



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

## Placental and Umbilical Cord Blood as a Source of Stem Cells

**Policy Number:** 7.01.50

**Last Review:** 12/2013

**Origination:** 12/2001

**Next Review:** 12/2014

### **Policy**

---

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for placental and umbilical cord blood as a source of stem cells when it is determined to be medically necessary because the criteria shown below are met.

### **When Policy Topic 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 stem-cell transplant.

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 possible need for allogeneic transplant.

### **When Policy Topic is not covered**

---

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 donor.

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

### **Considerations**

---

Through the National Marrow Donor Program's Related Donor Cord Blood Program, eligible families within the U.S. can collect and store their neonate's cord blood unit free of charge. When the stored unit is transplanted, a fee is charged. A family is considered eligible if:

- the sibling of the neonate has been diagnosed with a disease treatable by a related cord blood transplant;
- the neonate does not have the same disease as the affected biological sibling (determined after birth);
- the affected sibling and the neonate have the same biological parents;

or if:

- an affected biological parent is enrolled in a clinical or research trial that would accept a haploidentical, related, allogeneic cord blood unit as a treatment option.

Charges for the acquisition of cord blood through a cord blood bank will be submitted as part of the hospital bill.

Reimbursement for stem cell collection and storage are considered payable under the Transplant Benefit when billed as a one-time, all-inclusive charge.

### **Transplant Benefit**

The date on which the Transplant Benefit starts accumulating is determined by the transplant coordinator. The Transplant Benefit ends when the Transplant Lifetime Maximum benefit (if applicable) has been exhausted.

Benefits include:

- hospitalization of the recipient for medically recognized transplants from a donor to a transplant recipient;
- evaluation tests requiring hospitalization to determine the suitability of both potential (member's benefits must be verified with regard to the potential donor who does not turn out to be the actual donor) and actual donors, when such tests cannot be safely and effectively performed on an outpatient basis (**Note:** The member's benefits must be verified with regard to the **potential** donor who does not turn out to be the **actual** donor.);
- hospital room, board and general nursing in semi-private rooms;
- special care units, such as coronary and intensive care;
- hospital ancillary services;
- physicians' services for surgery, technical assistance, administration of anesthetics, and medical care;
- acquisition, preparation, transportation, and storage of organ / tissue / cells;
- diagnostic services;
- drugs which require a prescription by federal law;
- medical and surgical care of the donor (related to the procurement of the organ / tissue / cells) if coverage is not available to the donor from any other source. (Covered services provided to a donor will be applied against the recipient's transplant maximum benefit, if applicable)

If the donor and recipient are both listed on the same (family) policy, Blue Cross and Blue Shield of Kansas City (Blue KC) charges only one deductible and one coinsurance, if applicable.

In addition to the specific organ criteria, transplant candidates must also meet the following general criteria, including, but not limited to:

- Since compliance is a major factor in transplant graft survival, the patient (or legal guardian) must have the ability to accept and understand the transplant procedure and to maintain compliance with long-term medical management and immunosuppression.
- If applicable, patients with a history of malignancy must have passed the recommended length of time to be considered cured for that specific cancer. A complete metastatic evaluation must be performed before a patient will be considered an acceptable transplant candidate.
- Patients with a history of alcohol or substance abuse must have a six month history of abstinence as evidenced by negative urine or serum drug screens taken randomly.
- The patient must have adequate cardiopulmonary status.
- The patient must be free from active infection.

A covered person is eligible for retransplantation as deemed medically necessary and appropriate by Blue Cross and Blue Shield of Kansas City (Blue KC). Review of a retransplantation request will include review of the covered person's compliance with relevant transplant selection criteria including, but not limited to, adherence to medication regimens, follow-up examinations and abstinence from the use of alcohol and drugs.

Clinical trials of autologous or allogeneic stem cell transplantation for conditions other than those allowed in this policy may be available in the research setting. However, these trials are considered investigational and/or experimental and therefore contract exclusions.

*Note: there are some state mandates in place that require insurance carriers to cover certain clinical trials under very specific guidelines.*

## **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. (1) Several cord blood banks have now been developed in Europe and in the U.S..

