CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2551	**Date: September 24, 2012**
	Change Request 7806

NOTE: Transmittal 2543, dated September 7, 2012, is being rescinded and replaced by Transmittal 2551, dated September 24, 2012, to include the deletion of ICD-9 Code, 996.88 in the Claims Processing Manual, section 190.2. All other information remains the same.

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.

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/revised 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	32/190/Billing Requirements for Extracorporeal Photopheresis
R	32/190.2/Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code
R	32/190.3/Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code

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. 100-04	Transmittal: 2551	Date: September 24, 2012	Change Request: 7806

NOTE: Transmittal 2543, dated September 7, 2012, is being rescinded and replaced by Transmittal 2551, dated September 24, 2012, to include the deletion of ICD-9 Code, 996.88 in the Claims Processing Manual, section 190.2. All other information remains the same.

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
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
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)

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 MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7806-04.1	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	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	110.4, of the NCD Manual and chapter 32, section 190, Medicare Claims Processing Manual.										
7806-04.2	Effective for claims with dates of service on and after April 30, 2012, contractors shall accept and pay for hospital outpatient and physician claims containing HCPCS procedure code 36522 along with one of the following ICD-9-CM diagnosis codes: 996.84, 491.9, 491.20, 491.21, and 496 (ICD-10: J42, J44.1, J44.9, T86.810, T86.811, T86.812, T86.818, T86.819) for extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation in the context of an approved, clinical study when all of the following are present: • Diagnosis code V70.7 (secondary dx) (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*) • Value Code D4 with an 8-digit clinical trial number (optional)(FIs only)	X		X	X		X				
7806-04.3	Contractors shall return to provider/return as unprocessable claims for extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation only in the context of an approved, clinical study containing HCPCS procedure code 36522 along with one of the following ICD-9-CM diagnosis codes: 996.84, 491.9, 491.20, 491.21, and 496 (ICD-10 Codes: J42, J44.1, J44.9, T86.810, T86.811, T86.812, T86.818, T86.819) but is missing one of the following: • Diagnosis code V70.7 (secondary dx) (ICD-10 Z00.6) • Condition code 30 (Institutional claims only) • Clinical trial modifier Q0 • Value Code D4 with an 8-digit clinical trial number (optional)(FIs only)	X		X	X		X	X			
7806-04.3.1	Contractors shall use the following messages when returning claims in 3 above:	X			X			X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	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.										
7806-04.4	Contractors shall note that the appropriate ICD-10 code(s) are listed below. Contractors shall track the ICD-10 code/edits (and add the code(s)/edit(s) to their systems when applicable) and ensure that the updated edit is functional as part of the ICD-10 implementation. **NOTE: You will not receive a separate Change Request instructing you to implement updated edits.** J42, J44.1, J44.9, T86.810, T86.811, T86.812, T86.818, T86.819, Z00.6.	X		X	X		X	X		X	
7806-04.5	Contractors shall not retroactively adjust claims from April 30, 2012, through the implementation of this CR. However, contractors may adjust claims that are brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7806-04.6	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.brocatosimons@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.

190 – Billing Requirements for Extracorporeal Photopheresis

(Rev. 2551, Issued: 09-24-12, Effective: 04-30-12, Implementation: 10-01-12)

Effective for dates of services on and after December 19, 2006, Medicare has expanded coverage for extracorporeal photopheresis for patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppresive drug treatment and patients with chronic graft versus host disease whose disease is refractory to standard immunosuppresive drug treatment. (See Pub. 100-03, chapter 1, section 110.4, for complete coverage guidelines).

Effective for claims with dates of service on or after April 30, 2012, CMS has expanded coverage for 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 bronchialitis obliterans syndrome (BOS) following lung allograft transplantation. Further coverage criteria is outlined in Publication 100-03, Section 110.4 of the NCD.

190.2 – Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code

(Rev. 2551, Issued: 09-24-12, Effective: 04-30-12, Implementation: 10-01-12)

The following HCPCS procedure code is used for billing extracorporeal photopheresis

- 36522 - Photopheresis, extracorporeal

The following are the applicable ICD-9-CM diagnosis codes for the new expanded coverage:

- 996.83 - Complications of transplanted heart, or
- 996.85 - Complications of transplanted bone marrow

Effective for services for BOS following lung allograft transplantation the following is a list of applicable ICD-9-CM diagnosis codes:

- *996.84 – Complications of transplanted lung*
- *491.9 - Unspecified chronic bronchitis*
- *491.20 – Obstructive chronic bronchitis without exacerbation*
- *491.21 – Obstructive chronic bronchitis with (acute) exacerbation*
- *496 – Chronic airway obstruction, not elsewhere classified*

The following is the applicable ICD-9-CM procedure code for the new expanded coverage:

- 99.88 - Therapeutic photopheresis.

NOTE: Contractors shall edit for an appropriate oncological and autoimmune disorder diagnosis for payment of extracorporeal photopheresis according to the National Coverage Determination

Effective for claims with dates of service on or after April 30, 2012, in addition to HCPCS 36522, the following ICD-CM/ICD-10 codes are applicable for extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation only with ECP is provided under a clinical research study as outlined in Section 190 above:

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

ICD9 CODE	LONG DESCRIPTION	ICD10 CODE	I10 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
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
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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)

Contractors must also report modifier Q0 - (Investigational clinical service provided in a clinical research study that is in an approved research study) on these claims. Contractors must use diagnosis code V70.7 and condition code 30 (FIs only) for these claims.

190.3 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code

(Rev. 2551, Issued: 09-24-12, Effective: 04-30-12, Implementation: 10-01-12)

Contractors shall continue to use the appropriate existing messages that they have in place when denying claims submitted that do not meet the Medicare coverage criteria for extracorporeal photopheresis.

Contractors shall deny claims when the service is not rendered to an inpatient or outpatient of a hospital, including critical access hospitals (CAHs) using the following codes:

- Claim Adjustment Reason code: 58 – “Claim/service denied/reduced because treatment was deemed by payer to have been rendered in an inappropriate or invalid place of service.”

- MSN 16.2 - “This service cannot be paid when provided in this location/facility." Spanish translation: "Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad." (Include either MSN 36.1 or 36.2 dependant on liablity.)

- RA MA 30 - "Missing/incomplete/invalid type of bill." (FIs and A/MACs only)

- *Group Code - CO (Contractual Obligations) or PR (Patient Responsibility) dependant on liability.*

Contractors shall return to provider/ return as unprocessable claims for BOS containing HCPCS procedure code 36522 along with one of the following ICD-9-CM diagnosis codes: 996.84, 491.9, 491.20, 491.21, and 496 but is missing Diagnosis code V70.7 (as secondary diagnosis, Institutional only), Condition code 30 Institutional claims only), Clinical trial modifier Q0. 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.*