

MEDICAL POLICY – 8.02.02

Plasma Exchange

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RELATED MEDICAL POLICIES:


7.03.04 Intestinal and Multivisceral Organ Transplant Surgery

8.01.36 Extracorporeal Photopheresis

8.02.04 Lipid Apheresis

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Introduction

Blood is made up of solids and liquids. The solid parts include red and white blood cells and platelets. Plasma is the liquid portion of blood. Plasma makes up about half of all blood and contains water, salts, enzymes, antibodies, and proteins. It is responsible for many important functions, including helping to maintain blood pressure and providing particular proteins for clotting. Plasma exchange is the process of replacing plasma in the body. Whole blood is withdrawn and a specialized machine separates the solids from the liquid. The plasma is then discarded, and the blood cells, platelets, and other solids are mixed with a protein fluid. This mixture is then returned to the patient with a special pump. Plasma exchange is a proven technique for a number of autoimmune, blood, nervous system, and kidney conditions as well as in certain transplant situations. This policy describes when plasma exchange may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Condition	Medical Necessity
Autoimmune	<p>Plasma exchange is considered medically necessary for the following autoimmune diseases:</p> <ul style="list-style-type: none"> Severe multiple manifestations of mixed cryoglobulinemia (MC) such as cryoglobulinemic nephropathy, skin ulcers, sensory motor neuropathy, and widespread vasculitis in combination with immunosuppressive treatment Catastrophic antiphospholipid syndrome
Hematologic conditions	<p>Plasma exchange is considered medically necessary for the following hematologic conditions:</p> <ul style="list-style-type: none"> ABO-incompatible hematopoietic progenitor cell transplantation Hyperviscosity syndromes associated with multiple myeloma or Waldenström macroglobulinemia Idiopathic thrombocytopenic purpura in emergency situations Thrombotic thrombocytopenic purpura (TTP) Atypical hemolytic uremic syndrome Post-transfusion purpura HELLP syndrome of pregnancy (a severe form of preeclampsia, characterized by hemolysis [H], elevated liver enzymes [EL], and low platelet [LP] counts) Myeloma with acute renal failure
Neurologic conditions	<p>Plasma exchange is considered medically necessary for the following neurologic conditions:</p> <ul style="list-style-type: none"> Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome [GBS]; severity grade 1–2 within 2 weeks of onset; severity grade 3–5 within 4 weeks of onset; and children younger than 10 years -old with severe GBS) Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) Multiple sclerosis (MS); with acute fulminant central nervous system (CNS) demyelination Myasthenia gravis in crisis or as part of preoperative preparation



Condition	Medical Necessity
	<ul style="list-style-type: none"> • Paraproteinemia polyneuropathy; immunoglobulin A and G • N-methyl-D-aspartate receptor antibody encephalitis; • Progressive multifocal leukoencephalopathy associated with natalizumab
Renal diseases	<p>Plasma exchange is considered medically necessary for the following renal diseases:</p> <ul style="list-style-type: none"> • Antiglomerular basement membrane disease (Goodpasture syndrome) • Antineutrophil cytoplasmic antibody-associated vasculitis (eg, Wegener granulomatosis [also known as granulomatosis with polyangiitis] with associated renal failure • Dense deposit disease with factor H deficiency and/or elevated C3 nephritic factor
Transplantation	<p>Plasma exchange is considered medically necessary in the following transplant situations:</p> <ul style="list-style-type: none"> • ABO-incompatible solid organ transplantation: <ul style="list-style-type: none"> ○ Kidney ○ Heart (infants) • Renal transplantation: antibody mediated rejection; human leukocyte antigen desensitization • Focal segmental glomerulosclerosis after renal transplant

Condition	Investigational
All other conditions	<p>Plasma exchange is considered investigational in all other conditions not listed above, including, but not limited, to the following:</p> <ul style="list-style-type: none"> • ABO-incompatible solid organ transplant; liver • Acute disseminated encephalomyelitis • Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome) in children younger than 10 years old with mild or moderate forms • Acute liver failure • Amyotrophic lateral sclerosis; • Antineutrophil cytoplasmic antibody-associated rapidly progressive glomerulonephritis (Wegener granulomatosis or granulomatosis with polyangiitis without renal failure)



