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Original Effective Date: 01/15/13

Reviewed: 04/27/23

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Subject: Extracorporeal Photopheresis

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Extracorporeal photopheresis (ECP) is a leukapheresis-based immunomodulatory procedure that involves the following steps:

1. Blood is collected into a centrifuge system that separates the leukocyte-rich portion (buffy coat) from the rest of the blood.
2. The photosensitizer agent 8-methoxypsoralen (8-MOP) is added to the lymphocyte fraction, which is then exposed to ultraviolet (UV) A (320-400 nm wavelength) light at a dose of 1-2 J per square cm.
3. The light-sensitized lymphocytes are reinfused into the candidate.

POSITION STATEMENT:

Organ Rejection after Solid-Organ Transplant

Extracorporeal photopheresis **meets the definition of medical necessity** to treat cardiac allograft rejection, including acute rejection, that is either recurrent or that is refractory to standard immunosuppressive drug treatment.

Extracorporeal photopheresis is considered **experimental or investigational** for all other indications related to treatment or prevention of rejection in solid-organ transplantation.

Acute Graft-Versus-Host Disease

Extracorporeal photopheresis **meets the definition of medical necessity** as a technique to treat acute graft-versus-host disease that is refractory to medical therapy.

Extracorporeal photopheresis is considered **experimental or investigational** as a technique to treat acute graft-versus-host disease that is either previously untreated or is responding to established therapies.

Chronic Graft-Versus-Host Disease

Extracorporeal photopheresis **meets the definition of medical necessity** as a technique to treat chronic GVHD that is refractory to medical therapy.

Extracorporeal photopheresis is considered **experimental or investigational** as a technique to treat chronic GVHD that is either previously untreated or is responding to established therapies.

Cutaneous T-cell Lymphoma

Extracorporeal photopheresis **meets the definition of medical necessity** as a technique to treat:

- Late-stage (III/IV) cutaneous T-cell lymphoma, **OR**
- Early stage (I/II) cutaneous T-cell lymphoma that is progressive and refractory to established nonsystemic therapies.

Extracorporeal photopheresis is considered **experimental or investigational** as a technique to treat early stage (I/II) cutaneous T-cell lymphoma that is either previously untreated or is responding to established non-systemic therapies.

Autoimmune Diseases

Extracorporeal photopheresis is considered **experimental or investigational** as a technique to treat either the cutaneous or visceral manifestations of autoimmune diseases, including but not limited to scleroderma, systemic lupus erythematosus, rheumatoid arthritis, pemphigus, psoriasis, multiple sclerosis, diabetes, autoimmune bullous disorders, severe atopic dermatitis, or Crohn's disease.

Other

The use of extracorporeal photopheresis **for all other indications** is considered **experimental or investigational**. The clinical evidence in peer-reviewed literature is insufficient to permit conclusions on efficacy and net health outcomes for indications other than those noted above.

BILLING/CODING INFORMATION:

CPT Coding:

36522	Photopheresis, extracorporeal

ICD-10 Diagnosis Codes That Support Medical Necessity:

C84.00 – C84.09	Mycosis fungoides
C84.10 – C84.19	Sezary's disease
D89.810 – D89.813	Graft-versus-host disease
T86.00 – T86.09	Complications of bone marrow transplant
T86.21 – T86.22	Heart transplant rejection or failure

T86.290	Cardiac allograft vasculopathy

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Extracorporeal Photopheresis (110.4) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Autoimmune disease: when the body's immune system attacks the cells it is supposed to protect. This is a heterogeneous group of immune-mediated disorders, with some of the most common types being multiple sclerosis (MS), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and systemic sclerosis/scleroderma.

Graft-versus host disease (GVHD): a rare disorder that can strike persons whose immune system is deficient or suppressed and who have received a bone marrow transplant or a non-irradiated blood transfusion. Symptoms may include skin rash, intestinal problems and liver dysfunction.

Cutaneous T-cell lymphoma (CTCL): a group of disorders characterized by abnormal accumulation of malignant T-cells in the skin, potentially resulting in the development of rashes, plaques and tumors. CTCLs belong to a larger group of disorders known as non-Hodgkin's lymphomas (NHLs).

RELATED GUIDELINES:

None applicable.

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

CELLEX®

Extracorporeal photochemotherapy
UVAR® XTS Photopheresis System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/27/23.

GUIDELINE UPDATE INFORMATION:

01/15/13	New Medical Coverage Guideline.
12/15/13	Scheduled review. Revised description, program exceptions section and index terms. Updated references.
10/15/14	Scheduled review. Revised position statement, description section and index terms. Updated references.
10/01/15	Revision; updated ICD10 coding section.
10/15/15	Scheduled review. Position statement maintained. Updated references.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/16	Scheduled review. Position statement maintained. Revised ICD10 coding section. Updated references.
11/15/17	Scheduled review. Position statement maintained. Updated references.
11/15/18	Scheduled review. Revised description section. Maintained position statement. Updated references.
10/15/19	Scheduled review. Maintained position statement and updated references.
05/15/21	Scheduled review. Revised description and maintained position statement. Updated references.
05/15/23	Scheduled review. Maintained position statement and updated references.
05/22/23	Update to Program Exceptions section.