

Corporate Medical Policy

Cord Blood as a Source of Stem Cells

File Name:	cord_blood_as_a_source_of_stem_cells
Origination:	2/2001
Last CAP Review:	3/2012
Next CAP Review:	3/2013
Last Review	3/2012

Description of Procedure or Service

This policy addresses the collection, storage, and transplantation of placental/umbilical cord blood (“cord blood”) as a source of stem cells for allogeneic and autologous stem-cell transplantation. Potential indications for use of cord blood are included in the disease-specific reference policies.

Background

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 from 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 hopefully minimizing the incidence of graft-versus-host disease (GVHD) and permitting the broader use of unrelated cord blood transplants. Unrelated donors are typically typed at low resolution for human leukocyte antigens (HLA) -A and -B and at high resolution only for HLA-DR; HLA 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 now been developed in Europe and in the U.S.

The U.S. Food and Drug Administration (FDA) requires licensing of establishments and their products for unrelated-donor allogeneic transplant of minimally manipulated placental and umbilical cord blood stem cells. Facilities that prepare cord blood units only for autologous or related-donor transplants are required to register and list their products, adhere to Good Tissue Practices issued by the FDA, and use applicable processes for donor suitability determination.

Other cord blood banks are offering the opportunity of collecting and storing a neonate’s cord blood for some unspecified future use in the unlikely event that the child develops a condition that would require autologous transplantation. In addition, some cord blood is collected and stored from a neonate for use by a sibling in whom an allogeneic transplant is anticipated due to a history of leukemia or other condition requiring allogeneic transplant.

As with any biologic product, there are issues unique to cord blood as an unrelated donor source; some of these are as follows:

- Cell dose available is much closer to the minimum needed for engraftment
- Interbank variability in the quantification of hematopoietic potential

Cord Blood as a Source of Stem Cells

- Donors who may have hematologic/immunologic disorders may not have manifested their disease at the time of donation or follow-up
- Units may have been banked years earlier at a time when the collection and storage process may not have reflected current accreditation standards, and,
- The initial product characterization at the end of processing may not reflect the product at the time of release due to freeze, storage, or transport insults.

For the reasons cited above, instituting international standards and accreditation for cord blood banks is critical. This will assist transplant programs in knowing whether individual banks have important quality control measures in place to address such issues as monitoring cell loss, change in potency, and prevention of product mix-up. Two major organizations are working toward these accreditation standards; NetCord/FACT and the American Association of Blood Banks (AABB). NetCord, Foundation for the Accreditation of Cellular Therapy (FACT) has developed and implemented a program of voluntary inspection and accreditation for cord blood banking. The program includes standards for collection, testing, processing, storage, and release of cord blood products. Forty-two banks have applied for accreditation, 21 are fully accredited while the rest are in process. AABB also runs an accreditation process, in which an AABB representative inspects the program. Twenty-seven banks in the U.S. have been accredited, along with 33 international sites.

The U.S. Food and Drug Administration intends to regulate cord blood banking by requiring Biologic License Applications and/or Investigational New Drug applications by October 2011 for any bank that will supply units to patients in the United States. With the international exchange of cord blood units being integral to the availability of a matched unit, it is unclear how this change will affect the practice of acquiring cord blood units.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will cover Cord Blood as a Source of Stem Cells when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Some health benefit plans may exclude benefits for cord blood stem cell transplantation.

When cord blood as a source of stem cells is covered

Transplantation of cord blood stem cells from related or unrelated donors may be considered medically necessary in patients with an appropriate indication for allogeneic bone marrow transplant, but without a hematopoietic stem cell donor with the same or better HLA (Human Leukocyte Antigen) matching characteristics.

Collection and storage of cord blood from a neonate may be considered medically necessary when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the

Cord Blood as a Source of Stem Cells

possible need for allogeneic transplant.

When cord blood as a source of stem cells is not covered

Transplantation of cord blood stem cells from related or unrelated donors is considered investigational in all other situations.

Prophylactic collection and storage of cord blood from a neonate is non-covered by most health benefit plans when proposed for unspecified future use as an autologous stem-cell transplant in the original donor, or for unspecified future use as an allogeneic stem cell transplant in a related or unrelated recipient. Please refer to the Member's Benefit Booklet for availability of benefits for cord blood collection and storage for unspecified future use.