Condition	Investigational
	<ul style="list-style-type: none"> • Aplastic anemia • Asthma • Autoimmune hemolytic anemia; warm autoimmune hemolytic anemia; cold agglutinin disease • Chronic fatigue syndrome • Coagulation factor inhibitors • Cryoglobulinemia; except for severe mixed cryoglobulinemia, as noted above • Dermatomyositis and polymyositis • Focal segmental glomerulosclerosis (other than after renal transplant) • Heart transplant rejection treatment • Hemolytic uremic syndrome, typical (diarrheal-related) • Idiopathic thrombocytopenic purpura; refractory or nonrefractory • Inclusion body myositis • Lambert-Eaton myasthenic syndrome • Multiple sclerosis with chronic progressive or relapsing remitting course • Neuromyelitis optica • Mushroom poisoning • Myasthenia gravis with anti-MuSK antibodies • Overdose and poisoning (other than mushroom poisoning) • Paraneoplastic syndromes • Paraproteinemia polyneuropathy; IgM • Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections • Pemphigus vulgaris • Phytanic acid storage disease (Refsum disease) • POEMS (polyneuropathy, organomegaly, endocrinopathy, M protein, skin changes) • Psoriasis • Red blood cell alloimmunization in pregnancy • Rheumatoid arthritis • Sepsis • Scleroderma (systemic sclerosis) • Stiff person syndrome



Condition	Investigational
	<ul style="list-style-type: none"> • Sydenham chorea • Systemic lupus erythematosus (including systemic lupus erythematosus nephritis) • Thyrotoxicosis • Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström macroglobulinemia)

Note: This policy only addresses plasma exchange (PE) as a therapeutic apheresis procedure.

Additional Guidelines
<p>Patients receiving PE as a treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) should meet the diagnostic criteria for CIDP that are included in the Appendix.</p>
<p>Patients receiving PE as a treatment of acute inflammatory demyelinating polyneuropathy, also known as Guillain-Barré syndrome (GBS), should meet the criteria of diagnostic severity that are included in the Appendix.</p>
<p>The use of PE in patients with acute, life-threatening complications of chronic autoimmune diseases, such as rheumatoid arthritis (RA) and systemic lupus erythematosus, may need to be considered on an individual basis. An example of such a situation would be the development of a severe vasculitis, in which it is hoped that the use of PE can acutely lower the level of serum autoantibodies until an alternate long-term treatment strategy can be implemented. However, in these situations, the treatment goals and duration of treatment with PE need to be clearly established before its initiation; without such treatment goals, the use of an acute short-term course of PE may insidiously evolve to a chronic use of PE with uncertain benefit.</p>

Coding

Code	Description
CPT	
36514	Therapeutic apheresis; for plasma pheresis



Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

The terms therapeutic apheresis, plasmapheresis, and PE are often used interchangeably, but when properly used denote different procedures. The American Society for Apheresis (ASFA) definitions for these procedures are as follows:

Apheresis: An umbrella term for procedures in which blood of the patient or donor is passed through a medical device which separates out one or more components of the blood, takes that component away, and returns the rest of the blood to the person. This term includes plasmapheresis (in which plasma is taken away).

Plasmapheresis: A procedure in which the blood of a patient or donor is passed through a medical device which separates out plasma from the other components of blood and the plasma is removed, but not replaced.

Plasma exchange: A therapeutic procedure in which blood of the patient is passed through a medical device which separates out plasma from other components of blood. The plasma is removed and is replaced with a solution such as colloid solution (eg, albumin and/ or plasma) or a combination of crystalloid/colloid solution.

Evidence Review

Description

Plasma exchange (PE) is a procedure in which the plasma is isolated, then discarded and replaced with a fluid such as albumin. PE is a nonspecific therapy, because the entire plasma is discarded. PE has been used in a wide variety of acute and chronic conditions, as well as in the setting of solid organ transplantation.



