08.01.16 Therapeutic Plasmapheresis or Plasma Exchange

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Related Policies:

- None

Summary

Description

The goal of plasmapheresis or plasma exchange (PE) is the removal of harmful plasma component(s), theoretically, decreasing the concentration of these harmful plasma component(s), to improve the course of the individuals condition. Abnormal components potentially removed with plasmapheresis/PE include toxins, metabolic substances, and plasma components, such as complement or antibodies. Plasmapheresis/PE has been utilized in various acute and chronic conditions, as well as in the setting of solid organ transplantation. Pheresis techniques are not intended to be curative treatments for most indications, rather, they are used to address related symptoms.

Summary of Evidence

For individuals who receive plasmapheresis or plasma exchange (PE) to acutely lower the circulating pathogenic substance in various self-limited diseases and acute exacerbations of fulminant exacerbations of chronic diseases, the evidence includes systematic reviews, randomized controlled trials (RCTs) and retrospective observational studies. Relevant outcomes of interest include symptoms, change in disease status, morbid events, functional outcomes, health status measures, quality of life (QOL), and treatment-related morbidity. Data from the peer reviewed published medical literature to include medical society guidelines have established that therapeutic plasmapheresis/PE improves symptom, change disease status, improve functional outcomes and subsequently improve QOL for the medically necessary indications listed in the Policy criteria statement below (Connelly-Smith et.al. 2023). Thus, the evidence is sufficient to determine the technology results in improvement in net health outcome.

For individuals who receive plasmapheresis or PE in the absence of acute self-limited diseases and acute fulminant exacerbations of chronic diseases as indicated in the Policy statements below, the evidence includes systematic reviews, RCTs and retrospective observational studies. Relevant outcomes of interest include symptoms, change in disease status, morbid events, functional outcomes, health status measures, QOL, and treatment-related morbidity. Data from the peer-reviewed, published medical literature and medical society guidelines have not yet established that therapeutic plasmapheresis/PE improves symptoms, changes disease status, improves functional outcomes or subsequently improve QOL (Connelly-Smith et.al. 2023). Additionally, the optimum role of therapeutic plasmapheresis/PE to remove specific autoantibodies, proteins and complements in the pathogenesis of many other conditions have not been established or the evidence demonstrated the therapy could be ineffective or harmful. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to determine whether plasmapheresis/plasma exchange (PE) when used for the treatment of various conditions including but not limited to the following: selected autoimmune, hematologic, neurologic, renal, and transplantation conditions improves net health outcomes.

PRIOR APPROVAL

Not applicable.

POLICY

Therapeutic plasmapheresis or plasma exchange (PE) may be considered **medically necessary** for any of the following conditions listed below:

- Acute disseminated encephalomyelitis (ADEM) steroid refractory
- Acute liver failure in individuals bridging to liver transplantation
- Acute inflammatory demyelinating polyradiculoneuropathy (Guillain-Barre syndrome)
- Acute idiopathic transverse myelitis steroid refractory

