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.)

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<tr>
<th>R/N/D</th>
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<tr>
<td>R</td>
<td>1/110.8.1/ Stem Cell Transplantation</td>
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*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
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

<table>
<thead>
<tr>
<th>Requirement #</th>
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III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

<table>
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<tr>
<th>X-Ref Requirement #</th>
<th>Instructions</th>
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B. Design Considerations: N/A

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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

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