UMBILICAL CORD BLOOD HARVESTING AND STORAGE FOR FUTURE USE

Policy Number: 2017T0109M

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, 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. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Some benefit documents specifically exclude coverage for long term storage (more than 30 days). Examples include, but are not limited to, long term storage of blood, blood products, sperm, eggs and any other body parts.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Collection and storage of umbilical cord blood for possible later use is unproven and not medically necessary for a person currently healthy but desiring to provide the opportunity for a hypothetical, future transplantation.
Published clinical evidence on the use of umbilical cord blood is limited to diagnosis-specific indications for persons who would otherwise be eligible for bone marrow or stem cell transplants. Current available clinical evidence does not support the hypothesis that storage for hypothetical future use improves health outcomes.

For additional information and coverage of umbilical cord blood stem cell transplantation, please refer to the UnitedHealth Group Hematopoietic Stem Cell Transplantation Review Guidelines.

**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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>38205</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic</td>
</tr>
<tr>
<td>38206</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous</td>
</tr>
<tr>
<td>38207</td>
<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
</tr>
<tr>
<td>88240</td>
<td>Cryopreservation, freezing and storage of cells, each cell line</td>
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</tbody>
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*CPT® is a registered trademark of the American Medical Association*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
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</table>

**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 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).
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.


A rule published in the 2001 Federal Register requires that establishments supplying human cells, tissue and cellular or tissue-based products register and list their products with the FDA. The final rule also lists regulations that must be observed related to donor selection and tissue processing. See the following website for more information:


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:


**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 April 27, 2017)

**REFERENCES**


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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| 07/01/2017 | Updated list of related policies:  
|            | o Added reference link to Clinical Guideline titled Hematopoietic Stem Cell Transplantation Review Guidelines  
|            | o Removed reference link to Clinical Guideline titled Transplant Review Guidelines  
|            | Updated benefit considerations:  
|            | o Removed language indicating long term storage services do not meet the definition of a Covered Health Service  
|            | o Modified list of examples of long term storage service exclusions; replaced “any other body or body parts” with “any other body parts”  
|            | Updated coverage rationale:  
|            | o Modified language pertaining to clinical evidence/study findings; replaced language indicating “published clinical evidence on the use of umbilical cord blood is limited to diagnosis-specific indications for persons who would otherwise be eligible for human leukocyte antigen (HLA)-compatible allogeneic bone marrow or stem cell transplants” with “published clinical evidence on the use of umbilical cord blood is limited to diagnosis-specific indications for persons who would otherwise be eligible for bone marrow or stem cell transplants”  
|            | Updated supporting information to reflect the most current clinical evidence and references  
|            | Archived previous policy version 2016T0109L |