

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



In response to shortage of liposomal doxorubicin (Doxil), the Food and Drug Administration is permitting the temporary importation of Lipodox, a brand of liposomal doxorubicin hydrochloride. Visit <http://www.FDA.gov/NewsEvents/Newsroom/PressAnnouncements/ucm292658.htm> for additional information. The Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Quarterly Update includes two new codes (Q2048 and Q2049) for liposomal doxorubicin that will become effective Sunday, July 1, 2012. The code descriptors are worded in a manner that distinguishes Lipodox and Doxil. As of Sunday, July 1, 2012, HCPCS code J9001 will not be used for Medicare billing. CMS will release a Change Request (CR) with additional instructions in the near future.

MLN Matters® Number: MM7806

Related Change Request (CR) #: CR 7806

Related CR Release Date: September 24, 2012

Effective Date: April 30, 2012

Related CR Transmittal #: R143NCD and R2551CP

Implementation Date: October 1, 2012

Extracorporeal Photopheresis (ICD-10)

Note: This article was revised on September 18, 2014, to add a reference to MLN Matters® article MM8808 available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8808.pdf>, which clarifies requirements that covers extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS), following lung allograft transplantation, only when 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. All other information is unchanged.

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers who bill Medicare Carriers, Fiscal Intermediaries (FIs), or Medicare Administrative Contractors (A/B MACs) for providing extracorporeal photopheresis procedures for the treatment of Bronchiolitis Obliterans Syndrome (BOS) following lung allograft transplantation.

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Provider Action Needed

Effective for claims with dates of service on and after April 30, 2012, Medicare will cover extracorporeal photopheresis for the treatment of Bronchiolitis Obliterans Syndrome (BOS) following lung allograft transplantation, but only when provided under an approved clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. You should make sure that your billing staffs are aware of the expanded coverage provided in this NCD.

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 (CAH) settings. In the procedure, some of a patient's removed 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, stimulating their immune system in a series of cascading reactions. This activation of the immune system then impacts the illness being treated.

Currently, Medicare covers extracorporeal photopheresis for the following indications:

- Palliative treatment of skin manifestations of CTCL 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.

As a result of the reconsideration, effective for claims with dates of service on and after April 30, 2012, Medicare will begin to cover extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation; but only when provided under a clinical research study that meets specific requirements to assess its effect in the treatment of BOS following lung allograft transplantation.

NCD Clinical Research Study Requirements

This is a National Coverage Determination (NCD). In keeping with this NCD, any clinical research study that includes Medicare coverage of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation must be approved by meeting the requirements listed below. Additionally, consistent with Section 1142 of the Social Security

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Act, AHRQ supports clinical research studies that CMS determines meet these standards and address the research questions.

An approved clinical research study:

1. Must address one or more aspects of the following question:

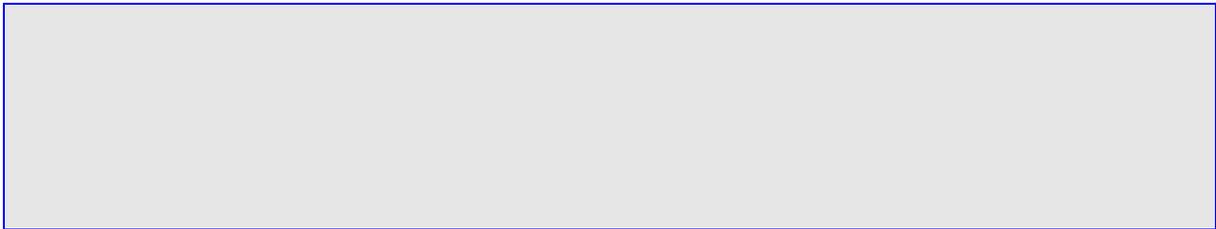
Prospectively, do Medicare beneficiaries who have received lung allografts, developed BOS refractory to standard immunosuppressive therapy, and received extracorporeal photopheresis, experience improved patient-centered health outcomes as indicated by:

- a. Improved Forced Expiratory Volume in One Second (FEV1);
 - b. Improved survival after transplant; and/or
 - c. Improved quality of life?
2. Must adhere to the following standards of scientific integrity and relevance to the Medicare population:
- a. Its principal purpose is to test whether extracorporeal photopheresis potentially improves the participants' health outcomes;
 - b. It 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. It does not unjustifiably duplicate existing studies;
 - d. Its design is appropriate to answer the research question being asked in the study;
 - e. It is sponsored by an organization or individual capable of successfully executing the proposed study;
 - f. It is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 Code of Federal Regulations 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 of its aspects are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>);
 - h. It has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for Coverage with Evidence Development (CED) coverage;
 - i. It 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 Section 312.81(a) and the patient has no other viable treatment options;
 - j. It is registered on the ClinicalTrials.gov website (<http://clinicaltrials.gov>) by the principal sponsor/investigator prior to the enrollment of the first study subject;

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- k. Its 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. It explicitly discusses 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
- m. Its 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.



Billing Requirements

Effective for claims with dates of service on and after April 30, 2012, your carrier, FI, or A/B MAC will accept and pay for hospital outpatient and physician claims containing Healthcare Common Procedure Coding System (HCPCS) procedure code 36522 along with one of the International Classification of Diseases (ICD-9-CM or ICD-10) diagnosis codes displayed in the following table.

ICD 9 CM	ICD 9 CM Description	ICD-10	ICD-10 Description
491.20	Obstructive chronic bronchitis without exacerbation	J44.9	Chronic obstructive pulmonary disease, unspecified
491.21	Obstructive chronic bronchitis with (acute) exacerbation	J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
491.9	Unspecified chronic bronchitis	J42	Unspecified chronic bronchitis

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ICD 9 CM	ICD 9 CM Description	ICD-10	ICD-10 Description
496	Chronic airway obstruction, not elsewhere classified	J44.9	Chronic obstructive pulmonary disease, unspecified
996.84	Complications of transplanted lung	T86.810	Lung transplant rejection
996.84	Complications of transplanted lung	T86.811	Lung transplant failure
996.84	Complications of transplanted lung	T86.812	Lung transplant infection (not recommended for ECP coverage)
996.84	Complications of transplanted lung	T86.818	Other complications of lung transplant
996.84	Complications of transplanted lung	T86.819	Unspecified complication of lung transplant
V70.7	Examination of participant in clinical trial	Z00.6	Encounter for examination for normal comparison and control in clinical research program (needed for CED)

Please note that your claims will only be paid when they also contain all of the following:

- Diagnosis code V70.7 (as secondary diagnosis) (ICD-10 Z00.6);
- Condition code 30 (institutional claims only);
- Clinical trial modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved research study); and
- Value Code D4 with an 8-digit clinical trial number (optional)(FIs only).

Additionally, should your Medicare contractor return your claims as unprocessable because they are missing: 1) Diagnosis code V70.7 (as secondary diagnosis), 2) Condition code 30 (Institutional claims only), 3) Clinical trial modifier Q0 (Institutional claims only), and 4) Value Code D4 with an 8-digit clinical trial number (optional) (FIs only); they will use the following messages:

- CARC 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC MA 130 – Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.
- RARC M16 – Alert: Please see our web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

Please keep in mind that your contractor will not retroactively adjust claims from April 30, 2012, processed prior to implementation of CR7806. However, they may adjust claims that you bring to their attention.

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Additional Information

The official instruction, CR7806, was issued in two transmittals. The first updates to the “Medicare National Coverage Determinations Manual” are available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R143NCD.pdf> on the CMS website. The second updates the “Medicare Claims Processing Manual” and it is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2551CP.pdf> on the CMS website.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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