- Anti-glomerular basement membrane disease (Goodpasture's syndrome)
    - Diffuse alveolar hemorrhage (DAH)
    - Dialysis independence
- Anti-neutrophil cytoplasmic antibodies (ANCA)-associated rapidly progressive glomerulonephritis
- Autoimmune hemolytic uremic syndrome – severe cold agglutinin
- Catastrophic antiphospholipid syndrome (CAPS)
- Chronic acquired demyelinating polyneuropathies IgG, IgA, IgM related
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)
- Cryoglobulinemia severe/symptomatic
- Familial hypercholesterolemia
- Focal segmental glomerulosclerosis recurrent in kidney transplant
- Hemolysis, elevated liver enzymes, and low platelets syndrome (HELLP Syndrome)
- Hyperviscosity syndromes associated with monoclonal gammopathies (such as multiple myeloma and Waldenstrom's macroglobulinemia)
- Lambert-Eaton Myasthenic Syndrome
- Multiple myeloma cast nephropathy (acute renal failure secondary to multiple myeloma)
- Multiple sclerosis (MS)
    - For adjunctive treatment of exacerbations in relapsing forms of MS
    - In the treatment of fulminant CNS demyelinating disease that fails to respond to high dose corticosteroid treatment (as second line therapy either as standalone treatment or in conjunction with or modes of treatment)
- Mushroom poisoning (wild mushrooms, particularly the Amanita family)
- Myasthenia gravis
- Neuromyelitis Optica (also known as Devic's disease) acute attack/relapse
- N-methyl-D-aspartate receptor antibody encephalitis
- Paraproteinemic demyelinating neuropathies with IgA, IgG or IgM monoclonal gammopathy of undetermined significance (MGUS)
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), exacerbation
- Pemphigus Vulgaris as second line therapy, that is resistant to standard therapy (dapsone, corticosteroids, immunosuppressants such as azathioprine or cyclosporine)
- Phytanic acid storage disease (Refsum's Disease)
- Post transfusion purpura
- Progressive multifocal leukoencephalopathy associated with natalizumab (tysarbi)
- Steroid responsive encephalopathy associated with autoimmune thyroiditis (Hashimoto's encephalopathy)
- Systemic lupus erythematous (SLE) with severe complications (diffuse alveolar hemorrhage (DHA), thrombotic microangiography, hyperviscosity, cryoglobulinemia, and CNS involvement)
- Thrombotic microangiopathy (Factor H autoantibody) and drug associated (Ticlopidine)
- Thrombotic thrombocytopenia purpura (TTP)
- Thyroid storm with severe symptoms who respond poorly to first line therapeutic measures
- Transplantation
    - Hematopoietic stem cell transplant:
        - Human leukocyte antigen (HLA) desensitization
    - Solid organ transplantation for the following:
        - Desensitization
          Antibody-mediated rejection
- Voltage gated potassium channel antibodies
- Wilson Disease, fulminant

Therapeutic plasmapheresis or PE is considered **investigational** for all other conditions, including, but not limited, to the following, because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Acute liver failure for liver regeneration or acute fatty liver of pregnancy (*except as indicated above*)
- Amyloidosis, systemic
- Amyotrophic lateral sclerosis (ALS)
- Anti-glomerular basement membrane disease (Goodpasture syndrome) – dialysis dependence, no diffuse alveolar hemorrhage (DAH)
- Aplastic anemia
- Asthma
- Atopic (neuro) dermatitis (atopic eczema), recalcitrant
- Autoimmune hemolytic anemia, severe: warm autoimmune hemolytic anemia (WAHA)
- Autoimmune retinopathy
- Burn shock resuscitation
- Cardiac neonatal lupus
- Central nervous system demyelinating diseases (except as indicated above for the following indications: Acute disseminated encephalomyelitis (ADEM) steroid refractory, Acute inflammatory demyelinating polyradiculoneuropathy (Guillain-Barre syndrome), Acute idiopathic transverse myelitis steroid refractory)
- Chronic fatigue syndrome
- Chronic focal encephalitis (Rasmussen Encephalitis)
- Coagulation factor inhibitors (alloantibody and autoantibody)
- Complex regional pain syndrome
- Dermatomyositis or polymyositis
- Dilated cardiomyopathy, idiopathic (NYHA II-IV)
- Erythropoietic protoporphyria, liver disease
- Focal segmental glomerulosclerosis except as indicated above
- Henoch-Schonlein purpura
- Hemolytic uremic syndrome (HUS)heal-related)
- Heparin induced thrombocytopenia (HIT)
    - Pre-cardiopulmonary bypass; or
    - Heparin induced thrombocytopenia with thrombosis (HITT)
- Hemophagocytic lymphocytosis (HLH); Hemophagocytic syndrome; Macrophage activating syndrome
- Hypertriglyceridemia pancreatitis
- Immune complex rapidly progressive glomerulonephritis
- Immune thrombocytopenia (refractory)
- Immunoglobin A nephropathy (Berger's Disease)
- Inclusion body myositis
- Inflammatory bowel disease (ulcerative colitis, Crohn's disease)
- Multiple Sclerosis, *except as indicated above*
- Nephrogenic systemic fibrosis
- Neuromyelitis Optica (Devic's syndrome) *except as indicated above*
- Overdose, envenomation, and poisoning
- Paraneoplastic neurological syndromes
- Paraproteinemic demyelinating polyneuropathies (except as indicated above) multiple myeloma; Anti-MAG neuropathy; multifocal motor neuropathy)