Background

The rationale for PE is based on the fact that circulating substances, such as toxins or autoantibodies, can accumulate in the plasma. Also, it is hypothesized that removal of these factors can be therapeutic in certain situations. PE is a symptomatic therapy, because it does not remove the source of the pathogenic factors. Therefore, the success of PE depends on whether the pathogenic substances are accessible through the circulation and whether their rate of production and transfer to the plasma component can be adequately addressed by PE. For example, PE can rapidly reduce levels of serum autoantibodies; however, through a feedback mechanism, this rapid reduction may lead to a rebound overproduction of the same antibodies. This rebound production of antibodies is thought to render the replicating pathogenic clone of lymphocytes more vulnerable to cytotoxic drugs; therefore, PE is sometimes used in conjunction with cyclophosphamide.

Applications

Applications of PE can be broadly subdivided into two general categories: (1) acute self-limited diseases, in which PE is used to acutely lower the circulating pathogenic substance; and (2) chronic diseases, in which there is ongoing production of pathogenic autoantibodies. Because PE does not address underlying pathology, and because of the phenomenon of rebound antibody production, its use in chronic diseases has been more controversial than in acute self-limited diseases.

Also, plasmapheresis has been used in the setting of solid organ transplantation. It has been used as a technique to desensitize high-risk patients before transplant and also as a treatment of antibody-mediated rejection (AMR) reaction occurring after transplant. Before transplant, plasmapheresis has been most commonly used to desensitize patients receiving an ABO mismatched kidney, often in combination with a splenectomy. As a treatment of AMR, plasmapheresis is often used in combination with intravenous immunoglobulin (IVIg) or anti-CD20 therapy (ie, Rituxan® (rituximab)).

Summary of Evidence

Data from published studies, clinical input, and/or guidelines from the American Society for Apheresis support the use of PE for selected autoimmune, hematologic, neurologic, renal, and transplantation conditions.



Ongoing And Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01442233	Plasma Exchanges in Multiple Sclerosis (MS) Relapses (PLASMASEP)	80	Dec 2017
NCT02622854	Plasma Exchange vs Conservative Management in Non-severe Acute Hypertriglyceridemic Pancreatitis	20	Dec 2018
NCT02647255	Trial of Plasma Exchange for Severe Crescentic IgA Nephropathy (RESCUE)	150	Dec 2019

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2012. There was consensus or near-consensus that PE for dense deposit disease with factor H deficiency and/or elevated C3 nephritis factor, catastrophic antiphospholipid syndrome, focal segmental glomerulosclerosis after renal transplant, and myeloma with acute renal failure may be considered medically necessary. Input was mixed on the medical necessity of hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström macroglobulinemia). Also, there was no consensus about an optimal creatinine threshold for instituting PE in patients with renal failure associated with ANCA-associated vasculitis or other diagnoses.



Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

In the current NCCN guidelines on multiple myeloma (v.2.2018), use of plasmapheresis to improve renal function is a category 2B recommendation.⁵³ Plasmapheresis should also be used as adjunctive therapy for hyperviscosity.

American Academy of Neurology (AAN)

In 2011, the AAN (Therapeutics and Technology Assessment Subcommittee) issued evidence-based guidelines on plasmapheresis in the treatment of neurologic disorders.⁵⁴ The primary conclusions, based on their evidence review, are provided in **Table 2**:

Table 2. Guidelines on Use Plasmapheresis to Treat Neurologic Disorders

Recommendation	Conclusion
Acute inflammatory demyelinating polyneuropathy/Guillain-Barré syndrome	Established effective
Chronic inflammatory demyelinating polyneuropathy, short-term treatment	Established effective
Relapses in multiple sclerosis	Probably effective
Fulminant demyelinating central nervous system disease	Possibly effective
Chronic or secondary progressive multiple sclerosis	Established ineffective
Myasthenia gravis	Insufficient evidence
Sydenham chorea	Insufficient evidence
Acute obsessive-compulsive disorder and tics in PANDAS	Insufficient evidence

PANDAS: pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections.

