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Medical Policy Manual

Topic: Placental and Umbilical Cord Blood as a Source of Stem Cells

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Section: Transplant

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1]

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. A variety of malignant diseases and non-malignant bone marrow disorders are treated with myeloablative therapy followed by infusion of allogeneic stem and progenitor cells collected from immunologically compatible donors. Stem cells may be obtained from the transplant recipient (autologous) or from a donor (allogeneic). For those with bone marrow disorders, stem cells are sought 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.[2] Several cord blood banks have now been developed in Europe and in the United States.

Regulatory Status

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 will be required to register and list their products, adhere to Good Tissue Practices issued by the FDA, and use applicable processes for donor suitability determination.[3]

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 which include:

- The cell dose available is much closer to the minimum needed for engraftment;
- There is interbank variability in the quantification of hematopoietic potential;
- Donors who may have hematologic/immunologic disorders may not have manifest 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 reflect 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.[4]

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.[4]

Two major organizations are working towards 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.[5] The program includes standards for collection, testing, processing, storage and release of cord blood products. Nine organizations in the United States of 42 fully accredited banks globally[6], have been fully accredited by NetCord/FACT. AABB also runs an accreditation process, where an AABB representative inspects the program. Twenty-seven banks in the US have been accredited by the AABB, along with 45 international sites.[7]

The US 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.[8]

MEDICAL POLICY CRITERIA

Note: See Cross References to access the specific medical policies for hematopoietic stem cell transplantation.

I. Transplantation of cord blood stem cells

A. Transplantation of cord blood stem cells from related or unrelated donors may be considered **medically necessary** in patients who meet the health plan's medical necessity criteria for allogeneic stem-cell transplant but who are without a hematopoietic stem-cell donor.

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

II. Collection and storage of cord blood stem cells

A. Collection and storage of cord blood from a neonate may be considered **medically necessary** when an allogeneic transplant is imminent in an identified recipient and the health plan's medical necessity criteria for the transplant are met.

B. *Prophylactic* collection and storage of cord blood from a neonate is considered **not medically necessary** when proposed for an unspecified future use as an autologous stem-cell transplant in the original donor, or for an unspecified future use as an allogeneic stem-cell transplant in a related or unrelated recipient.

SCIENTIFIC EVIDENCE[1]

Related Cord Blood Transplant

The first cord blood transplant was a related cord blood transplant for a child with Fanconi's anemia.[9] After the success of this initial transplant, approximately 60 others were performed in the matched-sibling setting. The results, demonstrating that cord blood contained sufficient numbers of hematopoietic stem and progenitor cells to reconstitute a pediatric patient, were reported to a volunteer international registry. A lower incidence of acute and chronic graft-versus-host disease (GVHD) when cord blood, as compared with bone marrow, was used as the source of donor cells was also observed.[10] This led to the hypothesis that cord blood could be banked and used as a source of unrelated donor cells, possibly without full HLA matching.[11]

Unrelated Cord Blood Transplant

Technology Assessment

This policy is based on 1996 and 2001 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessments[12,13] that focused on the use of placental and umbilical cord blood in children and adults, respectively. At its inception, placental and umbilical cord blood was used primarily in children due to concerns that the volume of harvested cells would not support hematopoiesis in larger individuals. The 2001 TEC Assessment focused on the use of placental and umbilical cord blood in adults and offered the following observations and conclusions:

- The available data show that hematopoietic recovery, as measured by neutrophil and platelet engraftment, is somewhat slower and less frequent among adults than among younger patients when placental or cord stem cells are used. Nevertheless, neutrophil counts are restored in the majority (74%–91%) of adult patients.
- Acute and chronic graft-versus-host disease and early mortality also are somewhat more frequent among adults than among younger patients given placental or cord stem cells. However, for adult patients who require urgent transplant and are unable to wait for a protracted donor search, the available data that show

survival 1 year after placental or cord stem-cell transplant is not worse than survival 1 year after an allogeneic stem-cell transplant from an unrelated donor.