## **Regulatory Issues**

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. (2)

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
- 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. ( 3 )

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. ( 3 ) 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. ( 3 )

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. ( 4 )

It is also important to note umbilical cord blood (UCB) samples are not routinely typed for private banking. This makes it difficult to search for unrelated human leukocyte antigen (HLA)-matched donors in private banks, or to transfer units into a public bank from a private bank. (5)

## **Rationale**

---

This policy was originally based on TEC Assessments in 1996 and 2001, (8, 9) which focused on the use of placental/umbilical cord blood in children and adults, respectively. The most recent update via MEDLINE was for the period September 2012 through July 25, 2013.

### **Related cord blood transplant**

The first cord blood transplant was a related cord blood transplant for a child with Fanconi's anemia.(10) 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.(11) 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.(12)

### **Unrelated cord blood transplant**

In 1996, outcome data from the first 25 unrelated cord blood transplants completed at Duke University were reported. (13) 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 human leukocyte antigen (HLA) matching between donor and recipient.

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 study 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 (14) and 78% in children with nonmalignant conditions. (15) 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. This slower engraftment leads to longer hospitalizations and greater utilization of medical resources. (16) In a retrospective multicenter study of 541 children with acute leukemia, rates of neutrophil recovery at day 60 were statistically different: 96% versus 80% for those receiving unrelated bone marrow and unrelated cord blood, respectively. (17) 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. (14, 18)

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. (19) 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. 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. (20) The adjusted 3-year overall survival rate was 51% (95% confidence interval [CI]: 38-63%) after related donor bone marrow transplantation, 53% (95% CI: 28-78%) after unrelated donor bone marrow transplantation and 45% (95% CI: 31-58) after unrelated donor cord blood transplantation; the difference among groups was not statistically different,  $p = 0.73$ .

In addition to the above studies, there have been numerous retrospective and registry studies. These have generally found that unrelated cord blood transplantation is effective in both children and adults with hematologic malignancies and children with a variety of nonmalignant conditions. The majority of cord blood transplants have been mismatched at 1 or 2 HLA loci. 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 minimum cell dose of  $2.5\text{--}3.0 \times 10^7$  nucleated cells/kg in the cord blood has been associated with superior clinical outcome. (13, 17, 21-24)

More recently, transplantation of 2 umbilical cord blood units (also known as double unit transplants) have been evaluated as a strategy to overcome cell-dose limitations with 1 cord blood unit in older and heavier patients. Initial experience at the University of Minnesota has shown that using 2 units of cord blood for a single transplant in adults improved rates of engraftment and overall survival. (25) Pilot studies have shown 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. (16) 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. (26) 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  $2.5\text{--}3.0 \times 10^7$  nucleated cells/kg. For the double transplants, the 2 units combined contained more than  $2.5\text{--}3.0 \times 10^7$  nucleated cells/kg, but in about half of cases, individual units contained less than the minimum amount required. In analyses adjusting for factors associated with outcomes, rates of transplantation-related mortality (hazard ratio [HR]: 0.91,  $p = 0.63$ ), relapse (HR: 0.90,  $p = 0.64$ ) and overall mortality (HR: 0.93,  $p = 0.62$ ) 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 (HR: 6.14, 95% CI: 2.54-14.87,  $p < 0.001$ ). In the later period, 2004-2009, rates of grade 2-4 acute GVHD did not differ significantly between groups (HR: 1.69, 95% CI: 0.68-4.18,  $p = 0.30$ ). Several prospective randomized controlled trials (RCTs) comparing the efficacy and safety of single and double cord blood unit grafts are ongoing (see section on Ongoing Clinical Trials, below.)

### **Autologous cord blood transplant**

Data regarding the use of cord blood for autologous 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. (27) 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 absence of a known indication. (28) Thus the practice of collecting and storing cord blood for a potential future use is considered not medically necessary.

## Ongoing Clinical Trials

Single Versus Double Umbilical Cord Blood Transplantation in Children With High Risk Leukemia and Myelodysplasia (BMT CTN 0501) (NCT00412360) (29): This RCT is comparing single or double cord blood unit transplantation for treating children with high-risk leukemia and myelodysplasia. The primary study outcome is overall survival. The expected enrollment is 224 patients and the expected date of study completion is May 2015.

A Study Comparing Single Versus Double Umbilical Cord Blood Transplantation in the Young With Acute Leukemia Remission (NCT01067300): (30) This RCT is comparing single or double cord blood unit transplantation in children and young adults (younger than age 35 years) with acute leukemia in remission. The primary outcome measure is the incidence of transplantation failure. The expected enrollment is 198 patients and the expected date of study completion is September 2013.

