NO. 91459

UMBILICAL CORD BLOOD TESTING AND STORAGE

Effective: 06/01/2026
Committee Review: 05/2026
Last Updated: 05/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy outlines coverage considerations for the testing and storage of umbilical cord blood.

Related policies:

- Stem Cell/Bone Marrow Transplantation #91066

I. MEDICAL NECESSITY CRITERIA

A. Compatibility testing of umbilical cord blood is medically necessary if **all** of the following apply:
   1. An accepted indication for an allogeneic transplant exists. See the Stem Cell/Bone Marrow Transplantation (91066) medical policy for allogeneic transplant coverage criteria.
   2. The intended recipient of the transplant is a first-degree relative (parent, sibling) of the infant.
   3. The intended recipient of the transplant is a current member.

B. Storage of umbilical cord blood is medically necessary if all of the following apply:
   1. A clinically acceptable match is present.

2. An accepted indication for an allogeneic transplant exists. See the Stem Cell/Bone Marrow Transplantation (91066) medical policy for allogeneic transplant coverage criteria
3. The intended recipient of the transplant is a current member.

C. Routine testing, freezing and/or storage of umbilical cord blood for unspecified possible future use are not medically necessary.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD 110.23 –Stem Cell Transplantation	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None Identified
First Coast Service Options, Inc.	None Identified
National Government Services, Inc.	None Identified
Noridian Healthcare Solutions	None Identified
Novitas Solutions, Inc.	None Identified
Palmetto GBA	None Identified
WPS Insurance Corporation	None Identified

III. BACKGROUND

Since the first successful umbilical cord blood transplant in 1988, it has been estimated that more than 35,000 transplants have been performed in children and adults for the correction of inborn errors of metabolism, hematopoietic malignancies, and genetic disorders of the blood and immune system. Two types of banks have emerged for the collection and storage of umbilical cord blood: 1) public banks and 2) private banks. Historically, umbilical cord blood had no identified value and was disposed of with the placenta. Umbilical cord blood is now known to contain hematopoietic stem cells that have potential life-saving benefit. When used in hematopoietic stem cell transplantation, umbilical cord blood offers several distinct advantages compared with bone marrow or peripheral stem cells. Biologically, a greater degree of human leukocyte antigen (HLA) mismatch is tolerated by the recipient and the incidence of acute graft-versus-host reaction is decreased when umbilical cord blood is used compared with unrelated donor

bone marrow. The predominant disadvantage of umbilical cord blood use is that there is often a low yield of stem cells acquired per unit. Only 8–12% of umbilical cord blood units have sufficient cell volume for transplant to a person weighing 80 kg (176 lb). However, the use of combined units of umbilical cord blood allows for the expansion of umbilical cord blood volume (and increased number of stem cells) to be used for adult hematopoietic transplants. (ACOG, 2019)

Umbilical cord blood stem cells can be used as an alternative to a conventional allogeneic bone marrow transplant for a variety of marrow-based disorders, such as leukemia, aplastic anemia and certain inherited metabolic disorders. Storage of umbilical cord blood for private use in the future as "biologic insurance" in case the need arises is not recommended by the American Society of Transplantation and Cellular Therapy (formerly the American Society for Blood and Marrow Transplantation [ASBMT]), the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics. Compatibility testing may be done on chorionic villous sampling (CVS) specimens, amniocytes obtained by amniocentesis, or on the cord blood itself.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Obstetricians and Gynecologists (ACOG)	Committee Opinion No. 771 (2019) Umbilical Cord Blood Banking | ACOG
American Medical Association	Umbilical Cord Blood Banking | AMA-Code (2007)
American Academy of Pediatrics (AAP)	Cord Blood Banking for Potential Future Transplantation Cord Blood Banking for Potential Future Transplantation | Pediatrics | American Academy of Pediatrics (2017)
American Academy of Family Physicians (AAFP)	Umbilical Cord Blood: A Guide for Primary Care Physicians Umbilical Cord Blood: A Guide for Primary Care Physicians (2011)
American Society for Transplantation and Cellular Therapy (ASTCT)	Collection and Preservation of Cord Blood for Personal Use (2008)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date

VI. CODING

ICD-10 Codes that may support medical necessity

Not specified

CPT/HCPCS Codes

No prior auth

59899	Unlisted procedure, maternity care and delivery
38999	Unlisted procedure, hemic or lymphatic system
59000	Amniocentesis; diagnostic
59012	Cordocentesis (intrauterine), any method
59015	Chorionic villus sampling, any method
86812	HLA typing; A, B, or C (eg, A10, B7, B27), single antigen
86813	HLA typing; A, B, or C, multiple antigens
86816	HLA typing; DR/DQ, single antigen
86817	HLA typing; DR/DQ, multiple antigens
86821	HLA typing; lymphocyte culture, mixed (MLC)
88240	Cryopreservation, freezing and storage of cells, each cell line
88241	Thawing and expansion of frozen cells, each aliquot

Auth required (see medical policy 91066 Stem Cell or Bone Marrow Transplantation)

38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem-cell transplantation, allogeneic

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines and Publications

1. American College of Obstetricians and Gynecologists (ACOG) Committee Opinion. Umbilical Cord Blood Banking Number 771. Obstetrics and Gynecology. 2019;133(3).
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3. Armson BA, Allan DS, Casper RF. Umbilical Cord Blood: Counselling, Collection, and Banking. J Obstet Gynaecol Can. 2015 Sep;37(9):832-844.
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6. Shearer, W. T., Lubin, B. H., Cairo, M. S., & Notarangelo, L. D.; Section on Hematology/Oncology; Section on Allergy and Immunology. (2017). Cord blood banking for potential future transplantation. Pediatrics, 140(5), e20172695. https://doi.org/10.1542/peds.2017-2695
7. Ballen, K. K., Barker, J. N., Stewart, S. K., Greene, M. F., & Lane, T. A. (2008). Collection and preservation of cord blood for personal use. Biology of Blood and Marrow Transplantation, 14(3), 356–363. https://doi.org/10.1016/j.bbmt.2007.12.489
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9. Armson, B. A., Allan, D. S., & Casper, R. F. (2015). Umbilical cord blood: Counselling, collection, and banking. Journal of Obstetrics and Gynaecology Canada, 37(9), 832–844. https://doi.org/10.1016/S1701-2163(16)30026-1

SUMMARY OF CHANGES

Clarifications:

- I.C. – Wording clarified
- Updated background and references

Past committee review dates: 10/2002, 09/2003, 09/2004, 09/2005, 08/2006, 06/2007, 06/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/2013, 05/2014, 05/2015, 05/2016, 05/2017, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 05/2025, 05/2026

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