POLICY TITLE	PLASMA EXCHANGE (PE)
POLICY NUMBER	MP- 4.031

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I. POLICY

Plasma Exchange (PE)

Plasma exchange (PE) may be considered **medically necessary** for any of the conditions listed below:

AUTOIMMUNE DISEASES

- 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

- ABO incompatible hematopoietic progenitor cell transplantation;
- Hyperviscosity syndromes associated with multiple myeloma or Waldenstrommacroglobulinemia;
- Idiopathic thrombocytopenic purpura (ITP) 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.

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NEUROLOGIC CONDITIONS

- Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome; 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 Guillain-Barre syndrome);
- Chronic inflammatory demyelinating polyradiculoneuropathy;
- Multiple sclerosis, with acute fulminant central nervous system demyelination;
- Myasthenia gravis in crisis or as part of preoperative preparation;
- Paraproteinemia polyneuropathy; immunoglobulin A and G;
- *N*-methyl-d-aspartate receptor antibody encephalitis;
- Progressive multifocal leukoencephalopathy associated with natalizumab.

RENAL DISEASES

- Anti-glomerular basement membrane disease (Goodpasture syndrome);
- Antineutrophil cytoplasmic antibody-associated vasculitis (e.g., Wegener granulomatosis) (also known as granulomatosis with polyangiitis [GPA]) with associated renal failure;
- Dense deposit disease with factor H deficiency and/or elevated C3 nephritic factor.

TRANSPLANTATION

- ABO incompatible solid organ transplantation:
  - Kidney;
  - Heart (infants);
- Renal transplantation: antibody mediated rejection; human leukocyte antigen desensitization;
- Focal segmental glomerulosclerosis after renal transplant.

Plasma exchange (PE) is considered **investigational** in all other conditions, including, but not limited, to the following:

- ABO- incompatible solid organ transplant: liver;
- Acute disseminated encephalomyelitis;
- Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome) in children younger than 10 years old with mild or moderate forms;
- Acute liver failure;
- Amyotropic lateral sclerosis;
- Antineutrophil cytoplasmic antibody-associated rapidly progressive glomerulonephritis (Wegener granulomatosis or granulomatosis with polyangiitis (GPA) without renal failure);
- Aplastic anemia;

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- 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 non-refractory;
- 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;
- Sydenham’s chorea;
- Systemic lupus erythematosus (including systemic lupus erythematosus nephritis);
- Thyrotoxicosis; AND
- Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström macroglobulinemia).

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There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for the above listed indications.

Policy Guidelines

Patients receiving plasma exchange (PE) as a treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) should meet the diagnostic criteria for CIDP, which were established by the American Academy of Neurology in 1991 and have not been updated since. The use of PE in patients with acute, life-threatening complications of chronic autoimmune diseases, such as rheumatoid arthritis 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, for which it is hypothesized that the use of PE can acutely lower the level of serum autoantibodies until an alternative long-term treatment strategy can be implemented. However, in these situations, the treatment goals and treatment duration 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.

Cross-references:

MP-4.024 Lipid Apheresis
MP-9.053 Hematopoietic Cell Transplantation for Autoimmune Diseases

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

Note* **-** The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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Terminology

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

Apheresis is a procedure in which blood of the patient or donor is passed through a medical device that separates out one or more components of blood and returns remainder with or without extracorporeal treatment or replacement of the separated component.

Plasmapheresis is a procedure in which blood of a patient or the donor is passed through a medical device that separates plasma from the other components of blood and the plasma is removed (i.e., <15% of total plasma volume) without the use of replacement solution.

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Plasma exchange is a therapeutic procedure in which blood of the patient is passed through a medical device that separates plasma from other components of blood, the plasma is removed, and it is replaced with a replacement solution such as colloid solution (e.g., albumin and/ or plasma) or a combination of crystalloid/colloid solution.

This evidence review addresses only PE as a therapeutic apheresis procedure.

Plasma Exchange

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 2 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 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 antibody-mediated rejection, plasmapheresis is often used in combination with intravenous immunoglobulin or anti-CD20 therapy (i.e., rituximab).

Regulatory Status

The U.S. Food and Drug Administration 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 (e.g., immune globulin, albumin) and noninjectable products (e.g., in vitro devices such as blood bank reagents).[1]

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Product code for therapeutic exchange plasma: 57DI-65.

IV. RATIONALE

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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.

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Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statements are unchanged.

V. DEFINITIONS

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PATHOGENIC means capable of causing or producing a disease.

PLASMA refers to the watery straw-colored fluid part of the lymph and the blood in which the leukocytes, erythrocytes, and platelets are suspended. Plasma is made up of water, electrolytes, proteins, glucose, fats, bilirubin, and gases and is essential for carrying the cellular elements of the blood through circulation, transporting nutrients, maintaining the acid-base balance of the body, and transporting wastes from the tissue.

PROGENITOR CELL refers to a parent cell that gives rise to a distinct cell lineage by a series of cell divisions.

