Anthem

Medical Policy

Subject: Umbilical Cord Blood Progenitor Cell Collection, Storage and Transplantation
Document #: TRANS.00016
Status: Revised
Publish Date: 04/10/2024
Last Review Date: 02/15/2024

Description/Scope

This document addresses cord blood banking, which is a process of collecting hematopoietic progenitor stem cells from the umbilical cord and placental blood and cryogenically freezing them immediately after the birthing process. Both malignant and non-malignant diseases, including genetic diseases, may be treated with cord blood hematopoietic progenitor stem cell transplantation.

Note: For additional stem cell transplant information and criteria, see the applicable transplant document:

- TRANS.00023 Hematopoietic Stem Cell Transplantation for Multiple Myeloma and Other Plasma Cell Dyscrasias
- TRANS.00024 Hematopoietic Stem Cell Transplantation for Select Leukemias and Myelodysplastic Syndrome
- TRANS.00027 Hematopoietic Stem Cell Transplantation for Pediatric Solid Tumors
- TRANS.00028 Hematopoietic Stem Cell Transplantation for Hodgkin Disease and non-Hodgkin Lymphoma
- TRANS.00029 Hematopoietic Stem Cell Transplantation for Genetic Diseases and Aplastic Anemias
- TRANS.00030 Hematopoietic Stem Cell Transplantation for Germ Cell Tumors
- TRANS.00031 Hematopoietic Stem Cell Transplantation for Autoimmune Disease and Miscellaneous Solid Tumors
- TRANS.00034 Hematopoietic Stem Cell Transplantation for Diabetes Mellitus

Position Statement

Medically Necessary:

A. The use of umbilical cord blood progenitor cell transplantation is considered **medically necessary** for selected individuals when ***all*** of the following criteria are met:
   1. One or two donor cord unit(s) is used for a single recipient; **and**
   2. The *total* nucleated cell (TNC) count is equal to or greater than 2.3×10^7 per kg; **and**
   3. The umbilical cord blood stem cell unit(s) is used for an allogeneic stem cell transplant for an approved indication and the appropriate stem cell transplant criteria are met.

B. Collection and storage of cord blood is considered **medically necessary** only when an allogeneic transplant is imminent for an identified recipient and the above criteria are met. Storage will only be authorized at centers approved by **one** of the following:
   1. Foundation for the Accreditation of Cellular Therapy (FACT); **or**
   2. NetCord-FACT; **or**
   3. National Cancer Institute (NCI); **or**
   4. National Marrow Donor Program (NMDP); **or**
   5. AABB (formerly known as American Association of Blood Banks); **or**
   6. California Department of Public Health.

Investigational and Not Medically Necessary:

The use of umbilical cord blood progenitor cell transplantation is considered **investigational and not medically necessary** when criterion A is not met.

Prophylactic collection and storage of umbilical cord blood is considered **investigational and not medically necessary** when proposed for an unspecified future use for 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 donor.

Rationale

Cord Stem Cell Transplant

A variety of malignant diseases and non-malignant disorders may be treated with an allogeneic hematopoietic stem cell transplant (HSCT) which involves myeloablative or nonmyeloablative preparative regimens followed by hematopoietic stem cell infusion (HSCI) to restore hematopoietic function and reconstitute the immune system (LeMaistre, 2013). Hematopoietic progenitor stem cells may be collected from a compatible donor such as a related family member or an unrelated donor identified by the transplant facility. Donor stem cells from related donors are typically collected by an accredited facility. Less than 30% of transplant recipients have a human leukocyte antigen (HLA)-identically matched family member that could be a suitable donor. For individuals without a matched related donor, searches for matching unrelated donors are conducted through nationally recognized and accredited bone marrow and/or hematopoietic stem cell banks (for example, FACT, NetCord-FACT, NMDP) that have passed inspections and demonstrated compliance with the established standards for cellular therapies. In many cases, a suitable bone marrow donor is not found (Wagner, 2002). In these situations, suitably matched umbilical cord blood containing hematopoietic progenitor cells may be used as a source of donor cells for HSCT.

There are multiple ongoing studies involving the use of umbilical cord blood as a source of progenitor cells to restore hematopoiesis and bone marrow function to individuals during a stem cell transplant process. The initial success of utilizing single unit cord blood transplants was noted in pediatric leukemia studies. Because of the positive pediatric outcomes and the lack of alternatives for adults that require allogeneic stem cell transplant, cord blood stem cell transplants have been performed in adults. Prospective, randomized studies to assess the efficacy of umbilical cord transplants compared to matched unrelated allogeneic donor transplants are not feasible since cord stem cell transplantation is utilized only when no matched donor is identified.

