UMBILICAL CORD BLOOD HARVESTING AND STORAGE FOR FUTURE USE

Policy Number: 2014T0109J  
Effective Date: August 1, 2014

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit 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

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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
Long term storage services are not a Covered Health Service. In the 2001 Certificate of Coverage (COC), long term storage services are excluded per the exclusion for services not meeting the definition of a Covered Health Service. The 2007/2011 COCs 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 or body parts.

**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 human leukocyte antigen (HLA)-compatible allogeneic 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 [Transplant Review Guidelines](#).

**APPLICABLE CODES**

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<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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<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
</tbody>
</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.
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 (AAP)
In a 2007 policy statement, the AAP states that cord blood donation should be discouraged when cord blood stored in a bank is to be directed for later personal or family use, because most conditions that might be helped by cord blood stem cells already exist in the infant’s cord blood. Cord blood donation should be encouraged when the cord blood is stored in a bank for public use. In addition, because there are no scientific data at the present time to support autologous cord blood banking and given the difficulty of making an accurate estimate of the need for autologous transplantation and the ready availability of allogeneic transplantation, private storage of cord blood as "biological insurance" should be discouraged (AAP, 2007).

Institutions or organizations (private or public) involved in cord blood banking should consider the following recommendations:

1. Cord blood-banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women and their families and friends. Efforts should be made to minimize the effect of this vulnerability on cord blood-banking decisions.

2. 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. Parents should recognize that 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.

3. A policy should be developed by cord blood banks regarding disclosing to the parents any abnormal findings in the harvested blood.

4. Specific permission for maintaining demographic medical information should be obtained, and the potential risks of breaches of confidentiality should be disclosed.

5. Written permission for obtaining cord blood should be obtained before onset of active labor.

6. If the cord blood bank is conducting research, an institutional review board must review and approve recruitment strategies and consent forms.

7. Cord blood collection should not be performed in complicated deliveries. The cord blood stem cell collection program should not alter routine practice for the timing of umbilical cord clamping.

8. Regulatory agencies (e.g., U.S. Food and Drug Administration (FDA), Federal Trade Commission, and state equivalents of these federal agencies) are encouraged to have an active role in providing oversight of the cord blood program. All cord blood-banking programs should comply with Foundation for the Accreditation of Cellular Therapy (FACT or equivalent accreditation standards.

9. Physicians or other professionals who recruit pregnant women and their families for for-profit placental cord blood stem cell banking should disclose any financial interest or
other potential conflict of interest they have in the procedure to their patients.

10. Professionals affiliated with institutions or organizations that promote for-profit placental blood stem cell banking should make annual financial-disclosure and potential-conflicts-of-interest statements to an appropriate institutional review committee that possesses oversight authority.

11. Targeted efforts should be made to recruit underserved minorities (black, Hispanic, American Indian/Alaska Native individuals) in public cord blood banking programs to extend to them potential treatments afforded other segments of society (AAP, 2007).

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

In a committee opinion on umbilical cord blood banking, ACOG states that balanced and accurate information regarding the advantages and disadvantages of public versus private cord blood banking should be provided if a patient requests information on umbilical cord blood banking. The remote chance of an autologous unit being used for a child or family member (approximately 1 in 2,700 individuals) should be disclosed. ACOG also states that directed donation should be considered when there is a specific diagnosis of a disease known to be treatable by hematopoietic transplant for an immediate family member (ACOG, 2008; reaffirmed 2012).

**American Medical Association (AMA)**

In a report of the council of ethical and judicial affairs on umbilical cord blood banking, 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)**

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 Web site for more information: [http://www.fda.gov/OHRMS/DOCKETS/98fr/97N-484S-nfr0001.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/97N-484S-nfr0001.pdf). Accessed April 24, 2014.

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 for umbilical cord blood collection and/or storage. However, there are LCDs that mention cell cryopreservation/storage. Refer to the LCDs for Cyogenetic Analysis and Cyogenetic Analysis. (Accessed April 25, 2014)

REFERENCES


**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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| 08/01/2014 | - Reorganized policy content  
- Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate:  
  - 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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage  
- Updated coverage rationale; added language to indicate the unproven service is “not medically necessary”  
- Updated supporting information to reflect the most current FDA and CMS information and references  
- Archived previous policy version 2013T0109I |