

Medical Coverage Policy



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Umbilical Cord Blood Banking

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Overview

This Coverage Policy addresses umbilical cord blood banking.

Coverage Policy

In the absence of a planned or expected hematopoietic transplantation where cord blood cells will be required, collection and storage costs associated with the banking of umbilical cord blood is considered not medically necessary.

General Background

Umbilical cord blood, also known as cord blood, is the blood left in the umbilical cord and placenta after the baby is born and the cord is cut. It contains both hematopoietic stem cells and pluripotent mesenchymal cells which may be used in the treatment of some types of leukemias, lymphomas, hemoglobinopathies, immunodeficiencies and inborn errors of metabolism. Umbilical cord blood has been shown to be effective as an alternative source of hematopoietic cells for transplantation and its use in transplantation of selected children with various disorders is a standard of care. Due to the use of better banking techniques, reduced intensity transplants, and double cord blood transplantation, the majority of cord blood transplants are being performed in adults (Ballen, 2010).

Advantages to the use of umbilical cord blood compared with peripheral blood or bone marrow include a large available supply, the units are available on short notice, ethnic diversity is easier to achieve, painless collection of stem cells, higher proliferative capacity, and a lower rate of acute graft-versus-host disease. Compared with adult peripheral blood stem cells, cells found in the umbilical cord have immune innocence because of their minimal previous exposure to antigens. Because of this the cord blood cells have a reduced capacity to elicit an immune response against a recipient, and there is somewhat less likelihood of graft-versus-host disease. Disadvantages include the inability to obtain additional donor cells, fewer total cells due to small volumes, slower engraftment and high up-front costs (Moise, 2005). Although cord blood units have high concentrations of hematopoietic progenitor cells, they have relatively small volumes and fewer total cells. Very low cell doses can result in a higher risk of non-engraftment, especially in larger children and adults.

The recognition of umbilical cord blood as an appropriate source of stem cells for transplantation has led to the establishment of public, private, and directed-donation facilities, also known as 'banks', to collect, process, and store donated cord blood. Cord blood is collected from umbilical cords of women delivering healthy babies at term. Public banks involve donation of cord blood by an individual for use by the public when an allogeneic donor is required for transplantation. At present there are >400,000 cord blood units stored in banks for public use (Ballen, 2010). Public programs are funded by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH), the National Marrow Donor Program (NMDP), the American Red Cross, and others, and do not charge for the donation.

The banking of cord blood for private use is a controversial issue. Private cord blood banks, which charge for the collection and storage of the donated umbilical cord blood, were initially established for autologous use by a specific child who might develop a disease later in life. More recently, private banks have promoted their services for collection and storage of cord blood for potential use by siblings and parents. The premise is one of biological insurance for the potential need of stem cells. At present >900,000 cord blood units are stored in private banks (Ballen, 2010). The likelihood of a child requiring a transplant with its own cord blood is small. This number is difficult to quantify but probably is as low as 0.04% (1:2500) to 0.0005% (1: 200000) in the first 20 years of life (Ballen, 2008). The type of disorder and the need for autologous cells versus allogeneic cells determines the actual potential for use of these cells (Moise, 2005). Concerns about storage of cord blood units for personal use include the small probability of need, the possibility of latent disease being present in the cells, and the quality and viability of stored units.

Although private banking of umbilical cord blood in the general population is not recommended, collection and storage of these cells may be appropriate for selected individuals when hematologic transplantation using umbilical cord blood cells is planned or expected in the near future.

U.S. Food and Drug Administration (FDA)

The FDA passed Good Tissue Practice regulations in the Federal Register of 2001 which apply to human cellular and tissue products used for transplantation, including standards for collection, storage, documentation and labeling, and cord blood banking operations, and require companies supplying human cells, tissue, and cellular and tissue-based products to register and list their products with the FDA.

