

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 143	Date: May 18, 2012
	Change Request 7806

SUBJECT: Extracorporeal Photopheresis (ICD-10)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on or after April 30, 2012, CMS will cover 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 specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: April 30, 2012

IMPLEMENTATION DATE: October 1, 2012

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/110.4/Extracorporeal Photopheresis

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 143	Date: May 18, 2012	Change Request: 7806
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SUBJECT: Extracorporeal Photopheresis (ICD-10)

Effective Date: April 30, 2012

Implementation Date: October 1, 2012

I. GENERAL INFORMATION

A. Background: Extracorporeal photopheresis is a second-line treatment for a variety of oncological and autoimmune disorders that is performed in the hospital inpatient, hospital outpatient, and critical access hospital settings in which a patient's white blood cells are exposed first to the drug 8-methoxypsoralen (8-MOP) and then to ultraviolet A (UVA) light. After UVA light exposure, the treated white blood cells are re-infused into the patient. The dead white blood cells, once re-infused into the patient, stimulate multiple different cells and proteins of the patient's immune system in a series of cascading reactions. This activation of the immune system then impacts the illness being treated.

Currently, as of December 19, 2006, Medicare covers extracorporeal photopheresis for the following indications:

- Palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy.
- 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.

On August 4, 2011, the Centers for Medicare & Medicaid Services (CMS) accepted a formal request for a reconsideration to add coverage for extracorporeal photopheresis treatment for patients who have received lung allografts and then developed progressive bronchiolitis obliterans syndrome (BOS) refractory to immunosuppressive drug treatment.

B. Policy: Effective for claims with dates of service on or after April 30, 2012, CMS will cover extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation.

Any clinical study undertaken pursuant to this NCD must be approved no later than April 30, 2014, two (2) years from the effective date of this NCD. If there are no approved clinical studies on or before April 30, 2014, this NCD for extracorporeal photopheresis treatment for patients who have received lung allografts and then developed progressive BOS refractory to immunosuppressive drug treatment will expire, and coverage will revert to the policy in effect prior to April 30, 2012. Any clinical study approved by April 30, 2014, will adhere to the timeframe designated in the approved clinical study protocol.

A reference listing of ICD-9 CM and ICD-10 coding and descriptions is listed below:

ICD9 CODE	LONG DESCRIPTION	ICD10 CODE	I10 Description
49120	Obstructive chronic bronchitis without exacerbation	J449	Chronic obstructive pulmonary disease, unspecified
49121	Obstructive chronic bronchitis with (acute) exacerbation	J441	Chronic obstructive pulmonary disease with (acute) exacerbation
4919	Unspecified chronic bronchitis	J42	Unspecified chronic bronchitis
496	Chronic airway obstruction, not elsewhere classified	J449	Chronic obstructive pulmonary disease, unspecified
99684	Complications of transplanted lung	T86810	Lung transplant rejection
99684	Complications of transplanted lung	T86811	Lung transplant failure
99684	Complications of transplanted lung	T86812	Lung transplant infection (not recommended for ECP coverage)
99684	Complications of transplanted lung	T86818	Other complications of lung transplant
99684	Complications of transplanted lung	T86819	Unspecified complication of lung transplant
V707	Examination of participant in clinical trial	Z006	Encounter for examination for normal comparison and control in clinical research program (needed for CED)

Refer to Pub. 100-04, chapter 32, section 69, on information regarding CEDs, and previous CRs/TRs containing Pub 100-03 NCD Manual 110.4 and Pub 100-04 Claims Processing Manual chapter 32, section 190. In addition, there are additional billing requirements specific to this NCD in the below business requirements.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A B M A C	D M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7806-03.1	Effective for claims with dates of service on or after April 30, 2012, contractors shall accept and pay for Extracorporeal Photopheresis for the treatment of BOS following lung allograft transplantation only in the context of an approved, clinical study in addition to the coverage criteria outlined in Pub 100-03, section 110.4, of the NCD Manual and chapter 32, section 190, Medicare Claims Processing Manual.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R I E R	R H H I S S	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7806.2-03	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Long, Coverage, 410-786-5702, kimberly.long@cms.hhs.gov; Wanda Belle, wanda.belle@cms.hhs.gov, Coverage, 410-786-7491; Patricia Brocato-Simons, Coverage, 410-786-0261, patricia.brocato-simons@cms.hhs.gov, Yvette Cousar, Part B Claims Processing, 410-786-2160 yvette.cousar@cms.hhs.gov, Yvonne Young, Part B Claims Processing, 410-786-1886, Yvonne.Young@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

110.4 - Extracorporeal Photopheresis

(Rev.143, Issued: 05-18-12, Effective: 04-30-12, Implementation: 10-01-12)

A. General

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.

B. Nationally Covered Indications

The *Centers for Medicare & Medicaid Services (CMS)* has determined that extracorporeal photopheresis is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (*the Act*) under the following circumstances:

1. Effective April 8, 1988, Medicare provides coverage for:

Palliative treatment of skin manifestations of *cutaneous T-cell lymphoma* that has not responded to other therapy.

2. Effective December 19, 2006, 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.

3. *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 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:

- a. *improved forced expiratory volume in one second (FEV1);*
- b. *improved survival after transplant; and/or,*
- c. *improved quality of life?*

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

- a. *The principal purpose of the research study is to test whether extracorporeal photopheresis potentially improves the participants' health outcomes.*
- b. *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.*
- c. *The research study does not unjustifiably duplicate existing studies.*
- d. *The research study design is appropriate to answer the research question being asked in the study.*
- e. *The research study is sponsored by an organization or individual capable of successfully executing the proposed study.*
- f. *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.*
- g. *All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).*
- h. *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.*
- i. *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.*
- j. *The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.*

k. 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>).

l. 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 affect 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.

m. 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.

C. Nationally Non-Covered Indications

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

D. Other

Claims processing instructions can be found in chapter 32, section 190 of the Medicare Claims Processing Manual.

(This NCD last reviewed April 2012.)