Coverage Summary

Extracorporeal Photopheresis

Policy Number: E-004
Products: UnitedHealthcare Medicare Advantage Plans
Original Approval Date: 02/26/2008
Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee
Last Review Date: 05/11/2018
Related Medicare Advantage Policy Guideline: Extracorporeal Photopheresis (NCD 110.4)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

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I. COVERAGE

Coverage Statement: Extracorporeal photopheresis (also known as extracorporeal photochemotherapy) is covered when Medicare criteria are met.

Guidelines/Notes:
1. Extracorporeal photopheresis is covered for the following:
   a. Palliative treatment of skin manifestations of CTCL (cutaneous T-cell lymphoma) that has not responded to other therapy (effective April 8, 1988)
   b. Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment (effective December 19, 2006); and
   c. Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment (effective December 19, 2006).

See the NCD for Extracorporeal Photopheresis (110.4). (Accessed May 3, 2018)

2. Treatment of bronchiolitis obliterans syndrome (BOS): Effective April 30, 2012, Medicare also provides coverage for extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets the criteria outlined in the NCD for Extracorporeal Photopheresis (110.4). (Accessed May 3, 2018)

For payment rules for NCDs requiring CED; see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

Also see the CMS Transmittal 2551 (Change Request 7806) Extracorporeal Photopheresis (ICD-10: September 24, 2012). (Accessed May 3, 2018)


3. Extracorporeal photopheresis is not covered for the treatment of bullous pemphigoid and pemphigus vulgaris and all other indications unless specified above. See the NCD for Extracorporeal Photopheresis (110.4). (Accessed May 3, 2018)

Note: Today extracorporeal photopheresis is commonly administered via the UVAR® XTS™ system, which is an FDA-approved wholly-contained, automated processing system manufactured by Therakos, Inc. This system is a single unit that handles the collection of the patient’s blood, the isolation of the white blood cells, and the ex vivo administration of 8-MOP and UVA. The UVAR® XTS™ system evolved from the FDA-approved UVAR® system, which used the oral formulation of 8-MOP. Other systems and protocols have been used to administer extracorporeal photopheresis; however, in the National Coverage Decision Memorandum for Extracorporeal Photopheresis dated December 19, 2006, CMS evaluated the extracorporeal photopheresis procedure, and not a specific system for administering extracorporeal photopheresis. (Accessed May 3, 2017)

II. DEFINITIONS

Extracorporeal Photopheresis: A medical procedure in which a patient’s white blood cells are exposed first to a drug called 8-methoxypsoralen (8-MOP) and then to ultraviolet A (UVA) light. The procedure starts with the removal of the patient's blood, which is centrifuged to isolate the white blood cells. The drug is typically administered directly to the white blood cells after they have been removed from the patient (referred to as ex vivo administration) but the drug can alternatively be administered directly to the patient before the white blood cells are withdrawn. After UVA light exposure, the treated white blood cells are then re-infused into the patient. Extracorporeal photopheresis is usually performed on two consecutive days at four-week intervals with clinical evaluation at six months to determine response. The duration of treatment varies significantly depending on the medical condition being treated, and the patient’s response to the treatments. NCD for Extracorporeal Photopheresis (110.4). (Accessed May 3, 2018)

III. REFERENCES

See above

IV. REVISION HISTORY

5/11/2018 Annual review; no updates.
05/16/2017 Annual review; no updates.
05/17/2016 Annual review; no updates.
05/19/2015  Annual review; no changes.

04/21/2015  Guideline #2 [Treatment of bronchiolitis obliterans syndrome (BOS)]
- Added reference link to the list of Medicare approved clinical trials.
- Added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.

10/21/2014  Guideline # 2 [Treatment of bronchiolitis obliterans syndrome (BOS)] - Added reference link to the CMS Transmittal 3050 (Change Request 8808) Extracorporeal Photopheresis; August 22, 2014 which provides clarification for certain requirements for coverage of extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS).

05/20/2014  Annual review with the following updates:
- Guideline #2 (Treatment of bronchiolitis obliterans syndrome) - Replaced the reference and link from CMS Transmittal 2494 for Extracorporeal Photopheresis (ICD10) (rescinded September 7, 2012) to CMS Transmittal 2551 for Extracorporeal Photopheresis (ICD-10).
- Definitions - Updated definition of Extracorporeal Photopheresis [added reference to NCD for Extracorporeal Photopheresis (110.4)].

06/24/2013  Annual review; no updates.

08/20/2012  Updated to include Guidelines #2 Treatment of bronchiolitis obliterans syndrome (BOS) based on the NCD for Extracorporeal Photopheresis (110.4).

06/30/2012  Annual review; no updates.

06/30/2011  Annual review; no updates.