



Geisinger Health Plan Policies and Procedure Manual

Policy: MP377

Section: Medical Policy

Subject: Therapeutic Apheresis

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Therapeutic Apheresis

II. Purpose/Objective: To provide a policy of coverage regarding therapeutic apheresis

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Therapeutic apheresis includes a family of procedures in which whole blood is removed from the body, its cellular elements are separated from the plasma by centrifugation or filtration, one or more components is separated out or manipulated, and the remainder is returned to the circulation.

Therapeutic plasma exchange (TPE, a.k.a. PLEX, PEX, plasmapheresis) a procedure in which the plasma is separated from the blood, discarded in total, and replaced with a substitution fluid such as albumin or with donated plasma. TPE is generally performed to remove harmful substances (e.g., toxins or autoantibodies), which have accumulated in the plasma.

INDICATIONS:

TPE or Plasmapheresis

TPE or plasmapheresis is considered medically necessary for the treatment of any of the following conditions, often in combination with various immunosuppressive or cytoreductive drugs:

Autoimmune

- Severe manifestations of mixed cryoglobulinemia such as cryoglobulinemic nephropathy, skin ulcers, sensorimotor neuropathy, and widespread vasculitis
- Catastrophic antiphospholipid syndrome
- Anti-Factor H antibody-associated thrombotic microangiopathy
- Systemic lupus erythematosus with organ or life-threatening symptoms when medical therapy has failed or with diffuse alveolar hemorrhage
- Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (e.g., Wegener's granulomatosis also known as granulomatosis with polyangiitis with associated diffuse alveolar hemorrhage)
- Paraneoplastic syndromes thought to be antibody-mediated, only if treatment of the causative neoplasm is to begin within 14 days.

Hematologic

- Hyperviscosity syndromes associated with multiple myeloma or Waldenstrom's macroglobulinemia
- Idiopathic thrombocytopenic purpura in emergency situations
- Thrombotic thrombocytopenic purpura (TTP)

- Ticlopidine-induced thrombotic microangiopathy (TMA)
- Autoimmune hemolytic anemia: Severe cold agglutinin disease or warm autoimmune hemolytic anemia unresponsive to medical therapies
- Catastrophic antiphospholipid syndrome (CAPS)
- Cryoglobulinemia, severe/symptomatic
- Post-transfusion purpura
- HELLP syndrome of pregnancy (preeclampsia, hemolysis, elevated liver enzymes, and low platelet counts) that fails to resolve after delivery
- Myeloma with acute renal failure (aka, myeloma kidney or myeloma cast nephropathy).
- Wilson's disease

Neurological

- Acute inflammatory demyelinating polyneuropathies (e.g. transverse myelitis, Guillain-Barré syndrome; 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 steroid-refractory or with fulminant central nervous system demyelination
- Myasthenia gravis in crisis or as part of preoperative preparation
- Myasthenia gravis when patient is intolerant of or inadequately responsive to conventional medical therapy
- Neuromyelitis optica spectrum disorders with failure of medical therapy
- Autoimmune encephalitis (e.g., anti-NMDAR AIE, steroid-responsive encephalopathy associated with autoimmune thyroiditis or SREAT)
- Lambert-Eaton syndrome
- Voltage-gated potassium channel antibody-related diseases (anti-VGKC antibodies; e.g. AIE, Isaac's Syndrome, Morvan's Syndrome)
- Paraproteinemic demyelinating neuropathies/ chronic acquired demyelinating polyneuropathy; IgA, IgG, IgM.

Renal

- Anti-glomerular basement membrane disease (Goodpasture's syndrome)
- Monoclonal gammopathy of renal significance (MGRS), in combination with plasma cell directed therapy. This includes free light chain disease as well as IgG, IgA, or IgM-related MGRS, when there is paraproteinemia/paraproteinuria and otherwise unexplained renal damage, AND the patient is not dialysis-dependent
- Focal segmental glomerulosclerosis (FSGS) recurrent after renal transplant or steroid-refractory in native kidney (although LA is clinically preferable when available)

Transplantation

- Hematopoietic progenitor cell transplantation: desensitization
- Liver, Kidney, Heart, or Lung transplant: antibody-mediated rejection, desensitization

Metabolic/Hepatic/Toxic

- Severe hypertriglyceridemia (TG > 500) non-responsive to multiple medical therapies
- Acute liver failure: bridge to transplant or recovery
- Fulminant Wilson's Disease
- Phytanic acid storage disease
- Thyroid storm
- Severe drug reactions when the implicated drug is highly albumin-bound or is otherwise highly removable by TPE (e.g., immune checkpoint inhibitors, mushroom poisoning)

Extracorporeal Photopheresis

Extracorporeal Photopheresis (ECP a.k.a. photopheresis or photo) is a procedure and cell therapy modality that involves selective collection of buffy coat white blood cells, addition of a psoralen compound and UV-photoactivation outside the body and return of those modified WBC to the patient. This is considered medically necessary for any of the following:

- Graft-versus-host disease (GVHD), whether "acute" (<100 days post-transplant or "chronic" (≥ 100 days post-transplant).
 - ECP may be initiated when initial corticosteroid therapy fails.
- Cutaneous T-cell lymphoma (CTCL a.k.a. Mycosis Fungoides, Sezary Syndrome)
 - ECP should be initiated immediately in the setting of frank erythroderma or Sezary Syndrome.

