Coverage of any medical intervention discussed in a Prevea360 Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or summary plan description (SPD) and applicable state and/or federal laws.

Therapeutic Apheresis (TA) – Plasmapheresis, Plasma Exchange MP9627

Covered Service: Yes

Prior Authorization Required: No

Additional Information: See Extracorporeal Photophoresis (Photochemotherapy) MP9558 for additional information

The criteria in this policy do not apply to those devices which have been granted a humanitarian device exemption (HDE) by the FDA, which are considered medically necessary when all FDA-required criteria are met.

For a current list of HDE approved devices, refer to the FDA HDE database at: Listing of CDRH Humanitarian Device Exemptions | FDA

Prevea360 Health Plan Medical Policy:

Extracorporeal Column Immunoadsorption Apheresis

1.0 Therapeutic aphaeresis (TA) employing extracorporeal immunoadsorption (ECI) **does not require** prior authorization and is considered medically necessary for **ANY** of the following indications:

- 1.1 Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome, acute) primary treatment
- 1.2 Chronic inflammatory demyelinating polyradioculoneuropathy (CIDP)
- 1.3 Cryoglobulinemia, severe/symptomatic
- 1.4 Dilated idiopathic cardiomyopathy, NYHA II-IV
- 1.5 Encephalitis associated with N-methyl D aspartate receptor antibodies
- 1.6 Focal segmental glomerulosclerosis, recurrent in kidney transplant
- 1.7 Multiple sclerosis, acute attack/relapse
- 1.8 Myasthenia gravis, acute/short term and long term treatment
- 1.9 Neuromyelitis optica spectrum disorders, acute attack or relapse (Devic's syndrome)

1.10 Renal transplantation, ABO incompatible

1.10.1 Antibody-mediated rejection

1.10.2 Desensitizations, living donor

1.11 Voltage-gated potassium channel antibody-related diseases

2.0 TA employing ECI is experimental and investigational, and therefore not medically necessary for **ALL** other indications including but not limited to treatment for:

2.1 Coagulation factor inhibitors, alloantibody or autoantibody

2.2 Multiple sclerosis, chronic

2.3 Atopic (neuro) dermatitis (atopic eczema), recalcitrant

2.4 Immune thrombocytopenia, refractory

2.5 Paraneoplastic neurologic syndromes

2.6 Paraproteinemic demyelinating polyneuropathies, IgG/IgA/IgM

2.7 Pemphigus vulgaris, severe

2.8 Thrombotic microangiopathy, infection associated: Shiga toxin-mediated (STEC-HUS)

2.9 Renal transplantation, ABO compatible

2.9.1 Desensitization, deceased donor

3.0 The experimental and investigational determination does not apply to HDE approved devices. HDE approved devices are covered for the following:

3.1 Excorim® Immunoadsorption System (H970004) for the treatment of individuals with hemophilia A and have Factor VIII or Factor IX inhibitor titers above 10 BU/ml.

Extracorpeal Low-Density Lipoprotein Apheresis

4.0 TA employing Extracorpeal low-density lipoprotein apheresis **does not require** prior authorization and is considered medically necessary for the treatment of **ANY** of the following:

4.1 Familial hypercholesterolemia, refractory, either homozygous or heterozygous

4.2 Lipoprotein (a) hyperlipoproteinemia

4.3 Peripheral vascular disease

4.4 Phytanic acid storage disease (Refsum's disease)

5.0 TA employing extracorporeal low-density lipoprotein apheresis is considered experimental and investigational, and therefore not medically necessary for **ALL** other indications, including but not limited to:

5.1 Hypertriglyceridemic pancreatitis, severe, including prevention of relapse

5.2 Steroid-resistant focal segmental glomerulosclerosis in native kidney, recurrent in kidney transplant

5.3 Sudden sensorineural hearing loss

6.0 The experimental and investigational determination does not apply to devices that have been granted a Humanitarian Device Exemption by the FDA, FDA-approved HDE device is considered medically necessary when all FDA-required criteria are met.

6.1 LIPOSORBER® LA-15 System (H170002) has FDA HDE approval for the treatment of adult and pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis, when standard treatment options, including corticosteroid and/or calcineurin inhibitors treatments, are unsuccessful or not well tolerated and the patient has a glomerular filtration rate (GFR) greater than or equal to 60 ml/min/1.73m2 or the patient is post renal transplantation.

Standard Plasmapheresis/Plasma Exchange

7.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following autoimmune/rheumatic indications:

7.1 Hyperglobulinemias and macroglobulinemias producing hyperviscosity syndromes, including but not limited to multiple myeloma, cryoglobulinemia, and Waldenstrom's macroglobulinemia

7.2 Systemic lupus erythematous, severe complications (e.g., cerebritis, diffuse alveolar hemorrhage)

7.3 Catastrophic antiphospholipid syndrome (CAPS)

8.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following hematologic indications:

8.1 Autoimmune hemolytic anemia, severe cold agglutinin disease

8.2 Hyperviscosity in monoclonal gammopathies (e.g., treatment of symptoms; prophylaxis for rituximab)

8.3 Acquired thrombotic thrombocytopenic purpura (TTP), autoimmune

9.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for (hepatic indications) acute liver failure requiring high volume apheresis.