In 2003, the American Academy of Neurology published a practice parameter on Guillain-Barré syndrome (GBS).⁵⁵ The following are the key findings: (1) treatment with plasma exchange (PE) or intravenous immunoglobulin hastens recovery from GBS; (2) combining the 2 treatments is not beneficial; and (3) steroid treatment given alone is not beneficial. The American Academy of Neurology's recommendations are:



- PE is recommended for adults with GBS who are nonambulant and who seek treatment within 4 weeks of the onset of neuropathic symptoms;
- PE should be considered for ambulant patients examined within 2 weeks of the onset of neuropathic symptoms;
- PE is a treatment option for children with severe GBS.

American Society for Apheresis (ASFA)

In 2016, the ASFA updated its guidelines on the use of therapeutic apheresis (Seventh Special Issue).⁵⁶ Previously, the guidelines had been updated in 2013 (Sixth Special Issue).⁵⁷ The following is a description of the Society categories (see [Table 3](#)) and 2013 recommendations (see [Table 4](#)) and new indications added in 2016 (see [Table 5](#)).

Table 3. American Society for Apheresis Categories

Category	Description
I	Diseases for which TA is accepted as first-line treatment, either as a primary standalone treatment or in conjunction with other treatments. Note that this designation need not imply that TA is mandatory in all cases.
II	Diseases for which TA is accepted as second-line treatment, either as a standalone treatment or in conjunction with other treatments.
III	Diseases for which the optimum role of TA is not established and treatment decisions on an individual basis are recommended.
IV	Disorders for which published evidence suggests or demonstrates that TA is ineffective or harmful.

TA: therapeutic apheresis.

Table 4. American Society for Apheresis 2013 Key Recommendations

Disease Group/Name/Condition	2013 Category
Autoimmune	
Catastrophic antiphospholipid syndrome	II
Cryoglobulinemia	I
Pemphigus vulgaris	III



Disease Group/Name/Condition	2013 Category
Systemic lupus erythematosus	
Manifestations other than nephritis	NC
Severe	II
Nephritis	IV
Hematologic	
ABO-incompatible hematopoietic progenitor cell transplantation	II
Aplastic anemia	III
Pure red blood cell aplasia	III
Idiopathic thrombocytopenic purpura	NC
Coagulation factor inhibitors	IV
Hyperviscosity in monoclonal gammopathies	I
Refractory immunoadsorption	NC
Refractory or nonrefractory	NC
Autoimmune hemolytic anemia	
Warm autoimmune hemolytic anemia	III
Cold agglutinin disease	II
Myeloma and acute renal failure (in 2010 and 2013 myeloma cast nephropathy)	
Post-transfusion purpura	III
Red blood cell alloimmunization in pregnancy	III
Thrombotic thrombocytopenic purpura	I
Metabolic	
Acute liver failure	III
Sepsis	III
Thyrotoxicosis	III
Neurologic	
Acute disseminated encephalomyelitis	II
AIDP (Guillain-Barré syndrome)	I
AIDP, post IVIg	III
Chronic inflammatory demyelinating polyradiculoneuropathy	I
Lambert-Eaton myasthenic syndrome	II
Multiple sclerosis	



Disease Group/Name/Condition	2013 Category
Acute CNS inflammatory demyelinating disease	II
Devic syndrome	NC
Chronic progressive	III
Myasthenia gravis	
In 2013, moderate-severe	I
In 2013, pre-thymectomy	I
Paraneoplastic neurologic syndromes	III
Paraproteinemic polyneuropathies	
IgG/IgA	I
IgM	I
Multiple myeloma	III
Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections; SC	
PANDAS (2007, severe)	I
SC (2007, severe)	I
Rasmussen encephalitis	III
Stiff person syndrome	III
Neuromyelitis optica spectrum disorders	
Acute	II
Maintenance	III
Renal	
ANCA-associated rapidly progressive glomerulonephritis (Wegener granulomatosis)	
Dialysis dependence	I
Dialysis independence	III
Antiglomerular basement membrane disease (Goodpasture syndrome)	
DAH	I
Dialysis dependence and no DAH	III
Dialysis independence	I
Focal segmental glomerulosclerosis	
Primary	NC



