Sentara® Health Plans

Medicaid

Apheresis

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses the medical necessity of Apheresis.

Description & Definitions:

Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood components (plasma, leukocytes, platelets, or cells) from whole blood, treat, and return back to the blood circulation. During the procedure, whole blood is removed from the body and the blood plasma and blood cells are separated. Antibodies are found in plasma, so the plasma is discarded. The blood cells are recombined with a plasma substitute, or donor plasma, and is returned to the body.

Plasmapheresis is one form of apheresis. Other types of apheresis are designed to isolate and remove specific pathogenic factors (e.g., cytopheresis isolates and removal of cellular components of the blood, while low-density lipid apheresis isolates and removes low-density lipoproteins; Protein A column pheresis (aka extracorporeal immunoadsorption) isolates and removes pathogenic immunoglobulins).

Therapeutic plasmapheresis resembles dialysis but, in addition, can remove protein-bound toxic substances. To be of benefit, plasmapheresis should be used for diseases in which the plasma contains a known pathogenic substance, and plasmapheresis should remove this substance more rapidly than the body can produce it.

Criteria:

Therapeutic apheresis may be indicated for **1 or more** of the following:

- Acute disseminated encephalomyelitis, as indicated with **All** the following:
  - where conventional treatment (including corticosteroids) has failed (i.e., severe neurological deficits have persisted after treatment with corticosteroids)

    - last resort
- Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome), as indicated by **All** of the following:
    - Individual has grades 3 to 5 disease.
    - Treatment will be initiated within 2 weeks of onset of neuropathic symptoms for ambulant individuals and within 4 weeks of symptom onset for non-ambulant individuals.
- Antiphospholipid syndrome (catastrophic), as indicated by **ALL** of the following:
    - Acute involvement of 3 or more organs, systems, or tissues
    - Antiphospholipid antibodies present
- Age-related macular degeneration (dry)
- Amanita mushroom poisoning
- Antiglomerular basement membrane disease, as indicated by **1 or more** of the following:
    - Diffuse alveolar hemorrhage.
    - Individual not dialysis dependent, and creatinine less than 6.6 mg/dL (583 micromoles/L)
- Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis, (Wegener's granulomatosis, microscopicas polyangiitis, Churg-Strauss syndrome) indicated by **ALL** of the following:
    - Antineutrophil cytoplasmic antibody positive
    - Appropriate clinical condition, as indicated by **1 or more** of the following:
        - Dialysis dependent
        - Dialysis is imminent.
        - Diffuse alveolar hemorrhage.
- Autoimmune encephalitis
- Babesiosis (severe) as indicated by **1 or more** of the following:
    - Disseminated intravascular coagulation.
    - Greater than 10% parasitemia
    - Pulmonary, renal, or hepatic dysfunction
    - Significant hemolysis (eg, blood hemoglobin level less than 10 g/dL (100 g/L), hemoglobinuria)
- Cardiac transplant, as indicated by **1 or more** of the following:
    - Cellular or recurrent rejection treatment needed.
    - Desensitization prior to transplant
    - Rejection prophylaxis needed.
- Chronic inflammatory demyelinating polyradiculoneuropathy, as indicated by **ALL** of the following:
    - Hyporeflexia or areflexia present in most limbs.
    - Insufficient response to corticosteroids or intravenous immunoglobulin
    - Progressive or relapsing motor and sensory impairment of more than one limb
- Chronic relapsing polyneuropathy, as indicated by **ALL** of the following:
    - Individual has severe or life threatening symptoms.
    - Individual failed to respond to conventional therapy.
- Cryoglobulinemia, as indicated by **1 or more** of the following:
    - Membranoproliferative glomerulonephritis
    - Neuropathy (eg, mononeuritis multiplex)
    - Ulcerating purpura
    - Vasculitis
- Focal segmental glomerulosclerosis, as indicated by **1 or more** of the following:
    - Post transplant: recurrent focal segmental glomerulosclerosis
    - Pretransplant: to prevent or delay recurrence.
- Glomerulonephritis (Goodpasture's syndrome) associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage.
- Graft vs host disease, steroid-dependent or steroid-refractory
- HELLP (hemolysis, elevated liver enzymes, and low platelets) syndrome of pregnancy, if thrombocytopenia, hemolysis, or renal failure continues to worsen 48-72 hours postpartum.
- Hemochromatosis (hereditary)