## 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 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. There is some evidence from retrospective studies that double umbilical cord blood transplants may be a safe and effective alternative to single-unit transplants and several prospective RCTs are underway. 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 considered not medically necessary.

## Practice Guidelines and Position Statements

On behalf of the American Society for Blood and Marrow Transplantation, in 2009 Ballen and colleagues (31) 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.

## References

1. Godley LA, van Besien K. The next frontier for stem cell transplantation: finding a donor for all. *JAMA* 2010; 303(14):1421-2.
2. U.S. Food and Drug Administration. Guidance for Industry: Minimally manipulated, unrelated allogeneic placental/umbilical cord blood intended for hematopoietic reconstitution for specified indications. Available online at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM187144.pdf>
3. Wall DA. Regulatory issues in cord blood banking and transplantation. *Best Pract Res Clin Haematol* 2010; 23(2):171-7.

4. NetCord-FACT. International standards for cord blood collection banking and release of information accreditation manual- Fifth Edition. September 2012. Available online at: [http://www.factwebsite.org/uploadedFiles/FACT\\_News/Draft%205th%20Edition%20NetCord-FACT%20Cord%20Blood%20Accreditation%20Manual.09.04.12.pdf](http://www.factwebsite.org/uploadedFiles/FACT_News/Draft%205th%20Edition%20NetCord-FACT%20Cord%20Blood%20Accreditation%20Manual.09.04.12.pdf).
5. American Association of Blood Banks (AABB). AABB Accredited Cord Blood (CB) Facilities Available online at: <https://www.aabb.org/sa/facilities/celltherapy/Pages/CordBloodAccrFac.aspx>.
6. Barker JN, Byam C, Scaradavou A. How I treat: the selection and acquisition of unrelated cord blood grafts. *Blood* 2011; 117(8):2332-9.
7. Rao M, Ahrlund-Richter L, Kaufman DS. Concise review: Cord blood banking, transplantation and induced pluripotent stem cell: success and opportunities. *Stem Cells* 2012; 30(1):55-60.
8. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Placental and Umbilical Cord Blood as a Source of Stem Cells for Hematopoietic Support. *TEC Assessments* 1996; Volume 11, Tab 17.
9. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transplanting Adult Patients with Hematopoietic Stem Cells from Placental and Umbilical Cord Blood. *TEC Assessments* 2001; Volume 16, Tab 17.
10. Gluckman E, Broxmeyer HA, Auerbach AD et al. Hematopoietic reconstitution in a patient with Fanconi's anemia by means of umbilical-cord blood from an HLA-identical sibling. *N Engl J Med* 1989; 321(17):1174-8.
11. Wagner JE, Rosenthal J, Sweetman R et al. Successful transplantation of HLA-matched and HLA-mismatched umbilical cord blood from unrelated donors: analysis of engraftment and acute graft-versus-host disease. *Blood* 1996; 88(3):795-802.
12. Broxmeyer HE, Douglas GW, Hangoc G et al. Human umbilical cord blood as a potential source of transplantable hematopoietic stem/progenitor cells. *Proc Natl Acad Sci U S A* 1989; 86(10):3828-32.
13. Kurtzberg J, Laughlin M, Graham ML et al. Placental blood as a source of hematopoietic stem cells for transplantation into unrelated recipients. *N Engl J Med* 1996; 335(3):157-66.
14. Kurtzberg J, Cairo MS, Fraser JK et al. Results of the cord blood transplantation (COBLT) study unrelated donor banking program. *Transfusion* 2005; 45(6):842-55.
15. Martin PL, Carter SL, Kernan NA et al. Results of the cord blood transplantation study (COBLT): outcomes of unrelated donor umbilical cord blood transplantation in pediatric patients with lysosomal and peroxisomal storage diseases. *Biol Blood Marrow Transplant* 2006; 12(2):184-94.
16. Kurtzberg J. Update on umbilical cord blood transplantation. *Curr Opin Pediatr* 2009; 21(1):22-9.
17. Rocha V, Cornish J, Sievers EL et al. Comparison of outcomes of unrelated bone marrow and umbilical cord blood transplants in children with acute leukemia. *Blood* 2001; 97(10):2962-71.
18. Fraser JK, Cairo MS, Wagner EL et al. Cord Blood Transplantation Study (COBLT): cord blood bank standard operating procedures. *J Hematother* 1998; 7(6):521-61.
19. Zhang H, Chen J, Que W. A meta-analysis of unrelated donor umbilical cord blood transplantation versus unrelated donor bone marrow transplantation in acute leukemia patients. *Biol Blood Marrow Transplant* 2012; 18(8):1164-73.
20. Peffault de Latour R, Brunstein CG, Porcher R et al. Similar Overall Survival Using Sibling, Unrelated Donor, and Cord Blood Grafts after Reduced-Intensity Conditioning for Older Patients with Acute Myelogenous Leukemia. *Biol Blood Marrow Transplant* 2013.
21. Gluckman E, Rocha V, Boyer-Chammard A et al. Outcome of cord-blood transplantation from related and unrelated donors. Eurocord Transplant Group and the European Blood and Marrow Transplantation Group. *N Engl J Med* 1997; 337(6):373-81.
22. Kurtzberg J, Prasad VK, Carter SL et al. Results of the Cord Blood Transplantation Study (COBLT): clinical outcomes of unrelated donor umbilical cord blood transplantation in pediatric patients with hematologic malignancies. *Blood* 2008; 112(10):4318-27.
23. Prasad VK, Kurtzberg J. Emerging trends in transplantation of inherited metabolic diseases. *Bone Marrow Transplant* 2008; 41(2):99-108.
24. Rubinstein P, Carrier C, Scaradavou A et al. Outcomes among 562 recipients of placental-blood transplants from unrelated donors. *N Engl J Med* 1998; 339(22):1565-77.

