasthenic Syndrome (LEMS)
   1. Neurophysiology studies (e.g., electromyography)
   2. A positive anti- P/Q type voltage-gated calcium channel antibody test
G. Idiopathic thrombocytopenic purpura
   1. Laboratory report with pre-treatment/current platelet count
   2. Chronic/persistent ITP: copy of medical records supporting trial and failure with corticosteroid or anti-D therapy (unless contraindicated)
H. Parvovirus B19-indicated Pure Red Cell Aplasia (PRCA)
   1. Copy of test result confirming presence of parvovirus B19
I. Stiff-person syndrome
   1. Anti-glutamic acid decarboxylase (GAD) antibody testing results
   2. Clinical records describing standard treatments tried and failed
J. Toxic shock syndrome or toxic necrotizing fasciitis due to group A streptococcus
   1. Documented presence of fasciitis (toxic necrotizing fasciitis due to group A streptococcus only)
   2. Microbiological data (culture or Gram stain)

V. CRITERIA FOR INITIAL APPROVAL

A. Primary Immunodeficiency

Initial authorization of 6 months may be granted for members with any of the following diagnoses:

1. Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia):
   a. Diagnosis confirmed by genetic or molecular testing, or
   b. Pretreatment IgG level < 200 mg/dL, or
   c. Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only)
2. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
   a. Diagnosis confirmed by genetic or molecular testing (if applicable), and
   b. History of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
   c. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
3. Common variable immunodeficiency (CVID):
   a. Age 2 years or older, and
   b. Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy), and
   c. Pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age, and
   d. History of recurrent bacterial infections, and
   e. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
4. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
   a. History of recurrent bacterial infections, and
   b. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A), and
   c. Any of the following pre-treatment laboratory findings:
      i. Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
      ii. Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
      iii. Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
      iv. IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels

v. Specific antibody deficiency: normal IgG, IgA and IgM levels

5. Other predominant antibody deficiency disorders must meet a., b., and c.i. in section 4. above.
6. Other combined immunodeficiency must meet criteria in section 2. above.

Re-authorization of 12 months may be granted when the following criteria are met:
1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy, AND
2. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication), OR
3. The prescriber will re-evaluate the dose of IG and consider a dose adjustment (when appropriate).

B. Myasthenia Gravis

1. Authorization of 1 month may be granted to members who are prescribed IG for worsening weakness, acute exacerbation, or in preparation for surgery.
   a. Worsening weakness includes an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, and limb weakness. Acute exacerbations include more severe swallowing difficulties and/or respiratory failure
   b. Pre-operative management (e.g., prior to thymectomy)
2. Authorization of 6 months may be granted to members with refractory myasthenia gravis who have tried and failed 2 or more standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab).

C. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

1. Initial authorization of 3 months may be granted when the following criteria are met:
   a. Disease course is progressive or relapsing/remitting for 2 months or longer
   b. Moderate to severe functional disability
   c. The diagnosis was confirmed by electrodiagnostic studies
2. Re-authorization of 6 months may be granted when the following criteria are met:
   a. Significant improvement in disability and maintenance of improvement since initiation of IG therapy
   b. IG is being used at the lowest effective dose and frequency

D. Dermatomyositis or Polymyositis

1. Initial authorization of 3 months may be granted when the following criteria are met:
   a. Member has at least 4 of the following:
      i. Proximal muscle weakness (upper or lower extremity and trunk)
      ii. Elevated serum creatine kinase (CK) or aldolase level
      iii. Muscle pain on grasping or spontaneous pain
      iv. Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
      v. Positive for anti-synthetase antibodies (e.g., anti-Jo-1, also called histadyl tRNA synthetase)
      vi. Non-destructive arthritis or arthralgias
      vii. Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method)
      viii. Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen), and
   b. Standard first-line treatments (corticosteroids) and second-line treatments (immunosuppressants) have been tried but were unsuccessful or not tolerated, or
   c. Member is unable to receive standard first-line and second-line therapy because of a contraindication or other clinical reason.
2. Re-authorization of 6 months may be granted when the following criterion is met:
   a. Significant improvement in disability and maintenance of improvement since initiation of IG therapy

