CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 526 | **Date: APRIL 15, 2005**

CHANGE REQUEST 3797

SUBJECT: Updated Requirements for Autologous Stem Cell Transplantation (AuSCT)

I. SUMMARY OF CHANGES: This CR updates Pub 100-04, chapter 3, section 90.3.2 (FI claims), and chapter 32, section 90.3 (carrier claims) with new coverage guidelines for primary amyloid light chain (AL) amyloidosis. When recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan together with autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary subject to certain criteria. To clarify existing coverage, AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (high dose chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies. The criteria for multiple myeloma (Durie-Salmon) within the FI section is also revised to coincide with the Nation Coverage Determinations Manual (NCD) section 110.8.1 and in chapter 32, section 90.3.2, the non-coverage guidelines have been updated to remove the age requirement language to coincide with the NCD Manual, Pub.100-03, section 110.8.1. Also, in chapter 3, section 90.3.3, we removed reference to revenue code 0891 since that revenue code no longer exists. We also removed the reference to physicians that does not belong in the hospital chapter. All other information within the claims processing manual remains the same.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 15, 2005
IMPLEMENTATION DATE*: May 16, 2005

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	3/90.3.2/Autologous Stem Cell Transplantation (AuSCT)
R	3/90.3.3/Billing for Stem Cell Transplantation
R	32/90/Stem Cell Transplantation
R	32/90.2/HCPCS and Diagnosis Coding
R	32/90.3/Non-Covered Conditions

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

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

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

Attachment - Business Requirements

Pub. 100-04	**Transmittal: 526**	**Date: April 15, 2005**	**Change Request 3797**

SUBJECT: Updated Requirements for Autologous Stem Cell Transplantation (AuSCT)

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) previously had a national non-coverage policy for high-dose melphalan together with autologous stem cell transplantation (HDM/AuSCT) for primary amyloid light chain (AL) amyloidosis (ICD-9-CM 277.3) for Medicare beneficiaries age 64 years or older. This non-coverage policy was based on the lack of sufficient data to establish definitive conclusions regarding the efficacy of AuSCT. For those beneficiaries age 63 years or younger, coverage of HDM/AuSCT was left to local contractor discretion.

B. Policy: Effective for services on or after March 15, 2005 (and dates of service on or after March 15, 2005, for a hospital outpatient and discharges on or after March 15, 2005, for a hospital inpatient), when recognized clinical risk factors are employed to select patients for transplantation, HDM together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary 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. To clarify existing coverage, AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (high dose chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies.

Refer to Pub. 100-03, National Coverage Determinations Manual, section 110.8.1 for complete coverage guidelines, and Pub. 100-04, Medicare Claims Processing Manual, chapter 3, section 90.3.2 (FI) and chapter 32, section 90-90.6 (carrier) for complete claims processing guidance.

II. BUSINESS REQUIREMENTS

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

Requirement Number	**Requirements**	**Responsibility ("X" indicates the columns that apply)**					
		FI	RHH	Car	DME	Shared System Maintainers	Other

						FISS	MCS	VMS	CWF	
3797.1	Medicare contractors shall educate providers that effective for services on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, HDM together with AuSCT is considered reasonable and necessary for Medicare beneficiaries of any age group with primary AL amyloidosis (ICD-9-CM CODE 277.3) who meet the following criteria: • amyloid deposition in 2 or fewer organs; and, • cardiac left ventricular ejection fraction (EF) greater than 45%.	X		X						
3797.2	Contractors shall remove any age restriction editing currently in place for AuSCTs.	X				X	X	X		

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3797.3	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
3797.1 and 3797.2	The Type of Bills involved for billing the Medicare FIs for AuSCTs are 11X, 13X, or 85X.