- Pediatric autoimmune neuropsychiatric disorders (PANDAS) (except as indicated above for pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), exacerbation)
- Pemphigus vulgaris *except as indicated above*
- POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M protein, skin changes)
- Progressive multifocal leukoencephalopathy associated with natalizumab (tysarbi), *except as indicated above*
- Pruritus due to hepatobiliary diseases
- Psoriasis
- Pure red cell aplasia
- Red cell alloimmunization in pregnancy
- Rheumatoid arthritis
- Schizophrenia
- Scleroderma (progressive systemic sclerosis)
- Sepsis with multiorgan failure
- Status epilepticus
- Stiff-person syndrome
- Sudden sensorineural hearing loss
- Sydenham's Chorea
- Systemic lupus erythematous *except as indicated above*
- Thrombotic microangiopathy (*except as indicated above*) - coagulation mediated: THBD, DGKE, and PLG mutations; complement mediated: complement factor gene mutations; drug associated: clopidogrel, gemcitabine or quinine; transplantation associated
- Thyroid storm *except as indicated above*
- Toxic epidermal necrolysis, refractory

POLICY GUIDELINES

***Note**: For the treatment of solid organ transplantation antibody-mediated rejection (ABMR or AMR) plasmapheresis is typically performed for this indication within the first year of the transplantation. There is a lack of evidence regarding the treatment of late onset (after the first year of transplantation) for antibody-mediate rejection with plasmapheresis.*

Coding

See the Codes table for details.

BACKGROUND

Therapeutic plasmapheresis/PE is essentially symptomatic therapy because it does not remove the source of the pathogenic factors. Therefore, the success of therapeutic plasmapheresis/plasma exchange will depend on whether the pathogenic substances are accessible through the circulation and whether the rate of production and transfer to the plasma component can be adequately addressed by plasmapheresis/plasma exchange.

Applications of therapeutic plasmapheresis/PE can be broadly subdivided into three general categories:

- Acute self-limited diseases
- Acute fulminant exacerbations of chronic diseases; and
- Chronic diseases

In self-limited diseases and acute exacerbations of fulminant exacerbations of chronic diseases, therapeutic plasmapheresis/PE is used to acutely lower the circulating pathogenic substance. In chronic disease, there is ongoing production of pathogenic autoantibodies. Because therapeutic plasmapheresis/plasma exchange does not address underlying pathology, and, due to phenomenon of rebound antibody production, its use in chronic diseases has been less effective than in acute, self-limiting diseases. For this reason, chronic conditions are not amendable to plasmapheresis treatment.

The terms plasmapheresis, apheresis, and plasma exchange (PE) are often used interchangeably, however there are some differences. The American Society of Apheresis (ASFA) definitions for these procedures are as follows:

- **Apheresis:** is a general term describing removal of blood from a subject; a portion of the blood is separated and retained while the rest is returned to the donor.
- **Plasmapheresis**: removes a smaller amount of plasma, usually less than 15% of the patient's blood volume and therefore does not require replacement of the removed plasma.
- **Plasma Exchange (PE):** is the procedure that is preformed most. A large volume of plasma is removed from a patient. The volume removed is such that if it were not replaced, significant hypovolemia resulting in vasomotor collapse would occur. As a result, the removed plasma must be replaced with some form of replacement fluid such as albumin.

Therapeutic plasmapheresis/plasma exchange (PE) are typically performed in outpatient settings, including blood banks, dialysis centers, hospital clinics, and physician's offices. Reinfusion with human plasma may cause anaphylaxis and bleeding complications, and though rare, may require replacement of clotting factors. Therefore, plasmapheresis procedures should be performed by appropriately trained clinicians in a setting that can respond to medical emergencies at all times.

Regulatory Status

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 (e.g., immune globulin, albumin) and noninjectable products (e.g., in vitro devices such as blood bank reagents).