- Hemolytic uremic syndrome (Atypical HUS, non-diarrhea associate HUS, or HUS associated with complement factor antibodies)
- Heterozygous familial hypercholesterolemia, as indicated by **1 or more** of the following:
    - Individual with progressive coronary artery disease and **1 or more** of the following:
        - LDL cholesterol is greater than 200 mg/dL (5.18 mmol/L) or has decreased by less than 40% with medical therapy for 6 or more months.
        - Lipoprotein(a) is greater than 60 mg/dL (2.14 micromoles/L) and LDL cholesterol is greater than 125 mg/dL (3.24 mmol/L) despite medical therapy for 6 or more months.
    - Individual without coronary artery disease and **ALL** of the following:
        - LDL cholesterol is greater than 300 mg/dL (7.77 mmol/L).
        - LDL cholesterol has decreased by less than 40% with medical therapy for 6 or more months.
- Homozygous familial hypercholesterolemia, as indicated by **ALL** of the following:
    - Age is older than 2 years.
    - LDL cholesterol is greater than 500 mg/dL (12.95 mmol/L).
- Hyperviscosity due to clonal thrombocytosis (eg, from essential thrombocythemia or other myeloproliferative disorder), as indicated by **1 or more** of the following:
    - Platelet count 1,500,000/mm3 (1500 x109/L) or greater.
    - Platelet count 450,000/mm3 (450 x109/L) or greater and 1 or more of the following:
        - History of thrombosis or bleeding
        - Vascular stasis signs or symptoms
- Hyperviscosity due to erythrocytosis, as indicated by **ALL** of the following:
    - Hematocrit greater than 55% (0.55)
    - Hyperviscosity symptoms
    - Simple phlebotomy has failed to reverse symptoms.
- Hyperviscosity due to leukocytosis, as indicated by **ALL** of the following:
    - Vascular stasis signs or symptoms
    - White blood cell count greater than 50,000/mm3 (50 x109/L)
- Hyperviscosity due to monoclonal gammopathy (eg, Waldenstrom macroglobulinemia, multiple myeloma with IgA, IgG, or kappa light chains), as indicated by **1 or more** of the following:
    - Neurologic signs or symptoms
    - Spontaneous bleeding from mucous membranes
    - Vascular stasis signs or symptoms
    - Visual disturbance due to retinopathy
    - Used as a prophylactic treatment in persons with IgM greater than or equal to 5000 mg/dL and is being treated with rituximab or ofatumumab.
- Leukemia as indicated by **All** of the following:
    - The treatment will be used for acute debulking only,
    - When the white blood cells count is greater than 100,000/µL.
- Lipoprotein(a) hyperlipoproteinemia, as indicated by **ALL** of the following:
    - LDL cholesterol is greater than 125 mg/dL (3.24 mmol/L) despite medical therapy for 6 or more months.
    - Lipoprotein(a) greater than 60 mg/dL (2.14 micromoles/L)
    - Progressive coronary artery disease
- Liver failure (acute)
- Liver transplant (ABO-incompatible), as indicated by **ALL** of the following:
    - Desensitization prior to transplant
    - Living related donor
- Lung allograft rejection, as indicated by **ALL** of the following:
    - Bronchiolitis obliterans syndrome
    - Failure of steroids or other immunosuppressive agents to halt syndrome progression.
- Multiple sclerosis as indicated by **ALL** of the following:
    - The member has acute, severe neurological deficits,