Disease Group/Name/Condition	2013 Category
Secondary	NC
Recurrent	I
HUS; thrombotic microangiopathy; transplant-associated microangiopathy	
Idiopathic HUS	NC
Transplant-associated microangiopathy	NC
Diarrhea-associated pediatric	NC
Atypical HUS due to complement factor H	I
Diarrhea-associated HUS or typical HUS	
In 2013, Shiga toxin-associated	IV
Streptococcus pneumoniae associated	III
Renal transplantation: antibody-mediated rejection; HLA desensitization	
Antibody-mediated rejection	I
HLA desensitization	II
Desensitization, living-donor, positive cross-match due to donor-specific HLA antibody	I
High PRA: cadaveric donor	III
Rheumatic	
Scleroderma (progressive systemic sclerosis)	III
Transplantation	
ABO-incompatible solid organ transplantation	
Kidney	
In 2013, desensitization, living-donor	I
Humeral rejection	II
Heart (infants)	NC
Liver (2010 perioperative)	
In 2013, desensitization living-donor	I
Desensitization, deceased-donor	II
Humeral rejection	III
Heart transplant rejection	
Treatment	NC

ABO: A, B, and O blood types; AIDP: acute inflammatory demyelinating polyneuropathy; ANCA: antineutrophil cytoplasmic antibody; CNS: central nervous system; DAH: diffuse alveolar hemorrhage; HLA: human leukocyte antigen; HUS: hemolytic uremic syndrome; Ig: immunoglobulin; IVIg: intravenous immunoglobulin; NC: not categorized;



PANDAS: pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection; PRA: Panel Reactive Antibody; SC: Sydenham chorea.

Table 5. American Society for Apheresis New Indications in 2016

Disease Group/Name/Condition	2016 Category
Atopic (neuro-) dermatitis (atopic eczema), recalcitrant	III
Cardiac neonatal lupus	III
Complex regional pain syndrome	III
Erythropoietic porphyria, liver disease	III
Hashimoto encephalopathy: steroid-responsive encephalopathy associated with autoimmune thyroiditis	II
HELLP syndrome^a	
Postpartum	III
Antepartum	IV
Hematopoietic cell transplantation, human leukocyte antigen desensitization	III
Hemophagocytic lymphohistiocytosis; hemophagocytic syndrome; macrophage activating syndrome	III
N-methyl-d-aspartate receptor antibody encephalitis	I
Prevention of Rhesus D alloimmunization after red blood cell exposure	III
Progressive multifocal leukoencephalopathy associated with natalizumab	I
Pruritus due to hepatobiliary diseases	III
Thrombotic microangiopathy, coagulation mediated	III
Vasculitis	
HBV-PAN	II
Idiopathic PAN	IV
EGPA	III
Behçet disease	III

EGPA: eosinophilic granulomatosis with polyangiitis; HBV: hepatitis B virus; PAN: polyarteritis nodosa.

^a A severe form of preeclampsia, characterized by hemolysis, elevated liver enzymes, and low platelet counts.



Medicare National Coverage

The national coverage determination for apheresis (therapeutic pheresis)⁵⁸ last revised in 1992, states:

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukapheresis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP);
- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritus of cholestatic liver disease; Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- Treatment of Guillain-Barre Syndrome; and
- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.



Regulatory Status

The U.S. Food and Drug Administration (FDA) has a compliance program to ensure that source plasma, source leukocytes, and therapeutic exchange plasma for further manufacture into products for human use are safe, pure, potent, and appropriately labeled. The compliance program covers products intended for use both in injectable drug products (eg, immune globulin, albumin) and noninjectable products (eg, in vitro devices such as blood bank reagents).¹

Product code for therapeutic exchange plasma: 57DI-65

Appendix

Diagnostic Criteria for Diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

The following criteria are adapted from the Task Force Report of the Ad Hoc Subcommittee of the American Academy of Neurology AIDS Task Force (Neurology 1991; 41:617-18, PMID 2027473). The report included mandatory, supportive, and exclusionary diagnostic criteria. Only the mandatory criteria are excerpted here. The criteria are based on a combination of clinical observations, physiologic studies, pathologic features (ie, nerve biopsy), and studies of the cerebral spinal fluid (CSF).

