
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Transmittal 32

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

Date: APRIL 15, 2005

CHANGE REQUEST 3797

SUBJECT: Autologous Stem Cell Transplantation (AuSCT)

I. SUMMARY OF CHANGES: Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan (HDM) together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,
- Cardiac left ventricular ejection fraction (EF) greater than 45%.

Primary AL amyloidosis is covered for all beneficiaries who meet the above criteria regardless of age. All forms of non-primary (AL) amyloidosis remain non-covered.

(This revision to section 110.8.1, to Pub. 100-03, is a National Coverage Determinations (NCD) Manual made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR section 405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 15, 2005

IMPLEMENTATION DATE*: May 16, 2005

II. CHANGES IN MANUAL INSTRUCTIONS:

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/110.8.1/Stem Cell Transplantation (See Various Effective Dates)

***III. FUNDING:** These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

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

***Medicare contractors only**

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25) Coverage Determinations

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(Rev.32, 04-15-05)

110.8.1 – Stem Cell Transplantation (Various Effective Dates Below)

110.8.1 – Stem Cell Transplantation (Various Effective Dates Below)
(Rev.32, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

A. General

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.

1. 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.

a. Covered Indications

The following uses of allogeneic bone marrow transplantation are covered under Medicare:

- Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary; and
- Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID), and for the treatment of Wiskott-Aldrich syndrome.

b. Noncovered Indications

Effective for services performed on or after May 24, 1996, allogeneic stem cell transplantation is not covered as treatment for multiple myeloma.

2. Autologous Stem Cell Transplantation (AuSCT)

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

a. Covered Indications

Effective for services performed on or after April 28, 1989, AuSCT is considered reasonable and necessary under §1862(a)(1)(A) of the Social Security 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 lymphomas 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 requirements:

- 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% 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
- Adequate cardiac, renal, pulmonary, and hepatic function.

Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high dose melphalan (HDM) together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria:

- *Amyloid deposition in 2 or fewer organs; and,*
- *Cardiac left ventricular ejection fraction (EF) greater than 45%.*

b. Noncovered Indications

Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT 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 AuSCT) for patients with multiple myeloma;

- Effective October 1, 2000, non primary AL amyloidosis; and,
- Effective October 1, 2000, *thru March 14, 2005*, primary AL **amyloidosis** for Medicare beneficiaries age 64 or older.

In these cases, AuSCT is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

B. Other

All other indications for stem cell transplantation not otherwise noted above as covered or noncovered nationally remain at local contractor discretion.

(This NCD last reviewed March 2005.)