Umbilical Cord Blood Banking

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.
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.

The worldwide proliferation of cord blood banks has raised questions related to accessibility; the adequacies of the cord blood inventories; the standardization of cord blood collection, processing, and storage methods and documentation; and quality control (National Academy of Science, 2005). The AABB (formerly known as the American Association of Blood Banks) and the Foundation for Accreditation of Cellular Therapy (FACT-NETCORD) have created guidelines pertaining to collection, testing, processing, and banking of umbilical cord blood for transplantation and accreditation of the banking facility.

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): ACOG (December 2015) Committee Opinion on Umbilical Cord Blood Banking notes that once considered a waste product that was discarded with the placenta, umbilical cord blood is now known to contain potentially life-saving hematopoietic stem cells. When used in hematopoietic stem cell transplantation, umbilical cord blood offers several distinct advantages over bone marrow or peripheral stem cells. However, umbilical cord blood collection is not part of routine obstetric care and is not medically indicated. Umbilical cord blood collection should not compromise obstetric or neonatal care or alter routine practice for the timing of umbilical cord clamping. If a patient requests information on umbilical cord blood banking, balanced and accurate information regarding the advantages and disadvantages of public and private umbilical cord blood banking should be provided. The routine storage of umbilical cord blood as “biologic insurance” against future disease is not recommended. Under Recommendations, ACOG states “The current indications for cord blood transplant are limited to select genetic, hematologic, and malignant disorders”.

ACOG (January 2017) Committee Opinion on Delayed Umbilical Cord Clamping After Birth addresses Effect on Umbilical Cord Blood Banking, noting 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.

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**

**Royal College of Obstetricians and Gynaecologists:** The College (2006) notes, “There is still insufficient evidence to recommend directed commercial cord blood collection and stem-cell storage in low-risk families.” Likewise, the French National Consultative Ethics Committee’s recommendation to decision makers is that they should encourage a considerable extension of cord blood public banks for essentially allogeneic purposes, rather than subscribing to the creation of private banks for strictly autologous purposes, the potential therapeutic usefulness of which, is, as of yet, in no way corroborated (Moise, 2005).

**Coding/Billing Information**

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

- 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:**

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**References**


https://www.ama-assn.org/search/ama-assn/Umbilical%20cord%20blood