- Clinical: Mandatory
 - Progressive or relapsing motor and sensory, rarely only motor or sensory, dysfunction of more than 1 limb or a peripheral nerve nature, developing over at least 2 months.
 - Hypo- or areflexia. This will usually involve all four limbs.
- Physiologic Studies: Mandatory

Nerve conduction studies including studies of proximal nerve segments in which the predominant process is demyelination.

Must have 3 out of 4 of the following criteria in the list of second-level bullets:



- Reduction in conduction velocity (CV) in 2 or more motor nerves
 - < 80% of lower limit of normal (LLN) is amplitude > 80% of LLN
 - < 70% of LLN is amplitude < 80% of LLN
- Partial conduction block or abnormal temporal dispersion in 1 or more motor nerves: either peroneal nerve between ankle and below fibular head, median nerve between wrist and elbow, or ulnar nerve between wrist and below elbow.
- Criteria suggestive of partial conduction block: < 15% change in duration between proximal and distal sites and > 20% drop in negative-peak (p) area or peak to peak (p-p) amplitude between proximal and distal sites.
- Criteria for abnormal temporal dispersion and possible conduction block: > 15% change in duration between proximal and distal sites and > 20% drop in p area or p-p amplitude between proximal and distal sites and > 20% drop in p or p-p amplitude between proximal and distal sites. These criteria are only suggestive of partial conduction block as they are derived from studies of normal individuals.
- Additional studies, such as stimulation across short segments or recording of individual motor unit potentials, are required for confirmation.
- Prolonged distal latencies in two or more nerves:
 - >125% of upper limit of normal (LEN) is amplitude > 80% of LLN
 - >150% of LEN if amplitude < 80% of LLN
- Absent F waves or prolonged minimum:
 - > 120% of ULN if amplitude > 80% of LLN
 - > 150% of ULN if amplitude < 80% of LLN
- Pathologic Features: Mandatory

Nerve biopsy showing unequivocal evidence of demyelination and remyelination.

Demyelination by either electron microscopy (> 5 fibers) or teased fiber studies >12% of 50 fibers, minimum of 4 internodes each, demonstrating demyelination/ remyelination.

- CSF Studies: Mandatory
 - Cell count <10/mm³ if HIV-seronegative or <50/mm³ if HIV seropositive



- Negative VDRL

Guillain-Barré Syndrome Disability Scale

The scale appears below as it did in the Hughes et al. 2007 systematic review published in Brain 2007; 130⁹:2245-2257.²²

0. Healthy
1. Minor symptoms or signs of neuropathy but capable of manual work/capable of running
2. Able to walk without support of a stick (5 m across an open space) but incapable of manual work/running
3. Able to walk with a stick, appliance or support (5m across an open space)
4. Confined to bed or chair bound
5. Requiring assisted ventilation (for any part of the day or night)
6. Death

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History

Date	Comments
11/13/01	Replace Policy - Revised Policy replaces P8.02.100
08/13/02	Replace Policy - Policy reviewed; new indications added.
05/13/03	Replace Policy - Update CPT codes only.
05/11/04	Replace Policy - Policy reviewed with literature search; references added. No change in policy statement.
06/14/05	Replace Policy - Policy updated with literature search; no change in policy statement. Reference 22 updated, and comparison between ASA recommendations and policy statement included in the Rationale Section.
02/06/06	Codes updated - No other changes.
05/16/06	Update Scope and Disclaimer - No other changes.



