Stem Cell Transplantation

Policy Number: HS-069

Original Effective Date: 12/18/2008


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Stem-cell transplantation refers to the transplantation of hematopoietic stem cells (HSCs) into a patient. HSCs are immature cells that can develop into any of the three types of blood cells (red cells, white cells or platelets). HSCs are created in the bone marrow and are found in the bone marrow (BM) and peripheral blood. There is also a high concentration of HSCs in umbilical-cord blood. HSC transplantation (HSCT) can be either autologous (i.e., using the patient’s own stem cells) or allogeneic (i.e., using stem cells from a donor). HSCT is provided to patients with hematological disorders to rescue the patients from treatment-induced aplasia after high-dose chemotherapy and/or radiotherapy has been administered to eliminate the recipient’s immune system.

Durie-Salmon Classification for Multiple Myeloma

Stage I - The earliest stage of multiple myeloma and is characterized by the following:
• No sign of anemia (hemoglobin values are normal; greater than 10 g/dL)
• No sign of hypercalcemia (serum calcium values are normal; less than 12 mg/dL)
• X rays of bone are normal or exhibit only a single bone plasmacytoma
• Low M protein production rates:
  o IgG value is less than 5 g/dL
  o IgA value is less than 3 g/dL
  o Bence-Jones protein (free immunoglobulin light chains in urine) as measured by protein electrophoresis is less than 4 g/24h

**Stage II** - Intermediate stage of multiple myeloma; more advanced than Stage I but not as advanced as Stage III.

**Stage III** - Advanced stage of multiple myeloma; classification assigned if one or more of the following are present:
• Anemia (hemoglobin value is less than 8.5 g/dL)
• Hypercalcemia (serum calcium value greater than 12 mg/dL)
• X-rays reveal multiple bone lesions
• High M protein production rates:
  o IgG value is greater than 7 g/dL
  o IgA value is greater than 5 g/dL
  o Bence-Jones protein is greater than 12 g/24h

**POSITION STATEMENT**

**Applicable To:**
- Medicaid
- Medicare

**Exclusions**

Allogeneic bone marrow transplantation is considered experimental and NOT a covered benefit for the treatment of multiple myeloma or any other indication not listed below.

Autologous Stem Cell Transplantation (AuSCT) is considered experimental and NOT a covered benefit for treatment for the following indications:
• Acute leukemia not in remission; OR,
• Chronic granulocytic leukemia; OR,
• Solid tumors (other than neuroblastoma); OR,
• Tandem transplantation (multiple rounds of AuSCT) for members with multiple myeloma; OR,
• Non-primary AL amyloidosis; OR,
• Indications not listed above.

**Coverage**

**Allogeneic Stem Cell Transplantation**

Members undergoing Allogenic Stem Cell Transplantation (ASCT) must complete a pre-transplant evaluation as evidenced by all of the following:
• Psychosocial screen to include the following three items:
  o Drug / alcohol screen with no drug / alcohol abuse by history OR drug / alcohol free for ≥ 6 months
  o Behavioral health disorder with no behavioral health disorder by history and physical examination OR treated behavioral health disorder; AND
  o Adequate social / family support.
• Performance status of Karnofsky score ≥ 70% OR Eastern Cooperative Oncology Group grade 0-2.
Allogeneic bone marrow transplantation is **considered medically necessary and a covered benefit** for the treatment of the following indications:

- Aplastic anemia; **OR**
- Leukemia; **OR**
- Leukemia in remission; **OR**
- Multiple myeloma; **OR**
- Myelofibrosis; **OR**
- Sickle cell disease; **OR**
- Severe combined immunodeficiency disease (SCID); **OR**
- Wiskott-Aldrich syndrome.

**ASCT for Acute Myelogenous Leukemia (AML)**

**ASCT is considered medically necessary and a covered benefit** for AML if **ALL** of the following criteria are met:

- HLA matched donor; **AND,**
- Therapeutic response confirmed by bone marrow Bx as evidenced by one of the following:
  - First remission in intermediate / high-risk patient; **OR,**
  - Second remission; **OR,**
  - Relapsed disease; **OR,**
  - Induction failure.
- Pre-transplant evaluation (see criteria above).