Neutrophil and platelet engraftment, signs of hematopoietic recovery after umbilical cord blood transplantation, have been delayed in adults when compared to children. It was determined that the weight of the recipient had a significant influence in the rate of treatment morbidity and mortality. However, there is insufficient data to determine a maximum weight and the corresponding minimal cell dose

based on weight of the recipient. Authors of studies have noted the use of cord units with lower stem cell counts and the corresponding increased risk of treatment related morbidity and mortality may be options for individuals that have no other source of stem cells (Laughlin, 2001; Parody, 2006; Takahashi, 2006, 2007; Tamura, 2006).

Rocha and colleagues (2004) performed a retrospective review comparing cord blood stem cell transplants with unrelated bone marrow transplants. The median TNC of 0.23 x 10^8 per kilogram (kg) was utilized and acceptable transplant outcomes could be achieved in adults. Although hematopoietic recovery of neutrophils was significantly delayed in the cord blood group (relative risk [RR], 0.49; 95% confidence interval [CI], 0.41 to 0.58; p<0.001), there were no significant differences in the incidence of chronic graft-versus-host disease (GVHD), leukemia-free survival, relapse rate, and transplant-related mortality (TRM). Significant differences noted between the two study cohorts included a younger age (median age 24.5 years) for cord blood transplant and an older age (32 years) for unrelated bone marrow transplant. The cord blood recipients also weighed less with a median weight of 58 kg compared with a median weight of 68 kg for bone marrow recipients. The cord blood recipients had more extensive disease in 52% compared with 34% in the marrow group.

In reviews of the available data on cord blood, it has been noted there was a “ten-fold decrease in risk of leukemia relapse in patients with acute leukemia treated with double umbilical cord progenitor cell transplantation compared to patients who received a single unit umbilical cord transplant” (Brunstein, 2007; Tse, 2008). Brunstein (2007) reported unpublished single institution experience with double cord transplants in the myeloablative setting (n=61) with a probability of disease-free survival and overall survival at 2 years of 55% and 63%. The author noted there was no significant difference in outcomes when compared to individuals who were treated with the same conditioning regimen but received a single umbilical cord blood graft.

In a registry outcome study, Rodrigues and colleagues (2009) analyzed 104 adults (mean age of 41 years) transplanted with unrelated donor cord blood cell transplantation. Twenty-six of these individuals received double umbilical cord blood units. Chimerism data were available on 17 out of 21 assessable individuals treated with double umbilical cord blood transplants (UCBT). A total of 94% (16 recipients) had complete chimerism, and 6% (1 recipient) had mixed chimerism. The cumulative 1 and 2 year incidence of relapse or progression of disease was 31% and 35%, respectively. Double UCBT was associated with lower relapse risk (p=0.02) in the multivariate analysis. The authors noted UCBT is a viable alternative for adults with advanced lymphoma and chronic lymphocytic leukemia (CLL) who lack an HLA-matched donor.

Barker and colleagues (2010) conducted a retrospective analysis of the effect of TNC dosing and HLA match on 1061 individuals who received a single-unit cord blood transplant after myeloablative therapy for leukemia or myelodysplasia. The authors noted “TNC dose was associated with neutrophil and platelet engraftment in a dose-response relationship with progressively faster and greater engraftment rates as the dose increased.”

The evidence from multiple case series studies indicates that the pattern of immune reconstitution with umbilical cord blood is similar to that reported for other stem cell sources, and it is also an effective means for increasing survival rates. Optimal cell dose also had a positive impact on 5-year overall survival (OS) and disease-free survival (DFS) in children who received umbilical cord transplantation for nonmalignant diseases (Jaing, 2010).

A retrospective analysis of pooled data from 514 individuals transplanted from 1995-2005 with a single unit of unmanipulated cord blood from three international registries was performed by Cohen and colleagues (2011). The primary mortality rates at 100 days and 1 year, along with 180-day mortality and engraftment failure, were analyzed. Similar mortality rates for all three registries at 1 year were noted with deaths within 100 days of 44% (227 individuals). Overall Kaplan-Meier survival was 56%, 46% and 37% for 100 day, 180 day and 1 year survival, respectively (Cohen, 2011). In a review of the potential prognostic factors, the authors noted cell dose less than 2.5 x 10^7/kg was associated with poor prognosis. However, the authors noted the proportion of individuals who received the lower TNC dosing has declined sharply from 1995 (67%) to 2002-2005 (24%).