RATIONALE

This evidence review was created in February 2000 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through March 15, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Therapeutic Plasmapheresis or Plasma Exchange

Clinical Context and Therapy Purpose

The purpose of plasmapheresis or plasma exchange (PE) in the treatment of various conditions including but not limited to the following: selected autoimmune, hematologic, neurologic, renal, and transplantation conditions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals with a concentration of harmful plasma components from various conditions.

Interventions

The intervention of interest is therapeutic plasmapheresis or PE.

Therapeutic Plasmapheresis or PE is a procedure in which the plasma is isolated, then discarded or replaced with a substitution fluid such as albumin. The goal of therapeutic plasmapheresis/plasma exchange is the removal of harmful plasma components.

Comparators

The comparator of interest is standard medical care without therapeutic plasmapheresis or PE.

Outcomes

The outcomes of interest are symptoms, change in disease status, morbid events, functional outcomes, health status measures, quality of life, and treatment-related morbidity.

Study Selection Criteria

We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months of outcomes, and systematic reviews of RCTs. It is preferred to have double-blinded sham interventions to control for placebo effects.
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Review of Evidence

The evidence in the peer reviewed medical literature includes systematic reviews, RCTs, and retrospective observational studies regarding plasmapheresis/PE to acutely lower the circulating pathogenic substance in various self-limited diseases and acute exacerbations of fulminant exacerbations of chronic diseases. Data from this published medical literature (Connelly-Smith et.al. 2023) and medical society guidelines have established that therapeutic plasmapheresis/PE improves symptoms, changes disease status, improves functional outcomes and subsequently improves QOL for the medically necessary indications listed in the Policy criteria statement above. See also Practice Guideline and Position Statements to review guidelines that include the American Society of Apheresis.

The evidence in the peer reviewed medical literature includes systematic reviews, RCTs, and retrospective observational studies regarding plasmapheresis or plasma exchange (PE) in the absence of acute self-limited diseases and acute fulminant exacerbations of chronic diseases as indicated in the Policy statement above, Data from (Connelly-Smith et.al. 2023) regarding the therapeutic role of plasmapheresis/PE in the removal of specific autoantibodies, proteins and complements in the pathogenesis of many other conditions has not been established or the evidence demonstrated the therapy could be ineffective or harmful.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

In 2011, the American Academy of Neurology (Therapeutics and Technology Assessment Subcommittee) issued an evidence-based guideline on plasmapheresis in the treatment of neurological disorders. The primary conclusions based on their evidence review are as follows:

Acute Inflammatory Demyelinating Polyneuropathy/Guillain-Barre Syndrome	
What is the efficacy of plasmapheresis in the treatment of acute inflammatory demyelinating polyneuropathy (AIDP), also known as Guillain-Barre Syndrome (GBS)?	
Strong evidence	Plasmapheresis should be offered in the treatment of AIDP/GBS severe enough to impair independent walking or to require mechanical ventilation (Level A).
Good evidence	Plasmapheresis should be considered in the treatment of milder clinical presentations with AIDP/GBS (Level B).
Clinical context	IV immunoglobulin (IVIg) is an alternative treatment used in patients with AIDP/GBS. There is insufficient evidence to demonstrate the superiority of one treatment over the other.
Chronic Inflammatory Demyelinating Neuropathy	
What is the efficacy of plasmapheresis in the treatment of chronic inflammatory demyelinating neuropathy (CIDP)?	
Strong evidence	Plasmapheresis should be offered as a short-term treatment for patients with CIDP (Level A).
Clinical context	Steroids, IVIg, and immunosuppressants also have been used in the treatment of CIDP.
Dysimmune Neuropathies	
What is the efficacy of plasmapheresis in the treatment of dysimmune neuropathies?	
Good evidence	Plasmapheresis should be considered in polyneuropathy associated with IgA and IgG monoclonal gammopathy of undetermined significance (MGUS) (Level B).
	Plasmapheresis should not be considered in the treatment of polyneuropathy associated with IgM MGUS (Level B).
Myasthenia Gravis	
What is the efficacy of plasmapheresis in the treatment of myasthenia gravis (MG)?	
Insufficient evidence	Because of lack of randomized controlled studies with masked outcomes, there is insufficient evidence to support or refute the efficacy of plasmapheresis in the treatment of myasthenic crisis (Level U) or MG prethymectomy (Level U)
CNS Demyelinating Disease	
What is the efficacy of plasmapheresis in the treatment of CNS demyelinating disease?	
Strong evidence	Plasmapheresis should not be offered for chronic progressive or secondary progressive multiple sclerosis (MS) (Level A).
Good evidence	Plasmapheresis should be considered for the adjunctive treatment of exacerbations in relapsing forms of MS (Level B).
Weak evidence	Plasmapheresis may be considered in the treatment of fulminant CNS demyelinating diseases that fail to respond to high dose corticosteroid treatment (Level C).
Clinical context	No studies on the efficacy of plasmapheresis compared to other treatment options in MS are available.
Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection	
What is the efficacy of plasmapheresis in the treatment of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)?	