**ASCT for Lymphocytic Leukemia**

**ASCT is considered medically necessary and a covered benefit** for lymphocytic leukemia if **ALL** of the following criteria are met:

- HLA matched donor; **AND,**
- Therapeutic response confirmed by bone marrow Bx as evidenced by one of the following:
  - First remission in intermediate / high-risk patient; **OR,**
  - Second remission; **OR,**
  - Relapsed disease; **OR,**
  - Induction failure.
- **AND,**
- Pre-transplant evaluation to include (in addition to items listed above), a neurological screen with results of one of the following:
  - Normal by history and physical examination; **OR,**
  - Positive symptoms from normal cytology by LP and treated CNS disease.

**ASCT for Myelodysplastic Syndrome**

**ASCT is considered medically necessary and a covered benefit** for myelodysplastic syndrome if **ALL** of the following criteria are met:

- HLA matched donor; **AND,**
- Intermediate-risk / high-risk patient by IPSS*; **AND,**
- Pre-transplant evaluation (see criteria above).

* NOTE: IPSS = International Prognostic Scoring System
ASCT for Chronic Myelogenous Leukemia (CML)

ASCT is considered medically necessary and a covered benefit for CML if ALL of the following criteria are met:
- HLA matched donor; AND,
- Disease stage confirmed by bone marrow Bx – chronic phase OR accelerated phase OR blast crisis; AND,
- No / incomplete response to imatinib mesylate; AND,
- Pre-transplant evaluation (see criteria above).

ASCT for Non-Hodgkin’s Lymphoma

ASCT is considered medically necessary and a covered benefit for Non-Hodgkin’s Lymphoma if ALL of the following criteria are met:
- HLA matched donor; AND,
- Type of Non-Hodgkin’s Lymphoma includes one of the following:
  - Diffuse large B cell with first remission in intermediate high-risk patient OR relapsed disease; OR,
  - Mantle cell and first remission; OR,
  - Burkitt’s lymphoma as evidenced by the following:
    - Therapeutic response with first remission OR relapsed disease in chemosensitive patient; AND,
    - A neurological screen with results of one of the following:
      - Normal by history and physical examination; OR,
      - Positive symptoms from normal cytology by LP and treated CNS disease.

  AND

  - Pre-transplant evaluation (see criteria above).

ASCT for Chronic Lymphocytic Leukemia (CLL)

ASCT is considered medically necessary and a covered benefit for CLL if ALL of the following criteria are met:
- HLA matched donor; AND,
- Therapeutic response confirmed by bone marrow Bx as evidenced by one of the following:
  - First remission in intermediate / high-risk patient; OR,
  - Second remission; OR,
  - Relapsed disease; OR,
  - Induction failure.
- Pre-transplant evaluation (see criteria above).

Autologous Stem Cell Transplantation (AuSCT)

Members undergoing AuSCT must complete a pre-transplant evaluation as evidenced by all of the following:
- Serum creatinine / creatinine clearance results; AND,
- Psychosocial screen to include the following three items:
  - Drug / alcohol screen with no drug / alcohol abuse by history OR drug / alcohol free for > 6 months
  - Behavioral health disorder with no behavioral health disorder by history and physical examination OR treated behavioral health disorder; AND
  - Adequate social / family support.
- Performance status of Karnofsky score ≥ 70% OR Eastern Cooperative Oncology Group grade 0-2.
AuSCT for Multiple Myeloma

AuSCT is considered medically necessary and a covered benefit for Durie-Salmon Stage II or III members if ALL of the following criteria are met:

- Newly diagnosed or responsive multiple myeloma*; AND,
- Adequate cardiac, renal, pulmonary, and hepatic function; AND,
- Treatment responsive as evidenced by at one of the following post induction therapy for active myeloma; o Improved symptoms; OR,
  o Relapsed disease; OR,
  o Refractory disease.