Wagner and colleagues (2014) compared the 1-year overall survival rate in children and adolescents receiving a double-unit (n=111) or single-unit (n=113) cord blood transplant. The authors theorized that the greater numbers of hematopoietic cells in two units of cord blood would result in improved transplant outcomes. In an open-label, phase 3, multicenter, randomized trial, individuals aged 1 to 21 with high risk acute leukemia, chronic myeloid leukemia, or myelodysplastic syndrome received units with at least 2.5 × 10^7 nucleated cells per kg in the primary unit and 1.5 × 10^7 nucleated cells per kg in a secondary unit. The overall survival rate at 1 year was 65% (95% CI, 56 to 74) in those receiving two units and 73% (95% CI, 63 to 80) in those receiving a single unit (p=0.17). The 1-year disease-free survival results were similar: 64% (95% CI, 54 to 72) in double-unit recipients versus 70% (95% CI, 60 to 77) in single-unit recipients (p=0.11). Both treatment arms were also comparable in regards to several other secondary outcomes including incidences of relapse, treatment-related deaths, neutrophil recovery, infections, immunologic reconstitution, and grade II–IV acute GVHD. Those who received a single unit did show significantly improved platelet recovery and significantly lower incidences of grade III and IV acute and extensive chronic GVHD. The study was limited by the fact that individuals were only followed for 1 year; long-term survival was not evaluated.

In an attempt to evaluate risk factors and their effect on outcomes, Chen and associates (2016) performed an analysis of 1404 individuals who received an umbilical cord blood transplantation (UCBT). Individuals under the age of 18 who received a single unit (n=810) and those 18 and older who received a double unit (n=594) were included. The authors noted the incidence of acute GVHD is similar to those achieved through conventional sources; however, the incidence of chronic GVHD appears to be lower. The authors also noted that the development of chronic GVHD following a single UCBT was associated with an increase in non-relapse mortality (NRM). In a double UCBT, chronic GVHD was associated with less disease relapse.

Individual umbilical cord units have variable TNC doses per donated unit. Attempts to reduce the treatment related morbidity and mortality of umbilical cord stem cell transplant include studies to increase TNC volume through various techniques such as ex vivo cell expansion or haploidentical (haplo) – cord transplantation, which combines both UCB and CD34- selected cells typically from human leukocyte antigen mismatched donors (Van Besien, 2016). In addition, there is ongoing research to determine the safety and efficacy of using three or more cord units, as well as pooled units of cord blood to provide sufficient TNC doses for transplantation. At this time, there is a paucity of published literature for the use of three or more umbilical cord units for a single transplant.

In 2017, Baron and colleagues performed a retrospective, multicenter, registry study to compare single-unit and double-unit cord blood transplants following reduced-intensity conditioning. The researchers included leukemic individuals with leukemia who had received a first single unit (n=172) or first double unit (n=362) cord transplant between 2004 and 2014. The researchers found that administering double units was safe for individuals who did not have access to a single unit containing at least 2.5 × 10^7 TNC/kg. However, the relapse rate at 2 years was similar for the single-unit group (35%) and the double-unit group (32%; p=0.5). The authors concluded that double-unit cord blood transplants after reduced-intensity conditioning did not lead to better outcomes for persons with leukemia. They noted that prospective studies are needed to confirm the findings.

Cord Blood Stem Cell Storage

Several public and private cord blood banks have now been developed in Europe and in the United States. Other for-profit 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. Public cord blood banks collect and maintain donated cords for allogeneic transplants. Accreditation of most cord blood banks are done by FACT, NMDP and NetCord-FACT (primarily for international centers).

Purtill and colleagues (2014) reported results of an analysis of 402 cord blood units thawed at a single institution. The cord blood unit TNC precryopreservation, postthaw and engraftment rates were analyzed. A total of 350 (87%) out of 402 units were obtained from cord blood banks accredited by NetCord-FACT. The authors concluded, after "multivariate analysis, only lack of bank Netcord-FACT accreditation was independently associated with low CD34+ cell recovery."

The indications for autologous umbilical cord stem cell transplantation are limited, and the potential for future expansion is unlikely. This position is supported by multiple case series. A survey of pediatric transplant physicians (Thornley, 2009) noted few pediatric hematopoietic transplant physicians would "endorse private cord blood banking in the absence of an identified recipient." Given the lack of scientific data and difficulty in estimating the need for using one's own cord blood cells for transplantation, there is a paucity of evidence to support the private storage of cord blood for "biological insurance."