Insufficient evidence	There is insufficient evidence to support or refute the use of plasmapheresis in the treatment of acute obsessive-compulsive disorder (OCD) and tic symptoms in the setting of PANDAS (Level U).
Sydenham Chorea	
What is the efficacy of plasmapheresis in the treatment of Syndenham Chorea?	
Insufficient evidence	There is insufficient evidence to support or refute the use of plasmapheresis in the treatment of Sydenham chorea (Level U).

Classification of Recommendations:

- A = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies).*
- B = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies).
- C = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies).
- U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome > 5 and the lower limit of the confidence interval is > 2).

American Heart Association (AHA)

In 2015, the American Heart Association (AHA) issued a scientific statement regarding antibody-mediated rejection (AMR) in cardiac transplantation, which included the following:

The following are 10 points to remember from this American Heart Association Scientific Statement about antibody-mediated rejection (AMR) in cardiac transplantation:

1. AMR is a "clinical entity with specific histopathologic, immunopathologic, and serological characteristics."
2. Risk factors for AMR includes elevated PRA, CMV seropositivity, prior mechanical circulatory support, prior treatment with muromoab-CD3 and development of antibodies against mouse monoclonal muromonab-CD3, history of retransplantation, multiparity, and positive crossmatch on T-cell flow cytometry.
3. It may present hyperacutely (within 0-7 days after transplantation), early (within the first month after transplantation), or late (months to years after transplantation).
4. Key diagnostic findings include: a) Clinical evidence of graft dysfunction, b) histopathologic evidence of acute capillary injury including changes in capillary endothelium and macrophages in capillaries, c) immunopathologic evidence for antibody-mediated injury including changes in C3d and/or C4d immunofluorescence staining or CD68 or C4d immunoperoxidase staining or severe fibrin in vessels, and d) serological evidence of anti-HLA or anti-donor antibodies.
5. The presentation of AMR may vary from mild heart failure to cardiogenic shock.
6. Endomyocardial biopsy is the gold standard for establishing the development of AMR.

7. There have been no large randomized clinical trials to evaluate therapies for AMR and hence there are no level I recommendations and all recommendations are therefore based on consensus.
8. The guiding principles for the management of AMR include removing circulating alloantibodies, reducing production of additional antibodies, and suppressing T-cell and B-cell responses.
9. Commonly used agents utilized in the treatment of AMR include: a) corticosteroids (act by suppression of T- and B-cell response), b) plasmapheresis (acts by eliminating circulating antibodies), c) IVIG (act by inhibiting residual antibodies and inhibition of complement), whereas less commonly used agents include: a) rituximab or splenectomy (act by suppression or depletion of B cells), b) bortezomib (act by suppression or depletion of plasma cells), c) eculizumab (by inhibition of complement), and d) mycophenolate mofetil, anti-lymphocyte antibodies, photopheresis, or total lymphoid irradiation (these act by suppression of T-cell response). In addition to treating AMR with cytotoxic or antibody-directed therapy, the background regimen should be optimized using potent B-cell receptors (mycophenolate and sirolimus).
10. AMR is associated with allograft failure, increased mortality, increased incidence of coronary artery vasculopathy, and overall poor prognosis.

