CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1206	Date: MARCH 16, 2007
	Change Request 5464

SUBJECT: Extracorporeal Photopheresis

I. SUMMARY OF CHANGES: This instruction provides billing guidance for expanded coverage of extracorporeal photopheresis for dates of service on or after December 19, 2006.

NEW / REVISED MATERIAL
EFFECTIVE DATE: DECEMBER 19, 2006
IMPLEMENTATION DATE: APRIL 2, 2007

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents
N	32/190/Billing Requirements for Extracorporeal Photopheresis
N	32/190.1/Applicable Intermediary Bill Types
N	32/190.2/Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code
N	32/190.3/Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code
N	32/190.4/Advance Beneficiary Notice and Hospital Issued Notice of Noncoverage Information

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1206	Date: March 16, 2007	Change Request: 5464

SUBJECT: Extracorporeal Photopheresis

Effective Date: December 19, 2006
Implementation Date: April 2, 2007

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 (CAH) settings. Formerly, Medicare only covered extracorporeal photopheresis when used in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy. On April 6, 2006, a request to reconsider additional indications for this national coverage determination (NCD) initiated a national coverage analysis. This change request communicates the findings resulting from that analysis.

B. Policy: The CMS has reviewed the evidence and expanded coverage to include 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. Extracorporeal photopheresis for these additional conditions is considered reasonable and necessary under §1862(a)(1)(A) of the Social Security Act. The revised NCD can be found in section 110.4 of the Medicare NCD Manual. Revised claims processing instructions can be found in chapter 32, section 190 of the Medicare Claims Processing Manual.

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	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5464.1	Effective for dates of service on or after December 19, 2006, contractors shall accept claims for extracorporeal photopheresis when submitted under the expanded coverage conditions found in section 110.4 of the Medicare NCD Manual.	X		X	X							
5464.1.1	Contractors shall accept hospital outpatient and physician claims containing HCPCS procedure code 36522 along with one of the following ICD-9-CM DX codes:	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	• 996.83 (complications of transplanted heart), or • 996.85 (complications of transplanted bone marrow). Type of Bills (TOBs) 13X and 85X											
5464.1.2	Contractors shall accept hospital inpatient, including CAH, claims containing ICD-9-CM procedure code 99.88 along with one of the following ICD-9-CM DX codes: • 996.83 (complications of transplanted heart), or • 996.85 (complications of transplanted bone marrow). TOB: 11X	X		X								
5464.2	Contractors shall pay for extracorporeal photopheresis based on normal payment methodology for type of bills (TOBs) 11X, 13X or 85X according to the expanded coverage conditions.	X		X								
5464.3	Contractors shall create a medical policy parameter (MPP) for extracorporeal photopheresis based on the NCD.	X		X								
5464.4	Contractors shall continue denying noncovered claims as specified in section 110.4 of the Medicare NCD Manual. NOTE: We are using the term "deny" rather than "reject" because beneficiaries are entitled to appeal rights.	X		X	X							
5464.4.1	Contractors shall continue to issue appropriate notices to providers and beneficiaries when denying claims.	X		X	X							
5464.5	Contractors shall advise hospitals, CAHs, and physicians to issue appropriate liability notices when extracorporeal photopheresis services are noncovered as specified in chapter 32, section 190.4 of the Medicare Claims Processing Manual.	X		X	X							
5464.6	Contractors shall not search for claims	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	processed before April 2, 2007 with dates of service on or after December 19, 2006, but shall adjust claims brought to their attention.											

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5464.7	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

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):
National Coverage: Susan Harrison, susan.harrison@cms.hhs.gov or 410-786-1806
Provider Claims Processing: Susan Guerin, susan.guerin@cms.hhs.gov or 410-786-6138
Physician Claims Processing: Yvette Cousar, yvette.cousar@cms.hhs.gov or 410-786-2160

Post-Implementation Contact(s): Regional office

VI. FUNDING

A. TITLE XVIII Contractors:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. Medicare Administrative Contractors:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

Medicare Claims Processing Manual
Chapter 32 - Billing Requirements for Special Services

Table of Contents
(Rev. 1206, 03-16-07)

190 – Billing Requirements for Extracorporeal Photopheresis

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

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).

190.1– Applicable Intermediary Bill Types

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

11X, 13X, or 85X

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

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

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.*

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*

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

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

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.*

190.4 – Advance Beneficiary Notice and Hospital Issued Notice of Noncoverage Information

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

If this service is not reasonable and necessary under 1862(a)(1)(A) of the Act (falls outside the scope of the revised NCD found in Pub. 100-03, chapter 1, section 110.4), contractors shall advise physicians and/or hospital outpatient departments, including critical access hospitals (CAHs), that they will be held liable for charges unless the physician and/or hospital has the beneficiary sign an Advance Beneficiary Notice in advance of providing the service.

If this service is provided to a hospital inpatient, including CAHs, for a reason unrelated to the admission (outside of the bundled payment) contractors shall advise hospitals billing for inpatient services that they will be held liable for charges unless the hospital has the beneficiary sign a Hospital Issued Notice of Noncoverage letter 11 in advance of providing the service.