

UMBILICAL CORD BLOOD HARVESTING AND STORAGE FOR FUTURE USE

Policy Number: 2019T0109P

Effective Date: January 1, 2019

[Instructions for Use](#) ⓘ

Table of Contents	Page
COVERAGE RATIONALE	1
APPLICABLE CODES	1
DESCRIPTION OF SERVICES	1
CLINICAL EVIDENCE	2
U.S. FOOD AND DRUG ADMINISTRATION	3
CENTERS FOR MEDICARE AND MEDICAID SERVICES	3
REFERENCES	3
POLICY HISTORY/REVISION INFORMATION	4
INSTRUCTIONS FOR USE	4

Related Commercial Policy

- [Transplant Review Guidelines: Hematopoietic Stem Cell Transplantation](#)

Community Plan Policy

- [Umbilical Cord Blood Harvesting and Storage for Future Use](#)

Medicare Advantage Coverage Summary

- [Transplants: Organ and Tissue Transplants](#)

COVERAGE RATIONALE

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 due to insufficient evidence of efficacy.

For additional information and coverage of umbilical cord blood stem cell transplantation, refer to the UnitedHealth Group [Transplant Review Guidelines: 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 and Coverage Determination Guidelines 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.

Professional Societies

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. 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, 2015; reaffirmed 2018).

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, 2016).

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)

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.

<http://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm236044.htm>. (Accessed May 2, 2018)

Establishments that supply human cells, tissues and cellular or tissue-based products regulated solely under section 361 of the Public Health Service Act are required to register with FDA pursuant to 21 CFR Part 1271. See the following website for more information:

<https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/IssueEstablishmentRegistration/default.htm>. (Accessed May 2, 2018)

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. Available at:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM415907.pdf>. (Accessed May 2, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for umbilical cord blood collection and/or storage. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed May 3, 2018)

REFERENCES

American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion #648. Umbilical cord blood banking. December 2015. Reaffirmed 2018.

American College of Obstetricians and Gynecologists (ACOG). FAQ 172. Cord blood banking. February 2016. Available at: <https://www.acog.org/-/media/For-Patients/faq172.pdf?dmc=1&ts=20160504T0902267844>. Accessed May 2, 2018.

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 May 2, 2018.

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 C, Wagner J. Umbilical cord blood transplantation and banking. Ann Rev Med. February 2006;57:403-417.

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: <http://www.lls.org/content/nationalcontent/resourcecenter/freeeducationmaterials/treatments/pdf/cordbloodstemcelltransplantation.pdf>. Accessed May 2, 2018.

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/globalassets/documents/guidelines/scientific-impact-papers/sip_2.pdf. Accessed May 2, 2018.

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). pii: e20172695.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none">• Reorganized policy template:<ul style="list-style-type: none">○ Simplified and relocated <i>Instructions for Use</i>○ Removed <i>Benefit Considerations</i> section• Simplified coverage rationale (no change to guidelines)• Updated supporting information to reflect the most current references• Archived previous policy version 2018T01090

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare 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 reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical 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.