Meta-Analysis

In 2012, Zhang and colleagues published a meta-analysis of studies comparing unrelated donor cord blood transplantation to unrelated donor bone marrow transplantation in patients with acute leukemia.[14] The authors identified 7 studies with a total of 3,389 patients. Pooled rates of engraftment failure (n=5 studies) were 127 events in 694 patients (18%) in the cord blood transplantation group and 57 events in 951 patients (6%) in bone marrow transplantation patients. The rate of engraftment graft failure was significantly higher in cord blood transplantation recipients, $p<0.0001$. However, rates of acute GVHD were significantly lower in the group receiving cord blood transplantation. Pooled rates of GVHD (n=7 studies) were 397 of 1,179 (34%) in the cord blood group and 953 of 2,189 (44%) in the bone marrow group, $p<0.0001$. Relapse rates, reported in all studies, did not differ significantly between groups. Several survival outcomes including overall survival, leukemia-free survival and non-relapse mortality favored the bone marrow transplantation group.

Non-Randomized Trials

In 1996, outcome data from the first 25 unrelated cord blood transplants completed at Duke University were reported.[15] This study concluded that cord blood contained sufficient numbers of stem cells and progenitor cells to reconstitute the marrow of children who underwent myeloablative treatments, without full HLA matching between donor and recipient. Patients who underwent unrelated cord blood transplant experienced a lower incidence and severity of both acute and chronic graft-versus-host disease (GVHD), compared with patients receiving unrelated matched bone marrow. Cell dose was strongly correlated with clinical outcome, including but not limited to time to and probability of engraftment as well as overall survival.[15-19] Since this time, research has been ongoing to study the effectiveness of placental/umbilical cord blood for the treatment of various conditions.

The first prospective trial of unrelated cord blood transplant was the Cord Blood Transplantation study (COBLT) from 1997-2004. COBLT was designed to examine the safety of unrelated cord blood transplantation in infants, children, and adults. In children with malignant and nonmalignant conditions, 2-year event-free survival was 55% in children with high-risk malignancies[20] and 78% in children with nonmalignant conditions.[21] Across all groups, the cumulative incidence of engraftment by day 42 was 80%. Engraftment and survival were adversely affected by lower cell doses, pretransplant cytomegalovirus seropositivity in the recipient, non-European ancestry, and higher HLA mismatching. Slower engraftment leads to longer hospitalizations and greater utilization of medical resources.[22] In the COBLT study, outcomes in adults were inferior to the outcomes achieved in children. This study also established three new cord blood banks and standard operating procedures addressing donor recruiting and screening, cord blood collection, processing, testing, cryopreservation, storage, and thawing for transplantation.[23,24]

Double Cord Blood Transplant

Recent studies have examined the effects of transplanting two partially HLA-matched donor cord blood units in an effort to increase the total transplanted nucleated cells (TNC) appropriate for the patient's body mass. In general, when two units are used in a single transplant, one unit engrafts and the other is rejected. The exact role of the non-engrafting unit is unclear. However, standard practice continues to be to transplant one unit. In general, a minimum cell dose of $2.5–3.0 \times 10^7$ nucleated cells/kg in the cord blood has been associated with superior clinical outcome and is the current gold standard.[15,17-20,25]

- A recent trial from the University of Minnesota has shown that using two units of cord blood for a single transplant in adults improved rates of engraftment and overall survival.[26]

- Pilot studies show engraftment being achieved by at least 90% with overall survival at 1 year ranging from 60–80%, depending on the initial disease, comorbidities, and disease status at the time of transplant.[22]
- In 2013, Scaradavou and colleagues reported a retrospective analysis using data from the Center for International Blood and Marrow Transplant Research (CIBMTR) and the U.S.-based National Cord Blood Program.[27] The authors reported data on adults with acute leukemia who received 1 (n=106) or 2 (n=303) umbilical cord blood units. All units used for single transplantation contained a minimum cell dose of 2.5–3.0 X 107 nucleated cells/kg. For the double transplants, the 2 units combined contained more than 2.5–3.0 X 107 nucleated cells/kg, but in about half of cases, individual units contained less than the minimum amount required. The primary outcomes of rates of transplantation-related mortality (p=0.63), relapse (p=0.64) and overall mortality (p=0.62) were similar in the groups that received single and double transplantations. For patients treated in the earlier period, 2002-2004, there was a significantly higher risk of grade 2-4 acute GVHD in recipients of double cord blood units (p<0.001). In the later period, 2004-2009, rates of grade 2-4 acute GVHD did not differ significantly between groups (p=0.30).