American Society for Apheresis (ASFA)

In 2023, the American Society for Apheresis (ASFA) released the ninth special issue of their guidelines on the use of therapeutic apheresis in clinical practice. The therapeutic apheresis procedures considered in this guideline include therapeutic plasma exchange (TPE).

Category Definitions for Therapeutic Apheresis

Category	Description
I	Disorders for which apheresis is accepted as first line therapy, either as primary standalone treatment or in conjunction with other modes of treatment
II	Disorders for which apheresis is accepted as second line therapy, either as standalone treatment or in conjunction with other modes of treatment
III	Optimum role of apheresis therapy is not established. Decision making should be individualized
IV	Disorders in which published evidence demonstrates or suggest apheresis to be ineffective or harmful. Institutional Review Board (IRB)/Ethics Committee approval is desirable if apheresis treatment is undertaken in these circumstances

Grading Recommendations: Strength and Quality of Evidence

Recommendation	Description	Quality of Evidence	Implications
Grade 1A	Strong recommendation, high quality evidence	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
Grade 1B	Strong recommendation, moderate quality evidence	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
Grade 1C	Strong recommendation, low quality or very low-quality evidence	Observational studies or case series	Strong recommendation, but may change when higher quality evidence becomes available
Grade 2A	Weak recommendation, high quality evidence	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
Grade 2B	Weak recommendation, moderate quality evidence	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
Grade 2C	Weak recommendation, low quality or very low-quality evidence	Observational studies or case series	Very weak recommendations: other alternatives may be equally reasonable

RCT, randomized controlled trial

Recommendations for Therapeutic Apheresis Exchange (TPE)

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
Acute disseminated encephalomyelitis (ADEM)	TPE	Steroid Refractory	II	2C
Acute Inflammatory demyelinating polyradiculoneuropathy	TPE	Primary Treatment	I	1A
Acute liver failure	TPE-HV	Acute liver failure- in select individuals bridging to liver transplantation	I	1A 2B

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
	TPE	Expected liver regeneration	III	2B
	TPE	Acute fatty liver of pregnancy[a]	III	2B
Acute toxins, venoms and poisons	TPE/RBC exchange	Other[a]	III	2C
	TPE	Mushroom poisoning	II	2C
	TPE	Envenomation	III	2C
Alzheimer's disease[a]	TPE	Mild or moderate	III	2A
Anti-glomerular basement membrane disease (Goodpasture's syndrome)	TPE	Dialysis dependence and no diffuse alveolar hemorrhage (DAH)	III	2B
	TPE	Dialysis independence	I	1B
	TPE	Diffuse alveolar hemorrhage (DAH)	III	2B
Atopic (neuro) dermatitis (atopic eczema), recalcitrant (new in 2016)	TPE/DFPP (double filtration plasmapheresis)		III	2C
Autoimmune dysautonomia[a]	TPE		III	2B
Autoimmune hemolytic anemia, severe	TPE	Severe cold agglutinin disease	II	2C
	TPE	Severe warm autoimmune hemolytic anemia	III	2C
Burn shock resuscitation	TPE		III	2B
Cardiac neonatal lupus	TPE		III	2C
Catastrophic antiphospholipid syndrome (CAPS)	TPE		I	2C
Chronic acquired demyelinating polyneuropathies	TPE	IgG/IgA/IgM related	I	1B
	TPE	Anti-myelin-associated glycoprotein	III	IC
	TPE	CANOMAD/CANDA[a]	III	2C

