Medical Policy
Plasma Exchange

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Policy Number: 466
BCBSA Reference Number: 8.02.02
NCD/LCD: National Coverage Determination (NCD) for APHERESIS (Therapeutic Pheresis) (110.14)

Related Policies
Immune Globulin Therapy, #310
Lipid Apheresis, #465

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Plasma exchange may be considered MEDICALLY NECESSARY for the conditions listed below:

Autoimmune
- 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
- ABO incompatible hematopoietic progenitor cell transplantation
- Hyperviscosity syndromes associated with multiple myeloma or Waldenstrom's macroglobulinemia
- Idiopathic thrombocytopenic purpura in emergency situations
- Thrombotic thrombocytopenic purpura (TTP)
- Atypical hemolytic-uremic syndrome
- Post-transfusion purpura, and
- 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.
Neurological
- 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); acute fulminating central nervous system (CNS) demyelination
- Myasthenia gravis in crisis or as part of preoperative preparation, and
- Paraproteinemia polyneuropathy; IgA, IgG.

Renal
- Anti-glomerular basement membrane disease (Goodpasture’s syndrome), and
- ANCA [antineutrophil cytoplasmic antibody]-associated vasculitis (e.g., Wegener’s 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), and
- Renal transplantation: antibody mediated rejection; HLA desensitization
- Focal segmental glomerulosclerosis after renal transplant.

Plasma exchange is **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,
- Amyotrophic lateral sclerosis,
- ANCA [antineutrophil cytoplasmic antibody]-associated rapidly progressive glomerulonephritis (Wegener’s granulomatosis or GPA without renal failure),
- 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 (HUS); 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,
- Mushroom poisoning,
- Myasthenia gravis with anti-MuSK antibodies,
- Neuromyelitis optica (NMO),
- Overdose and poisoning (other than mushroom poisoning),
- Paraneoplastic syndromes,
- Paraproteinemia polyneuropathy; IgM,
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS),
- Pemphigus vulgaris,
- Phytanic acid storage disease (Refsum’s 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 (SC),
- Systemic lupus erythematosus (including SLE [systemic lupus erythematosus] nephritis), and
- Thyrotoxicosis
- Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenstrom’s macroglobulinemia).

**Medicare HMO Blue℠ and Medicare PPO Blue℠ Members**

**Note:** This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

**Item/Service Description**

**General**
Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken. 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).

**Indications and Limitations of Coverage**

**Indications**
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 pruritis 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.
Settings
Apheresis is covered only when performed in a hospital setting (either inpatient or outpatient) or in a nonhospital setting, e.g., a physician directed clinic when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All nonphysician services are furnished under the direct, personal supervision of a physician.

National Coverage Determination (NCD) for APHERESIS (Therapeutic Pheresis) (110.14)
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=82&ncdver=1&CoverageSelection=National&KeyWord=apheresis&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=110.14&ncd_version=1&basket=ncd%25253A110%25252E14%25253AApheresis+%252528Therapeutic+Pheresis%252529&bc=gAAAAABAAAAAAA%3d%3d&

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required.

Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
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<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

<table>
<thead>
<tr>
<th>CPT Codes</th>
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<tbody>
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<td>CPT codes:</td>
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<td>36514</td>
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The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

<table>
<thead>
<tr>
<th>ICD-9 Diagnosis Codes</th>
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<tr>
<td>ICD-9-CM diagnosis codes:</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>203.00</td>
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<tr>
<td>203.01</td>
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<tr>
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**ICD-10 Diagnosis Codes**

<table>
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<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
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<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C88.0</td>
<td>Waldenström macroglobulinemia</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
<tr>
<td>D59.3</td>
<td>Hemolytic-uremic syndrome</td>
</tr>
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<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
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<td>D69.51</td>
<td>Posttransfusion purpura</td>
</tr>
<tr>
<td>D75.1</td>
<td>Secondary polycythemia</td>
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<tr>
<td>D89.1</td>
<td>Cryoglobulinemia</td>
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<tr>
<td>G35</td>
<td>Multiple sclerosis</td>
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<td>G36.1</td>
<td>Acute and subacute hemorrhagic leukoencephalitis [Hurst]</td>
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<td>G36.8</td>
<td>Other specified acute disseminated demyelination</td>
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<td>G36.9</td>
<td>Acute disseminated demyelination, unspecified</td>
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<td>G37.4</td>
<td>Subacute necrotizing myelitis of central nervous system</td>
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<td>G37.8</td>
<td>Other specified demyelinating diseases of central nervous system</td>
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<td>G37.9</td>
<td>Demyelinating disease of central nervous system, unspecified</td>
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<td>G61.0</td>
<td>Guillain-Barre syndrome</td>
</tr>
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<td>G61.81</td>
<td>Chronic inflammatory demyelinating polyneuritis</td>
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<tr>
<td>G62.81</td>
<td>Critical illness polyneuropathy</td>
</tr>
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<td>G70.00</td>
<td>Myasthenia gravis without (acute) exacerbation</td>
</tr>
<tr>
<td>G70.01</td>
<td>Myasthenia gravis with (acute) exacerbation</td>
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Description

Plasma exchange (PE) is a procedure in which the plasma is isolated, then discarded and replaced with a substitution fluid such as albumin. Plasma exchange is a nonspecific therapy, since 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.

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 (ASFA) definitions for these procedures is as follows:

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

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

- **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 replaced with a replacement solution such as colloid solution (e.g., albumin and/or plasma) or a combination of crystalloid/colloid solution.

PE is essentially a symptomatic therapy, since it does not remove the source of the pathogenic factors. Therefore the success of PE will depend 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.

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.

In addition, plasmapheresis has been used as a technique to desensitize high-risk patients prior to transplant and also as a treatment of antibody-mediated rejection reaction (AMR) occurring after transplant.

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*
Summary
Plasma exchange (PE) is a procedure in which the plasma is isolated, then discarded and replaced with a substitution 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.

Due to data from published studies and/or clinical support, PE is considered medically necessary for selected conditions. For conditions in which there is a lack of efficacy data and clinical support, PE is considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>10/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>7/2014</td>
<td>BCBSA National medical policy review. Minor changes to bullet points on multiple sclerosis for clarity only.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<td>5/2009</td>
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<tr>
<td>11/2008</td>
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</table>
No changes to policy statements.


2/2008  BCBSA National medical policy review. Changes to policy statements.


Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


