Medical Policy
Placental/Umbilical Cord Blood as a Source of Stem Cells

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Policy Number: 285
BCBSA Reference Number: 7.01.50
NCD/LCD: N/A

Related Policies
• Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas, #143
• Allogeneic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms, #155
• Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias, #190
• Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer, #204
• Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults, #191
• Hematopoietic Cell Transplantation for Autoimmune Diseases, #192
• Hematopoietic Cell Transplantation for Acute Myeloid Leukemia, #150
• Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma, #205
• Hematopoietic Cell Transplantation for Hodgkin Lymphoma, #207
• Hematopoietic Cell Transplantation for Chronic Myelogenous Leukemia, #212
• Hematopoietic Cell Transplantation as a Treatment of Acute Lymphoblastic Leukemia, #076
• High-Dose Rate Temporary Prostate Brachytherapy, #353
• Hematopoietic Cell Transplantation in the Treatment of Germ Cell Tumors, #247
• Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia, #322

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Transplantation of cord blood stem cells from related or unrelated donors may be MEDICALLY NECESSARY in patients with an appropriate indication for allogeneic stem-cell transplant.

Collection and storage of cord blood from a neonate may be MEDICALLY NECESSARY when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant.
Transplantation of cord blood stem cells from related or unrelated donors in all other situations is **INVESTIGATIONAL**.

Prophylactic collection and storage of cord blood from a neonate when proposed for some unspecified future use as an autologous stem-cell transplant in the original donor, or for some unspecified future use as an allogeneic stem-cell transplant in a related or unrelated donor is **NOT MEDICALLY NECESSARY**.

**Prior Authorization Information**

**Inpatient**
- For services described in this policy, precertification/preauthorization is **required** for all products if the procedure is performed **inpatient**.

**Outpatient**
- For services described in this policy, see below for products where prior authorization might be **required** if the procedure is performed **outpatient**.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Prior Authorization Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is required.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is required.</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>Prior authorization is required.</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>Prior authorization is required.</td>
</tr>
</tbody>
</table>

**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2142</td>
<td>Cord blood-derived stem-cell transplantation, allogeneic</td>
</tr>
<tr>
<td>S2150</td>
<td>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 pre and post-transplant care in the global definition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Procedure Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30233Y0</td>
<td>Transfusion of Autologous Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>30233X0</td>
<td>Transfusion of Autologous Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach</td>
</tr>
</tbody>
</table>
Description

Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in cancer patients who receive bone marrow-toxic doses of cytotoxic drugs with or without whole-body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or a donor (allogeneic HCT [allo-HCT]). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allogeneic stem cell transplantation, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the gene complex expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome six. An acceptable donor will match the patient at all or most of the HLA loci.

Conditioning for Hematopoietic Cell Transplantation

Conventional Conditioning

The conventional (“classical”) practice of allo-HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to cause bone marrow ablation in the recipient. The beneficial treatment effect of this procedure is due to a combination of the initial eradication of malignant cells and subsequent graft-versus-malignancy effect mediated by non-self-immunologic effector cells. While the slower graft-versus-malignancy effect is considered the potentially curative component, it may be overwhelmed by existing disease in the absence of pretransplant conditioning. Intense conditioning regimens are limited to patients who are sufficiently medically fit to tolerate substantial adverse effects. These include opportunistic infections secondary to loss of endogenous bone marrow function and organ damage or failure caused by cytotoxic drugs. Subsequent to graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease, which increases susceptibility to opportunistic infections.
The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy, with or without radiotherapy, to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of the bone marrow with presumably normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not graft-versus-host disease.

Reduced-Intensity Conditioning Allogeneic Hematopoietic Cell Transplantation
RIC refers to the pretransplant use of lower doses of cytotoxic drugs or less intense regimens of radiotherapy than are used in traditional full-dose myeloablative conditioning treatments. Although the definition of RIC is variable, with numerous versions employed, all regimens seek to balance the competing effects of relapse due to residual disease and non-relapse mortality. The goal of RIC is to reduce disease burden and to minimize associated treatment-related morbidity and non-relapse mortality in the period during which the beneficial graft-versus-malignancy effect of allogeneic transplantation develops. RIC regimens range from nearly total myeloablative to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Patients who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. In this review, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative.

Summary
This evidence review addresses the collection, storage, and transplantation of placental and umbilical cord blood (“cord blood”) as a source of stem cells for allogeneic and autologous stem cell transplantation. Potential indications for the use of cord blood are not addressed herein; they are discussed in the disease-specific evidence reviews.

For individuals who have an appropriate indication for allogeneic stem cell transplant who receive cord blood as a source of stem cells, the evidence includes a number of observational studies, a meta-analysis of observational studies, and a randomized controlled trial comparing outcomes after single- or double-cord blood units. The relevant outcomes are overall survival, disease-specific survival, resource utilization, and treatment-related mortality. The meta-analysis of observational studies found similar survival outcomes and lower graft-versus-host disease after cord blood transplantation than bone marrow transplantation. In the randomized controlled trial, survival rates were similar after single- and double-unit cord blood transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have an unspecified potential future need for stem cell transplant who receive prophylactic collection and storage of cord blood, the evidence includes no published studies. The relevant outcomes are overall survival, disease-specific survival, resource utilization, and treatment-related mortality. No evidence was identified on the safety or effectiveness of autologous cord blood transplantation from prophylactically stored cord blood for the treatment of malignant neoplasms. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>4/2020</td>
<td>Bone marrow harvesting code removed. Outpatient prior authorization is not required.</td>
</tr>
<tr>
<td>8/2019</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>3/2019</td>
<td>BCBSA National medical policy review. Description, summary and references</td>
</tr>
<tr>
<td>2/2018</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>2/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
</tbody>
</table>
Clarified coding information.

New references added from BCBSA National medical policy.

New references added from BCBSA National medical policy.

Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.

New medically necessary indications described. Effective 12/9/2013.

New references from BCBSA National medical policy.

Updated to add new CPT code 38243.

Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.

Updated to remove information referencing related policies #092 and #126. The same information was removed from policy #092, Allogeneic Stem Cell Transplants.

New policy effective 1/1/2011 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


