

Protocol

Placental and Umbilical Cord Blood as a Source of Stem Cells

(70150)

Medical Benefit	Effective Date: 04/01/13	Next Review Date: 07/15
Preauthorization	Yes	Review Dates: 04/07, 05/08, 07/11, 07/12, 07/13, 07/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required and must be obtained through Case Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

This Protocol addresses the collection, storage, and transplantation of placental/umbilical cord blood ("cord blood") as a source of stem cells for allogeneic and autologous stem-cell transplantation. Potential indications for use of cord blood are included in the disease-specific reference Protocols.

Background

A variety of malignant diseases and nonmalignant bone marrow disorders are treated with myeloablative therapy followed by infusion of allogeneic stem and progenitor cells collected from immunologically compatible donors, either from family members or an unrelated donor identified through a bone marrow donor bank. In some 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. This "cord" blood has been used as an alternative source of allogeneic stem cells. Cord blood is readily available and is thought to be antigenically "naive," thus hopefully, minimizing the incidence of graft-versus-host disease (GVHD) and permitting the broader use of unrelated cord blood transplants. Unrelated donors are typically typed at low resolution for human leukocyte antigens (HLA) -A and -B and at high resolution only for HLA-DR; HLA matching at four of six loci is considered acceptable. Under this matching protocol, an acceptable donor can be identified for almost any patient. (1) Several cord blood banks have now been developed in Europe and in the U.S.

Regulatory Issues

The U.S. Food and Drug Administration (FDA) requires licensing of establishments and their products for unrelated-donor allogeneic transplant of minimally manipulated placental and umbilical cord blood stem cells. Facilities that prepare cord blood units only for autologous or related-donor transplants are required to register and list their products, adhere to Good Tissue Practices issued by the FDA, and use applicable processes for donor suitability determination. (2)

Other cord blood banks are offering the opportunity of collecting and storing a neonate's cord blood for some unspecified future use in the unlikely event that the child develops a condition that would require autologous transplantation. In addition, some cord blood is collected and stored from a neonate for use by a sibling in whom an allogeneic transplant is anticipated due to a history of leukemia or other condition requiring allogeneic transplant.

As with any biologic product, there are issues unique to cord blood as an unrelated donor source; some of these are as follows:

- Cell dose available is much closer to the minimum needed for engraftment
- Interbank variability in the quantification of hematopoietic potential
- Donors who may have hematologic/immunologic disorders may not have manifested their disease at the time of donation or follow-up
- Units may have been banked years earlier at a time when the collection and storage process may not have reflected current accreditation standards, and,
- The initial product characterization at the end of processing may not reflect the product at the time of release due to freeze, storage, or transport insults. (3)

For the reasons cited above, instituting standards and accreditation for cord blood banks is critical. This will assist transplant programs in knowing whether individual banks have important quality control measures in place to address such issues as monitoring cell loss, change in potency, and prevention of product mix-up. (3) Two major organizations are working toward these accreditation standards; NetCord/FACT and the American Association of Blood Banks (AABB). NetCord, Foundation for the Accreditation of Cellular Therapy (FACT) has developed and implemented a program of voluntary inspection and accreditation for cord blood banking. In September 2012, NetCord and FACT released the fifth edition of international standards for cord blood collection, banking and release. (4) The voluntary program includes standards for collection, testing, processing, storage, and release of cord blood products. As of August 2013, 27 blood banks in the U.S. have been accredited, along with 45 international sites. (5)

The U.S. Food and Drug Administration intends to regulate cord blood banking by requiring Biologic License Applications and/or Investigational New Drug applications by October 2011 for any bank that will supply units to patients in the United States. With the international exchange of cord blood units being integral to the availability of a matched unit, it is unclear how this change will affect the practice of acquiring cord blood units. (6)

It is also important to note umbilical cord blood (UCB) samples are not routinely typed for private banking. This makes it difficult to search for unrelated human leukocyte antigen (HLA)-matched donors in private banks, or to transfer units into a public bank from a private bank. (7)

Policy (Formerly Corporate Medical Guideline)

Transplantation of cord blood stem cells from related or unrelated donors may be considered **medically necessary** in patients with an appropriate indication for allogeneic stem-cell transplant.

Transplantation of cord blood stem cells from related or unrelated donors is considered **investigational** in all other situations.

Collection and storage of cord blood from a neonate may be considered **medically necessary** when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant.

Prophylactic collection and storage of cord blood from a neonate is considered **not medically necessary** when proposed for some unspecified future use as an autologous stem-cell transplant in the original donor, or for some unspecified future use as an allogeneic stem-cell transplant in a related or unrelated donor.

Policy Guidelines

Please refer to the separate Protocols for specific conditions/diseases that have patient selection criteria regarding situations for which allogeneic stem-cell transplantation may be considered **medically necessary**.

Benefit Application

Individual transplant facilities may have their own *additional* requirements or protocols that must be met in order for the patient to be eligible for a transplant at **their** facility.

Medicare Advantage

If a transplant is needed, we arrange to have the transplant center review and decide whether the patient is an appropriate candidate for the transplant.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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