EXTRACORPOREAL PHOTOPHERESIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

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Description:

Extracorporeal Photopheresis (ECP):
Extracorporeal photopheresis (ECP) is a leukapheresis-based immunomodulatory procedure that involves the following steps: the individual’s blood is collected and the leukocyte-rich portion (buffy coat) is separated, the photosensitizer agent 8-methoxypsoralen (8-MOP) is added to the lymphocyte fraction, which is then exposed to ultraviolet A light, and the light-sensitized lymphocytes are reinfused into the individual.
EXTRACORPOREAL PHOTOPHERESIS (cont.)

Description: (cont.)

Cutaneous T-Cell Lymphoma (CTCL):
CTCL is a disease in which certain cells of the lymph system (T-lymphocytes) become cancerous and affect the skin. CTCL is generally resistant to chemotherapy and radiotherapy.

Graft-Versus-Host Disease (GVHD):
GVHD is a complication of allogeneic stem cell/bone marrow transplant. Infection fighting cells from the donor recognize the recipient’s body as being foreign. These cells attack tissues in the recipient’s body (e.g., liver, gastrointestinal tract and skin) just as if they were attacking an infection. Chronic GVHD occurs 100 days or more after transplantation. Acute GVHD occurs within the first 100 days.

Refractory Rejection:
Rejection that fails to respond adequately to a standard regimen of immunosuppressive therapy.

Recurrent Allograft Rejection:
Having at least 2 rejection episodes that recurred after standard immunosuppressive therapy.

Criteria:

- Extracorporeal photopheresis is considered medically necessary for ANY of the following:
  1. Acute or chronic graft-versus-host disease that is refractory to established therapy (see Description section for definition of acute and chronic)
  2. Cardiac allograft rejection, including acute rejection, that is either recurrent or that is refractory to standard immunosuppressive drug treatment
  3. Cutaneous T-cell lymphoma that is refractory to established therapy
EXTRACORPOREAL PHOTOPHERESIS (cont.)

Criteria: (cont.)

- Extracorporeal photopheresis for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to:

- Autoimmune diseases
- Autoimmune bullous disorders
- Crohn’s disease
- Cutaneous T cell lymphoma, early stage (I/II) that is either previously untreated or is responding to established nonsystemic therapies
- Dermatitis/eczema, atopic
- Diabetes
- GVHD, chronic, that is either previously untreated or is responding to established therapy
- Multiple sclerosis
- Pemphigus
- Psoriatic arthritis
- Psoriasis
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Systemic sclerosis (scleroderma)
- Treatment or prevention of rejection in solid-organ transplantation other than cardiac allograft rejection as stated above
EXTRACORPOREAL PHOTOPHERESIS (cont.)

Resources:


