
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 13

Date: MAY 28, 2004

CHANGE REQUEST 3265

I. SUMMARY OF CHANGES: In accordance with section 522 of the Benefits Improvement and Protection Act of 2000, national coverage determinations (NCDs) do not include a determination of what code is assigned to a particular item or service. Thus, we are removing the coding guidance in section 110.8.1, under section A of the NCD manual. Coding guidance remains in the claims processing manual.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 1, 2004

***IMPLEMENTATION DATE: July 6, 2004**

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: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/110.8.1/ Stem Cell Transplantation

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

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SUBJECT: Removal of Coding from National Coverage Determination on Stem Cell Transplantation

I. GENERAL INFORMATION

A. Background: Section 522 of the Benefits Improvements and Protections Act of 2000 states that national coverage determinations (NCDs) do not include a determination of what code is assigned to a particular item or service.

B. Policy: We are removing the coding guidance that was contained in the NCD for stem cell transplantation at section 110.8.1, under section A of the NCD Manual. Coding guidance remains in the Claims Processing Manual.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
N/A		

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: July 1, 2004</p> <p>Implementation Date: July 6, 2004</p> <p>Pre-Implementation Contact(s): Jackie Sheridan-Moore 410-786-4635</p> <p>Post-Implementation Contact(s): Jackie Sheridan-Moore 410-786-4635</p>	<p>These instructions shall be implemented within your current operating budget.</p>
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110.8.1 - Stem Cell Transplantation

(Rev. 13, 05-28-04)

CIM 35-30.1

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. The transplant can 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.

A - Allogeneic Stem Cell Transplantation

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

1 - Covered Conditions - The following uses of allogeneic bone marrow transplantation are covered under Medicare:

- For the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary; and
- For the treatment of severe combined immunodeficiency disease (SCID), and for the treatment of Wiskott - Aldrich syndrome.

2 - Noncovered Conditions - Allogeneic stem cell transplantation is not covered as treatment for multiple myeloma.

B - Autologous Stem Cell Transplantation

Autologous stem cell transplantation is a technique for restoring stem cells using the patient's own previously stored cells.

1 - Covered Conditions - Autologous stem cell transplantation is considered reasonable and necessary under [§1862\(a\)\(1\)\(A\)](#) of the Act for the following conditions and is covered under Medicare for patients with:

- Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- Resistant non-Hodgkin's or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma; or
- Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients that fit the following requirement:

- a. Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial

response to prior chemotherapy (defined as a 50 percent decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and

b. Adequate cardiac, renal, pulmonary, and hepatic function.

NOTE: Tandem transplantation for multiple myeloma remains noncovered.

2 - Noncovered Conditions - Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- Acute leukemia not in remission;
- Chronic granulocytic leukemia;
- Solid tumors (other than neuroblastoma);
- Up to October 1, 2000, multiple myeloma;
- Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;
- Effective **October 1, 2000**, non-primary (AL) amyloidosis; and
- Effective **October 1, 2000**, primary (AL) amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is **not** considered reasonable and necessary within the meaning of [§1862\(a\)\(1\)\(A\)](#) of the Act and is **not covered** under Medicare.