E. Idiopathic Thrombocytopenic Purpura ITP/(Immune Thrombocytopenia)

1. Newly diagnosed ITP (diagnosed within the past 3 months) or initial therapy: authorization of 1 month may be granted when the following criteria are met:
   a. Children (< 18 years of age)
      i. Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding) or
      ii. High risk for bleeding* (see Appendix B), or
      iii. Rapid increase in platelets is required* (e.g., surgery or procedure)
   b. Adults (≥ 18 years of age)
      i. Platelet count < 30,000/mcL, or
      ii. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required*, and
      iii. Corticosteroid therapy is contraindicated and IG will be used alone or IG will be used in combination with corticosteroid therapy
2. Chronic/persistent ITP (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy: authorization of 6 months may be granted when the following criteria are met:
   a. Platelet count < 30,000/mcL, or
   b. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding* or rapid increase in platelets is required*, and
   c. Relapse after previous response to IG or inadequate response/intolerance/contraindication to corticosteroid or anti-D therapy
3. Adults with refractory ITP after splenectomy: authorization of 6 months may be granted when either of the following criteria is met:
   a. Platelet count < 30,000/mcL, or
   b. Significant bleeding symptoms
4. ITP in pregnant women: authorization through delivery may be granted to pregnant women with ITP.

* The member's risk factor(s) for bleeding (see Appendix B) or reason requiring a rapid increase in platelets must be provided.

F. B-cell Chronic Lymphocytic Leukemia (CLL)

1. Initial authorization of 6 months may be granted when all of the following criteria are met:
   a. IG is prescribed for prophylaxis of bacterial infections.
   b. Member has a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization.
   c. Member has a pretreatment serum IgG level <500 mg/dL.
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

G. Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients

1. Initial authorization of up to 6 months may be granted to pediatric members with HIV infection when any of the following criteria are met:
   a. IG is prescribed for primary prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL, or
   b. IG is prescribed for secondary prophylaxis of bacterial infections for members with a history of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period), or
   c. Member has failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine, or
   d. Member lives in an area where measles is highly prevalent and who have not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live, or
   e. Member has been exposed to measles and request is for a single dose, or
   f. Member has chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

H. Bone marrow transplant/hemopoietic stem cell transplant (BMT/HSCT)

1. Initial authorization of 6 months may be granted to members who are BMT/HSCT recipients when the following criteria are met:
   a. Therapy will be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic), septicemia, and other infections (e.g., cytomegalovirus infections [CMV], recurrent bacterial infection).
   b. Either of the following:
      i. IG is requested within the first 100 days post-transplant.
      ii. Member has a pretreatment serum IgG < 400 mg/dL.
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

I. Multifocal Motor Neuropathy (MMN)

1. Initial authorization of 3 months may be granted when the following criteria are met:
   a. Member experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in 2 or more nerves for at least 1 month
   b. The diagnosis was confirmed by electrodiagnostic studies
2. Re-authorization of 6 months may be granted when significant improvement in disability and maintenance of improvement have occurred since initiation of IG therapy

J. Guillain-Barre Syndrome (GBS)

Authorization of 1 month total may be granted for GBS when the following criteria are met:

1. Member has severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)
2. Onset of neurologic symptoms occurred less than 4 weeks from the anticipated start of therapy

K. Lambert-Eaton Myasthenic Syndrome (LEMS)

1. Initial authorization of 6 months may be granted for LEMS when the following criteria are met:
   a. Diagnosis has been confirmed by either of the following:
      i. Neurophysiology studies (e.g., electromyography)
      ii. A positive anti- P/Q type voltage-gated calcium channel antibody test
   b. Anticholinesterases (eg pyridostigmine) and amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) have been tried but were unsuccessful or not tolerated
   c. Weakness is severe or there is difficulty with venous access for plasmapheresis
2. Re-authorization of 6 months may be granted when member is responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

L. Kawasaki Syndrome

Authorization of 1 month may be granted for pediatric members with Kawasaki syndrome.

M. Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)

Authorization of 6 months may be granted for treatment of F/NAIT.

N. Parvovirus B19-induced Pure Red Cell Aplasia (PRCA)

Authorization of 6 months may be granted for severe, refractory anemia associated with bone marrow suppression, with parvovirus B19 viremia.

O. Stiff-person Syndrome

Authorization of 6 months may be granted for stiff-person syndrome when the following criteria are met:

1. Diagnosis has been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing
2. Member had an inadequate response to first-line treatment (benzodiazepines and/or baclofen)

P. Management of immune checkpoint inhibitor-related toxicities

Authorization of 1 month may be granted for management of immune checkpoint-inhibitor toxicities when all of the following criteria are met:

1. Member has experienced a moderate or severe adverse event to a PD-1 or PD-L1 inhibitor (e.g., pembrolizumab, nivolumab, atezolizumab, avelumab, durvalumab)
2. The offending medication has been held or discontinued
3. Member experienced one or more of the following adverse events: myocarditis, bullous dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, pneumonitis, myasthenia gravis, peripheral neuropathy, encephalitis, transverse myelitis, severe inflammatory arthritis, Guillain-Barre syndrome, or steroid-refractory myalgias or myositis

Q. Acquired Red Cell Aplasia
Authorization of 6 months may be granted for acquired red cell aplasia.

R. Acute Disseminated Encephalomyelitis
Authorization of 1 month may be granted for acute disseminated encephalomyelitis in members who have had an insufficient response or a contraindication to intravenous corticosteroid treatment.

