



Cigna Medical Coverage Policy

Effective Date 6/15/2014
Next Review Date 6/15/2015
Coverage Policy Number 0466

Subject **Umbilical Cord Blood Banking**

Table of Contents

Coverage Policy	1
General Background.....	1
Coding/Billing Information	3
References.....	4

Hyperlink to Related Coverage Policies

[Transplantation Donor Charges](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Cigna covers collection and storage costs associated with the banking of umbilical cord blood as medically necessary when hematopoietic transplantation using cord blood cells is planned for a recipient who is covered under the plan.

In the absence of a planned or expected hematopoietic transplantation where cord blood cells will be required, Cigna does not cover collection and storage costs associated with the banking of umbilical cord blood because it is considered not medically necessary.

General Background

Umbilical cord blood, also known as cord blood, is the blood left in the umbilical cord and placenta after the baby is born and the cord is cut. It contains both hematopoietic stem cells and pluripotent mesenchymal cells which may be used in the treatment of some types of leukemias, lymphomas, hemoglobinopathies, immunodeficiencies and inborn errors of metabolism. Umbilical cord blood has been shown to be effective as an alternative source of hematopoietic cells for transplantation and its use in transplantation of selected children with various disorders is a standard of care. Due to the use of better banking techniques, reduced intensity transplants, and double cord blood transplantation, the majority of cord blood transplants are being performed in adults (Ballen, 2010).

Advantages to the use of umbilical cord blood compared with peripheral blood or bone marrow include a large available supply, the units are available on short notice, ethnic diversity is easier to achieve, painless collection

of stem cells, higher proliferative capacity, and a lower rate of acute graft-versus-host disease. Compared with adult peripheral blood stem cells, cells found in the umbilical cord have immune innocence because of their minimal previous exposure to antigens. Because of this the cord blood cells have a reduced capacity to elicit an immune response against a recipient, and there is somewhat less likelihood of graft-versus-host disease. Disadvantages include the inability to obtain additional donor cells, fewer total cells due to small volumes, slower engraftment and high up-front costs (Moise, 2005). Although cord blood units have high concentrations of hematopoietic progenitor cells, they have relatively small volumes and fewer total cells. Very low cell doses can result in a higher risk of non-engraftment, especially in larger children and adults.

The recognition of umbilical cord blood as an appropriate source of stem cells for transplantation has led to the establishment of public, private, and directed-donation facilities, also known as 'banks', to collect, process, and store donated cord blood. Cord blood is collected from umbilical cords of women delivering healthy babies at term. Public banks involve donation of cord blood by an individual for use by the public when an allogeneic donor is required for transplantation. At present there are >400,000 cord blood units stored in banks for public use (Ballen, 2010). Public programs are funded by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH), the National Marrow Donor Program (NMDP), the American Red Cross, and others, and do not charge for the donation.

The banking of cord blood for private use is a controversial issue. Private cord blood banks, which charge for the collection and storage of the donated umbilical cord blood, were initially established for autologous use by a specific child who might develop a disease later in life. More recently, private banks have promoted their services for collection and storage of cord blood for potential use by siblings and parents. The premise is one of biological insurance for the potential need of stem cells. At present >900,000 cord blood units are stored in private banks (Ballen, 2010). According to the American Academy of Pediatrics ([AAP], 2007), empirical evidence that children could use their own cord blood for future use is lacking; the likelihood of a child requiring a transplant with its own cord blood is small. This number is difficult to quantify but probably is as low as 0.04% (1:2500) to 0.0005% (1: 200000) in the first 20 years of life (Ballen, 2008). The type of disorder and the need for autologous cells versus allogeneic cells determines the actual potential for use of these cells (Moise, 2005). Concerns about storage of cord blood units for personal use include the small probability of need, the possibility of latent disease being present in the cells, and the quality and viability of stored units.

The worldwide proliferation of cord blood banks has raised questions related to accessibility; the adequacies of the cord blood inventories; the standardization of cord blood collection, processing, and storage methods and documentation; and quality control (Institutes of Medicine [IOM], 2005). The AABB (formerly known as the American Association of Blood Banks) and the Foundation for Accreditation of Cellular Therapy (FACT-NETCORD) have created guidelines pertaining to collection, testing, processing, and banking of umbilical cord blood for transplantation and accreditation of the banking facility.

