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# Medicare Intermediary Manual

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## Part 3 - Claims Process

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Department of Health and  
Human Services (DHHS)  
HEALTH CARE FINANCING  
ADMINISTRATION (HCEA)

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents - Chapter VII	6-1 - 6-2 (2 pp.)	6-1 - 6-2 (2 pp.)
3614.1 - 3614.4	6-136.3 - 6-136.5 (3 pp.)	6-136.3 - 6-136.4 (2 pp.)

**NEW/REVISED MATERIAL--*EFFECTIVE DATE: 10/01/00***  
***IMPLEMENTATION DATE: 10 /01/00***

Section 3614, Stem Cell Transplantation, provides claims processing instructions for the coverage of stem cell transplants. It has been updated to include both the covered and noncovered diagnosis and procedure codes for allogeneic and autologous stem cell transplants. In addition to clarifying the current coverage as described in the Coverage Issues Manual §35-30.1, effective 10/01/2000, autologous stem cell transplantation will also be covered for Medicare beneficiaries with multiple myeloma, less than age 78 who have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma with adequate cardiac, renal, pulmonary, and hepatic function. Multiple rounds of autologous stem cell transplantation (known as tandem transplantation) will, however, remain non-covered. The Coverage Issues Manual also includes nonprimary amyloidosis as a noncovered condition and primary (AL) amyloidosis as a noncovered condition for Medicare beneficiaries age 64 or older.

Section 3614.1, Allogeneic Stem Cell Transplantation, provides background, coverage, and coding information on Allogeneic stem cell transplantation.

Section 3614.2, Autologous Stem Cell Transplantation, provides background, coverage, and coding information on Autologous stem cell transplantation.

Section 3614.3, Acquisition Costs, provides information on stem cell acquisition charges.

Please notify your providers of these changes.

**These instructions should be implemented within your current operating budget.**

**DISCLAIMER:** The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

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## 3614. STEM CELL TRANSPLANTATION

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.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. Effective 10/01/90, these cases are assigned DRG 481, Bone Marrow Transplant.

See Coverage Issues Manual, §35-30.1 for a complete description of covered and noncovered conditions.

The **Outpatient** Code Editor (**OCE**) will edit stem cell transplant procedure codes against diagnosis codes to determine which cases may meet the specified coverage criteria. Those cases with a diagnosis code for a covered condition will pass (as covered) the **OCE** noncovered procedure edit. Pay any claims that pass the **OCE** for eligible beneficiaries. When a stem cell transplant case is selected for review based on the random selection of beneficiaries, the PRO will review the case on a post-payment basis to assure proper coverage decisions. **Stem Cell transplants are typically performed in the outpatient setting. Should complications occur, then the procedure would be performed on an inpatient basis. When performed on an inpatient basis, the claim would go through the Medicare Code Editor (MCE), instead of the OCE.**

The **OCE/MCE** classifies procedure code 41.00 (Bone marrow transplant, not otherwise specified) as noncovered. Return the claim to the provider for a more specific procedure code.

3614.1 Allogeneic Stem Cell Transplantation.--

A. General.--Allogeneic stem cell transplantation (**ICD-9-CM Procedure Codes 41.02, 41.03, 41.05, and 41.08, CPT-4 Code 38240**) is a procedure in which a portion of a healthy donor's stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect.

Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell, and ordinary follow-up care.

B. Covered Conditions.--

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

o For the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91), or aplastic anemia (ICD-9-CM codes 284.0 through 284.9) when it is reasonable and necessary; and

## 2. Effective for services performed on or after June 3, 1985:

o For the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2), and for the treatment of Wiskott - Aldrich syndrome (ICD-9-CM 279.12).

C. Noncovered Conditions.--

## 1. Effective for services performed on or after May 24, 1996:

o Allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.00 and 203.01 ).

**NOTE:** Coverage for conditions other than these specifically designated as covered or noncovered in this section or §35-30.1 of the CIM are left to individual intermediary's discretion.

D. Billing for Allogeneic Stem Cell Transplants.--The donor is covered for medically necessary inpatient hospital days of care in connection with the stem cell transplant operation. Expenses incurred for complications are covered only if they are directly and immediately attributable to the stem cell donation procedure.

Hospital services furnished in connection with a stem cell transplant are covered under Part A. Charges are reported on the hospital billing form submitted for the recipient. Days of care used by the donor are not charged against the recipient's utilization record. For purposes of cost reporting, include the covered donor days and charges as Medicare days and charges. Physicians' services are billed under Part B to the carrier, on the account of the recipient, and are paid at 80 percent of reasonable charges.

Charges for the transplant itself will generally be shown in revenue center code 362, although selection of the cost center is up to the hospital.

#### 3614.2 Autologous Stem Cell Transplantation.--

A. General.--Autologous stem cell transplantation (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.

#### B. Covered Conditions.--

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

o 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;

o 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;

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

o 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 10/01/00:

o Multiple myeloma (ICD-9-CM code 203.00 and 238.6), for beneficiaries less than age 78, who have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma and adequate cardiac, renal, pulmonary and hepatic functioning. Multiple rounds of autologous stem cell transplantation (known as tandem transplantation) will, however, remain non-covered.

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o Primary amyloidosis (ICD-9-CM code 277.3), for beneficiaries under the age of 64, **coverage is at the intermediary's discretion.**

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

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

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

o Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0-199.1);

o Multiple myeloma (ICD-9-CM code 203.00 and 238.6), **through 9/30/00**

o Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma (ICD-9-CM code 203.00 and 238.6)

o Non-primary (AL) amyloidosis (ICD-9-CM code 277.3), **effective 10/01/00**; or

o Primary (AL) amyloidosis (ICD-9-CM code 277.3) for Medicare beneficiaries age 64 or older, **effective 10/01/00.**

**NOTE:** Coverage for conditions other than these specifically designated as covered or noncovered in this section or §35-30.1 of the CIM is left to the intermediary's discretion.

D. Billing for Autologous Stem Cell Transplants.--Since there are no covered acquisition charges for autologous stem cell transplants, all charges are shown in the usual manner. Charges for the transplant itself are shown in revenue center code 362 or other appropriate cost center.

**3614.3** Acquisition Costs.--Stem cell acquisition charges are identified separately in FL 42 of Form HCFA-1450 by using revenue codes 819 (Other Organ Acquisition) and/or 891 (Other Donor Bank, Bone). Do not make separate payment for these acquisition charges as payment is included in the DRG payment.

For allogeneic stem cell transplants (procedure codes 41.02, 41.03, **41.05, or 41.08**), where interim bills are submitted, the acquisition charge appears on the billing form for the period during which the transplant took place. Since claims for stem cell transplants are paid using PPS, process an adjustment bill to recover payment if you have already paid the interim bill. Where no interim bills are involved, all charges appear on the transplant bill.

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 are reflected in the transplant hospital's stem cell/bone marrow acquisition cost center. Include charges for all services required in acquisition of stem cells, i.e., tissue typing and post-operative evaluation, in revenue codes 819 and 891.

For allogeneic stem cell transplants (procedure codes 41.02, 41.03, **41.05, or 41.08**), charges for acquisition and any applicable storage charges will appear on the recipient's transplant bill. Acquisition charges do not apply to autologous stem cell acquisitions. The charges, cost report days, and utilization days for the stay in which the stem cells were obtained are reported on the transplant bill.

**3614.4** Notifying Carriers.--Carriers will automatically be notified via a CWF trailer.