AND,
- Pre-transplant evaluation (see criteria above).

*NOTE: This includes those members 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 one month), and those in responsive relapse.

AuSCT for Leukemia, Neuroblastoma, Hodgkin’s Lymphoma & Non-Hodgkin’s Lymphoma

AuSCT is considered medically necessary for the treatment of members with the following indications:

- Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched; OR,
- Resistant non-Hodgkin’s lymphomas or those presenting with poor prognostic features following initial response; OR,
- Recurrent or refractory neuroblastoma; OR,
- Advanced Hodgkin’s disease who have failed conventional therapy and have no HLA-matched donor

AuSCT is considered medically necessary for Hodgkin’s Lymphoma if a therapeutic response is evidenced by one of the following:

- Induction failure; OR,
- Partial remission; OR,
- Relapsed disease.

AND,
- Pre-transplant evaluation (see criteria above).

AuSCT is considered medically necessary and a covered benefit when diagnosed with one of the following types of Non-Hodgkin’s Lymphoma:

- Diffuse large B cell with first remission in intermediate high-risk patient OR relapsed disease; OR,
- Mantle cell and first remission; OR,
- Burkitt’s lymphoma as evidenced by the following:
  o Therapeutic response with first remission OR relapsed disease in chemosensitive patient; AND,
  o A neurological screen with results of one of the following:
    ➢ Normal by history and physical examination; OR,
    ➢ Positive symptoms from normal cytology by LP and treated CNS disease.

AND

- Pre-transplant evaluation (see criteria above).

AuSCT for Acute Myelogenous Leukemia (AML)

AuSCT is considered medically necessary for the treatment of members with AML meeting the following criteria:

- Identified human leucocyte antigens (HLA) donor; AND,
Therapeutic response confirmed by bone marrow with first remission ≥ 6 months AND second complete remission attained; AND,

Pre-transplant evaluation to include (in addition to items listed above), a neurological screen with results of one of the following:
- Normal by history and physical examination; OR,
- Positive symptoms from normal cytology by LP and treated CNS disease.

**AuSCT for Breast Cancer**

AuSCT is considered medically necessary for breast cancer if ONE of the following criteria are met:
- Chemosensitive Stage IV disease; OR,
- Stage IV disease with relapse after a complete response to first line therapy for metastatic disease; OR,
- Therapy is administered as part of a clinical trial.

## CODING

### Covered CPT® Codes

- 38204 Management of recipient hematopoietic progenitor cell donor search and cell acquisition
- 38205 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
- 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
- 38207 Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
- 38208 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
- 38209 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor
- 38210 Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
- 38211 Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
- 38212 Transplant preparation of hematopoietic progenitor cells; red blood cell removal
- 38213 Transplant preparation of hematopoietic progenitor cells; platelet depletion
- 38214 Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
- 38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or Buffy coat layer
- 38220 Bone marrow; aspiration only
- 38221 Bone marrow; biopsy, needle or trocar
- 38230 Bone marrow harvesting for transplantation; allogeneic
- 38232 Bone marrow harvesting for transplantation; autologous
- 38240 Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
- 38241 Hematopoietic progenitor cell (HPC); autologous transplantation
- 38242 Allogeneic lymphocyte infusions
- 38243 Hematopoietic progenitor cell (HPC); HPC boost

### Covered HCPCS Codes

- S2150 Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of per pre- and post-transplant care in the global definition.

### ICD-10-PCS (Inpatient Only)

Refer to the following ICD-10-PCS tables for specific code assignment based on physician documentation.

