



MEDICAL POLICY

Date Reviewed: 10/22/99, 03/24/00, 01/25/02, 02/22/02, 03/22/03, 01/23/04, 03/24/06, 04/20/07, 02/15/08, 01/23/09, 02/05/10, 04/15/11

Subject: Apheresis (Therapeutic Pheresis)

Description: Therapeutic apheresis is a term used to describe a process where blood is removed from the body, separated into various components, and then returned to the patient. Plasmapheresis is a process that removes substances from the blood, separates the plasma from the formed elements, and then returns various components to the patient by reinfusion. The goal of plasmapheresis is to decrease the concentration of harmful plasma components, which may improve the patient's symptoms. The harmful components removed by plasmapheresis include toxins, metabolic substances, and plasma components.

Indications of Coverage:

Apheresis is considered medically necessary for any of the following diagnoses:

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 for 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 (also known as chronic inflammatory demyelinating neuropathy (CIDP)) 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 (including acute inflammatory demyelinating polyneuropathy (AIDP))

Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration

When plasmapheresis is utilized for the management of an acute (fulminant) episode or exacerbation of the relapsing form of Multiple Sclerosis that has not responded to high-dose corticosteroid treatment.

When plasmapheresis is utilized for the management of acute disseminated encephalomyelitis (ADEM), neuromyelitis optica (NMO), or transverse myelitis (TM) that has not responded to respond to high-dose corticosteroid treatment.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Plasmapheresis for the management of forms of Multiple Sclerosis other than relapsing Multiple Sclerosis, such as chronic progressive, secondary progressive, primary progressive, or progressive relapsing Multiple Sclerosis is considered investigational. There is insufficient peer-reviewed scientific literature supporting the use of plasmapheresis for these forms of Multiple Sclerosis.

Documentation required:

Office notes

Rationale: Apheresis has been proposed as a treatment for a variety of diseases. A Medicare guideline created in 1992 documented several conditions for which apheresis has been proven to be of benefit. The covered conditions in the Medicare guideline have not change since that time. Typically, there is insufficient peer-reviewed scientific literature supporting the use of apheresis for other diagnoses.

Recently, there has been renewed interest in the use of apheresis when other more conservative therapies are ineffective. Although the literature supporting the use of apheresis is limited, the American Academy of Neurology recently updated their guidelines regarding the use of apheresis for Multiple Sclerosis and other degenerative diseases of the myelin sheath, the insulating material around nerves. Due to improvements in the diagnosis of Multiple Sclerosis based on the use of the McDonald criteria, the condition can be identified sooner, which allows for therapy to be started sooner. Attacks of Multiple Sclerosis are usually treated with the intravenous administration of high dose steroids. If the Multiple Sclerosis symptoms are not improved, then plasmapheresis can be considered. The guideline from the American Academy of Neurology specifically supports the use of apheresis for the relapsing form of multiple sclerosis, but also notes that the literature does not support the use of apheresis for progressive forms of Multiple Sclerosis.

- References: Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD): Apheresis (Therapeutic Apheresis). NCD 110.14. Baltimore, MD. Effective date: 07/30/1992. Available at: www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed: 3 Mar 11.
- Cortese I, Chaudhry V, So YT, Cantor F, Cornblath DR, Rae-Grant A. Evidence-based guideline update: Plasmapheresis in neurologic disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2011 Jan 18;76(3):294-300. Available at: www.neurology.org/content/76/3/294.full.pdf+html. Accessed: 3 Mar 11.
- Polman CH, Reingold SC, Edan G, Filippi M, Hartung HP, Kappos L, Lublin FD, Metz LM, McFarland HF, O'Connor PW, Sandberg-Wollheim M, Thompson AJ, Weinshenker BG, Wolinsky JS. Diagnostic criteria for multiple sclerosis: 2005 revisions to the "McDonald Criteria". *Ann Neurol*. 2005 Dec;58(6):840-6. Available at: onlinelibrary.wiley.com/doi/10.1002/ana.20703/pdf. Accessed: 3 Mar 11.
- Schroder A, Linker RA, Gold R. Plasmapheresis for neurological disorders. *Expert Rev Neurother*. 2009 Sep; 9(9):1331-9.
- Szczepiorkowski ZM, Winters JL, Bandarenko N, Kim HC, Linenberger ML, Marques MB, Sarode R, Schwartz J, Weinstein R, Shaz BH; Apheresis Applications Committee of the American Society for Apheresis. Guidelines on the use of therapeutic apheresis in clinical practice--evidence-based approach from the Apheresis Applications Committee of the American Society for Apheresis. *J Clin Apher*. 2010;25(3):83-177.

These guidelines are designed for reference purposes only, do not guarantee coverage, and should not be construed as medical advice. See full Medical Policy Disclaimer.

Approved by the Medical Director