CMS Manual System Pub. 100-04 Medicare Claims Processing	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Transmittal 766	Date: DECEMBER 2, 2005
-	CHANGE REQUEST 4173

**SUBJECT: Stem Cell Transplantation** 

I. SUMMARY OF CHANGES: This CR includes clarifying language specific to the current national coverage policy on stem cell transplantation. CMS is clarifying that bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high does chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

## NEW/REVISED MATERIAL - EFFECTIVE DATE\*: December 28, 2005 **IMPLEMENTATION DATE: January 3, 2006**

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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:**

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/90.3/Stem Cell Transplantation
R	32/90/Stem Cell Transplantation

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

#### **IV. ATTACHMENTS:**

X	<b>Business Requirements</b>
X	Manual Instruction
	<b>Confidential Requirements</b>
	One-Time Notification
	Recurring Update Notification

<sup>\*</sup>Unless otherwise specified, the effective date is the date of service.

# **Attachment - Business Requirements**

Pub. 100-04 Transmittal: 766 Date: December 2, 2005 Change Request: 4173

**SUBJECT: Stem Cell Transplantation** 

#### I. GENERAL INFORMATION

A. Background: The CMS has a coverage policy for stem cell transplantation. Currently section 110.8.1 of Pub. 100-03, National Coverage Determination (NCD) Manual, states that stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. The transplant can be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function.

**B. Policy:** Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

#### II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

<sup>&</sup>quot;Should" denotes an optional requirement

Requirement	Requirements	Re	espo	nsi	bilit	ty ("	<b>X"</b> i	indi	icate	es the
Number		columns that apply)								
		FI	R H H I	C a r r i e	D M E R C		mtair M C S		C W F	Other
4173.1	Medicare contractors shall use this entire instruction to clarify existing coverage policy to providers regarding stem cell transplantation: Effective for services performed on or after November 29, 2005, when bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.	X		X						

Requirement	Requirements	Responsibility ("X" indicates the							
Number		columns that apply)							
		F I	R H H I	C a r r i e r	D M E R C	Shared Maintain  F M I C S S S S	ners		Other
	Refer to Pub. 100-03, part 1, section 110.8.1 (coverage), and Pub. 100-04, chapter 3, sections 90.3, chapter 32, sections 90 (FI and carrier claims processing).								

#### III. PROVIDER EDUCATION

Requirement	Requirements	Re	espo	nsi	bilit	ty ("	X":	indi	cat	es the
Number		co	lum	ns	that apply)					
		F I	R H	C a	D M	Shared System Other Maintainers			Other	
			H	r r i e r	E R C	F I S S	M C S	V M S	C W F	
4173.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites.	X		X						
4173.3	Contractors shall include information about this entire instruction in a listserv message within 1 week of the release of this instruction.	X		X						
4173.4	Contractors shall include the entire instruction in their next regularly scheduled bulletin.	X		X						
4173.5	Contractors shall incorporate the entire instruction into any educational events on this topic.	X		X						

## IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: NA

X-Ref Requirement #	Instructions

# B. Design Considerations: NA

C. Interfaces: NA

D. Contractor Financial Reporting /Workload Impact: NA

E. Dependencies: NA

F. Testing Considerations: NA

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date\*: December 28, 2005 Implementation Date: January 3, 2006

Pre-Implementation Contact(s): Susan Harrison, susan.harrison@cms.hhs.gov, 410-786-1806 (coverage), Yvette Cousar, Yvette.cousar@cms.hhs.gov (Carrier), 410-786-2160, Sarah Shirey-Losso, sarah.shirey-losso@cms.hhs.gov (FI), 410-786-0187

Post-Implementation Contact(s): Appropriate RO

No additional funding will be provided by CMS. Medicare contractors shall implement these instructions within their current 2006 operating budgets.

<sup>\*</sup>Unless otherwise specified, the effective date is the date of service.

### 90.3 - Stem Cell Transplantation

(Rev.766, Issued: 12-02-05, Effective: 12-28-05, Implementation: 01-03-06) A3-3614, HO-416.1

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplants (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. Effective October 1, 1990, these cases were assigned to the DRG 481, Bone Marrow Transplant.

The FI's Medicare Code Editor (MCE) will edit stem cell transplant procedure codes against diagnosis codes to determine which cases meet specified coverage criteria. Cases with a diagnosis code for a covered condition will pass (as covered) the MCE noncovered procedure edit. When a stem cell transplant case is selected for review based on the random selection of beneficiaries, the QIO will review the case on a post-payment basis to assure proper coverage decisions

Procedure code 41.00 (bone marrow transplant, not otherwise specified) will be classified as noncovered and the claim will be returned to the hospital for a more specific procedure code.

## 90 - Stem Cell Transplantation

#### (Rev. 766, Issued: 12-02-05, Effective: 12-28-05, Implementation: 01-03-06)

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.8.1, for a complete description of covered and noncovered conditions. The following sections contain claims processing instructions for carrier claims. For institutional claims processing instructions, please refer to Pub. 100-04, chapter 3, section 90.3.