**NOTE:** Per ICD-10-PCS Coding Guidelines, “ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code”.

- 079 Med/Surg Lymphatic and Hemic Systems Drainage
- 07D Med/Surg Lymphatic and Hemic Systems Extraction
- 302 Administration Circulatory Transfusion
- 6A5 Extracorporeal therapies; physiological systems; pheresis

### Covered ICD-10-CM Diagnosis Codes

- **ASCT - Allogeneic Stem Cell Transplantation Covered Diagnosis**
  - C83.10 Mantle cell lymphoma, unspecified site
  - C83.70 - C83.79 Burkitt lymphoma, unspecified site (C83.70)
  - C85.80 - C85.89 Other specified types of non-Hodgkin lymphoma unspecified site (C85.80)
  - C91.00 Acute lymphoblastic leukemia not having achieved remission
  - C92.00 - C92.92 Acute myeloblastic leukemia, not having achieved remission (C92.00)
**Covered ICD-10 Diagnosis Codes**

- **C82.51** Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
- **C82.52** Diffuse follicle center lymphoma, intrathoracic lymph nodes
- **C82.53** Diffuse follicle center lymphoma, intra-abdominal lymph nodes
- **C82.54** Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
- **C82.55** Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
- **C82.56** Diffuse follicle center lymphoma, intrapelvic lymph nodes
- **C82.57** Diffuse follicle center lymphoma, spleen
- **C82.58** Diffuse follicle center lymphoma, lymph nodes of multiple sites
- **C83.10** Mantle cell lymphoma, unspecified site
- **C83.11** Mantle cell lymphoma, lymph nodes of head, face, and neck
- **C83.12** Mantle cell lymphoma, intrathoracic lymph nodes
- **C83.13** Mantle cell lymphoma, intra-abdominal lymph nodes
- **C83.14** Mantle cell lymphoma, lymph nodes of axilla and upper limb
- **C83.15** Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
- **C83.16** Mantle cell lymphoma, intrapelvic lymph nodes
- **C83.17** Mantle cell lymphoma, spleen
- **C83.18** Mantle cell lymphoma, lymph nodes of multiple sites
- **C83.19** Mantle cell lymphoma, extradural and solid organ sites
- **C83.70** Burkitt lymphoma, unspecified site
- **C83.71** Burkitt lymphoma, lymph nodes of head, face, and neck
- **C83.72** Burkitt lymphoma, intrathoracic lymph nodes
- **C83.73** Burkitt lymphoma, intra-abdominal lymph nodes
- **C83.74** Burkitt lymphoma, lymph nodes of axilla and upper limb
- **C83.75** Burkitt lymphoma, lymph nodes of inguinal region and lower limb
- **C83.76** Burkitt lymphoma, intrapelvic lymph nodes
- **C83.77** Burkitt lymphoma, spleen
- **C83.78** Burkitt lymphoma, lymph nodes of multiple sites
- **C83.79** Burkitt lymphoma, extradural and solid organ sites
- **C84.91** Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
- **C84.92** Mature T/NK-cell lymphomas, intrathoracic lymph nodes
- **C84.93** Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
- **C84.94** Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
- **C84.95** Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb

**Clinical Coverage Guideline**

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<th>Description</th>
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C92.02 Acute myeloblastic leukemia, in relapse
C92.41 Acute promyelocytic leukemia, in remission
C92.42 Acute promyelocytic leukemia, in relapse
C92.51 Acute myelomonocytic leukemia, in remission
C92.52 Acute myelomonocytic leukemia, in relapse
C92.61 Acute myeloid leukemia with 11q23-abnormality in remission
C92.62 Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A1 Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2 Acute myeloid leukemia with multilineage dysplasia, in relapse

C90.00 - C90.02 Multiple myeloma not having achieved remission (C90.00)

C90.10 Tandem transplantation (multiple rounds of AuSCT) for members with multiple myeloma
C92.10 Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11 Chronic myeloid leukemia, BCR/ABL-positive, in remission
C95.00 Acute leukemia of unspecified cell type not having achieved remission
C95.10 Chronic leukemia of unspecified cell type, not having achieved remission
E85.0 - E85.9 Amyloidosis, unspecified (E85.9)

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<th>Action</th>
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<td>Approved by MPC. Updated item from CMS NCD.</td>
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<td>5/2/2013</td>
<td>Approved by MPC. Added additional criteria for autologous and allogeneic stem cell transplantation.</td>
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<td>5/13/2012</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
</tr>
<tr>
<td>8/12/2011</td>
<td>Approved by MPC. No changes.</td>
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