PLATELET refers to the smallest cells in the blood, essential for coagulation and for hemostasis.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

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VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
36514								

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ICD-10-CM Diagnosis Codes	Description
C88.0	Waldenstrom macroglobulinemia
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
D59.3	Hemolytic-uremic syndrome
D68.61	Antiphospholipid syndrome
D69.3	Immune thrombocytopenic purpura
D69.51	Posttransfusion purpura
D89.1	Cryoglobulinemia
E88.09	Other disorders of plasma-protein metabolism, not elsewhere classified
G35	Multiple sclerosis
G61.0	Guillan Barre disease

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ICD-10-CM Diagnosis Codes	Description
G61.81	Chronic inflammatory demyelinating polyneuritis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G72.49	Other inflammatory and immune myopathies, not elsewhere classified
M31.0	Hypersensitivity angiitis
M31.1	Thrombotic microangiopathy
M31.31	Wegener's granulomatosis with renal involvement
N00.A	Acute nephritic syndrome with C3 glomerulonephritis
N00.6	Acute nephritic syndrome with dense deposit disease
N01.A	Rapidly progressive nephritic syndrome with C3 glomerulonephritis
N01.6	Rapidly progressive nephritic syndrome with dense deposit disease
N02.A	Recurrent and persistent hematuria with C3 glomerulonephritis
N02.6	Recurrent and persistent hematuria with dense deposit disease
N03.A	Chronic nephritic syndrome C3 glomerulonephritis
N03.6	Chronic nephritic syndrome with dense deposit disease
N04.A	Nephrotic syndrome with C3 glomerulonephritis
N04.1	Nephrotic syndrome with focal and segmental glomerular lesions
N04.6	Nephrotic syndrome with dense deposit disease
N05.A	Unspecified nephritic syndrome with C3 glomerulonephritis
N05.5	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N05.6	Unspecified nephritic syndrome with dense deposit disease
N26.9	Renal sclerosis, unspecified
O14.20	HELLP syndrome (HELLP), unspecified trimester
O14.22	HELLP syndrome (HELLP), second trimester
O14.23	HELLP syndrome (HELLP), third trimester
O14.24	HELLP syndrome, complicating childbirth
O14.25	HELLP syndrome, complicating the puerperium
T86.11	Kidney transplant rejection
T86.19	Other complication of kidney transplant
T86.21	Heart transplant rejection
T86.298	Other complications of heart transplant

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MP 4.024- Prior to 7/27/10	**CAC 2/25/03**
	CAC 6/29/04
	CAC 1/25/05
	CAC 7/26/05
	CAC 2/28/06 Consensus.
	CAC 6/27/06
	CAC 7/25/06
	CAC 7/31/07
Policy #4.031 **As of 7/27/10**	**CAC 5/27/08**
	CAC 5/26/09 Consensus.
	CAC 7/27/10 Revised with additional medical necessity indications and exclusions. Adopted BCBSA language
	CAC 11/22/11 Consensus Review.
	CAC 01/29/13 Minor revision. The indications of myeloma with acute renal failure and catastrophic antiphospholipid syndrome were changed to medically necessary. Dense deposit disease with Factor H deficiency and/or elevated C3 nephritis factor and focal segmental glomerulosclerosis after renal transplant were also added as medically necessary indications. The investigational statement on focal segmental glomerulosclerosis was modified to indicate that it applied to situations other than after renal transplant. Hyperviscoscity syndromes with renal failure (other than associated with multiple myeloma or Waldenstrom's macroglobulinermia) was added as investigational. In addition, the serum creatinine threshold was removed from the policy statement on ANCA-associated vasculitis.
	CAC 1/28/14 Consensus review. References updated. No changes to the policy statements. Rationale added. Policy guidelines and appendix added.
	6/10/14 Corrected policy history to reflect correct policy number.
	CAC 1/27/15 Consensus review. No change to policy statements. References and rationale updated. Codes Reviewed.
	CAC 3/29/16 Minor review. Added post transfusion purpura to list of medically necessary indications. Neuromyelitis optica (NMO) added as investigational. Rationale and references updated. Coding updated.
	1/1/17 Administrative Update. Variation reformatting. New Diagnosis codes added effective 10/1/16

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CAC 3/28/17 Consensus review. References updated. Coding reviewed.
1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
1/17/18 Minor review. *N*-methyl-D-aspartate receptor antibody encephalitis and progressive multifocal leukoencephalopathy associated with natalizumab added to medically necessary statement. Revised the investigational indication for Systemic lupus erythematosus (SLE) from "manifestations other than nephritis" to "including systemic lupus erythematosus nephritis" to clarify that it includes SLE nephritis. Coding review. Rationale and references updated.
2/13/19 Consensus review. No changes to the policy statements. References reviewed. Rationale revised. Appendix removed**.**
10/1/19 Administrative update. Diagnosis coding updated.
4/7/2020 Consensus review. No change to policy statement. Rationale, references and coding reviewed. FEP clarification added.
9/1/2020 Administrative update. New ICD 10 codes added (N00A, N01A, N02A, N03A, N04A, N05A).

TOP

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