- ECP may be initiated for earlier stage CTCL when progression occurs despite steroid therapy or in the setting of steroid-dependent stable disease.
- Chronic lung or heart allograft dysfunction or rejection
- Systemic sclerosis, Sjogren's Syndrome, Scleroderma, and related connective tissue disorders.
 - ECP may be initiated as salvage therapy when conventional medical therapy has failed.

Lipid Apheresis

Lipid Apheresis (LA, a.k.a. Low-density lipid apheresis or lipoprotein apheresis) is a procedure in which plasma is separated from cellular blood components and then passes through selective absorption columns that remove low- and very-low density lipoproteins (LDL, VLDL), Lipoprotein A (Lp(a)), and triglycerides (TG) and is considered medically necessary for individuals with any of the following:

- Homozygous familial hypercholesterolemia;
- Severe, refractory heterozygous familial hypercholesterolemia who have failed a 6-month trial of diet therapy and maximum tolerated combination drug therapy AND who meet either of the following FDA-approved indications:
 - Functional hypercholesterolemic heterozygotes with low-density lipoprotein (LDL) that is greater than 300 mg/dL; or
 - Functional hypercholesterolemic heterozygotes with LDL that is greater than 200 mg/dL and documented coronary artery disease
- Lipoprotein (a) hyperlipoproteinemia when there has been an inadequate response to or failure of medical therapy
- Focal segmental glomerulosclerosis (FSGS) recurrent after renal transplant or steroid-refractory in native kidney
 - Preferred over TPE because up to 50% of FSGS treated with a course of 12 LA procedures will go into remission. Remission is not observed with TPE, only maintenance.

Erythrocytapheresis, including Red Cell Exchange and Red Cell Reduction (RCE a.k.a. Red Blood Cell Exchange or RBCX) and Red Cell Reduction (RCR) are procedures in which the RBCs are selectively removed from the blood. In RCE, the patient blood is replaced with donor RBC units. In RCR, the RBC volume may be replaced with saline or albumin at the provider's discretion. These procedures are considered medically necessary for any of the following:

Sickle Cell Disease, Acute (RCE)

- Stroke
- Acute chest syndrome
- Hepatosplenic sequestration crisis
- Priapism

Sickle Cell Disease, Non-Acute (RCE)

- Secondary stroke prophylaxis
- Pregnancy
- Recurrent vaso-occlusive crisis
- Pre-operative optimization for urgent or emergent surgery

Intra-erythrocytic Infectious Diseases (RCE)

- Malaria, clinically severe
- Babesiosis, clinically severe

Polycythemia a.k.a erythrocytosis (RCR), severe or with thrombotic complications

- Polycythemia vera
- Secondary polycythemia

Plateletpheresis

Plateletpheresis is a procedure in which the platelets are selectively removed from the blood in order to lower risk of thrombosis and is considered medically necessary for any of the following:

- Essential thrombocytosis
- Secondary thrombocytosis

FOR MEDICARE BUSINESS SEGMENT:

Coverage will be in accordance with NCD110.14 Apheresis (Therapeutic Pheresis) and any applicable local carrier determinations.

EXCLUSIONS:

Any use of therapeutic apheresis not listed under Indication will be considered Unproven and therefore not covered. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of the use of this technology on health outcomes for other indications when compared to established tests or technologies. A partial listing of conditions for which therapeutic apheresis is considered unproven includes, but is not limited to:

- Chronic Lyme disease
- Complex regional pain syndrome
- Psoriasis
- Amyotrophic lateral sclerosis
- Multiple sclerosis, chronic
- Heavy metal intoxication
- Age related macular degeneration
- Atopic dermatitis, recalcitrant
- Inflammatory bowel disease, Crohn's Disease
- Stiff-person syndrome
- Sudden sensorineural hearing loss
- Burn shock resuscitation
- Cardiac neonatal lupus
- Coagulation factor deficiency and inhibitors
- Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via TPE
- Erythropoietic protoporphyria, liver disease
- Hemophagocytic lymphohistiocytosis
- Heparin induced thrombocytopenia and thrombosis
- Nephrogenic systemic fibrosis
- Pemphigus vulgaris
- Red blood cell alloimmunization, related to RhD, prophylactic
- Sepsis with multiorgan failure
- Steroid-responsive encephalopathy associated with autoimmune thyroiditis
- Sydenham's chorea, severe
- Thrombotic microangiopathy associated with gemcitabine or quinine

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 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 immunoadsorption, selective adsorption or selective filtration and plasma reinfusion
- 36522 Photopheresis, extracorporeal
- 38205 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogeneic
- 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, autologous
- 38240 Hematopoietic progenitor cell, allogeneic transplantation, per donor

38241 Hematopoietic progenitor cell, autologous transplantation, per donor

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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NCCN Clinical Practice Guidelines in Oncology® (NCCN) National Comprehensive Cancer Network

- Acute Myeloid Leukemia v 6.2023
- Multiple Myeloma v2.2024
- Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma v2.2024

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/24

Revised: 10/24 (add exclusion)

Reviewed:

CMS UM Oversight Committee Approval: 7/24, 12/24

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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