DEPARTMENT:	Utilization Management
SUBJECT:	IVIG
PRODUCT LINE:	All
POLICY NUMBER:	UM129
ORIGINAL POLICY EFFECTIVE DATE:	12/12/2025
LAST REVISED DATE:	N/A
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SCOPE:
To ensure Group Health Cooperative-Eau Claire administers IVIG and subcutaneous IG consistently and according to nationally recognized clinical practice guidelines.

POLICY:
Immunoglobin (SQ and IV) requires prior authorization. Both IV and SQ immunoglobin can be administered in the home setting. SQ can be self-administered in the home setting.

PROCEDURE:
Immunoglobin is medically necessary for the following conditions and when coverage criteria are met.

Dermatology

Autoimmune bullous diseases [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]

1. Diagnosis of an autoimmune bullous disease; and
2. Extensive and debilitating disease; and
3. Failure of more conservative and cost-effective treatments including systemic corticosteroids with concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil)

Toxic epidermal necrolysis or Stevens-Johnson syndrome

1. Diagnosis of Stevens-Johnson Syndrome; and
2. Extensive disease; and
3. Failure of corticosteroids, cyclosporine, and TNF-alpha inhibitors (etanercept, infliximab)

Hematology

Feto-neonatal alloimmune thrombocytopenia (AIT)

For Pregnant Women

1. Diagnosis of feto-neonatal alloimmune thrombocytopenia (AIT); and
2. One or more of the following:
    a. Previously affected pregnancy
    b. Family history of the disease
    c. Platelet alloantibodies found on screening

For Newborns

1. Diagnosis of feto-neonatal alloimmune thrombocytopenia; and
2. Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

Thrombocytopenia

1. Must have a diagnosis of Idiopathic thrombocytopenic purpura (ITP), posttransfusion purpura, HIV, or Hepatitis C virus; and

2. Documented platelet count < 50,000/ L (obtained within the past 30 days); and
3. Failure of corticosteroid and other therapies indicated for the specific disease state such as antiviral therapy and
4. Failure of splenectomy for ITP

Warm autoimmune hemolytic anemia

1. Diagnosis of warm autoimmune hemolytic anemia; and
2. Other types of autoimmune hemolytic anemia have been ruled out; and
3. Failure of glucocorticoids (prednisone, methylprednisolone); and
4. Failure of immunosuppressive agents including azathioprine, cyclophosphamide, cyclosporin A, danazol, mycophenolate mofetil, sirolimus, Tavalisse (fostamatinib); and
5. Continues to be transfusion dependent after immunosuppressive agents

Neurology

Acute disseminated encephalomyelitis

1. Diagnosis of acute disseminated encephalomyelitis; and
2. Failure of intravenous glucocorticoids

Chronic inflammatory demyelinating polyneuropathy

1. Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by all of the following:
    a. Progressive symptoms present for at least 2 months; and
    b. Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb; and
    c. Electrodiagnostic findings indicating at least one of the following criteria are present:
        i. Motor distal latency prolongation in 2 nerves
        ii. Reduction of motor conduction velocity in 2 nerves
        iii. Prolongation of F-wave latency in 2 nerves
        iv. Absence of F-waves in at least 1 nerve
        v. Partial motor conduction block of at least 1 motor nerve
        vi. Abnormal temporal dispersion in at least 2 nerves
        vii. Distal CMAP duration increase in at least 1 nerve

Encephalitis, immune checkpoint inhibitor-induced, severe, or progressive

1. Diagnosis of encephalitis, immune checkpoint inhibitor-induced, severe, or progressive; and
2. Failure of glucocorticoids (e.g., methylprednisolone); and
3. The use of the immune checkpoint inhibitor has been interrupted; and

Guillain-Barré syndrome (GBS)

1. Diagnosis of Guillain-Barré Syndrome; and
2. Severe disease requiring aid to walk; and
3. Onset of neuropathic symptoms within the last four weeks.

Lambert-Eaton myasthenic syndrome

1. Diagnosis of Lambert-Eaton myasthenic syndrome; and
2. Failure of corticosteroids; and
3. Failure of immunomodulator monotherapy such as azathioprine
4. Concomitant immunomodulator therapy (azathioprine or corticosteroids) for long-term management

Lennox Gastaut syndrome

1. Diagnosis of Lennox Gastaut syndrome; and
2. Failure of traditional anti-epileptic pharmacotherapy (multiple adequate trials of different classes must be tried)

Multifocal motor neuropathy

1. Diagnosis of multifocal motor neuropathy as confirmed by all of the following:
    a. Weakness with slowly progressive or stepwise progressive course over at least one month; and
    b. Asymmetric involvement of two or more nerves; and
    c. Absence of motor neuron signs and bulbar signs

Multiple sclerosis, relapsing forms

Note: Treatment of any other type of multiple sclerosis with immune globulin is not supported by clinical evidence.

1. Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); and
2. Must have failure of other MS treatments; and
3. Will be reviewed on a case-by-case basis.

Myasthenia Gravis

Note: Evidence does not support the use of immune globulin maintenance therapy for ocular myasthenia.