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10.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following metabolic indications:

- 10.1 Factor H autoantibodies, thrombotic microangiopathy, complement related
- 10.2 Familial hypercholesterolemia, homozygous with small blood volume
- 10.3 Overdose, venoms, and poisoning: mushroom poisoning
- 10.4 Refsum's disease (phytanic acid storage disease)
- 10.5 Thrombotic microangiopathy:
  - 10.5.1 Complement-mediated: Factor H autoantibodies
  - 10.5.2 Drug-associated: Ticlopidine
- 10.6 Thyroid storm
- 10.7 Vasculitis: Hepatitis B virus-associated polyarteritis nodosa (HBC-PAN)
- 10.8 Voltage-gated potassium channel antibody related diseases
- 10.9 Wilson's disease, fulminant hepatic failure with hemolysis

11.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following neurological indications:

- 11.1 Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome, acute), primary treatment
- 11.2 Multiple sclerosis, acute attack/relapse
- 11.3 Acute disseminated encephalomyelitis, steroid refractory
- 11.4 Multiple myeloma, severe/symptomatic cryoglobulinemia
- 11.5 Chronic inflammatory demyelinating polyradioculoneuropathy (CIDP)
- 11.6 Paraproteinemic demyelinating polyneuropathies (e.g., IgG/IgA/IgM)
- 11.7 Lambert-Eaton myasthenic syndrome
- 11.8 Myasthenia gravis, acute/short term and long term treatment
- 11.9 Neuromyelitis optica spectrum disorders, acute attack or relapse (Devic's syndrome)
- 11.10 Pediatric autoimmune neuropsychiatric disorders associated with:
  - 11.10.1 Streptococcal infections (PANDAS), exacerbation
- 11.11 Steroid responsive encephalopathy associated with autoimmune thyroiditis (Hashimoto's encephalopathy)

11.12 Encephalitis associated with N-methyl D-aspartate receptor antibodies.

12.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following renal (other than transplant-related) indications:

12.1 Anti-glomerular basement membrane disease (Goodpasture's syndrome):

12.1.1 When dialysis independent

12.1.2 With diffuse alveolar hemorrhage (DAH)

12.2 ANCA-associated vasculitis:

12.2.1 When dialysis dependent or imminent

12.2.2 With diffuse alveolar hemorrhage (DAH)

12.3 Myeloma cast neuropathy

13.0 TA employing standard plasmapheresis/plasma exchange methodology **does not require** prior authorization and is considered medically necessary for **ALL** of the following transplantation indications:

13.1 Cardiac transplantation, desensitization

13.2 Focal segmental glomerulosclerosis, recurrent, in transplanted kidney

13.3 Hematopoietic stem cell transplant (HSCT), major ABO incompatibility (ABOi)

13.4 Liver transplantation, ABO incompatible: live donor desensitization

13.5 Renal transplantation, ABO compatible:

13.5.1 Antibody mediated rejection

13.5.2 Living donor desensitization

13.6 Renal transplantation, ABO incompatible:

13.6.1 Antibody mediated rejection

13.6.2 Living donor desensitization

14.0 All other applications of TA employing standard plasmapheresis/plasma exchange are considered experimental and investigational, and therefore not medically necessary. including **ANY** of the following:

14.1 Autoimmune/rheumatic indications:

14.1.1 Dermatomyositis, polymyositis, or inclusion body myositis Inclusion body myositis

14.1.2 Neonatal lupus, cardiac

14.1.3 Pemphigus vulgaris, severe

14.1.4 Progressive system sclerosis (scleroderma)

14.1.5 Psoriasis, disseminated pustular

14.1.6 Rheumatoid arthritis, refractory

14.1.7 Toxic epidermal necrolysis, refractory

14.2 Hematologic indications:

14.2.1 Hemophagocytic lymphocytosis (HLA); macrophage activating syndrome

14.2.2 Warm autoimmune hemolytic anemia, severe

14.2.3 Coagulation factor inhibitors, alloantibody or autoantibody

14.2.4 Red cell alloimmunization in pregnancy, gestational age less than 20 weeks

14.2.5 Thrombocytopenic purpura (TP), other than thrombotic TP (e.g., Henoch-Schonlein purpura, post-transfusion purpura, refractory immune thrombocytopenia)