Although private banking of umbilical cord blood in the general population is not recommended, collection and storage of these cells may be appropriate for selected individuals when hematologic transplantation using umbilical cord blood cells is planned or expected in the near future.

U.S. Food and Drug Administration (FDA)

The FDA passed Good Tissue Practice regulations in the Federal Register of 2001 which apply to human cellular and tissue products used for transplantation, including standards for collection, storage, documentation and labeling, and cord blood banking operations, and require companies supplying human cells, tissue, and cellular and tissue-based products to register and list their products with the FDA.

Professional Societies/Organizations

American Academy of Pediatrics (AAP): The AAP (2007) notes "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 (i.e. premalignant changes in stem cells)." In addition, "Cord blood donation should be encouraged when the cord blood is stored in a bank for public use." The Recommendations further note " 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."

American College of Obstetrics and Gynecology (ACOG): ACOG (2008, reaffirmed 2012) notes “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. 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.”

American Medical Association (AMA): The AMA (2007) notes “Umbilical cord blood stem cells are useful for some therapeutic purposes.” Further, “The utility of umbilical cord blood stem cells is greater when the donation is to a public rather than private bank. Therefore, physicians should encourage women who wish to donate cord blood to donate to a public bank if one is available.” The AMA also notes “Private banking should be considered in the unusual circumstance when there exists 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.”

American Society for Blood and Marrow Transplantation (ASBMT): On behalf of the ASBMT, Ballen et al. (2008) published recommendations related to public and private banking of umbilical cord blood:

- “public banking of cord blood is encouraged where possible
- storage of cord blood for personal use is not recommended
- family member banking (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 HLA-antigens between the parents”

Use Outside of the US

Royal College of Obstetricians and Gynaecologists: The College (2006) notes, “There is still insufficient evidence to recommend directed commercial cord blood collection and stem-cell storage in low-risk families.” Likewise, the French National Consultative Ethics Committee’s recommendation to decision makers is that they should encourage a considerable extension of cord blood public banks for essentially allogeneic purposes, rather than subscribing to the creation of private banks for strictly autologous purposes, the potential therapeutic usefulness of which, is, as of yet, in no way corroborated (Moise, 2005).

Summary

The use of umbilical cord blood is an established treatment modality for hematopoietic transplantation. Collection and storage of umbilical cord blood may be appropriate for selected individuals when hematologic transplantation using umbilical cord blood cells is planned or expected within the next 36 months.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary:

CPT®*	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.

