MEDICAL POLICY

Excellus

SUBJECT: PLACENTAL AND UMBILICAL CORD BLOOD AS A SOURCE OF STEM CELLS	**EFFECTIVE DATE: 06/06/01** **REVISED DATE: 01/17/02, 03/20/03, 01/15/04, 01/20/05, 01/19/06** **ARCHIVED DATE: 01/18/07** **EDITED DATE: 10/18/07, 12/18/08, 11/19/09, 6/17/10, 06/16/11, 07/19/12, 07/18/13, 07/17/14, 07/16/15, 07/21/16, 07/20/17, 07/19/18**
POLICY NUMBER: 7.01.48 **CATEGORY: Technology Assessment**	**PAGE: 1 OF: 4**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, transplantation of cord blood stem cells, from related or unrelated donors with sufficient cells per kilogram of recipient body weight to permit timely engraftment, has been medically proven to be effective and therefore, **medically appropriate** when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant but is without an identified hematopoietic stem cell donor.

A transplant is considered imminent when there is a high clinical likelihood that it will occur in the next few months.

II. Based upon our criteria and assessment of the peer-reviewed literature, *prophylactic* collection and storage of cord blood from a neonate for some unspecified future use does not improve patient outcomes and is **not medically necessary** for the following indications:
   A. as an autologous stem cell transplant in the original donor; OR
   B. for some unspecified future use as an allogeneic stem cell transplant in a related or unrelated donor.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

A variety of malignant diseases and non-malignant bone marrow disorders are treated with high dose chemotherapy and/or total body irradiation followed by an infusion of allogeneic stem cells to rescue the patient by re-establishing his/her bone marrow, which has been eradicated by the treatment (myeloablation). The allogeneic stem cells are collected from immunologically compatible donors, either from family members or an unrelated donor identified through a bone marrow donor bank. In many cases, a suitable donor is not found.

Blood harvested from the umbilical cord and placenta shortly after delivery of neonates contains stem and progenitor cells capable of restoring hematopoietic function after myeloablation. These "cord" blood or placental and umbilical cord blood stem cell transplants (PCB-SCT) have been used as an alternative source of allogeneic stem cells transplants. Cord blood is readily available and is thought to be antigenically "naive," thus minimizing the incidence of graft-versus-host disease (GVHD) and permitting the broader use of unrelated cord blood transplants. Retrospective analysis of outcome data demonstrates that recipient body weight influences outcome of PCB SCT primarily by its effect on the cells dose transplanted.

Cord blood for future transplantation should be collected, processed and stored at cord blood banks that adhere to the standards drafted or adopted by appropriate professional organizations (e.g., the Foundation for the Accreditation of Hematopoietic Cell Therapy, the American Association of Blood Banks). The FDA Center for Biologics Evaluation and Research "Tissue Action Plan" is a framework for regulating human tissues, cells, and cell- or tissue-based products to

register with the FDA and list all relevant products. Thus, the plan applies to all aspects of harvesting, processing, storing, banking, and using cord blood stem cells.

RATIONALE:

HLA matched sibling donor UBCT or 0-2 mismatched unrelated donor umbilical cord blood transplant (UBCT) is now an acceptable alternative to bone marrow transplant in the pediatric population. Studies have shown that body weight and age influence outcomes of UCBT. An acceptable dose of cells is required for appropriate engraftment and the number of cells derived from cord blood limits its use in larger individuals. UCB has the advantages of speedy availability; tolerance of 1-2 antigen mismatched, allowing extension of the donor pool and; a low incidence of severe GVHD. The available data show that hematopoietic recovery, as measured by neutrophil and platelet engraftment, is somewhat slower and less frequent among adults than among younger patients transplanted with PCB-SCT. Nevertheless, PCB-SCT restores neutrophil counts in the majority (74-91%) of adult patients. Less data are available to evaluate platelet counts in adults, but 44-55% of patients engrafted in the 2 studies that reported platelet recovery. The American Academy of Pediatrics Workgroup on Core Blood Banking, in its recommendations on information pediatricians can provide to parents, states that 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" is unwise. It should be considered if there is a family member with a current or potential need to undergo a stem cell transplantation. Philanthropic donation at no cost for allogeneic transplantation is encouraged.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic transplantation per donor
HCPCS:	S2140	Cord blood harvesting for transplantation, allogenic
	S2142	Cord blood-derived stem cell transplantation, allogenic
	S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post-transplant care in the global definition
ICD10:	Multiple diagnosis codes (Refer to either the Allogeneic or Autologous transplant policies for diseases for which transplant is medically appropriate.)	

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* key article

KEY WORDS:

Cord blood storage, Placental blood storage, Stem cells.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Stem Cell Transplantation. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=366&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d&