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Policy Effective Date	12/15/2025

## Hematopoietic Cell Transplantation for Breast Cancer

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Related Policies (if applicable)
None

### Disclaimer

#### Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Coverage

Autologous or allogeneic hematopoietic cell transplantation **is considered experimental, investigational and/or unproven** to treat any stage of breast cancer.

### Policy Guidelines

None.

### Description

#### Hematopoietic Cell Transplantation

Hematopoietic cell transplantation (HCT) refers to a procedure in which hematopoietic cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole-body radiation therapy. Hematopoietic cells may be obtained from the transplant recipient (autologous HCT) or from a donor (allogeneic HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in

it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

Immunologic compatibility between infused hematopoietic cells and the recipient is not an issue in autologous HCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic HCT. Compatibility is established by typing of human leukocyte antigen (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the Class I and Class II loci on chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

### **Conventional Preparative Conditioning for HCT**

The success of autologous HCT is predicated on the ability of cytotoxic chemotherapy with or without radiotherapy to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic cells obtained from the patient before undergoing bone marrow ablation. As a consequence, autologous HCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HCT are susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

The conventional (“classical”) practice of allogeneic HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect mediated by non-self-immunologic effector cells that develop after engraftment of allogeneic cells within the patient’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease without the use of pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allogeneic HCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections.

### **Reduced-Intensity Conditioning for Allogeneic HCT**

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiotherapy than are used in traditional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden and to minimize as much as possible associated treatment-related morbidity and nonrelapse mortality in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of nonrelapse mortality and relapse due to residual disease. RIC

regimens can be viewed as a continuum in effects, from nearly totally myeloablative to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Patients who undergo RIC with allogeneic HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells.

**HCT in Solid Tumors in Adults**

HCT is an established treatment for certain hematologic malignancies; however, its use in solid tumors in adults continues to be largely experimental. Initial enthusiasm for the use of autologous transplant with the use of HDC and stem cells for solid tumors has waned with the realization that dose intensification often fails to improve survival, even in tumors with a linear-dose response to chemotherapy. With the advent of reduced-intensity allogeneic transplant, interest has shifted to exploring the generation of alloreactivity to metastatic solid tumors via a graft-versus-tumor effect of donor-derived T cells.

**Regulatory Status**

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research (CBER), under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

**Rationale**

This policy is based on a review of relevant professional association recommendations.

**National Comprehensive Cancer Network (NCCN)**

NCCN guidelines (v5.2025) do not address the use of HCT in the treatment of breast cancer. (1)

**American Society for Transplantation and Cellular Therapy (ASTCT)**

In 2020, the ASTCT published guidelines on Indications for Autologous and Allogeneic Hematopoietic Cell Transplantation that state: (2)

	Allogeneic HCT	Autologous HCT
Breast cancer, adjuvant high risk	N	N
Breast cancer, metastatic	D	N

N: Not generally recommended; C: standard of care, clinical evidence available; S: standard of care; R: standard of care, rare indication; D: developmental.

**National Cancer Institute (NCI)**

No mention of stem cell transplant in the NCI Breast Cancer Treatment (PDQ®)–Health Professional Version (Updated: April 25, 2025). (3)

**Coding**

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	36511, 38204, 38205, 38206, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38220, 38221, 38222, 38230, 38232, 38240, 38241, 38242, 38243, 81265, 81266, 81267, 81268, 81370, 81371, 81372, 81373, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81382, 81383, 86805, 86806, 86807, 86808, 86812, 86813, 86816, 86817, 86821, 86825, 86826, 86828, 86829, 86830, 86831, 86832, 86833, 86834, 86835, 86849, 86950, 86985, 88240, 88241
<b>HCPCS Codes</b>	S2140, S2142, S2150

\*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

## References

1. NCCN – Breast Cancer. NCCN Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network. Version 5.2025. Available at <<http://www.nccn.org>> (accessed November 19, 2025).
2. Kanate A, Majhail N, Savani B, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy. Biol Blood Marrow Transplant. Jul 2020; 26(7):1247-1256. PMID 32165328
3. NCI – Breast Cancer Treatment (PDQ) – Health Professional Version. Updated April 25, 2025. Available at <<https://www.cancer.gov>> (accessed November 19, 2025).

## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
12/15/2025	Document updated. Coverage unchanged. No new references added; some updated and others removed.
06/15/2024	Document updated with literature review. Coverage unchanged. References 23, 31, and 32 added.
3/15/2023	Reviewed. No changes.
5/15/2022	Document updated with literature review. Coverage unchanged. Updated reference 29.
6/15/2021	Reviewed. No changes.
4/15/2020	Document updated with literature review. Coverage unchanged. The following references were added/updated: 21-22 and 28-29. Title changed from: Hematopoietic Stem-Cell Transplantation for Breast Cancer.
6/15/2018	Reviewed. No changes.
7/15/2017	Document updated with literature review. Coverage unchanged.
6/1/2016	Reviewed. No changes.
1/1/2015	Document updated with literature review. Coverage language modified, without change to coverage position. CPT/HCPCS code(s) updated. Title changed from: Stem-Cell Transplant for Breast Cancer.
10/15/2013	Document updated with literature review. The following was added: 1) Donor leukocyte infusion and hematopoietic progenitor cell boost are considered experimental, investigational and unproven; and 2) Any related services for the treatment of breast cancer, such as short tandem repeat (STR) markers, are considered experimental, investigational and unproven. Otherwise, coverage unchanged. Description and Rationale significantly revised.
4/1/2010	<p>New medical document originating from: SUR703.017, Peripheral/Bone Marrow Stem-cell Transplantation (PSCT/BMT) for Non-Malignancies; SUR703.018, Peripheral/Bone Marrow Stem-cell Transplantation (PSCT/BMT) for Malignancies; SUR703.022, Cord Blood as a Source of Stem-cells (CBSC); SUR703.023, Donor Leukocyte Infusion (DLI); and SUR703.024, Tandem/Triple High-Dose Chemoradiotherapy with Stem-cell Support for Malignancies. Stem-cell transplant continues to be medically necessary when stated criteria are met.</p> <p>[NOTE: A link to the medical policies with the following titles can be found at the end of the medical policy SUR703.002, Stem-Cell Reinfusion or Transplantation Following Chemotherapy (General Donor and Recipient Information):</p> <ul style="list-style-type: none"> <li>Peripheral/Bone Marrow Stem-cell Transplantation (PSCT/BMT) for Non-Malignancies;</li> <li>Peripheral/Bone Marrow Stem-cell Transplantation (PSCT/BMT) for Malignancies;</li> <li>Cord Blood as a Source of Stem-cells;</li> </ul>

	<ul style="list-style-type: none"><li>• Donor Leukocyte Infusion (DLI); and</li><li>• Tandem/Triple High-Dose Chemoradiotherapy with Stem-cell Support for Malignancies.</li></ul>
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