Medical Policy

Placental/Umbilical Cord Blood as a Source of Stem Cells

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Policy Number: 285

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NCD/LCD: N/A

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Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] 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**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.
Medicare HMO Blue℠	Prior authorization is **required**.
Medicare PPO Blue℠	Prior authorization is **required**.

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:

CPT Codes

CPT codes:	Code Description
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38243	Hematopoietic progenitor cell (HPC); HPC boost

HCPCS Codes

HCPCS codes:	Code Description
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem-cell transplantation, allogeneic
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 pre and post-transplant care in the global definition

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
30233Y0	Transfusion of Autologous Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30233X0	Transfusion of Autologous Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach
30233X1	Transfusion of Non autologous Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach
30233Y1	Transfusion of Non autologous Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30243X0	Transfusion of Autologous Cord Blood Stem Cells into Central Vein, Percutaneous Approach
30243X1	Transfusion of Non autologous Cord Blood Stem Cells into Central Vein, Percutaneous Approach
30243Y0	Transfusion of Autologous Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30243Y1	Transfusion of Non autologous Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30263X0	Transfusion of Autologous Cord Blood Stem Cells into Central Artery, Percutaneous Approach
30263X1	Transfusion of Non autologous Cord Blood Stem Cells into Central Artery, Percutaneous Approach
30263Y0	Transfusion of Autologous Hematopoietic Stem Cells into Central Artery, Percutaneous Approach
30263Y1	Transfusion of Non autologous Hematopoietic Stem Cells into Central Artery, Percutaneous Approach
3E03305	Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach
3E04305	Introduction of Other Antineoplastic into Central Vein, Percutaneous Approach
3E05305	Introduction of Other Antineoplastic into Peripheral Artery, Percutaneous Approach
3E06305	Introduction of Other Antineoplastic into Central Artery, Percutaneous Approach

Description

Bone Marrow Disorders

A variety of malignant diseases and nonmalignant bone marrow disorders are treated with myeloablative therapy followed by infusion of allogeneic stem and progenitor cells collected from immunologically compatible donors, either family members or an unrelated donor identified through a bone marrow donor bank. In some cases, a suitable donor is not found.

Blood harvested from the umbilical cord and placenta shortly after delivery of neonates contains stem and progenitor cells capable of restoring hematopoietic function after myeloablation. This cord blood has been used as an alternative source of allogeneic stem cells. Cord blood is readily available and is thought to be antigenically “naive,” thus potentially minimizing the incidence of graft-versus-host disease and permitting the broader use of unrelated cord blood transplants. Unrelated donors are typically typed at low resolution for human leukocyte antigen–A and –B and at high resolution only for human leukocyte antigen–DR; human leukocyte antigen matching at 4 of 6 loci is considered acceptable. Under this matching protocol, an acceptable donor can be identified for almost any patient.

Several cord blood banks have been created in the United States and Europe. In addition to obtaining cord blood for specific related or unrelated patients, some cord blood banks collect and store neonate cord blood for some unspecified future use in the unlikely event that the child develops a condition that would require autologous transplantation. Also, some neonate cord blood is collected and stored for use

by a sibling in whom an allogeneic transplant is anticipated due to a history of leukemia or other condition requiring an allogeneic transplant.

Standards and accreditation for cord blood banks are important for assisting transplant programs in knowing whether individual banks have quality control measures in place to address issues such as monitoring cell loss, change in potency, and prevention of product mix-up.[1] Two major organizations have created accreditation standards for cord blood banks in the U.S.: the American Association of Blood Banks and the International NetCord Foundation/Foundation for the Accreditation of Cellular Therapy (NetCord/FACT). Both the AABB and the NetCord/FACT have developed and implemented a program of voluntary inspection and accreditation for cord blood banking. The AABB and the NetCord/FACT publish standards for cord blood banks that define the collection, testing, processing, storage, and release of cord blood products.[2]

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

Date	Action
3/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
2/2018	New references added from BCBSA National medical policy.
2/2017	New references added from BCBSA National medical policy.
12/2016	Clarified coding information.
3/2016	New references added from BCBSA National medical policy.
11/2015	New references added from BCBSA National medical policy.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
12/2013	New medically necessary indications described. Effective 12/9/2013.
12/2013	New references from BCBSA National medical policy.
12/2012	Updated to add new CPT code 38243.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
5/2011	Updated to remove information referencing related policies #092 and #126. The same information was removed from policy #092, Allogeneic Stem Cell Transplants.

1/1/2011	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

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