Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Therapeutic Apheresis

Effective: October 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☐ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☐ Tufts Health One Care Plan – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Therapeutic Apheresis (TA) refers to an extracorporeal blood processing technique in which whole blood is withdrawn, a targeted cellular or plasma component—such as platelets, leukocytes, or plasma—is selectively separated and removed, and the remaining constituents are reinfused into the patient. It is a treatment that discriminately removes abnormal cells or substances in the blood that are associated with or cause certain disease states. The basic premise of TA is that by eliminating or decreasing levels of certain pathologic substances from the plasma or cells from the blood, prevention of further damage or reversal of a toxic process can occur. This term encompasses all therapeutic and collection procedures utilizing apheresis technology and is also referred to as pheresis. Plasmapheresis (PP), plasma exchange (PE), or therapeutic plasma exchange (TPE) is a type of therapeutic apheresis.

The American Society for Apheresis (ASFA) guidelines synthesize therapeutic apheresis outcomes and specify evidence-based practice recommendations. These guidelines incorporate a systematic evaluation of the quality of available evidence and assign strength-of-recommendation grades based on that evidence. A comprehensive review of conditions and indications based on detailed literature reviews is published approximately every two to three years by the ASFA. ASFA categorizes indications to include the following:

- Category I - Disorders for which apheresis is accepted as first-line therapy, either as a primary standalone treatment or in conjunction with other modes of treatment.
- Category II – Disorders for which apheresis is accepted as second-line therapy, either as a standalone treatment or in conjunction with other modes of treatment.
- Category III – Optimum role of apheresis therapy is not established. Decision making should be individualized.
- Category IV – Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or

harmful. IRB/Ethics Committee approval is desirable if apheresis treatment is undertaken in these circumstances.

Clinical Guideline Coverage Criteria

The Plan considers therapeutic apheresis reasonable and medically necessary for members when documentation confirms diagnosis of ONE of the following:

1. Acute disseminated encephalomyelitis (ADEM): Steroid refractory
2. Acute inflammatory demyelinating polyneuropathy, primary treatment
3. Acute liver failure [requiring high volume therapeutic plasma exchange]
4. Anti-glomerular basement membrane disease
    a. Dialysis independent
    b. Diffuse alveolar hemorrhage
5. Catastrophic antiphospholipid syndrome
6. Chronic acquired demyelinating polyneuropathies
    a. IgG/IgA/IgM related
    b. Anti-myelin-associated glycoprotein
7. Chronic inflammatory demyelinating polyneuropathy
8. Cryoglobulinemia, second line therapy
9. Cutaneous T-cell lymphoma; erythrodermic mycosis fungoides; Sézary syndrome
10. Erythrocytosis, polycythemia vera
11. Dilated cardiomyopathy, idiopathic, New York Heart Association class II-IV, via immunoadsorption
12. Familial hypercholesterolemia
    a. Homozygotes, lipoprotein apheresis
    b. Heterozygotes, lipoprotein apheresis; second line therapy
    c. All patients via therapeutic plasma exchange
13. Focal segmental glomerulosclerosis, recurrent in transplanted kidney, second line therapy
14. Graft-versus-host disease
    a. Acute
    b. Chronic, second line therapy
15. HELLP syndrome of pregnancy (a severe form of preeclampsia, characterized by hemolysis [H], elevated liver enzymes [EL], and low platelet [LP] counts)
16. Hereditary hemochromatosis
17. Hypertriglyceridemic pancreatitis, severe
18. Hyperviscosity in hypergammaglobulinemia
19. Inflammatory bowel disease, ulcerative colitis, Crohn’s disease via adsorptive cytapheresis
20. Lipoprotein(a) hyperlipoproteinemia
21. Multiple sclerosis, acute attack, or relapse, second line therapy
22. Myasthenia gravis, acute
23. Myeloma cast nephropathy (light chain cast nephropathy, or myeloma associated with acute renal failure), second line therapy
24. Neuromyelitis optica spectrum disorders, acute or relapse, second line therapy
25. N-methyl D-aspartate receptor antibody encephalitis
26. Paraproteinemic demyelinating neuropathies associated with IgA, IgG or IgM monoclonal gammopathy of undetermined significance (MGUS) (excluding multiple myeloma)
27. Pediatric autoimmune neuropsychiatric disorders, PANDAS/PANS exacerbation
28. Peripheral vascular diseases
29. Post-transfusion purpura
30. Progressive multifocal leukoencephalopathy associated with natalizumab
31. Pruritus due to hepatobiliary diseases, treatment resistant
32. Rheumatoid arthritis, refractory, second line therapy
33. Sickle cell disease
    a. Acute stroke or multiorgan failure