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

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: dates of service on or after March 15, 2005 (for physician and outpatient hospital billing) or discharges on or after March 15, 2005 (for inpatient hospital billing) **Implementation Date: May 16, 2005**	**Medicare contractors shall implement these instructions within their current operating budgets.**

Pre-Implementation Contact(s): (coverage) Susan Harrison (sharrison2@cms.hhs.gov) 410-786-1806; (carriers) Yvette Cousar (ycousar@cms.hhs.gov), 410-786-2160, (FI) Sarah Shirey (SShirey@cms.hhs.gov) 410-786-0187 **Post-Implementation Contact(s):** Appropriate RO	

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

Medicare Claims Processing Manual
Chapter 3 - Inpatient Hospital Billing

Table of Contents

(Rev.526, 04-15-05)

90.3.2 – Autologous Stem Cell Transplantation (AuSCT)

90.3.2 - Autologous Stem Cell Transplantation *(AuSCT)*
(Rev.526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

A - General

Autologous stem cell transplantation (AuSCT) (ICD-9-CM procedure code 41.01, 41.04, 41.07, and 41.09 and CPT-4 code 38241) is a technique for restoring stem cells using the patient's own previously stored cells. *AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (high dose chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies.*

B - Covered Conditions

1. Effective for services performed on or after April 28, 1989:

   - Acute leukemia in remission (ICD-9-CM codes 204.01, lymphoid; 205.01, myeloid; 206.01, monocytic; 207.01, acute erythremia and erythroleukemia; and 208.01 unspecified cell type) patients who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;

   - Resistant non-Hodgkin's lymphomas (ICD-9-CM codes 200.00-200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88, and 202.90-202.98) or those presenting with poor prognostic features following an initial response;

   - Recurrent or refractory neuroblastoma (see ICD-9-CM Neoplasm by site, malignant); or

   - Advanced Hodgkin's disease (ICD-9-CM codes 201.00-201.98) patients who have failed conventional therapy and have no HLA-matched donor.

2. Effective for services performed on or after *October 1, 2000*:

   - *Durie-Salmon Stage II or III that fit the following requirement: Newly diagnosed or responsive multiple myeloma (ICD-9-CM codes 203.00 and 238.6). 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.*

3. 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, in treating Medicare beneficiaries of any

age group with primary amyloid light-chain (AL) amyloidosis who meet the following criteria:

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

C - 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 (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
- Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);
- Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0-199.1);
- Multiple myeloma (ICD-9-CM code 203.00 and 238.6), through *September 30, 2000.*
- Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma (ICD-9-CM code 203.00 and 238.6)
- Non-primary (AL) amyloidosis (ICD-9-CM code 277.3), effective *October 1, 2000*; or
- Primary (AL) amyloidosis (ICD-9-CM code 277.3) for Medicare beneficiaries age 64 or older, effective *October 1, 2000, through March 14, 2005*.

NOTE: Coverage for conditions other than these specifically designated as covered or non-covered is left to the FI's discretion.

90.3.3 - Billing for Stem Cell Transplantation

(Rev.526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

A - Billing for Acquisition Services

The hospital identifies stem cell acquisition charges separately in FL 42 of Form CMS-1450 by using revenue code 0819 (Other Organ Acquisition). The FI does not make separate payment for these acquisition charges, since they are included in the DRG payment.

For allogeneic stem cell transplants (procedure codes 41.02 or 41.03) where the hospital submits interim bills, the acquisition charge will appear on the billing form for the period during which the transplant took place. Since claims for stem cell transplants are paid using PPS, the hospital submits an adjustment bill whenever an interim bill has been processed. Charges will appear on the transplant bill if there are no interim bills involved.

The transplant hospital keeps an itemized statement that identifies the services furnished, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges will be reflected in the transplant hospital's stem cell/bone marrow acquisition cost center. Revenue code 0819 *is* to include all services required in acquisition of stem cell, e.g., tissue typing or post-operative evaluation.

For allogeneic stem cell transplants (procedure codes 41.02 and 41.03, 41.05, or 41.08), the hospital includes charges for acquisition and any applicable storage charges on the recipient's transplant bill.

Acquisition charges do not apply to autologous stem cell acquisitions. On the transplant bill, the hospital reports the charges, cost report days, and utilization days for the stay in which the stem cell was obtained.

B - Billing for Allogeneic Stem Cell Transplants

The donor is covered for medically necessary inpatient hospital days of care in connection with the bone marrow transplant operation. Expenses incurred for complications are covered only if they are directly and immediately attributable to the stem cell donation procedure

If the donor receives hospital services in connection with a stem cell transplant, they are covered under Part A. The hospital reports the charges on the billing form for the recipient. It does not charge the donor's days of care against the recipient's utilization record. For cost reporting purposes, it includes the covered donor days and charges as Medicare days and charges.