Cord Blood versus Bone Marrow Transplantation for Treatment of Leukemia

In addition to trial data, there have been numerous retrospective and registry studies comparing cord blood to bone marrow transplants in patients with leukemia. In general, studies have supported the conclusion that unrelated cord blood transplantation is effective treatment option in both children and adults with hematologic malignancies.[28]

- The majority of cord blood transplants have been mismatched at one or two HLA loci. In a retrospective multicenter study of 541 children with acute leukemia, the difference at day 60 in rates of neutrophil recovery was 96% for those receiving unrelated bone marrow (n=262) versus 80% for unrelated cord blood (n=99).[19]
- A 2007 retrospective comparative analysis from the Center for International Blood and Marrow Transplant Research compared outcomes after unrelated cord blood versus unrelated bone marrow transplant. This study showed similar 5-year leukemia-free survival for those receiving allele-matched marrow and those who received unrelated cord blood with a 1 or 2 antigen mismatch.
- A 2013 study compared survival rates after bone marrow transplantation or unrelated cord blood transplantation in patients older than age 50 years with acute myelogenous leukemia who received reduced-intensity conditioning.[29] The adjusted 3-year overall survival rate was 51% after related donor bone marrow transplantation, 53% after unrelated donor bone marrow transplantation and 45% after unrelated donor cord blood transplantation; the difference among groups was not statistically different, p=0.73.

Autologous Cord Blood Transplant

Data regarding the use of cord blood for autologous, when the donor and recipient are the same, stem cell transplantation are quite limited. However, blood banks are available for collecting and storing a neonate’s cord blood for a potential future use. A position paper from the American Academy of Pediatrics noted that there is no evidence of the safety or effectiveness of autologous cord blood transplantation for treatment of malignant neoplasms.[30] This report comments on evidence demonstrating the presence of DNA mutations in cord blood from children who subsequently develop leukemia. In addition, a survey of pediatric hematologists noted few transplants have been performed using cord blood stored in the absences of a known indication.[31]

Clinical Practice Guidelines

American Society for Blood and Marrow Transplantation (ASBMT)

On behalf of the ASBMT, Ballen and colleagues[32] published recommendations related to the banking of umbilical cord blood:

- Public banking of cord blood is encouraged when possible.
- Storage of cord blood for autologous (i.e., personal) use is not recommended.
- Family member banking (collecting and storing cord blood for a family member) is recommended when there is a sibling with a disease that may be successfully treated with an allogeneic transplant.
- Family member banking on behalf of a parent with a disease that may be successfully treated with an allogeneic transplant is only recommended when there are shared HLA antigens between the parents.

Summary

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 one or two HLA mismatches. Cord blood is also more readily available, generally within 1-2 weeks. Collection of the cells is painless, which facilitates recruitment providing 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. There is some recent evidence from retrospective studies that double umbilical cord transplants may be as safe as single cord blood transplants; however, additional study data are needed in order to determine whether there is any survival benefit over single cord blood transplant. Additional limitations include 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 may be considered medically necessary when the criteria above are met.

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 health outcomes. As a result, routinely collecting and storing cord blood for a potential future use is considered not medically necessary.

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Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood, Transplant, Policy No. 45.37

Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors, Transplant, Policy No. 45.38

Hematopoietic Stem-Cell Transplantation for Primary Amyloidosis or Waldenstrom Macroglobulinemia, Transplant, Policy No. 45.40

CODES	NUMBER	DESCRIPTION
CPT		No specific code
HCPCS	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