    - The member has had a poor response to treatment with high dose glucocorticoids.
- Myasthenia gravis, as indicated by **1 or more** of the following:
    - During initiation of immunosuppressive therapy
    - During myasthenic crisis with ventilatory insufficiency or failure
    - During postoperative period after thymectomy
    - Needs rapid improvement of strength before surgery or irradiation.
    - Symptomatic individual resistant to or intolerant of immunosuppressive therapy
- Mycosis fungoides (cutaneous T-cell lymphoma) for erythrodermic disease (stage III)
- Natalizumab-associated progressive multifocal leukoencephalopathy.
- Neuromyelitis optica (acute), when high-dose intravenous steroids fail to resolve symptoms.
- Paraproteinemic demyelinating neuropathies associated with IgA, IgG or IgM monoclonal gammopathy of undetermined significance (MGUS) (excluding multiple myeloma)
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), as indicated by **1 or more** of the following:
    - Refractory disease
    - Severe symptoms (eg, chorea, cognitive deficits, motor hyperactivity)
- Pemphigus vulgaris is indicated by **ALL** of the following:
    - Individual has failed or has a contraindication to at least two (2) alternative treatments (dapsone, corticosteroids, immunosuppressants such as azathioprine or cyclosporine);
- Phytanic acid storage disease (Refsum disease), as indicated by **1 or more** of the following:
    - Acute neurologic or cardiac symptoms
    - Disease exacerbation
    - Maintenance therapy
- Polyarteritis nodosa associated with hepatitis B virus, in combination with glucocorticoids.
- Polyneuropathy due to monoclonal gammopathy (paraprotein neuropathy) with IgA, IgG, or IgM
- Primary macroglobulinemia (Waldenstrom)
- Pruritis of Cholestatic Liver Disease (plasma perfusion of charcoal filters)
- Refsum's disease
- Renal transplant (ABO compatible), as indicated by **1 or more** of the following:
    - Antibody-mediated rejection
    - Desensitization prior to transplant with crossmatch-positive living donor
- Renal transplant (ABO-incompatible), as indicated by **1 or more** of the following:
    - Antibody-mediated rejection
    - Desensitization prior to living donor transplant
- Rheumatoid vasculitis, as indicated by **ALL** of the following:
    - Disease is life threatening
    - Treatment is a last resort.
- Scleroderma and polymyositis, as indicated by **ALL** of the following:
    - Disease is life threatening.
    - Individual failed to respond to conventional therapy.
- Sickle cell disease (acute) with complications, as indicated by **1 or more** of the following:
    - Acute stroke
    - Severe acute chest syndrome (ie, oxygen saturation less than 90% despite oxygen therapy)
- Sickle cell disease (nonacute) with complications, as indicated by **1 or more** of the following:
    - Cerebral infarct documented on brain MRI in absence of symptoms.
    - High risk for stroke, as documented by transcranial Doppler study with mean blood flow velocity in the internal carotid artery or middle cerebral artery of 200 cm/second or higher.
    - History of acute stroke or evidence of cerebral infarct on brain MRI
    - History of iron overload
- Systemic lupus erythematosus, as indicated by **ALL** of the following:
    - Disease is life threatening.

    - Conventional therapy has failed to prevent clinical deterioration.
    - Treatment is a last resort.
- Thrombotic microangiopathy (drug-related)
- Thrombotic thrombocytopenic purpura where treatment is a last resort.
- Transverse myelitis treatment when corticosteroid treatment has failed.
- Vasculitis associated with HIV.
- Wilson disease

Apheresis is considered **not medically necessary** for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Coding	Description
36511	Therapeutic apheresis; for white blood cells.
36512	Therapeutic apheresis; for red blood cells.
36513	Therapeutic apheresis; for platelets.
36514	Therapeutic apheresis; for plasma pheresis.
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion.

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2023: May
- 2022: May
- 2020: May, July
- 2018: September
- 2016: January, February, November
- 2015: February, March
- 2014: January, November
- 2013: April, October
- 2012: September, October

Reviewed Dates:

- 2021: May
- 2018: August
- 2017: November
- 2011: April
- 2010: April

- 2009: April

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- May 2008

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

SHP Apheresis, medical 128, Plasmapheresis, LDL Pheresis, Lipoprotein