The hospital shows charges for the transplant itself in revenue center code 0362. Selection of the cost center is up to the hospital.

C - Billing for Autologous Stem Cell Transplants

Since there are no covered acquisition charges for autologous stem cell transplant, the hospital shows all charges in the usual manner. It shows charges for the transplant, procedure code 41.01, in revenue center code 0362 or other appropriate cost center.

90 – Stem Cell Transplantation

(Rev.526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

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.

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

90.2 - HCPCS and Diagnosis Coding

(Rev.526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

- Allogeneic Stem Cell Transplantation

  - Effective for services performed on or after August 1, 1978:

    -- For the treatment of leukemia or leukemia in remission, providers shall use ICD-9-CM codes 204.00 through 208.91 and HCPCS code 38240.

    -- For the treatment of aplastic anemia, providers shall use ICD-9-CM codes 284.0 through 284.9 and HCPCS code *38240.*

  - Effective for services performed on or after June 3, 1985:

    -- For the treatment of severe combined immunodeficiency disease, providers shall use ICD-9-CM code 279.2 and HCPCS code 38240.

    -- For the treatment of Wiskott-Aldrich syndrome, providers shall use ICD-9-CM code 279.12 and HCPCS code *38240.*

  - Effective for services performed on or after May 24, 1996:

    -- Allogeneic stem cell transplantation, HCPCS code 38240 is not covered as treatment for the diagnosis of multiple myeloma ICD-9-CM codes 203.00 or 203.01.

- Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services performed on or after April 28, 1989:

  - For the treatment of patients with acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA) matched, providers shall use ICD-9-CM code 204.01 lymphoid; ICD-9-CM code 205.01 myeloid; ICD-9-CM code 206.01 monocytic; or ICD-9-CM code 207.01 acute erythremia and erythroleukemia; or ICD-9-CM code 208.01 unspecified cell type and HCPCS code 38241.

  - For the treatment of resistant non-Hodgkin's lymphomas for those patients presenting with poor prognostic features following an initial response, providers shall use ICD-9-CM codes 200.00 - 200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88 or 202.90-202.98 and HCPCS code *38241.*

  - For the treatment of recurrent or refractory neuroblastoma, providers shall use ICD-9-CM codes Neoplasm by site, malignant, the appropriate HCPCS code and HCPCS code 38241.

  - For the treatment of advanced Hodgkin's disease for patients who have failed conventional therapy and have no HLA-matched donor, providers shall use ICD-9-CM codes 201.00 - 201.98 and HCPCS code ***38241.***

• Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services furnished on or after October 1, 2000:

- For the treatment of multiple myeloma (only for beneficiaries who are less than age 78, have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma, and have adequate cardiac, renal, pulmonary and hepatic functioning), providers shall use ICD- 9-CM code 203.00 or 238.6 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use appropriate code (see ICD-9-CM neoplasm by site, malignant) and HCPCS code 38241.

- *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 autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary for Medicare beneficiaries of any age group for the treatment of primary amyloid light chain (AL) amyloidosis, ICD-9-CM code 277.3 who meet the following criteria:*

  • *Amyloid deposition in 2 or fewer organs; and,*

  • *Cardiac left ventricular ejection fraction (EF) greater than 45%.*

90.3 - Non-Covered Conditions

(Rev.526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

Autologous stem cell transplantation is not covered for the following conditions:

• Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);

• Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);

• Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0 through 199.1); or

• Effective for services rendered on or after May 24, 1996 through September 30, 2000, multiple myeloma (ICD-9-CM code 203.00 and 203.01).

• *Effective for services on or after October 1, 2000, through March 14, 2005, for Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary (ICD-9-CM code 277.3)*

• Effective for services on or after 10/01/00, for all Medicare beneficiaries, non-primary amyloidosis (ICD-9-CM code 277.3).

NOTE: Coverage for conditions other than those specifically designated as covered in 90.2 or specifically designated as non-covered in this section will be at the discretion of the individual carrier.