S. Autoimmune Mucocutaneous Blistering Disease
Authorization of 6 months may be granted for autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita) when the following criteria are met:
1. Diagnosis has been proven by biopsy and confirmed by pathology report, and
2. Condition is rapidly progressing, extensive or debilitating, and
3. Member has failed or experienced significant complications (e.g., diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents).

T. Autoimmune Hemolytic Anemia
Authorization of 6 months may be granted for warm-type autoimmune hemolytic anemia in members who do not respond or have a contraindication to corticosteroids or splenectomy.

U. Autoimmune Neutropenia
Authorization of 6 months may be granted for autoimmune neutropenia where treatment with G-CSF (granulocyte colony stimulating factor) is not appropriate.

V. Birdshot Retinochoroidopathy
Authorization of 6 months may be granted for birdshot (vitiliginous) retinochoroidopathy that is not responsive to immunosuppressives (e.g., corticosteroids, cyclosporine).

W. BK Virus Associated Nephropathy
Authorization of 6 months may be granted for BK virus associated nephropathy.

X. Churg-Strauss Syndrome
Authorization of 6 months may be granted for severe, active Churg-Strauss syndrome as adjunctive therapy for members who have experienced failure, intolerance, or are contraindicated to other interventions.

Y. Enteroviral Meningoencephalitis
Authorization of 6 months may be granted for severe cases of enteroviral meningoencephalitis.

Z. Hematophagocytic Lymphohistiocytosis (HLH) or Macrophage Activation Syndrome (MAS)
Authorization of 6 months may be granted for treatment of hypogammaglobulinemia in HLH or MAS when total IgG is less than 400 mg/dL or two standard deviations below the mean for age.

AA. Hemolytic Disease of Newborn
Authorization of 6 months may be granted for isoimmune hemolytic disease in neonates.

BB. HIV-associated Thrombocytopenia

Authorization of 6 months may be granted for HIV-associated thrombocytopenia when the following criteria are met:

1. Pediatric members with IgG < 400 mg/dL and one of the following:
   a. 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent, or
   b. Received 2 doses of measles vaccine and lives in a region with a high prevalence or measles, or
   c. HIV-associated thrombocytopenia despite anti-retroviral therapy, or
   d. Chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy, or
   e. T4 cell count ≥ 200/mm^3
2. Adult members with significant bleeding, platelet count < 20,000/mcL, and failure of RhIG in Rh-positive patients

CC. Hyperimmunoglobulinemia E Syndrome

Authorization of 6 months may be granted to treat severe eczema in hyperimmunoglobulinemia E syndrome.

DD. Hypogammaglobulinemia from CAR-T therapy

Authorization of 6 months may be granted for members with IgG < 400 mg/dL receiving treatment with CAR-T therapy (including but not limited to idecabtagene vicleucel [Abecma], tisagenlecleucel [Kymriah], or axicabtagene ciloleucel [Yescarta]).

EE. Multiple Myeloma

Authorization of 6 months may be granted for multiple myeloma in members who have recurrent, serious infections despite the use of prophylactic antibiotics.

FF. Neonatal Hemochromatosis

Authorization of 6 months may be granted for prophylaxis in members who are pregnant with a history of pregnancy ending in documented neonatal hemochromatosis.

GG. Opsoclonus-myoclonus

Authorization of 6 months may be granted for treatment of either of the following:

1. Paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma
2. Refractory opsoclonus-myoclonus, as last-resort treatment

HH. Post-transfusion Purpura

Authorization of 1 month may be granted for post-transfusion purpura.

II. Rasmussen Encephalitis

Authorization of 6 months may be granted for Rasmussen encephalitis in members whose symptoms do not improve with anti-epileptic drugs and corticosteroids.

JJ. Renal Transplantation

Authorization of 6 months may be granted for a member undergoing renal transplantation from a live donor with ABO incompatibility or positive cross match.

KK. Secondary Immunosuppression Associated with Major Surgery, Hematological Malignancy, Major Burns, and Collagen-Vascular Diseases

Authorization of 6 months may be granted to prevent or modify recurrent bacterial or viral infections in members with secondary immunosuppression (IgG < 400 mg/dL) associated with major surgery, hematological malignancy, extensive burns, or collagen-vascular disease.