Other Considerations

In a report (Ballen, 2008) for the American Society for Transplantation and Cellular Therapy (ASTCT) (formerly the American Society for Blood and Marrow Transplantation [ASBMT]), the authors have published the following recommendations regarding public and private banking of umbilical cord blood:

1. A sibling of the expected child has a disease that can be successfully treated with hematopoietic stem cell transplantation (HSCT).
2. The parent of the expected child has a disease that can be successfully treated with HSCT, and there are shared HLA antigens between the parents.
3. The expectant parents should be encouraged to donate their newborn's cord blood to a public bank when possible.
4. Expectant parents should be informed that, although private cord banking is available for purchase, the chance of personally stored cord blood being of benefit to their child is extremely low (about the same chance of maternal death during childbirth), and that current knowledge is limited as to the long-term cord blood viability and the likelihood of success of autologous cord blood transplantation.

The American College of Obstetrics and Gynecology Committee Opinion (2019) provided recommendations which include:

> If a patient requests information on umbilical cord banking, balanced and accurate information regarding the advantages and disadvantages of public versus private umbilical cord blood banking should be provided. The routine storage of umbilical cord blood as "biologic insurance" against future disease is not recommended...Patients should be aware that in certain instances, use of one's own stem cells is contraindicated. Most conditions potentially treated by a patient's own umbilical cord blood already exist in his or her own cells and, therefore, the stored blood cannot be used to treat the same individual. The chance of an autologous unit of umbilical cord blood being used for a child or a family member is remote, unless a family member is known to have a medical condition that could be treated with transplant, and this fact should be disclosed to the patient. Directed cord blood banking should be encouraged when there is knowledge of a full sibling in the family with a medical condition (malignant or genetic) that could potentially benefit from cord blood transplantation.

In a 2017 opinion statement on *Delayed Umbilical Cord Clamping After Birth*, ACOG stated the following:

> Delayed umbilical cord clamping significantly decreased the volume and total nucleated cell counts of cord blood donations…in the absence of directed donation, the benefits to the infant of transfusion of additional blood volume at birth likely exceed the benefits of banking that volume for possible future use. Families who are considering banking of umbilical cord blood should be counseled accordingly.

In a 2017 policy statement *Cord Blood Banking for Potential Future Transplantation* (Shearer, 2017), the American Academy of Pediatrics (AAP) makes the following recommendations:

1. Public cord blood banking is the preferred method of collecting, processing, and using cord blood cells for use in transplantation in infants and children with fatal diseases, such as malignancies, blood disorders, immune deficiencies, and metabolic disorders. There is a more limited role of private cord blood banking with families with a known fatal illness that can be rescued by a healthy cord blood transplant within the family;
2. It is important that the concepts of autologous and allogeneic use of cord blood units be explained to parents by physicians and medical staff to enable expectant parents to make informed choices regarding where they should deposit their infant's cord blood and whether to restrict the blood for the infant's or family's use or release it to the public for any child in need of stem cell transplantation;
3. Physicians need to convey accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation to parents, including that autologous cord blood would not be used as a stem cell source if the donor developed leukemia later in life. It is important for parents to be aware that at this time, there are no scientific data to support the claim that autologous cord blood is a tissue source proven to be of value for regenerative medical purposes, although researchers are examining this possibility;
4. It is expected that physicians and designated medical staff obtain specific permission for maintaining demographic medical information and that the potential risks of breaches of confidentiality be disclosed to parents. Specific efforts need to be made to recruit underserved ethnic minorities for cord blood donations to enlarge the public cord blood repositories and better serve these patient populations. Before the onset of active labor, written permission needs to be obtained from parents to collect the cord blood for banking purposes. If the cord blood bank is conducting therapeutic human research involving cord blood, review and approval of the recruitment strategies and parental consent forms by the institutional review board are necessary;
5. The AAP advocates for regulatory agencies (eg, the Food and Drug Administration, the Federal Trade Commission, and state equivalents of these federal agencies) to have an active role in providing oversight of the cord blood program. It is important that all cord blood banking programs comply with FACT or equivalent accreditation standards; and
6. Physicians or other professionals who recruit pregnant women and their families for for-profit placental cord blood stem cell banking need to disclose any financial interest or other potential conflict of interest they have relative to the procedure to their patients. Similarly, professionals affiliated with institutions or organizations that promote for-profit placental blood stem cell banking need to make annual financial-disclosure and potential-conflicts-of-interest statements to an appropriate institutional review committee that possesses oversight authority.

