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Department of Origin: Integrated Healthcare Services	**Effective Date:** 12/03/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 12/03/24
Clinical Policy Document: Transplantation, Bone Marrow (Hematopoietic Stem Cell)	**Replaces Effective Clinical Policy Dated:** 12/12/23
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 most current Optum Clinical Guidelines for Hematopoietic Stem Cell Transplantation; 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

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.

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

REFERENCES:
1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clinical Policy: Investigative Services (MP/I001)
4. US Department of Health & Human Services. Organ Procurement and Transplantation Network (OPTN) Policies. 2023. Retrieved from https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Accessed 07-29-24.
5. Optum Clinical Guidelines. Hematopoietic Stem Cell Transplantation. 2023. Retrieved from https://www.uhcprovider.com/content/dam/provider/docs/public/policies/clinical-guidelines/transplant-review-guidelines-hematopoietic-stem-cell-transplantation.pdf. Accessed 10-02-24.

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PCHP:
Provides 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)

Provides 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 a Grievance Specialist.

If you believe that PCHP has 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:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist 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

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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Grievance Specialist
PreferredOne Insurance Company
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Minneapolis, MN 55459-0212
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Fax: 763.847.4010
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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)

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