Date	Comments
08/08/06	Replace Policy - Policy revised with addition of policy statements and discussion of plasmapheresis in the setting of solid organ transplantation, considered medically necessary; references added.
06/09/09	Replace Policy - Policy updated with literature search. Policy statement updated to include Wegener's Granulomatosis as a medically necessary indication.
04/13/10	Replace Policy - Policy reviewed with literature search The policy statement has been modified to include: Guillain-Barré syndrome severity grades 1-2 as medically necessary; use in the pediatric population is investigational for mild and moderate forms of GBS and medically necessary for the severe form of GBS; the policy statement has been modified to include severe manifestations of mixed cryoglobulinemia (MC) as medically necessary when used in combination with immunosuppressive therapy; typical- hemolytic uremic syndrome is investigational (considered medically necessary in previous updates) and investigational for treatment of PANDAS, Sydenham Chorea, Refsum's disease, cryoglobulinemia (except severe MC), myasthenia gravis with anti-MuSk antibodies; additional conditions were added as investigational based on American Society for Apheresis (ASFA) review. Title changed from "Plasma Exchange (Plasmapheresis) to "Plasma Exchange." References added.
06/08/10	Cross Reference Update - No other changes.
06/13/11	Replace Policy - Policy reviewed with literature search from May 2009 through January 2011. No changes to policy statements. Rationale rewritten. References 16, 24, 31 and 41 added; other references renumbered or removed. ICD-10 codes added to policy.
06/20/12	Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.
07/10/12	Replace policy. Policy statement revised with additional conditions that may be medically necessary myeloma with acute renal failure, catastrophic antiphospholipid syndrome; dense deposit disease with Factor H deficiency and/or elevated C3 nephritis factor and focal segmental glomerulosclerosis after renal transplant. The investigational statement on focal segmental glomerulosclerosis was modified to indicate that it applied to situations other than after renal transplant. Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenstrom's macroglobulinemia) added as investigational. In addition, the serum creatinine threshold was removed from the medically necessary policy statement on ANCA-associated vasculitis. Rationale rewritten. Updated literature review with references 22, 26 and 29 added, other references renumbered or removed.
09/28/12	Update Related Policies – Add 7.03.509; ICD-10 codes are now effective 10/01/2014.
02/11/13	Replace policy. Minor clarification regarding medical necessity of MS for acute and chronic forms. The intent of the policy statement is unchanged.
04/18/13	Update Related Policies. Change title to 8.01.36.
07/24/13	Replace policy. Policy reviewed with literature search through March 21, 2013. Policy statements unchanged. References 19, 23 and 40 added.



Date	Comments
08/15/13	Update Related Policies. Change title to 7.03.05.
10/18/13	Update Related Policies. Change title to 8.01.17.
07/31/14	Annual Review. Policy updated with literature review through April 3, 2014. Minor changes to bullet points on multiple sclerosis for clarity only. References 16, 25, 29, 30, 40, 44 and 46 added.
10/22/14	Update Related Policies. Change title to 8.02.04.
07/14/15	Annual Review. Neuromyelitis optica (NMO) added to the list of investigational conditions. CAPS, abbreviation for catastrophic antiphospholipid syndrome, removed from medically necessary policy statement. Policy updated with literature review through April, 2015. References 32-35, 47 added. Retained the criteria for CIDP and Guillain-Barré syndrome in the Appendix. Investigational policy statement updated as noted. ICD-9 diagnosis codes removed; these were listed for informational purposes only. Related Policies updated, the following were removed: 7.03.05, 7.03.509, 7.03.510, 8.01.17, 8.01.25 and 8.01.503.
09/01/15	Update Related Policies. Add 7.03.04.
06/01/16	Annual Review, approved May 10, 2016. No change to policy statements. No new literature added.
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through July 21, 2017. References 3, 19, 24, 30, 35-37, and 56 added. N-methyl-D-aspartate receptor antibody encephalitis and progressive multifocal leukoencephalopathy associated with natalizumab added to medically necessary statement.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



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Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

አማርኛ (Amharic):

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العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينه للحفاظ على تغطيتك الصحية أو المساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

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本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

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Tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnuv ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).