Background/Overview

In recent years, umbilical cord blood has been used successfully to treat a variety of genetic, hematologic and oncologic disorders. An estimated 30,000 individuals with malignant and non-malignant diseases have undergone hematopoietic stem cell transplantation with unrelated-donor umbilical cord blood since 1993 (Wagner, 2014). It has been shown that umbilical cord blood contains a large number of hematopoietic stem cells.

Blood harvested from the umbilical cord and placenta shortly after delivery of a neonate contains stem and progenitor cells capable of restoring hematopoietic function after myeloablative therapy. Cord blood is being used as an alternative source of allogeneic stem cells when a suitable donor is unavailable. Cord blood is readily available and is thought to be antigenically "naïve," hopefully minimizing the incidence of graft-versus-host disease (GVHD) and permitting the broader use of unrelated cord blood transplants.

Two characteristics that can influence the outcome of cord blood transplantation are the dose of cells infused and the recipient's weight. It is widely accepted that the dose of cells infused is a major factor contributing to durable long-term engraftment of bone marrow or peripheral blood stem cells. The minimal cell dose needed is variable, depending on parameters that include the preparative regimen used for marrow ablation, the nature of the underlying disease, the degree of immunologic mismatch between donor and recipient, and the source of stem cells to be used. Smaller volumes of cord blood and, thus, fewer nucleated cells can be harvested from the umbilical cord and placenta of a single neonate than is possible when bone marrow or peripheral blood stem cells are obtained from adults.

Private, for-profit companies offer fee-based services to harvest, process, and store cord blood stem cells for possible autologous use. However, empirical evidence that children will benefit from the use of their own cord blood in the future use is lacking. Several states have their own licensing requirements which apply to facilities which collect or store cord blood.

Definitions

Allogeneic: Stem cells harvested from a histocompatible donor. (**Note:** this document does not require a specific level of histocompatibility be present as part of the medical necessity evaluation).

Autologous: Stem cells harvested from the individual's own umbilical cord blood.

Chimerism: Cell populations derived from different individuals; may be mixed or complete.

Ex vivo: Occurring outside of the living body. Refers to a medical procedure in which an organ, cells, or tissue are taken from a living body for a treatment or procedure, and then returned to the living body.

Foundation for the Accreditation of Cellular Therapy (FACT): A non-profit corporation that performs voluntary inspection and accreditation in the field of cellular therapy. Co-founders are the International Society for Cellular Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT).

Hematologic: Relating to hematology, a branch of medical science that studies blood and blood forming tissues.

Hematopoietic stem cells: Cells that give rise to distinct daughter cells, one cell that replicates the stem cell and one cell that will further proliferate and differentiate into a mature blood cell.

Malignant: Cancerous tissue or cells.

National Marrow Donor Program (NMDP): A non-profit organization that operates a registry for hematopoietic stem cell and umbilical cord blood units. NMDP coordinates with a network of registered organizations to collect, store, transfer and transplant hematopoietic stem cell and umbilical cord blood units.

NetCord-FACT: A non-profit association of international umbilical cord blood banks. NetCord collaborates with FACT to sponsor standards and accreditation for cord blood banks.

Oncologic: Pertaining to cancer.

Prophylactic collection and storage of umbilical cord blood: Collection and storage of umbilical cord blood without an imminent transplant for an identified recipient.

Umbilical or placental cord blood: Blood taken post-partum from the umbilical cord or placenta.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage [when specified as cord blood]
38208-38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest [when specified as cord blood]
38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic [when specified as cord blood]

HCPCS

S2140	Cord blood harvesting for transplantation; allogeneic

ICD-10 Procedure

30233X2-30243X2	Transfusion of allogeneic related cord blood stem cells into peripheral or central vein, percutaneous approach [includes codes 30233X2, 30243X2]
30233X3-30243X3	Transfusion of allogeneic unrelated cord blood stem cells into peripheral or central vein, percutaneous approach [includes codes 30233X3, 30243X3]

30233X4-30243X4	Transfusion of allogeneic unspecified cord blood stem cells into peripheral or central vein, percutaneous approach [includes codes 30233X4, 30243X4]
6A550ZT	Pheresis of cord blood stem cells, single
6A551ZT	Pheresis of cord blood stem cells, multiple