HCPCS	Description
-------	-------------

Codes	
S2140	Cord blood harvesting for transplantation, allogeneic

***Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.**

References

1. AABB. Umbilical cord blood donation FAQs. AABB © 2014. Accessed May 5, 2014. Available at URL address: <http://www.aabb.org/sa/facilities/celltherapy/Pages/cordbloodfaqs.aspx>
2. American Academy of Pediatrics Section on Hematology/Oncology; American Academy of Pediatrics Section on Allergy/Immunology; Lubin BH, Shearer WT. Cord blood banking for potential future transplantation. *Pediatrics*. 2007 Jan;119(1):165-70.
3. American College of Obstetricians and Gynecologists (ACOG). Committee on Obstetric Practice, Committee on Genetics. ACOG Committee opinion number 399, February 2008, reaffirmed 2012: umbilical cord blood banking. *Obstet Gynecol*. 2008 Feb;111(2 Pt 1): 475-7.
4. American Medical Association. Report of the Council on Ethical and Judicial Affairs: Umbilical cord blood banking. CEJA Report 9-I-07. Accessed May 5, 2014. Available at URL address: <http://www.ama-assn.org/resources/doc/code-medical-ethics/2165a.pdf>
5. Ballen K. Challenges in umbilical cord blood stem cell banking for stem cell reviews and reports. *Stem Cell Rev*. 2010 Mar;6(1):8-14.
6. Ballen KK, Barker JN, Stewart SK, Greene MF, Lane TA, American Society of Blood and Marrow Transplantation. Collection and preservation of cord blood for personal use. *Biol Blood Marrow Transplant*. 2008 Mar;14(3):356-63.
7. Brunstein C, Wagner J. Umbilical cord blood transplantation and banking. *Ann Rev Med*. 2006 Feb;57:403-417.
8. Cord blood: establishing a national hematopoietic stem cell bank program. Copyright 2014 Institutes of Medicine. National Academies Press. Board on Health Sciences Policy. Washington, DC. 2005. Accessed May 5, 2014. Available at URL address: http://books.nap.edu/openbook.php?record_id=11269#toc
9. Keuhn BM. Pediatrics group recommends public cord blood banking. *JAMA*. 2007 Feb 14;297(6):576.
10. 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.
11. March of Dimes. Umbilical cord blood. ©2014 March of Dimes Foundation. Accessed May 5, 2014. Available at URL address: <http://www.marchofdimes.com/pregnancy/umbilical-cord-blood.aspx>
12. Moise K. Umbilical cord stem cells. *Obstet Gynecol*. 2005 Dec;106(6):1393-407.
13. National Consultative Bioethics Committee for Health and Life Sciences. Umbilical cord blood banks for autologous use or for research. Opinion N074. 2002 Dec 12. Accessed May 5, 2014. Available at URL address: <http://www.ccne-ethique.fr/docs/en/avis074.pdf>
14. National Consultative Bioethics Committee for Health and Life Sciences. Umbilical cord blood banks for autologous use or for research. Opinion N117. 2012 Feb 23. Accessed May 5, 2014. Available at URL address: http://www.ccne-ethique.fr/sites/default/files/publications/avis_117eng.pdf

15. National Cord Blood Program. Cord blood banking. © 2010 National Cord Blood program. Accessed May 5, 2014. Available at URL address:
http://www.nationalcordbloodprogram.org/donation/why_donate_to_public_bank.html
16. National Marrow Donor Program. Cord blood donation: frequently asked questions. Copyright © 1996–2014 National Marrow Donor Program. Accessed May 5, 2014. Available at URL address:
http://marrow.org/Get_Involved/Donate_Cord_Blood/Cord_Blood_FAQs.aspx
17. Royal College of Obstetricians and Gynaecologists. Scientific Advisory Committee Opinion Paper 2. Umbilical cord blood banking. Updated 2006 Jan. Accessed May 5, 2014. Available at URL address:
<http://www.rcog.org.uk/womens-health/clinical-guidance/umbilical-cord-blood-banking>
18. Smythe J, Armitage S, McDonald D, Pamphilon D, Guttridge M, Brown J, et al. Directed sibling cord blood banking for transplantation: the 10-year experience in the national blood service in England. *Stem Cells*. 2007 Aug;25(8):2087-93. Epub 2007 May 17.
19. Sun J, Allison J, McLaughlin C, Sledge L, Waters-Pick B, Wease S, et al. Differences in quality between private and publicly banked umbilical cord blood units: a pilot study of autologous cord blood infusion in children with acquired neurologic disorders. *Transfusion*. 2010 Sep;50(9):1980-7.
20. Templeton A, Braude P. Umbilical cord blood banking and the RCOG. *Lancet*. 2007 Mar 31;369(9567):1077.
21. Thornley I, Eapen M, Sung L, Lee SJ, Davies SM, Joffe S. Private cord blood banking: experiences and views of pediatric hematopoietic cell transplantation physicians. *Pediatrics*. 2009 Mar;123(3):1011-7.
22. U.S. Food and Drug Administration. Tissue and tissue products. Updated 2010 Dec 7. Accessed May 5, 2014. Available at URL address:
<http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>
23. Witte C. Cord blood storage: property and liability issues. *J Legal Med*. 2005.26:275-92.

The registered marks "Cigna" and the "Tree of Life" logo are owned by Cigna Intellectual Property, Inc., licensed for use by Cigna Corporation and its operating subsidiaries. All products and services are provided by or through such operating subsidiaries and not by Cigna Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, Cigna Health and Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation.