MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Extracorporeal Photochemotherapy/Photopheresis**
Policy Number	**8.01.01**
Category	**Technology Assessment**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, extracorporeal photochemotherapy (ECP), or photopheresis, has been medically proven to be effective and, therefore, is considered **medically appropriate** for **ANY** of the following indications:
   A. Palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (also called mycosis fungoides) Sézary syndrome that have not responded to other therapy;
   B. Acute and chronic extensive graft-versus-host disease (GVHD) that is refractory to conventional therapy;
   C. Cardiac allograft rejection that is recurrent or refractory to immunosuppressive treatment.

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of ECP (photopheresis) has not been medically proven to be effective and, therefore, is considered **investigational** for **ALL** other indications, including, but not limited to, the treatment of:
   A. Acute or chronic GVHD in previously untreated patients or those responding to conventional therapy;
   B. Lyme disease;
   C. Scleroderma (a.k.a. progressive systemic sclerosis (PSS), systemic sclerosis (SS), dermatosclerosis, or CREST syndrome);
   D. Autoimmune diseases (e.g., pemphigus vulgaris, pemphigus foliaceus, psoriatic arthritis, rheumatoid arthritis, systemic lupus erythematosus, severe atopic dermatitis);
   E. Crohn's disease;
   F. Allograft rejections of solid organs other than the heart;
   G. Diabetes Mellitus.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

ECP, or photopheresis, is an immune-modulating therapy technique used in the treatment of certain skin disorders. It involves an oral intake of 8-methoxypsoralen (8-MOP) and cytopheresis, or addition of 8-MOP to the cells after removal, followed by ultraviolet actinotherapy (UVA) irradiation and reinfusion of leukocytes into the patient.

The U.S. Food and Drug Administration (FDA) has approved, via premarket application, two photopheresis systems manufactured by Therakos, Inc. (West Chester, PA). Both systems are approved for use in ultraviolet A (UVA) irradiation treatment, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL), in persons who have not been responsive to other forms of treatment. The two systems are: the UVAR XTS Photopheresis System, FDA-approved in 1987, and CELLEX, FDA-approved in 2009. Treatment of GVHD is considered an off-label use of the device. Therefore, the use for treatment of autoimmune disease is considered off-label use.

RATIONALE

National Comprehensive Cancer Network guidelines on primary cutaneous lymphomas (v.3.2024) list the use of ECP as a category 2A treatment alone or in combination with other agents as first-line systemic therapy for advanced (stages III-IV) disease, as well as for patients with earlier stage mycosis fungoides with Sézary syndrome involvement.

Connelly-Smith et al. (2023) states the overall response rate of CTCL to ECP is approximately 60% with complete response rates of 14% to 26%. Response to ECP correlates with short duration of disease, early use of ECP in the treatment paradigm, lower blood Sézary cell burden and significant early response of skin lesions (i.e., >50% regression within 6 months).

Evidence supporting the use of ECP for the treatment of GVHD relates to both acute GVHD (aGVHD) and chronic GVHD (cGVHD) in pediatric and adult populations. The published literature lacks randomized trials. Evidence comprises retrospective reviews and non-randomized comparisons. The data consistently show improvement in GVHD that is unresponsive to standard therapy. Additionally, there is a lack of other treatment options for these patients, and this option has the added benefit of minimal side effects from ECP, as well as the possibility of reduction and often cessation of treatment with corticosteroids and other immunosuppressive agents, if there is a response to ECP. For patients with untreated disease or those who are showing improvement on standard therapy, there is no data to support the use of ECP.

Scleroderma is the most studied of the autoimmune diseases utilizing photopheresis, but the efficacy of photopheresis for these diseases, as yet, has not been demonstrated in well-designed clinical trials.

Photopheresis alone, or in combination with immunosuppressive therapy is also being investigated in the treatment of solid organ transplant rejection. While ECP has been utilized for prevention of cardiac allograft rejection and acute rejection, the strongest evidence in cardiac transplant patients revolves around its use for recurrent and refractory allograft rejection. While the evidence consists of non-randomized studies, the outcomes from these studies provide consistent evidence of the beneficial effect of ECP for cardiac transplant patients with rejection refractory to standard therapy. There is insufficient evidence to support the use of ECP for graft rejection in other solid organs, such as lung, liver, and kidney. Though preliminary results are promising, additional studies with longer follow-up are needed, to evaluate the ultimate effect of photopheresis on patient survival.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
36522	Photopheresis, extracorporeal

HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
C84.00-C84.09	Mycosis fungoides (code range)
C84.10-C84.19	Sézary syndrome (code range)
D89.810-D89.913	Graft-versus-host disease (code range)
T86.00-T86.09	Complication of bone marrow transplant (code range)
T86.20-T86.39	Complications of heart transplant or heart-lung transplant (code range)

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*Key Article

KEY WORDS

Graft Versus Host Disease, Mycosis fungoides, Sézary syndrome, T-cell lymphoma, Cardiac allograft rejection.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD 110.4) for extracorporeal photopheresis. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=113&ncdver=3&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&] accessed 08/22/24.