Medical Coverage Policy

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Umbilical Cord Blood Banking

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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. 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. 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). Private cord blood bank marketing advertises hypothetical future treatments (e.g., speculative future cell therapies that do not exist); this can be misleading (Murdoch,et al., 2020). 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.

According to the Cord Blood Association December 2021 Fact sheet, there are more than 800,000 units of cord blood stored in public banks around the world and more than 6 million units of cord blood stored in in nearly 200 private or family cord blood banks in 60 countries.

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).

The ACOG Committee Opinion (Number 814 December 2020, Interim Update that replaces Committee Opinion 684, January 2017) regarding Delayed Umbilical Cord Clamping After Birth states that in cases in which a patient and family are planning donation of umbilical cord blood, immediate cord clamping may increase the yield of cord blood obtained. However, 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 (ACOG, 2020).

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 Code of Medical Ethics Opinion 6.1.5. Umbilical Cord Blood Banking states the following:

Transplants of umbilical cord blood have been recommended or performed to treat a variety of conditions. Cord blood is also a potential source of stem and progenitor cells with possible therapeutic applications. Nonetheless, collection and storage of cord blood raise ethical concerns with regard to patient safety, autonomy, and potential for conflict of interest. In addition, storage of umbilical cord blood in private as opposed to public banks can raise concerns about access to cord blood for transplantation. Physicians who provide obstetrical care should be prepared to inform pregnant women of the various options regarding cord blood donation or storage and the potential uses of donated samples. Physicians who participate in collecting umbilical cord blood for storage should:

- Ensure that collection procedures do not interfere with standard delivery practices or the safety of a newborn or the mother.
- Obtain informed consent for the collection of umbilical cord blood stem cells before the onset of labor whenever feasible. Physicians should disclose their ties to cord blood banks, public or private, as part of the informed consent process.
- Decline financial or other inducements for providing samples to cord blood banks.
- Encourage women who wish to donate umbilical cord blood to donate to a public bank if one is available when there is low risk of predisposition to a condition for which umbilical cord blood cells are therapeutically indicated:
  - In view of the cost of private banking and limited likelihood of use
  - To help increase availability of stem cells for transplantation
- Discuss the option of private banking of umbilical cord blood when there is a family predisposition to a condition for which umbilical cord stem cells are therapeutically indicated.
- Continue to monitor ongoing research into the safety and effectiveness of various methods of cord blood collection and use.

American Society for Blood and Marrow Transplantation (ASBMT): 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.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Determination found.	
LCD		No Determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination.)

Coding 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

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