25. Barker JN, Weisdorf DJ, DeFor TE et al. Transplantation of 2 partially HLA-matched umbilical cord blood units to enhance engraftment in adults with hematologic malignancy. *Blood* 2005; 105(3):1343-7.
26. Scaradavou A, Brunstein CG, Eapen M et al. Double unit grafts successfully extend the application of umbilical cord blood transplantation in adults with acute leukemia. *Blood* 2013; 121(5):752-8.
27. Lubin BH, Shearer WT. Cord blood banking for potential future transplantation. *Pediatrics* 2007; 119(1):165-70.
28. Thornley I, Eapen M, Sung L et al. Private cord blood banking: experiences and views of pediatric hematopoietic cell transplantation physicians. *Pediatrics* 2009; 123(3):1011-7.
29. Sponsored by Medical College of Wisconsin. Single Versus Double Umbilical Cord Blood Transplantation in Children With High Risk Leukemia and Myelodysplasia (BMT CTN 0501) (NCT00412360). Available online at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Last accessed August, 2013.
30. Sponsored by Assistance Publique Hopitaux De Marseille. A Study Comparing Single Versus Double Umbilical Cord Blood Transplantation in the Young With Acute Leukemia Remission (NCT01067300). Available online at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Last accessed August, 2013.
31. Ballen KK, Barker JN, Stewart SK et al. Collection and preservation of cord blood for personal use. *Biol Blood Marrow Transplant* 2008; 14(3):356-63.

### **Billing Coding/Physician Documentation Information**

---

<b>38240</b>	Bone marrow or blood-derived peripheral stem cell transplantation; allogenic
<b>S2140</b>	Cord blood harvesting for transplantation, allogeneic
<b>S2142</b>	Cord blood-derived stem-cell transplantation, allogeneic
<b>S2150</b>	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 posttransplant care in the global definition

### **Additional Policy Key Words**

---

N/A

### **Policy Implementation/Update Information**

---

12/1/01	New policy. Added to Surgery section
7/1/02	Policy revised, cord blood as a source of stem cells is not longer restricted to children, considered medically necessary in adults.
12/1/02	No policy statement change
12/1/03	No policy statement change. Added new CPT codes
12/1/04	No policy statement change. Added new HCPCS codes (S2140, S2142)
12/1/05	No policy statement changes. Changed name of policy from <i>Cord Blood as a Source of Stem Cells</i> to <i>Placental and Umbilical Cord Blood as a Source of Stem Cells</i> .
4/1/06	Considerations section revised to include general criteria.
12/1/06	No policy statement changes.
12/1/07	No policy statement changes.
12/1/08	No policy statement changes.
12/1/09	No policy statement changes. Coding updated.
12/1/10	Investigational statement added regarding all other indications, however, there was no change to the intent of the policy.
12/1/11	No policy statement changes.
12/1/12	No policy statement changes.
12/1/13	No policy statement changes.

---

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.