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
Chronic focal encephalitis	TPE/IA (Immunoadsorption)		III	2C
Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)	TPE/IA (Immunoadsorption)		I	1B
Coagulation factor inhibitors	TPE		III	2C
Complex regional pain syndrome	TPE	Chronic	III	2C
Cryoglobulinemia	TPE/DFPP (double filtration plasmapheresis)	Severe/symptomatic	II	2A
Dilated cardiomyopathy, idiopathic	TPE	NYHA II-IV	III	2C
Erythropoietic protoporphyria, liver disease	TPE/RBC exchange		II	2C
Familial hypercholesterolemia	TPE	All patients	II	1B
Focal segmental glomerulosclerosis (FSGS)	TPE/IA (Immunoadsorption) TPE	Recurrent in kidney transplant Steroid resistant in native kidney	I III	1B 2C
Hemophagocytic: lymphohistiocytosis (HLH)	TPE		III	2C
Heparin induced thrombocytopenia and thrombosis (HIT/HITT)	TPE/IA (Immunoadsorption) TPE	Pre-procedure Refractory or with thrombosis	III III	2C 2C
Hypertriglyceridemia pancreatitis	TPE/LA (Lipoprotein apheresis) TPE/LA (Lipoprotein apheresis)	Severe Prevention of relapse	III III	1C 2C
Hyperviscosity in hypergammaglobulinemia	TPE TPE	Symptomatic Prophylaxis for rituximab	I I	1B 1C
Idiopathic inflammatory myopathies[a]	TPE TPE TPE	Anti-synthetase-syndrome Clinically amyopathic dermatomyositis Immune-mediated necrotizing myopathies	III III III	2B 2B 2B
IgA nephropathy (Berger's Disease)	TPE TPE	Crescentic Chronic Progressive	III III	2B 2C
Immune thrombocytopenia (ITP)	TPE/IA (Immunoadsorption)	Refractory	III	2C

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
Lambert Eaton myasthenic syndrome	TPE		II	2C
Multiple sclerosis	TPE TPE	Acute attack/relapse Chronic primary or secondary progressive	II III	1A 2B
Myasthenia gravis	TPE/DFPP/IA (Immunoadsorption) TPE/DFFP/IA (Immunoadsorption)	Acute, short-term treatment Long-term treatment	I II	1B 2B
Myeloma cast nephropathy	TPE		II	2B
Nephrogenic systemic fibrosis	ECP/TPE (Extracorporeal photopheresis/therapeutic plasma exchange)		III	2C
Neuromyelitis optical spectrum disorders (NMOSD)	TPE TPE	Acute attack/relapse Maintenance	II III	1B 2C
N-methyl-D-aspartate receptor antibody encephalitis	TPE/IA (Immunoadsorption)		I	1C
Paraneoplastic autoimmune retinopathies[a]	TPE		III	2C
Paraneoplastic neurologic syndromes	TPE/IA (Immunoadsorption)		III	2C
Pediatric autoimmune neuropsychiatric disorders	TPE TPE	PANDAS, exacerbation Sydenham’s chorea, severe	II III	1B 2B
Pemphigus vulgaris	TPE	Severe	III	2B
Phytanic acid storage disease	TPE/LA (Lipoprotein apheresis)		II	2C
Post transfusion purpura (PTP)	TPE		III	2C
Progressive multifocal leukoencephalopathy (PML) associated with natalizumab	TPE		III	1C
Pruritus due to hepatobiliary disease, treatment resistant	TPE	Treatment resistant	III	1C
Psoriasis	TPE	Disseminated pustular	IV	2C
Red cell alloimmunization, pregnancy complications	TPE	Hemolytic disease of the fetus and newborn	III	2C
Sepsis with multi-organ failure	TPE		III	2A

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
Steroid responsive encephalopathy associated with autoimmune thyroiditis	TPE		II	2C
Stiff person syndrome	TPE		III	2C
Sudden sensorineural hearing loss	TPE		III	2A
Systemic lupus erythematosus (SLE)	TPE	Severe	II	2C
Thrombotic microangiography, coagulation mediated	TPE	THBD, DGKE, and PLG mutations	III	2C
Thrombotic microangiopathy, complement mediated	TPE TPE	Factor H autoantibody Complement factor gene mutations	I III	2C 2C
Thrombotic microangiopathy, drug associated	TPE TPE TPE	Ticlopidine Clopidogrel Gemcitabine/Quinine	I III IV	2B 2B 2C
Thrombotic microangiopathy, infection associated	TPE/IA (Immunoadsorption) TPE	STEC-HUS severe pHUS	III III	2C 2C
Thrombotic microangiopathy, pregnancy associated	TPE TPE/LA (Lipoprotein apheresis)	Pregnancy associated severe Extremely preterm preeclampsia severe[a]	III III	2C 2C
Thrombotic microangiopathy, thrombotic thrombocytopenic purpura (TTP)	TPE		I	1A
Thrombotic microangiopathy, transplantation associated	TPE		III	2C
Thyroid storm	TPE		II	2C
Toxic epidermal necrolysis (TEN)	TPE	Refractory	III	2B
Transplantation, heart	TPE TPE TPE	Desensitization Antibody mediated rejection Rejection prophylaxis[a]	II III II	1C 2C 1C
Transplantation, hematopoietic stem cell, ABO incompatible (ABOi)	TPE TPE TPE	Major ABOi HPC(M) Major ABOi HPC(A)	II II III	1B 2B 2C