Policy Guidelines

Cord blood transplantation offers clear advantages over other sources of allogeneic stem cells; the most significant of these is the ability to perform a successful transplant from an unrelated donor with 1 or 2 HLA mismatches. Cord blood is also more readily available than other sources of stem cells, and generally can be prepared for clinical use within 1-2 weeks. Collection of the cells is painless, which facilitates recruitment and provides for a more ethnically diverse pool. Current limitations include small inventories, units with low cell doses, and too few donors to provide 5 of 6 and 6 of 6 matches for all patients in need. Longer hospital stays and higher utilization of medical resources are a consequence of slower engraftment when cord blood is used. Even with these limitations, cord blood is an important source of stem cells, increasing the access to allogeneic stem-cell transplantation for many patients. Because of these advantages, use of cord blood as a source of stem cells in this situation may be considered medically necessary.

However, the routine collection and storage of cord blood for possible future use is not considered current standard medical care and has not been shown to improve outcomes. As a result, routinely collecting and storing cord blood for a potential future use is not covered by most member benefit plans.

Refer to the individual member's benefit booklet for prior review requirements.

Refer to the specific medical policies for medically necessary allogeneic bone marrow transplant for malignant diseases and non-malignant diseases.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable Codes: 38205, 38206, 38230, 38232, 38240, 38242, S2140, S2142

Diagnoses: 650, 654.21, 656.61, V59.02, V59.09

Cord Blood as a Source of Stem Cells

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA TEC Evaluation 1996; Tab 17
BCBSA Medical Policy Reference Manual, 4/1/1998
BCBSA TEC Evaluation 2001
BCBSA Medical Policy Reference Manual, 2/15/02; 7.01.50
Specialty Matched Consultant Advisory Panel - 11/2002
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.50, 4/29/03
Specialty Matched Consultant Advisory Panel - 11/2004
Specialty Matched Consultant Advisory Panel - 11/2006
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.50, 6/10/2010
Specialty Matched Consultant Advisory Panel – 3/2011
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.50, 10/4/2011
Specialty Matched Consultant Advisory Panel - 3/2012

Policy Implementation/Update Information

1/01	Specialty Matched Consultant Advisory Group.
2/01	Original policy issued.
5/02	Revised under when it is covered. No longer restricted to children. Format changes.
2/03	Specialty Matched Consultant Advisory Panel review 11/2002. No change in criteria. Codes 86812-86822 removed; codes 38231 and 86915 deleted and codes 38242 and 38205 added to the Billing/Coding section. System coding changes.
3/04	Benefits Application and Billing/Coding sections updated for consistency.
7/29/04	HCPCS codes S2140, S2142 added to Billing/Coding section.
12/9/04	Specialty Matched Consultant Advisory Panel review 11/29/2004. No changes to criteria. Revised wording in When Cord Blood as a Source of Stem Cells is covered. Revised wording in When Cord Blood as a Source of Stem Cells is <u>not</u> covered, second bullet, to state; "Prophylactic collection and storage of cord blood from a neonate is considered not medically necessary 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 recipient". Removed the following statements from Policy Guideline section; "It is recommended that all transplant requests be reviewed by the Plan Medical Director or his or her designee. Only those patients accepted for transplantation by a transplantation center and actively listed for transplant should be considered for precertification or prior approval. Guidelines should be followed for transplant network or consortiums, if applicable. Claims will be reviewed for medical necessity by individual consideration or by prior approval methods." Policy number added to Policy Key Words section. References added.

Cord Blood as a Source of Stem Cells

- 12/11/06 Specialty Matched Consultant Advisory Panel review 11/6/2006. No changes to policy statement. Clarified second bullet under "When not covered" section from: "Prophylactic collection and storage of cord blood from a neonate is considered not medically necessary 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 recipient." to "Prophylactic collection and storage of cord blood from a neonate is non-covered 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 recipient." Policy status changed to: "Active policy, no longer scheduled for routine literature review". Added CPT code 38206 to "Billing/Coding" section. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 4/26/11 Policy reactivated from "Active policy, no longer scheduled for routine literature review. Specialty Matched Consultant Advisory Panel review March 30, 2011. "Description" section revised. Removed statement indicating "Services for or related to the search for a donor is not covered. Reformatted statements for consistency, no change in policy intent. References added. (btw)
- 11/22/11 Added the following diagnoses to the "Billing/Coding" section; 650, 654.21, 656.61, V59.02, and V59.09. (btw)
- 4/17/12 Description section revised. "with a diagnosis that is consistent with the possible need for allogeneic transplant" added to the second statement under the When Covered section. New 2012 CPT code, 38232, added to Billing/Coding section. References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 3/21/2012. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.