

# Umbilical Cord Blood Harvesting and Storage for Future Use

**Policy Number:** OUTPATIENT 040.20  
**Effective Date:** July 1, 2024

[Instructions for Use](#)

Table of Contents	Page
<a href="#">Coverage Rationale</a> .....	1
<a href="#">Applicable Codes</a> .....	1
<a href="#">Description of Services</a> .....	1
<a href="#">Clinical Evidence</a> .....	2
<a href="#">U.S. Food and Drug Administration</a> .....	3
<a href="#">References</a> .....	3
<a href="#">Policy History/Revision Information</a> .....	4
<a href="#">Instructions for Use</a> .....	4

Related Optum Clinical Guideline
<ul style="list-style-type: none"> <li><a href="#">Hematopoietic Stem Cell Transplantation</a></li> </ul>

## Coverage Rationale

Due to insufficient evidence of efficacy, collection and storage of umbilical cord blood is unproven and not medically necessary for a person who is currently healthy but desiring to provide the opportunity for a hypothetical, future transplantation.

For additional information and coverage of umbilical cord blood stem cell transplantation, refer to the Optum Clinical Guideline titled [Hematopoietic Stem Cell Transplantation](#).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	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
88240	Cryopreservation, freezing and storage of cells, each cell line

*CPT® is a registered trademark of the American Medical Association*

HCPCS Code	Description
S2140	Cord blood harvesting for transplantation, allogeneic

## Description of Services

Umbilical cord and placental blood are rich in stem cells that can be used to treat diseases such as leukemia, lymphoma, myeloma, aplastic anemia, and certain immunologic and metabolic disorders. Cord blood banking is a process of

salvaging the umbilical cord and placental blood and storing it for future transplant procedures by cryogenically freezing it immediately after the birthing process.

Use of cord blood as a source of hematopoietic (blood-forming) stem cells has led to the establishment of cord blood banks worldwide. Private cord blood banks store cord blood for future use by the child (autologous) or a family member (allogeneic) should the need arise. Public cord blood banks accept cord blood donations and make them available to anyone in need of a transplant due to illness.

## Clinical Evidence

A search of the published clinical evidence did not find any studies evaluating the storage of umbilical cord blood for hypothetical future use.

### Clinical Practice Guidelines

#### *American Academy of Pediatrics*

In a policy statement, the AAP states that although private cord blood banks serve parents who elect to store cord blood for potential self-use later in life, there is little evidence supporting use for this purpose. Accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation should be provided. Parents should be informed 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 is no scientific data to support the claim that autologous cord blood is a tissue source proven to be of value for regenerative medical purposes. (Shearer et al., 2017)

#### *American College of Obstetrics and Gynecology (ACOG)*

An ACOG committee opinion states that if a patient requests information about umbilical cord blood banking, balanced and accurate information regarding the advantages and disadvantages of public and private banking should be provided. 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 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 that could benefit from cord blood transplantation. They also state that the routine collection and storage of umbilical cord blood with a private cord blood bank is not supported by the available evidence. Patients should be made aware of the financial obligation for processing and annual storage fees related to for-profit cord blood banks. Families may consider the societal benefit from public umbilical cord blood donation to increase the chance for all groups of finding a matched cord blood unit. (ACOG, 2019)

In a separate FAQ, ACOG states that storing a child's stem cells in a private bank as "insurance" against future disease is not recommended. (ACOG, 2020; last updated February 2021; last reviewed July 2022)

#### *American Medical Association (AMA)*

In a report from the Council on Ethical and Judicial Affairs the AMA states that umbilical cord blood stem cells are useful for some therapeutic purposes and that the utility of umbilical cord blood stem cells is greater when the donation is to a public rather than private bank. Physicians should encourage women who wish to donate cord blood to donate to a public bank if one is available. The AMA also indicates that private banking should be considered in the unusual circumstance when 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. (AMA, 2007)

#### *American Society for Blood and Marrow Transplantation (ASBMT)*

ASBMT published the following recommendations related to banking of umbilical cord blood:

- Public banking of cord blood is encouraged where possible
- Storage of cord blood for personal use is not recommended
- 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 human leukocyte antigen (HLA)-antigens between the parents (Ballen et al., 2008)

## **Royal College of Obstetricians and Gynaecologists (RCOG)**

RCOG states that collection of non-directed donations and directed donations for at-risk families are acceptable procedures through established public sector cord blood banks. However, there is still insufficient evidence to recommend directed commercial cord blood collection and stem-cell storage in low-risk families. (RCOG, 2006)

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. July 2012.

<http://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm236044.htm>. (Accessed March 14, 2024)

Center for Biologics Evaluation and Research. Guidance for Industry and FDA Staff. Investigational New Drug applications for minimally manipulated unrelated allogeneic placental/umbilical cord blood intended for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system. March 2014.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ind-applications-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended>. (Accessed March 14, 2024)

## **References**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0109X]

American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion #771. Umbilical cord blood banking. 2019. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking>. Accessed March 14, 2024.

American College of Obstetricians and Gynecologists (ACOG). FAQ 172. Cord Blood Banking. Frequently Asked Questions: Pregnancy. Last updated February 2021. Last reviewed July 2022. Available at: <https://www.acog.org/patient-resources/faqs/pregnancy/cord-blood-banking>. Accessed March 14, 2024.

American Medical Association (AMA). Report of the Council on Ethical and Judicial Affairs. Umbilical cord blood banking. CEJA Report 9-I-07. 2007. Available at: <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i07-ceja-umbilical-cord-blood-banking.pdf>. Accessed March 14, 2024.

Ballen KK, Barker JN, Stewart SK, et al. American Society for Blood and Marrow Transplantation (ASBMT) Committee Report. Collection and preservation of cord blood for personal use. Biol Blood Marrow Transplant. 2008 Mar; 14(3):356-63.

Brunstein CG, Wagner JE. Umbilical cord blood transplantation and banking. Annu Rev Med. 2006;57:403-17.

Kurtzberg J, Lyerty A, Sugarman J. Untying the Gordian knot: policies, practices and ethical issues related to banking of umbilical cord blood. J Clin Invest. 2005 Oct. 115(10):2592-7.

Leukemia and Lymphoma Society. Cord blood stem cell transplantation. August 2007. Available at: [https://www.lls.org/sites/default/files/file\\_assets/cordbloodstemcelltransplantation.pdf](https://www.lls.org/sites/default/files/file_assets/cordbloodstemcelltransplantation.pdf). Accessed March 14, 2024.

Martin PL, Kurtzberg J, Hesse B. Umbilical cord blood: a guide for primary care physicians. Am Fam Physician. 2011 Sep 15; 84(6):661-6.

Royal College of Obstetricians and Gynaecologists (RCOG). Umbilical cord blood banking. Scientific Impact Paper #2. June 2006. Available at: [https://www.rcog.org.uk/media/24pjeoia/sip\\_2.pdf](https://www.rcog.org.uk/media/24pjeoia/sip_2.pdf). Accessed March 14, 2024.

Shearer WT, Lubin BH, Cairo MS, Notarangelo LD; Section on Hematology/Oncology; Section on Allergy and Immunology. Cord blood banking for potential future transplantation. Pediatrics. 2017 Nov;140(5):e20172695.

## Policy History/Revision Information

Date	Summary of Changes
07/01/2024	<ul style="list-style-type: none"><li data-bbox="337 205 971 233">• Routine review; no change to coverage guidelines</li><li data-bbox="337 235 1029 262">• Archived previous policy version OUTPATIENT 040.19</li></ul>

## Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual<sup>®</sup> criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.