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
		Major/Minor ABOi with pure RBC aplasia		
Transplantation, hematopoietic stem cell, HLA desensitization	TPE		III	2C
Transplantation, intestine[a]	TPE TPE	Antibody- mediated rejection Desensitization	III III	2C 2C
Transplantation, Kidney, ABO compatible	TPE/IA (Immunoadsorption) TPE/IA (Immunoadsorption)	Antibody-mediated rejection Desensitization/prophylaxis, living donor	I I	1B 1B
Transplantation, kidney, ABO incompatible	TPE/IA (Immunoadsorption) TPE/IA (Immunoadsorption)	Desensitization, living donor Antibody- mediated rejection	I II	1B 1B
Transplantation, liver	TPE TPE TPE	Desensitization, ABOi living donor Desensitization, ABOi deceased donor Antibody- mediated rejection	I III III	1C 2C 2C
Transplantation, lung	TPE TPE	Antibody- mediated rejection Desensitization	III III	2C 2C
Vaccine-induced immune thrombotic thrombocytopenia[a]	TPE	Refractoey	III	2C
Vasculitis, ANCA associated	TPE TPE TPE	Microscopic polyangiitis Granulomatosis with polyangiitis Eosinophilic granulomatosis with 17olyangiitis	III III III	1B 1B 2C
Vasculitis, IgA	TPE TPE	Crescentic RPGN Severe extrarenal manifestations	III III	2C 2C

Disease	Therapeutic Apheresis Modality	Indication	Category	Grade
Vasculitis, other	TPE TPE TPE	Hepatitis B polyarteritis nodosa Kawasaki disease[a] Multisystem inflammatory syndrome in children[a]	II III III	2C 2C 2C
Voltage gated potassium channel antibody related diseases	TPE/IA (Immunoadsorption)		II	1B
Wilson disease, fulminant	TPE		I	1C

[a]NEW fact sheet or indication

National Comprehensive Cancer Network (NCCN)

Current National Comprehensive Cancer Network (NCCN) guidelines:

Cancer Indication	Current Clinical Recommendation
Multiple Myeloma	Plasmapheresis should be used as an adjunctive therapy for symptomatic hyperviscosity.
Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma	Plasmapheresis for symptomatic hyperviscosity and before treatment with rituximab-containing regimen in patients with IgM ≥ 4000 mg/dL. IgM should be monitored closely in these patients thereafter and plasmapheresis should be considered again if symptomatic hyperviscosity recurs or if IgM is ≥ 4000 mg/dL while on rituximab-containing therapy. Red blood cell (RBC) transfusion, if indicated, should done after plasmapheresis to prevent added hyperviscosity load.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	36514	Therapeutic apheresis; for plasmapheresis
HCPCS		
	None	
Type of Service	Therapy	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
March 2025	Annual Review	Policy Revision
March 2024	Annual Review	Policy Revised
March 2023	Annual Review	Policy Revised

Date	Action	Action
May 2022	Annual Review	Policy Revised
May 2021	Annual Review	Policy Revised
May 2020	Annual Review	Policy Revised
September 2019	Interim Review	Policy Revised
May 2019	Annual Review	Policy Revised
May 2018	Annual Review	Policy Renewed
May 2017	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
June 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Revised
September 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
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