    b. Acute chest syndrome, severe, second line therapy
    c. Stroke prophylaxis
    d. Individuals requiring chronic transfusion (receiving transfusions once every 5 weeks or more frequently)
34. Thrombotic microangiopathy, thrombotic thrombocytopenic purpura (TTP)
35. Transplantation, heart, second line therapy
    a. Cellular rejection
    b. Recurrent rejection
    c. Desensitization
    d. In children less than 40 months of age, ABO incompatible
    e. Rejection prophylaxis via therapeutic plasma exchange
36. Transplantation, hematopoietic stem cell, ABO incompatible, second line therapy
    a. Hemopoietic progenitor cells collected from marrow [HPC(M)]
    b. Hemopoietic progenitor cells collected by apheresis [HPC(A)]
37. Transplantation, kidney, ABO compatible
    a. Antibody mediated rejection
    b. Desensitization/prophylaxis living donor
38. Transplantation, kidney, ABO incompatible, second line therapy
    a. Antibody mediated rejection
    b. Desensitization, living donor
39. Transplantation, liver, desensitization, ABO incompatible, living donor, via therapeutic plasma exchange
40. Transplantation, lung
    a. Bronchiolitis obliterans syndrome
    b. Chronic lung allograft dysfunction
41. Vasculitis, antineutrophil cytoplasmic antibodies (ANCA)-associated
    a. Microscopic polyangiitis
    b. Granulomatosis with polyangiitis
42. Voltage gated potassium channel antibody-related diseases
43. Wilson's disease, fulminant

Limitations

The Plan considers therapeutic apheresis as not medically necessary for all other indications.

Codes

The following code(s) are associated with this service:
Table 1: CPT/HCPCS Codes

Code	Description
36514	Therapeutic apheresis; for plasma pheresis
36516	Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion

List of Medically Necessary ICD-10 Codes: Therapeutic Apheresis

References:

1. Ipe TS, Pham HP, Williams LA, 3rd. Critical updates in the 7th edition of the American Society for Apheresis guidelines. J Clin Apher. Jun 27 2017. PMID 28653762
2. Connelly-Smith L, Alquist CR, et. al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice - Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue. J Clin Apher. 2023 Apr;38(2):77-278. doi: 10.1002/jca.22043. PMID: 37017433.
3. Schwartz J, Winters JL, Padmanabhan A, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the Writing Committee of the American Society.

4. Therapeutic apheresis. UpToDate.com/login [via subscription only]. Published April 16, 2025. Accessed January 15, 2026.
5. Padmanabhan A, et. al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice - Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Eighth Special Issue. J Clin Apher. 2019 Jun;34(3):171-354. doi: 10.1002/jca.21705. PMID: 31180581.
6. Guyatt GH, et. al., GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008 Apr 26;336(7650):924-6. doi: 10.1136/bmj.39489.470347.AD. PMID: 18436948; PMCID: PMC2335261.
7. Schwartz J, Padmanabhan A, et. al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice-Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Seventh Special Issue. J Clin Apher. 2016 Jun;31(3):149-62. doi: 10.1002/jca.21470. PMID: 27322218.

Approval And Revision History

February 18, 2026: Reviewed by the Medical Policy Approval Committee (MPAC) for effective date of June 1, 2026.

Subsequent endorsement date(s) and changes made:

- Coding update, effective October 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.