

# Extracorporeal Photopheresis (NCD 110.4)

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[Terms and Conditions](#)

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Related Medicare Advantage Coverage Summary
<ul style="list-style-type: none"> <li><a href="#">Extracorporeal Photopheresis</a></li> </ul>

## Policy Summary

[See Purpose](#)

### Overview

Extracorporeal photopheresis is 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administration) but the drug can alternatively be administered directly to the patient before the white blood cells are withdrawn.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.

### Guidelines

#### Nationally Covered Indications

Medicare has determined that extracorporeal photopheresis is reasonable and necessary under the following circumstances:

- Medicare provides coverage for: Palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy.
- Medicare also provides coverage for:
  - Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment; and,
  - Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment.
- 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 following conditions:
    - The clinical research study meets the requirements specified below to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. The clinical study must address one or more aspects of the following question:
      - Prospectively, do Medicare beneficiaries who have received lung allografts, developed BOS refractory to standard immunosuppressive therapy, and received extracorporeal photopheresis , experience improved patient-centered health outcomes as indicated by:

- Improved forced expiratory volume in one second (FEV1);
- Improved survival after transplant; and/or,
- Improved quality of life?

The required clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- The principal purpose of the research study is to test whether extracorporeal photopheresis potentially improves the participants' health outcomes.
- The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of successfully executing the proposed study.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must also be in compliance with 21 CFR parts 50 and 56.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- The clinical research study is registered on the [ClinicalTrials.gov](http://ClinicalTrials.gov) website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>).
- The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Any clinical study under which there is coverage of extracorporeal photopheresis for this indication pursuant to this national coverage determination (NCD) must be approved by April 30, 2014. If there are no approved clinical studies on this date, this NCD will expire and coverage of extracorporeal photopheresis for BOS will revert to the coverage policy in effect prior to the issuance of the final decision memorandum for this NCD.

### ***Nationally Non-Covered Indications***

All other indications for extracorporeal photopheresis not otherwise indicated above as covered remain non-covered.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study. The clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED).

Specifically, include the clinical trial identifier number if:

- The beneficiary is enrolled in an approved clinical trial; and
- The claim is for the investigational item or service, and/or,
- The costs are related to the investigational item or service, and/or
- The costs are related to routine care for the condition in the clinical trial.

CPT Code	Description
36522	Photopheresis, extracorporeal

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Modifier	Description
CED Only	
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Condition Code	Description
CED Only	
30	Qualifying clinical trial (institutional claims only)

## Questions and Answers

1	Q:	Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)?
	A:	<ul style="list-style-type: none"><li>• If no, clinical trial number, modifier Q0 and diagnosis code Z00.6 should not be submitted.</li><li>• If yes, the three requirements listed above are required. Claims without the required information will be denied.</li></ul>

## References

### CMS National Coverage Determinations (NCDs)

[NCD 110.4 Extracorporeal Photopheresis](#)

Reference NCD: [NCD 310.1 Routine Costs in Clinical Trials](#)

### CMS Claims Processing Manual

[Chapter 32; § 190 Billing Requirements for Extracorporeal Photopheresis](#)

### CMS Transmittal(s)

[Transmittal 1854, Change Request 10086, Dated 05/26/2017 \(ICD-10 Coding Revisions to National Coverage Determination \(NCDs\)\)](#)

[Transmittal 2382, Change Request 11491, Dated 11/01/2019 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2020 Update\)](#)

[Transmittal 2427, Change Request 11491, Dated 02/04/2020 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2020 Update\)](#)

## UnitedHealthcare Commercial Policy

[Apheresis](#)

### Other(s)

[CED: Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant, CMS Website](#)

[Decision Memo for Extracorporeal Photopheresis \(ECP\) \(CAG-00324R2\), CMS Website](#)

[National Institutes of Health Clinical Trials for Extracorporeal Photopheresis, clinicaltrials.gov](#)

## Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/14/2021	<ul style="list-style-type: none"><li>• Routine review; no change to guidelines</li><li>• Archived previous policy version MPG111.06</li></ul>

## Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

## Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document\* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making.

UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

\*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).