

Department of Origin: Integrated Healthcare Services	Effective Date: 12/06/22
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/06/22
Clinical Policy Document: Transplantation, Bone Marrow (Hematopoietic Stem Cell)	Replaces Effective Clinical Policy Dated: 12/07/21
Reference #: MC/T001	Page: 1 of 3

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria - Initial and repeat request must satisfy all of the following: I - III

- I. Approval by the requesting transplant center; and
- II. Covered Indications as determined by the health plan's designated third party transplant network guideline (available upon request); and
- III. The decision regarding the appropriateness of transplantation in the presence of one or more relative contraindications will be left up to transplanting facility.

EXCLUSIONS:

Refer to member's Certificate of Coverage or Summary Plan Description

The following is considered investigative (see Investigative List): Xenotransplantation

DEFINITIONS:

Allogeneic Stem Cell Transplant:

Donor and recipient are not of the same genetic origins. Stem cells may be from a matched related or unrelated donor or a donor without a complete match.

Autologous Stem Cell Transplant:

The patient's own stem cells are removed and stored for future use in restoration of bone marrow function after high dose chemotherapy or radiotherapy

Chemosensitive disease:

Malignant disease that responds, at least partially, to a course of chemotherapy

Hematopoietic Stem Cell Transplant:

Includes peripheral blood, bone marrow and cord blood transplants

Mini-transplant (non-myeloablative):

A type of allogeneic transplant that uses lower, less toxic doses of chemotherapy and/or total body irradiation to prepare the patient for the transplant. The use of low doses of anticancer drugs and total

Department of Origin: Integrated Healthcare Services	Effective Date: 12/06/22
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/06/22
Clinical Policy Document: Transplantation, Bone Marrow (Hematopoietic Stem Cell)	Replaces Effective Clinical Policy Dated: 12/07/21
Reference #: MC/T001	Page: 2 of 3

body irradiation eliminates some, but not all, of the patient’s bone marrow. It also reduces the number of cancer cells and suppresses the patient’s immune system to prevent rejection of the transplant. Once the bone marrow cells from the donor begin to engraft, they often cause what is called a “graft versus tumor effect” and may work to destroy the cancer cells that were not eliminated by the anticancer drugs or irradiation.

Reliable evidence:

Consensus opinions and recommendations reported in the relevant medical and scientific literature, peer-reviewed journals, reports of clinical trial committees, or technology assessment bodies, and professional consensus opinions of local and national health care providers.

Stem Cells:

Blood cells found in the bone marrow at its earliest stage of development; may be taken from the bone marrow, peripheral bloodstream, or from umbilical cord blood.

Syngeneic graft:

Donor and recipient are genetically identical, i.e. have the same genotype, as in identical twins.

Tandem transplant:

Two planned courses of high dose chemotherapy and stem cell transplant at intervals of two to six months depending on recovery from prior toxicity.

Transplant/Graft:

Portion of the body or complete organ removed from its natural site and transferred to a separate site in the same or different individual.

Treatment Response:

Improvement related to treatment

- Complete response/remission – disappearance of all signs of disease in response to treatment
- Partial response/remission – decrease in tumor size, or in the extent of cancer/disease in the body in response to treatment

Umbilical Cord Blood:

Blood harvested from the umbilical cord and placenta of a newborn that contains high concentrations of stem cells. These stem cells are associated with a lower incidence of rejection or graft vs. host disease. Cord blood transplants are usually used for children since the number of stem cells obtained in the collection is usually insufficient for the levels needed for an adult transplant.

BACKGROUND:

A designated transplant center/center of excellence may be required by the terms of the member’s benefit plan for maximum benefit coverage.

There are often many clinical trials and studies associated with transplants (where transplant is considered standard of care). Any component of the transplant that is part of a clinical trial or a study is not eligible for coverage.

Refer to benefit plan and medical policy for transplant and re-transplantation benefits, limitations and exclusions, non-coverage explanation of investigative and study generated protocol services, and eligible/non-eligible benefits for the donor.

Department of Origin: Integrated Healthcare Services	Effective Date: 12/06/22
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/06/22
Clinical Policy Document: Transplantation, Bone Marrow (Hematopoietic Stem Cell)	Replaces Effective Clinical Policy Dated: 12/07/21
Reference #: MC/T001	Page: 3 of 3

Prior Authorization: Yes, per network provider agreement.

Precertification: Yes

CODING:

CPT®

- 38240 Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
- 38241 Hematopoietic progenitor cell (HPC); autologous transplantation
- 38242 Allogeneic lymphocyte infusions (donor lymphocyte infusion [DLI])
- 38243 Hematopoietic progenitor cell (HPC); HPC boost

CPT codes copyright 2022 American Medical Association. All Rights Reserved. CPT is a trademark of the AMA. The AMA assumes no liability for the data contained herein.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/I001 Investigative Services
4. Clinical Policy: MP/T006 Transplantation, Designated Transplant Network Provider
5. US Department of Health & Human Services. Organ Procurement and Transplantation Network (OPTN) Policies. 2022. Retrieved from https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Accessed 07-21-22.

DOCUMENT HISTORY:

Created Date: 02/94
Reviewed Date: re-adopted 07/12/12, 07/09/13, 06/10/14, 06/10/15, 06/10/16, 11/15/16, 10/04/17, 10/04/18, 09/11/19, 08/03/20, 08/03/21, 07/21/22
Revised Date: 11/16/04, 11/15/05, 11/28/06, 05/22/07, 07/12/12, 08/06/13, 07/21/14, 09/28/15, 08/19/16, 11/15/16, 10/04/17, 11/06/18, 09/11/19
Retired Date: 06/24/04

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

We will:

- Provide free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provide free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404 (رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف
Arabic

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 1.866.631.8597) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY : 1.866.631.8597)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທສ 1.866.631.5404 (TTY: 1.866.631.8597).