LL. Solid Organ Transplantation

Authorization of 6 months may be granted for solid organ transplantation for allosensitized members.

MM. Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome

Authorization of 1 month may be granted for severe cases of toxic epidermal necrolysis or Stevens-Johnson syndrome.

NN. Toxic Shock Syndrome
Authorization of 1 month may be granted for staphylococcal or streptococcal toxic shock syndrome when the infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or the member has persistent oliguria with pulmonary edema.

OO. Systemic Lupus Erythematosus
Authorization of 6 months may be granted for severe, active SLE in members who have experienced inadequate response, intolerance or have a contraindication to first and second line therapies (e.g., hydroxychloroquine, glucocorticoids, anifrolumab, rituximab).

PP. Measles (Rubeola) prophylaxis
Authorization of 1 month may be granted for postexposure prophylaxis to prevent or modify symptoms of measles (rubeola) in susceptible members exposed to the disease less than 6 days previously.

QQ. Tetanus treatment and prophylaxis
Authorization of 1 month may be granted for treatment or postexposure prophylaxis of tetanus as an alternative when tetanus immune globulin (TIG) is unavailable.

RR. Varicella prophylaxis
Authorization of 1 month may be granted for postexposure prophylaxis of varicella in susceptible individuals when varicella-zoster immune globulin (VZIG) is unavailable.

SS. Toxic Necrotizing Fasciitis Due To Group A Streptococcus
Authorization of 1 month may be granted for members with fasciitis due to invasive streptococcal infection.

VI. CONTINUATION OF THERAPY

Authorization may be granted for continuation of therapy when either the following criteria is met:
a. For conditions with reauthorization criteria listed under section III: Members who are currently receiving IG therapy must meet the applicable reauthorization criteria for the member's condition.
b. For all other conditions, all members (including new members) must meet initial authorization criteria.

VII. APPENDICES

Appendix A: Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine
- Age 2 years and older: impaired antibody response demonstrated to vaccination with a pneumococcal polysaccharide vaccine
- Not established for children less than 2 years of age
- Excludes the therapy initiated in the hospital setting

Appendix B: Examples of Risk Factors for Bleeding (not all inclusive)
- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (eg, peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (eg, construction worker, fireman, professional athlete)

Initial Prior Authorization Universal States Mandate PANDAS PANS Immune Globulin (Human) and CD20-Directed Cytolytic Antibody

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Immune Globulin (Human)

Brand Name
Alyglo
Asceniv
Bivigam
Cutaquig
Cuvitru
Flebogamma
Gamastan
Gammagard Liquid
Gammagard S/D
Gammaked
Gammaplex
Gamunex -C
Hizentra
Hyqvia
Octagam
Panzyga
Privigen
Xembify
Yimmugo

CVS/caremark

CD20-Directed Cytolytic Antibody

Brand Name
Riabni
Rituxan
Ruxience
Truxima

Coverage Criteria

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections

Authorization may be granted when the patient has a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections.

Pediatric acute onset neuropsychiatric syndrome

Authorization may be granted when the patient has a diagnosis of pediatric acute onset neuropsychiatric syndrome.

Autoimmune encephalitis

Authorization may be granted when the patient has a diagnosis of autoimmune encephalitis.

Duration of Approval (DOA)

- 3117-A: DOA: 6 months

REFERENCES:

SECTION 1

1. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics Inc. March 2024.
2. Flebogamma 10% DIF [package insert]. Barcelona, Spain: Instituto Grifols, SA.; September 2019.
3. Flebogamma 5% DIF [package insert]. Barcelona, Spain: Instituto Grifols, SA.; September 2019.
4. Gammagard Liquid [package insert]. Lexington, MA: Baxalta US Inc; January 2024.
5. Gammagard S/D IgA less than 1 mcg/mL [package insert]. Lexington, MA:: Baxalta US Inc; March 2021.
6. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
7. Gammaplex 5% [package insert]. Durham, NC: Bio Products Laboratory Inc; November 2021.
8. Gammaplex 10% [package insert]. Durham, NC: Bio Products Laboratory Inc; November 2021.
9. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
10. Octagam 10% [package insert]. Paramus, NJ: Octapharma USA, Inc.; September 2023.
11. Octagam 5% [package insert]. Paramus, NJ: Octapharma USA, Inc.; September 2023.
12. Privigen [package insert]. Bern, Switzerland: CSL Behring AG; March 2022.

13. Panzyga [package insert]. Lingolsheim, France: Octapharma SAS, Inc; February 2021.
14. Asceniv [package insert]. Kankakee, IL: CSL Behring LLC; April 2019.
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