Medicare Coverage Issues Manual Transmittal 169 Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS) Date: APRRIL 25, 2003

CHANGE REQUEST 2604

HEADER SECTION NUMBERS PAGES TO INSERT 2 pp PAGES TO DELETE 2 pp

NEW/REVISED MATERIAL--EFFECTIVE DATE: October 1, 2000 IMPLEMENTATION DATE: May 9, 2003

<u>Section 35-30.1, Stem Cell Transplantation</u>, is revised to alter the existing substance of §35-30.1 by removing the reference to age as a limitation on coverage of stem cell transplantation for patients with multiple myeloma.

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.

Contractors should reprocess any claims brought to their attention.

These instructions should be implemented within your current operating budget.

- o Effective for services performed on or after June 3, 1985, 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).
- 2. <u>Noncovered Conditions</u>.--Effective May 24, 1996, allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.0 and 238.6).
- B. <u>Autologous Stem Cell Transplantation (Effective for Services Performed on or After 04/28/89)</u>.--Autologous stem cell transplantation (ICD-9-CM procedure codes 41.01, 41.04, 41.07, and 41.09) is a technique for restoring stem cells using the patient's own previously stored cells.
- 1. <u>Covered Conditions.</u>--Autologous stem cell transplantation (ICD-9-CM codes 41.01, 41.04, 41.07, 41.09, CPT-4 code 38241) 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:
- 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) 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) who have failed conventional therapy and have no HLA-matched donor;
- o 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 non-covered.
- 2. <u>Noncovered Conditions</u>.--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 Up to October 1, 2000, multiple myeloma;

- o Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;
 - o Effective October 1, 2000, non-primary (AL) amyloidosis (ICD-9-CM 277.3);
- o Effective October 1, 2000, primary (AL) amyloidosis (ICD-9-CM 277.3) 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.

35-31 TREATMENT OF DECUBITUS ULCERS

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

35-32 VERTEBRAL ARTERY SURGERY

Obstructions, which block the flow of blood through the vertebral artery, can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration or completed stroke.

Five types of surgical procedures are performed to relieve obstructions to vertebral artery blood flow. They are:

- o Vertebral artery endarterectomy, a procedure that cleans out arteriosclerotic plaques, which are inside the vertebral artery;
 - o Vertebral artery by-pass or resection with anastomosis or graft;
 - o Subclavian artery resection with or without endarterectomy;
- o Removal of laterally located osteophytes anywhere in the C6(C7)-C2 course of the vertebral artery; and
- o Arteriolysis which frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures can be medically reasonable and necessary, but only if each of the following conditions is met:

- o Symptoms of vertebral artery obstruction exist;
- o Other causes have been considered and ruled out;