# Geisinger

Policy: MP335

Section: Medical Benefit Policy

# Subject: Extracorporeal Photopheresis

## **Applicable Lines of Business**

Commercial	Х	СНІР	Х
Medicare	Х	ACA	Х
Medicaid	Х		

## I. Policy: Extracorporeal Photopheresis

## II. Purpose/Objective:

To provide a policy of coverage regarding Extracorporeal Photopheresis

## **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.

# 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:**

Extracorporeal photopheresis (ECP) is a leukapheresis-based immunomodulatory procedure that involves three steps. First, the patient's blood is centrifuged to separate the leukocyte-rich portion from the rest of the blood; then the photosensitizer agent 8-methoxypsoralen is added to the lymphocyte fraction, which is then exposed to ultraviolet-A light at a dose of 1 to 2 J/cm2. Lastly, the light-sensitized lymphocytes are reinfused into the patient.

## **INDICATIONS:**

Extracorporeal photopheresis may be considered medically necessary for any one of the following indications:

- Palliative treatment of skin manifestations of cutaneous T-cell lymphoma (e.g., mycosis fungoides, Sézary syndrome) that are refractory to other therapy
- Acute or chronic graft versus host disease refractory to standard immunosuppressive drug treatment
- Acute cardiac allograft rejection refractory to standard immunosuppressive drug treatment
- Bone marrow transplant rejection or failure
- Stem cell transplant complications
- Bronchiolitis obliterans syndrome following lung allograft transplantation
- Organ rejection after solid organ transplant (heart, lung, liver, kidney)

# FOR MEDICARE BUSINESS SEGMENT:

Per National Coverage Determination (NCD) for Extracorporeal Photopheresis (110.4), extracorporeal photopheresis may be considered medically necessary for any one of the following indications:

- Palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy
- Members with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment
- Members with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment
- Extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets the conditions outlined in NCD 110.4

## EXCLUSIONS:

The Plan does **NOT** provide coverage for the use of Extracorporeal photopheresis for any indication not listed in this policy because those applications are considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

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: Extracorporeal photopheresis**

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

36552 Photopheresis, extracorporeal

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.

#### **REFERENCES:**

Center for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Extracorporeal Photopheresis (110.4).

Kirklin JK, Brown RN, Huang ST, et al. Rejection with hemodynamic compromise: objective evidence for efficacy of photopheresis. J Heart Lung Transplant. Mar 2006;25(3):283-288.

Barr ML, Meiser BM, Eisen HJ, et al. Photopheresis for the prevention of rejection in cardiac transplantation. Photopheresis Transplantation Study Group. N Engl J Med. Dec 10 1998;339(24):1744-1751. PMID 9845709. Villanueva J, Bhorade SM, Robinson JA, et al. Extracorporeal photopheresis for the treatment of lung allograft rejection. Ann Transplant. Mar 2000;5(3):44-47.

Jaksch P, Scheed A, Keplinger M, et al. A prospective interventional study on the use of extracorporeal photopheresis in patients with bronchiolitis obliterans syndrome after lung transplantation. J Heart Lung Transplant. Sep 2012;31(9):950-957.

Morrell MR, Despotis GJ, Lublin DM, et al. The efficacy of photopheresis for bronchiolitis obliterans syndrome after lung transplantation. J Heart Lung Transplant. Apr 2010;29(4):424-431.

Abu-Dalle I, Reljic T, Nishihori T, et al. Extracorporeal photopheresis in steroid-refractory acute or chronic graft- versushost disease: results of a systematic review of prospective studies. Biol Blood Marrow Transplant. Nov 2014;20(11):1677-1686.

Weitz M, Strahm B, Meerpohl JJ, et al. Extracorporeal photopheresis versus standard treatment for acute graft- versushost disease after haematopoietic stem cell transplantation in paediatric patients. Cochrane Database Syst Rev. 2014;2:CD009759.

Zhang H, Chen R, Cheng J, et al. Systematic review and meta-analysis of prospective studies for ECP treatment in patients with steroid-refractory acute GVHD. Patient Prefer Adherence. Feb 2015;9:105-111.

Hefazi M, Langer KJ, Khera N, et al. Extracorporeal photopheresis improves survival in hematopoietic cell transplant patients with bronchiolitis obliterans syndrome without significantly impacting measured pulmonary functions. Biol Blood Marrow Transplant. 2018;24(9):1906-1913

Del Fante C, Perotti C. Extracorporeal photopheresis for bronchiolitis obliterans syndrome after allogeneic stem cell transplant: An emerging therapeutic approach? Transfus Apher Sci. 2017;56(1):17-19

Tamain M, Sayegh J, Lionet A, et al. Extracorporeal photopheresis for the treatment of graft rejection in 33 adult kidney transplant recipients. Transfus Apher Sci. 2019;58(4):515-524.

Du AX, Osman M, Gniadecki R. Use of extracorporeal photopheresis in scleroderma: A review. Dermatology. 2020;236:105-110.

Mehta RS, Bassett R, Rondon G, et al. Randomized phase II trial of extracorporeal phototherapy and steroids vs. steroids alone for newly diagnosed acute GVHD. Bone Marrow Transplant. Jun 2021; 56(6): 1316-1324

Batgi H, Dal MS, Erkurt MA, et al. Extracorporeal photopheresis in the treatment of acute graft-versus-host disease: A multicenter experience. Transfus Apher Sci. Oct 2021; 60(5): 103242

Dal MS, Batgi H, Erkurt MA, et al. Extracorporeal photopheresis in steroid-refractory chronic graft-versus-host disease: A retrospective multicenter study. Transfus Apher Sci. Oct 2021; 60(5)

Vazirani J, Routledge D, Snell GI, et al. Outcomes following extracorporeal photopheresis for chronic lung allograft dysfunction following lung transplantation: A single-center experience. Transplant Proc. 2021;53(1):296-302

Gokler J, Aliabadi-Zuckermann A, Zuckermann A, et al. Extracorporeal Photopheresis With Low-Dose Immunosuppression in High-Risk Heart Transplant Patients-A Pilot Study. Transpl Int. 2022; 35: 10320.

Leroux J, Hirschi S, Essaydi A, et al. Initiation of extracorporeal photopheresis in lung transplant patients with mild to moderate refractory BOS: A single-center real-life experience. Respir Med Res. May 2022; 81: 100913.

Kitko CL, Abdel-Azim H, Carpenter PA, et al. A Prospective, Multicenter Study of Closed-System Extracorporeal Photopheresis for Children with Steroid-Refractory Acute Graft-versus-Host Disease. Transplant Cell Ther. May 2022; 28(5): 261.e1-261.e7

Kansu E, Ward D, Sanchez AP, et al. Extracorporeal photopheresis for the treatment of chronic graft versus host disease. Hematology. Dec 2022; 27(1): 785-794

National Comprehensive Cancer Network (NCCN). NCCN Clinical practice Guidelines in Oncology: Primary Cutaneous Lymphomas. V1.2024

Solh MM, Farnham C, Solomon SR, et al. Extracorporeal photopheresis (ECP) improves overall survival in the treatment of steroid refractory acute graft-versus-host disease (SR aGvHD). Bone Marrow Transplant. Feb 2023; 58(2): 168-174

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

**Devised:** 03/20

Revised: 3/23 (Add Indication)

Reviewed: 3/21, 3/22, 3/24

#### CMS UM Oversight Committee Approval: 12/23

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.

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

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.