

Policy Name:	Extracorporeal Photopheresis (Photochemotherapy)
Effective Date:	8/16/2021

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Extracorporeal photopheresis (also known as extracorporeal photochemotherapy; ECP) is **COVERED** for:

1. Erythrodermic, cutaneous T-cell lymphoma (e.g., mycosis fungoides, Sézary syndrome)
2. Chronic or acute graft-versus-host disease
3. Heart transplantation allograft rejection
4. Heart transplantation rejection prophylaxis
5. Lung transplantation allograft rejection (bronchiolitis obliterans).

ECP is investigative and therefore **NOT COVERED** for all other indications, including but not limited to:

1. Non-erythrodermic, cutaneous T-cell lymphoma
2. Transplantation [other than heart or lung], (e.g, liver; kidney)
3. Pemphigus vulgaris
4. Scleroderma / progressive systemic sclerosis
5. Nephrogenic systemic fibrosis
6. Crohn’s disease
7. Psoriasis
8. Atopic (neuro-) dermatitis (atopic eczema), recalcitrant
9. Dermatomyositis/polymyositis

There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy; *Therapeutic Apheresis: Plasmapheresis, Plasma Exchange*

Description

Apheresis is a procedure which separates out one or more components of blood by passing the person’s blood through a medical device similar to that used in kidney dialysis procedures. Following separation of components, the remainder of the blood is reinfused into the bloodstream with or without extracorporeal treatment or replacement of the separated component(s).

Extracorporeal photopheresis (extracorporeal photochemotherapy; ECP) is a procedure that separates the white blood cell layer (commonly referred to as the ‘buffy coat’) from other components of the blood stream. The buffy

coat is then treated extracorporeally with a photoreactive chemical, commonly a psoralen, which diffuses rapidly into the nuclei of lymphocytes. The mixture is then exposed to ultraviolet-A light, which activates the drug. Following treatment, the light sensitized cells are reinfused into the bloodstream. ECP is theorized to change the patient's immune response to the chemically-modified lymphocytes, but the actual mechanism of action remains unclear. ECP can be performed either on an inpatient or outpatient basis usually within a hospital setting. The entire procedure is completed within approximately four hours. The recommended minimum series of treatments is six sets of two treatment sessions administered on consecutive days, with a one-month interval between each of the six treatment sets.

The American Society for Apheresis categorizes the appropriateness of ECP for various clinical applications. The categories range from I (currently accepted applications) through IV (applications not considered beneficial and/or advisable).

FDA Approval

ECP is a procedure, and therefore is not regulated by the FDA.

In 1989, the UVAR Photopheresis System (Therakos, Inc., Exton, PA, USA) received FDA approval for the palliative treatment of skin manifestations resulting from cutaneous T-cell lymphoma (CTCL), which are unresponsive to other treatments. In addition, Therakos markets UVAR XTS, a second generation of the system. Associated products also approved by the FDA include the TPS102 Photoreceptor Activation Chamber, the TPS101 Photopheresis blood tubing set, and Uvadex Solution (methoxsalen), also manufactured by Therakos and approved by the FDA for the same indication.

Uvadex was granted Orphan Drug status for use in conjunction with UVAR photopheresis to treat diffuse systemic sclerosis in June 1993 and for use in conjunction with UVAR photopheresis to treat graft versus host disease in October 1998. In addition, Uvadex was granted Orphan Drug status for prevention of acute rejection of cardiac allografts in May 1994.

Kiadis Pharma (Amsterdam, The Netherlands) recently completed a study using its Theralux extracorporeal photochemotherapy system in patients with chronic graft versus host disease. According to the manufacturer Web site, Theralux products have received investigative new drug approval (IND) from FDA and regulatory approval in Europe.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **36522** – Photopheresis, extracorporeal

Medica Coverage Policy



Original Effective Date: 10/1/2009
Re-Review Date(s): 4/24/2012
5/20/2015
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2/10/2020 – administrative update; format
6/16/2021
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