1. Diagnosis of generalized myasthenia gravis; and
2. Significant functional disability that prevents physical activity; and
3. Failure of corticosteroids; and
4. Failure of immunomodulator therapies including azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, and methotrexate. Medication trials must have had adequate doses and duration):

Neuromyelitis optica

1. Diagnosis of neuromyelitis optica spectrum disorder by a neurologist; and
2. Serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies has been performed; and
3. If anti-aquaporin-4 immunoglobulin G antibodies are positive one of the following or if anti-aquaporin-4 immunoglobulin G antibodies are negative two of the following must be present:
    a. Optic neuritis

   b. Acute neuritis
   c. Area postrema syndrome
   d. Acute brainstem syndrome
   e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions; and
4. Multiple sclerosis and other diagnoses have been ruled out; and
5. Failure of corticosteroids; and
6. Failure of
   a. Azathioprine
   b. Mycophenolate mofetil
   c. Complement inhibitors (eculizumab, ravulizumab)
   d. Anti-IL6 therapy [e.g., Actemra (tocilizumab), Enspryng (satralizumab-mwge)]
   e. Anti-CD19 therapy [e.g., Uplizna (inebilizumab-cdon)]

Stiff-person syndrome

1. Diagnosis of stiff-person syndrome; and
2. Failure of GABAergic medications including baclofen and benzodiazepines).

Primary Immunodeficiency

1. Diagnosis of primary immunodeficiency; and
2. Diagnosis confirmed by genetic or molecular testing when applicable; and
3. Other causes of immune deficiency have been excluded (drug induced, genetic disorders, infectious diseases such as HIV, malignancy); and
4. Total IgG < 200mg/dL (For IgG subclass deficiency the IgG subclass must be greater than 2 standard deviations below the age-specific normal range); and
5. Immunoglobin testing must be confirmed by 2 measurements at least 2 months apart while the member is free from infection; and
6. History of documented and significant recurrent sinopulmonary bacterial infections requiring hospitalization and multiple courses of prolonged antibiotic therapy; and
7. Failure or response to prophylactic antibiotic therapy; and
8. Documented management of any underlying medical condition that may be contributing; and
9. Inability to respond to IgG antibody production after antigenic challenge against diphtheria and tetanus toxoids and pneumococcal polysaccharide vaccine, as determined by the following criteria:
   a. Member has documented inability to mount an antibody response to protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained prior to immunization with diphtheria and/or tetanus vaccine and 3 to 4 weeks after immunization. An inadequate response is defined as a post vaccination titer less than 0.1 international units/mL for diphtheria, and 0.1 international units/mL or less for tetanus; and
   b. Member has documented inability to mount an adequate antibody response to polysaccharide antigens. Serum antibody titers to at least 14 pneumococcus serotypes should be measured prior to immunization and 4 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (e.g., Pneumovax). An inadequate

response is defined as lack of protective antibody titer (i.e., specific IgG concentration less than 1.3 mcg/mL) in at least 70 % of serotypes tested (in at least 50 % of serotypes tested in children aged 2 to 5 years). Note: Response to polysaccharide antigens is not reliable in children less than 2 years of age.

Rheumatology

Dermatomyositis or polymyositis

1. Diagnosis of dermatomyositis or polymyositis; and
2. Failure of corticosteroids; and
3. Failure of immunomodulators including cyclophosphamide, methotrexate, and azathioprine.

Kawasaki disease

1. Diagnosis of Kawasaki disease; and
2. IVIG treatment does not exceed five consecutive days

Transplantation

Bone marrow transplantation

Immune globulin is medically necessary after allogeneic BMT when all of the following criteria are met:

1. One of the following uses:
    a. Prevention of acute graft vs. host disease (GVHD); or
    b. Prevention of infection; and
2. Confirmed allogeneic bone marrow transplant within the last 100 days; and
3. IgG < 400 mg/dL.

Exclusions

Immune globulin is unproven and not medically necessary for the following conditions:

- Acquired hemophilia
- Adrenoleukodystrophy
- Alzheimer's disease
- Amyotrophic lateral sclerosis (ALS)
- Antiphospholipid antibody syndrome (APS) in pregnancy
- Asthma
- Atopic dermatitis
- Autism spectrum disorders
- Autoimmune liver disease
- Autoimmune neutropenia
- Bone marrow transplantation (BMT), prevention of acute or chronic graft vs. host disease (GVHD)
- Bone marrow transplantation (BMT), prevention of infection after autologous BMT
- Campylobacter species-induced enteritis
- Cerebral infarctions with antiphospholipid antibodies

- Chronic fatigue syndrome
- Demyelinative brain stem encephalitis
- Demyelinating neuropathy associated with monoclonal IgM
- Diabetes mellitus
- Dilated cardiomyopathy
- Hashimoto's encephalopathy
- HIV infection, to reduce viral load
- HTLV-1-associated myelopathy
- Idiopathic dysautonomia, acute
- Inclusion body myositis
- Isolated IgA deficiency
- Isolated IgE deficiency
- Isolated IgG4 deficiency
- Isolated IgM deficiency
- Lumbosacral or brachial plexitis
- Lyme disease
- Monoclonal gammopathy
- Myocarditis
- Neonatal isoimmune hemolytic jaundice
- Neonatal sepsis
- Ocular myasthenia
- Opsoclonus myoclonus
- Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy
- Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
- POEMS syndrome
- Postinfectious cerebellar ataxia
- Postoperative sepsis
- Primary progressive multiple sclerosis (MS) and secondary progressive MS, acute MS exacerbations
- Pseudomembranous colitis
- Rheumatic fever
- Sjogren's syndrome
- Spontaneous recurrent abortions, prevention
- Urticaria
- Vasculitides and antineutrophil antibody syndromes

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