Umbilical Cord Blood Harvesting and Storage for Future Use

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Instructions for Use

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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 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 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

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. 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, 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)

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.
http://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm236044.htm. (Accessed May 14, 2020)

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/TissueEstablishmentRegistration/default.htm. (Accessed May 14, 2020)

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.
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM415907.pdf. (Accessed May 14, 2020)

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. (Accessed May 20, 2020)

References

American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion #771. Umbilical cord blood banking. 2019. https://pubmed.ncbi.nlm.nih.gov/30801478/. Accessed May 14, 2020.

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ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i07-ceja-umbilical-cord-blood-banking.pdf. Accessed May 14, 2020.

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.

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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 14, 2020.

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Policy History/Revision Information

Date	Summary of Changes
08/01/2020	Template Update • Reformatted policy; transferred content to new template
07/01/2020	Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version 2019T0109Q

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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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.