14.3 Hepatic indications: acute liver failure, standard plasmapheresis/plasma exchange

14.4 Metabolic indications:

14.4.1 Atopic (neuro) dermatitis (atopic eczema), recalcitrant

14.4.2 Erythropoietic protoporphyria, liver disease

14.4.3 Hemolysis with elevated liver function tests and low platelet count (HELLP syndrome), antepartum or postpartum

14.4.4 Progressive multifocal leukoencephalopathy associated with natalizumab

14.4.5 Thrombotic microangiopathy when associated with:

14.4.5.1 Complement-mediated: complement factor gene mutations

14.4.5.2 Coagulation mediated: *THBD, DGKE*, and *PLG* mutations

14.4.5.3 Drug associated:

14.4.5.3.1. Clopidogrel

14.4.5.3.2. Gemcitabine

14.4.5.3.3. Quinine

14.4.5.4 Hemolytic uremic syndrome (HUS) infection associated with:

14.4.5.4.1. Shiga toxin-mediated (STEC-HUS), severe

14.4.5.4.2. Streptococcus pneumonia-related (pHUS)

14.4.5.5 Thrombocytopenia and thrombosis, heparin induced

14.4.5.6 Overdose or poisoning, drug

14.4.5.7 Overdose, venoms, and poisoning: all indications *other than* mushroom poisoning (e.g. envenomation)

14.4.5.8 Pruritus due to hepatobiliary disease, treatment resistant

14.4.5.9 Vasculitis

14.4.5.9.1. Bechet's disease

14.4.5.9.2. Eosinophilic granulomatosis with polyangiitis (EGPA)

14.4.5.9.3. Idiopathic polyarteritis nodosa (PAN)

14.5 Neurological indications:

14.5.1 Amyotrophic lateral sclerosis (ALS) or progressive systemic sclerosis

14.5.2 Chronic focal encephalitis (Rasmussen's encephalitis)

14.5.3 Multiple sclerosis, chronic

14.5.4 Neuromyelitis optica spectrum disorders, maintenance

14.5.5 Paraneoplastic neurologic syndromes

14.5.6 Pediatric autoimmune neuropsychiatric disorders associated with severe Sydenham's chorea

14.5.7 Stiff-person syndrome

14.5.8 Functional psychotic disorders (e.g. schizophrenia)

14.5.9 Paraproteinemic demyelinating polyneuropathy, chronic acquired:

14.5.9.1 Multiple myeloma

14.5.9.2 Anti-MAG neuropathy

14.5.9.3 Multifocal motor neuropathy

14.6 Renal indications:

14.6.1 Anti-glomerular basement membrane disease (Goodpasture's syndrome); when dialysis dependent with no diffuse alveolar hemorrhage (DAH)

14.6.2 Focal segmental glomerulosclerosis, steroid resistant in native kidney

14.6.3 Immunoglobin A nephropathy, chronic progressive or crescentic

14.6.4 Nephrogenic systemic fibrosis

14.7 Transplantation indications:

14.7.1 Liver transplant, ABO incompatible for either:

14.7.1.1 Desensitization, deceased donor

14.7.1.2 Living donor, antibody-mediated rejection or desensitization

14.7.2 Lung transplantation, antibody-mediated rejection or desensitization

14.7.3 Heart (Cardiac): Transplant antibody-mediated rejection, including ABO and HLA

14.7.4 Renal transplant, ABO compatible, for deceased donor desensitization

14.7.5 Hematopoietic stem cell transplant (HSCT)-associated, including thrombotic microangiopathy, or HLA desensitization, or major/minor ABO incompatibility with pure RBS aplasia

14.7.6 Thrombotic microangiopathy, transplantation associated

14.8 Miscellaneous indications:

14.8.1 Burn shock resuscitation

14.8.2 Cardiomyopathy/dilated idiopathic; NYHA II-IV

14.8.3 Complex regional pain syndrome

14.8.4 Acute liver failure, standard plasmapheresis/plasma exchange

14.8.5 Amyloidosis, systemic

14.8.6 Hypertriglyceridemic pancreatitis, severe, including prevention of relapse

14.8.7 POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, skin changes)

14.8.8 Sepsis/septic shock with multi-organ failure

14.8.9 Sensorineural hearing loss, sudden

14.8.10 All disorders not listed.

14.9 This experimental and investigational determination does not apply to devices that have been granted a Humanitarian Device Exemption by the FDA and is considered medically necessary when all of the FDA-required criteria are met.

14.9.1 The Plasma Delipidation System (PDS-2™ System) (H190001) has FDA HDE approval to reduce artery atheroma in adult patients with homozygous familial hypercholesterolemia who are inadequately

responsive to or intolerant of maximal therapy, including the latest medications or devices approved by the FDA.

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division	February 15, 2023
Revised:	Medical Policy Committee/Health Services Division	January 17, 2024
	Medical Policy Committee/Health Services Division	February 21,2024
Reviewed:	Medical Policy Committee/Health Services Division	January 17, 2024
	Medical Policy Committee/Health Services Division	February 21, 2024

Published: 03/01/2024

Effective: 03/01/2024