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above, when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

ICD-10 Procedure

30233X0	Transfusion of autologous cord blood stem cells into peripheral vein, percutaneous approach
30243X0	Transfusion of autologous cord blood stem cells into central vein, percutaneous approach

ICD-10 Diagnosis

All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted bullet “B” in the medically necessary criteria. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, References and Websites for Additional Information sections
Reviewed	02/17/2022	MPTAC review. Updated Rationale, References and Websites sections.
	10/01/2021	Updated Coding section with 10/01/2021 ICD-10-PCS changes; removed open approach codes deleted 09/30/2021.
Revised	02/11/2021	MPTAC review. Removed brackets from MN criteria A 2 and replaced with parentheses. Updated References and Websites sections. Updated Coding section with current ICD-10 procedure codes.
Reviewed	02/20/2020	MPTAC review. References and Websites sections updated.
	10/01/2019	Updated Coding section with 10/01/2019 ICD-10-PCS changes; removed codes 30250X0, 30250X1, 30253X0, 30253X1, 30260X0, 30260X1, 30263X0, 30263X1 deleted 09/30/2019.
Reviewed	03/21/2019	MPTAC review.
Reviewed	03/20/2019	Hematology/Oncology Subcommittee review. References and Websites sections updated.
Reviewed	05/03/2018	MPTAC review.

Reviewed	05/02/2018	Hematology/Oncology Subcommittee review. The document header wording updated from “Current Effective Date” to “Publish Date.” Rationale, References, and Websites sections updated.
Reviewed	05/04/2017	MPTAC review.
Reviewed	05/03/2017	Hematology/Oncology Subcommittee review. Updated Rationale, Background, References and Websites sections. Updated formatting in Position Statement section.
Reviewed	05/05/2016	MPTAC review.
Reviewed	05/04/2016	Hematology/Oncology Subcommittee review. Updated Rationale, Background/Overview, References and Websites Sections. Removed ICD-9 codes from Coding section.
Revised	05/07/2015	MPTAC review.
Revised	05/06/2015	Hematology/Oncology Subcommittee review. Deleted “accreditation bodies” from medically necessary statement #2. Added two additional entities to medically necessary statement #2. Updated Rationale, References and Websites Sections.
Reviewed	05/15/2014	MPTAC review.
Reviewed	05/14/2014	Hematology/Oncology Subcommittee review. Updated Rationale, References and Websites Sections.
Reviewed	05/09/2013	MPTAC review.
Reviewed	05/08/2013	Hematology/Oncology Subcommittee review. Updated References and Websites.
Reviewed	05/10/2012	MPTAC review.
Reviewed	05/09/2012	Hematology/Oncology Subcommittee review. Updated Rationale, References and Websites.
Revised	05/19/2011	MPTAC review.
Revised	05/18/2011	Hematology/Oncology Subcommittee review. Updated accreditation bodies information in medically necessary criteria. Updated Rationale, References and Websites.
Reviewed	05/13/2010	MPTAC review.
Reviewed	05/12/2010	Hematology/Oncology Subcommittee review. Updated rationale, references and websites.
Reviewed	05/21/2009	MPTAC review.
Reviewed	05/20/2009	Hematology/Oncology Subcommittee review. Modify medically necessary criteria to allow one or two umbilical cord units. Updated rationale, coding, references and websites.
Reviewed	11/20/2008	MPTAC review.
Reviewed	11/19/2008	Hematology/Oncology Subcommittee review. Updated rationale, coding, references and websites.
Revised	11/29/2007	MPTAC review.
Revised	11/28/2007	Hematology/Oncology Subcommittee review. Clarified single donor cord unit in medical necessity statement. Added criteria to include, “The patient does not have a human leukocyte antigen (HLA) - matched donor.” Updated rationale and references. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.”
	05/17/2007	Added note to the description section, cross referencing additional documents.
Revised	12/07/2006	MPTAC review.
Revised	12/06/2006	Hematology/Oncology Subcommittee review. References updated. Clarification of medical necessity statement. Reviewed issue of double cords.
Reviewed	12/01/2005	MPTAC review.
Reviewed	11/30/2005	Hematology/Oncology Subcommittee review. Reviewed issue of double cords. No change in position statement.
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	09/18/2003	TRANS.00016	Collection and Storage of Cord Blood as a Source of Stem Cells
WellPoint Health Networks, Inc.	12/02/2004	7.11.01	Umbilical Cord Blood Progenitor Cell Transplantation

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.