

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	EXTRACORPOREAL PHOTOCHEMOTHERAPY/ PHOTOPHERESIS
Policy Number	8.01.01
Category	Technology Assessment
Effective Date	11/19/99
Revised Date	01/17/02, 11/21/02, 10/15/03, 08/19/04, 06/16/05, 04/20/06, 02/15/07, 02/21/08, 01/15/09, 12/17/09, 01/20/11, 12/15/11, 12/20/12, 12/19/13, 11/20/14, 10/15/15, 10/20/16, 10/19/17, 11/15/18
Product Disclaimer	<ul style="list-style-type: none"> • 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

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

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus, these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity for those contracts.

DESCRIPTION

Extracorporeal photochemotherapy (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

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of 8-MOP to the cells after removal, followed by ultraviolet actinotherapy (UVA) irradiation and reinfusion of leukocytes into the patient.

RATIONALE

The U.S. Food and Drug Administration (FDA) has approved via premarket application for 2 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-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 2 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.

Long term follow-up data demonstrates that extracorporeal photochemotherapy provides significant disease remission and prolongation of life in patients with cutaneous T-cell lymphoma and Sézary syndrome. 50-83% of patients with CTCL demonstrated clinical cutaneous improvements with 18-25% showing a complete response. The long-term follow-up of patients with Sézary syndrome show an average survival time of greater than 100 months, compared to survival times of 30-40 months of patients treated with other therapies.

Evidence for the use of ECP for the treatment of GVHD relates to both aGVHD and cGVHD in pediatric and adult populations. The published literature lacks randomized trials. Evidence comprises retrospective reviews and nonrandomized comparisons. This data consistently shows improvement in GVHD that is unresponsive to standard therapy. Additionally, there is a lack of other treatment options for these patients, with 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 data is comprised of nonrandomized studies the outcomes from these studies provide consistent evidence for a 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.*

CPT Codes

Code	Description
36522	Photopheresis, extracorporeal

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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)
T86.00-T86.09	Complication bone marrow transplant (code range)
T86.20-T86.39	Complications of transplanted organ, heart (code range)

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*Key Article

KEY WORDS

Graft Versus Host Disease, Mycosis fungoides, Sezary syndrome, T-cell lymphoma.

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) 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=gAAAABAAAA&>