



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Umbilical Cord Blood Banking

Table of Contents

Coverage Policy	2
General Background	2
Coding/Billing Information	4
References	6
Policy History	8

Hyperlink to Related Coverage Policies

- Stem-Cell Transplantation for Acute Aplastic Anemia and Fanconi Anemia
- Stem-Cell Transplantation for Acute Lymphocytic/Lymphoblastic Leukemia
- Stem-Cell Transplantation for Acute Myelogenous Leukemia
- Stem-Cell Transplantation for Chronic Lymphocytic Leukemia
- Stem-Cell Transplantation for Chronic Myelogenous Leukemia
- Stem-Cell Transplantation for Hodgkin Disease
- Stem-Cell Transplantation for Inherited Metabolic Disorders
- Stem-Cell Transplantation for Primary Immunodeficiency Disorders
- Stem-Cell Transplantation for Myelodysplastic Syndromes
- Stem-Cell Transplantation for Myelofibrosis
- Stem-Cell Transplantation for Neuroblastoma
- Stem-Cell Transplantation for Non-Hodgkin Lymphoma
- Stem-Cell Transplantation for Sickle Cell Disease and Thalassemia Major
- Stem-Cell Transplantation for Solid Tumors in Children
- Stem-Cell Transplantation for Testicular Cancer
- Transplant Donor Charges

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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 within the next 36 months 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. Compared with adult peripheral blood stem cells, cells found in the umbilical cord have immune naiveté because of their minimal previous exposure to antigens. As such, the cord blood cells have a reduced capacity to elicit an alloreactive response, and there is somewhat less likelihood of graft-versus-host disease.

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. 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 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. A fee is charged when the unit(s) is accessed for transplantation. 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).

The banking of cord blood for private use is a controversial issue. 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) 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”

Institute of Medicine (IOM): The IOM (2005) recommended that the U.S. Department of Health and Human Services establish a new National Cord Blood Policy Board to set rules for the banking and use of lifesaving stem cells derived from donated umbilical cord blood.

European Group on Ethics: In Europe, the practice of private cord banking has been banned by law in Italy since 2002. In 2004, the European Group on Ethics published an Opinion which notes “It is highly hypothetical that cord blood cells kept for autologous use will be of any value in the future. The legitimacy of commercial cord blood banks for autologous uses should be questioned as they sell a service which has no real use regarding therapeutic options.”

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).

World Marrow Donor Association: The Association (2006) supports the establishment of public cord blood banks that are based on altruistic and voluntary cord blood donation. The Association further notes that the storage of cord blood units where there is a clear medical indication should be supported.

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: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	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 Codes	Description
S2140	Cord blood harvesting for transplantation, allogeneic

ICD-9-CM Diagnosis Codes	Description
160.0	Malignant neoplasm of nasal cavities
164.0-164.9	Malignant neoplasm of thymus, heart, and mediastinum
170.9	Malignant neoplasm of bone and articular cartilage, site unspecified
171.4	Malignant neoplasm of connective and other soft tissue of thorax
171.5	Malignant neoplasm of connective and other soft tissue of abdomen
171.7	Malignant neoplasm of connective and other soft tissue of trunk, unspecified site
171.8	Malignant neoplasm of other specified sites of connective and other soft tissue
171.9	Malignant neoplasm of connective and other soft tissue, site unspecified
186.0-186.9	Malignant neoplasm of testis
189.0	Malignant neoplasm of kidney, except pelvis
190.5	Malignant neoplasm of retina
192.0-192.9	Malignant neoplasm of other and unspecified parts of nervous system

191.0-191.9	Malignant neoplasm of brain
192.0-192.9	Malignant neoplasm of other and unspecified parts of nervous system
194.0	Malignant neoplasm of adrenal gland
195.1	Malignant neoplasm of thorax
195.2	Malignant neoplasm of abdomen
200.00-200.88	Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue
201.00-201.98	Hodgkin's disease
202.00-202.88	Other malignant neoplasms of lymphoid and histiocytic tissue
203.00-203.82	Multiple myeloma and immunoproliferative neoplasms
204.00-204.92	Lymphoid leukemia
205.00-205.92	Myeloid leukemia
233.6	Carcinoma in situ of other and unspecified male genital organs
238.4	Neoplasm of uncertain behavior of polycythemia vera
238.72	Low grade myelodysplastic syndrome lesions
238.73	High grade myelodysplastic syndrome lesions
238.74	Myelodysplastic syndrome with 5q deletion
238.75	Myelodysplastic syndrome, unspecified
238.76	Myelofibrosis with myeloid metaplasia
272.7	Lipidoses
277.30	Amyloidosis, unspecified
277.39	Other amyloidosis
277.5	Mucopolysaccharidosis
277.6	Other deficiencies of circulating enzymes
277.86	Peroxisomal disorders
279.01	Selective IgA immunodeficiency
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.06	Common variable immunodeficiency
279.09	Other deficiency of humoral immunity
279.11	DiGeorge's syndrome
279.12	Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
280.9	Iron deficiency anemia, unspecified
282.41-282.49	Thalassemias
282.60-282.69	Sickle-cell disease
284.01	Constitutional red blood cell aplasia
284.09	Other constitutional aplastic anemia
284.89	Other specified aplastic anemias
284.9	Unspecified aplastic anemia
288.1	Functional disorders of polymorphonuclear neutrophils
288.2	Genetic anomalies of leukocytes
289.83	Myelofibrosis
330.0	Leukodystrophy

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	6/15/2008	0466	Umbilical Cord Blood Banking

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