Cord blood stored for personal use and for use in first- or second-degree relatives that also meets other criteria in FDA's regulations does not require approval before use. Private cord banks must still comply with other FDA requirements, including establishment registration and listing, donor screening and testing for infectious diseases (except when used for the original donor), reporting and labeling requirements, and compliance with current good tissue practice regulations. Cord blood stored for potential future use by a patient unrelated to the donor meets the definition of "drug" under the Food, Drug & Cosmetic Act and "biological product" under Section 351 of the Public Health Service Act. Cord blood in this category must meet additional requirements and be licensed under a biologics license application (BLA), or subject to an investigational new drug application (IND) before use.

Cord blood can be used in hematopoietic stem cell transplantation procedures in patients with some disorders affecting the hematopoietic (blood forming) system. For example, cord blood transplants have been used to treat patients with certain blood cancers and some inherited metabolic and immune system disorders (FDA, 2012).

Professional Societies/Organizations

American College of Obstetrics and Gynecology (ACOG): The ACOG Committee Opinion (Number 771, March 2019) makes the following recommendations regarding Umbilical Cord Blood Banking:

- Umbilical cord blood collected from a neonate cannot be used to treat a genetic disease or malignancy in that same individual (autologous transplant) because stored cord blood contains the same genetic variant or premalignant cells that led to the condition being treated.
- The routine collection and storage of umbilical cord blood with a private cord blood bank is not supported by the available evidence.
- The current indications for umbilical cord blood transplantation are limited to select genetic, hematologic, and malignant disorders.
- Private umbilical cord blood banking may be considered when there is knowledge of a family member with a medical condition (malignant or genetic) who could potentially benefit from cord blood transplantation.
- Public umbilical cord blood banking is the recommended method of obtaining umbilical cord blood for use in transplantation, immune therapies, or other medically validated indications.
- Families of all ethnicities and races should consider the societal benefit of public umbilical cord blood donation to increase the availability of matched cord blood units for people of all backgrounds.
- Obstetrician–gynecologists and other obstetric care providers should be aware of state and local laws regarding umbilical cord blood banking, including the law in some states that requires physicians to inform patients about umbilical cord blood banking options.
- Health care providers with a financial interest in private umbilical cord blood banking should disclose these interests, incentives, or other potential conflicts of interest.
- If a patient requests information about umbilical cord blood banking, balanced and accurate information regarding the advantages and disadvantages of public and private umbilical cord blood banking should be provided.
- A variety of circumstances may arise during the process of labor and delivery that may preclude adequate collection.
- Umbilical cord blood collection should not compromise obstetric or neonatal care or alter routine practice of delayed umbilical cord clamping with the rare exception of medical indications for directed donation.
- It is important to inform patients that the medical condition of the woman or neonate may prevent adequate umbilical cord blood collection (ACOG, 2019).

American Academy of Pediatrics (AAP): The AAP published a Policy Statement on Cord Blood Banking for Potential Future Transplantation (Shearer, et al., 2017). Some of the summarized recommendations are as follows:

- 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.
- 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.
- 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.

American Medical Association (AMA): The AMA (2007) notes "Umbilical cord blood stem cells are useful for some therapeutic purposes." Further, "The utility of umbilical cord blood stem cells is greater when the donation

is to a public rather than private bank. Therefore, physicians should encourage women who wish to donate cord blood to donate to a public bank if one is available.” The AMA also notes “Private banking should be considered in the unusual circumstance when there exists a family predisposition to a condition in which umbilical cord stem cells are therapeutically indicated. However, because of cost, limited likelihood of use, and inaccessibility to others, private banking should not be recommended to low-risk families.”

American Society for Blood and Marrow Transplantation (ASBMT): Located on the current Policy Statements webpage, the ASBMT (Ballen, et al., 2008) published recommendations related to public and private banking of umbilical cord blood:

- public banking of cord blood is encouraged where possible
- storage of cord blood for 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

Use Outside of the US

The Society of Obstetricians and Gynaecologists of Canada (SOGC) Clinical Practice Guideline on Umbilical Cord Blood: Counselling, Collection, and Banking provides recommendations for education, counselling, obtaining informed consent, collection, and storage of umbilical cord blood (Armson, et al., 2015).

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found.	
LCD		No Local Coverage Determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage

HCPCS Codes	Description
S2140	Cord blood harvesting for transplantation, allogeneic

***Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

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