

MEDICAL POLICY – 8.01.24

Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

BCBSA Ref. Policy: 8.01.24


Effective Date: Apr. 1, 2025
Last Revised: Mar. 10, 2025
Replaces: N/A

RELATED MEDICAL POLICIES:

- 7.01.92 Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone
- 7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- 8.01.23 Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer
- 8.01.28 Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma
- 8.01.511 Hematopoietic Cell Transplantation for Solid Tumors of Childhood
- 8.01.532 Hematopoietic Cell Transplantation in the Treatment of Germ-Cell Tumors
- 8.01.539 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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Introduction

Hematopoietic stem cells are cells that form within the bone marrow and can become many different types of blood cells. In a hematopoietic stem cell transplant, stem cells can be taken from a donor's bone marrow, peripheral blood, or from a newborn baby's umbilical cord blood or placenta shortly after the baby is delivered. The stem cells can also be harvested from an individual before they are given any high dose chemotherapy. If the hematopoietic stem cells are harvested from another person, it is called an allogeneic transplant. If the cells come from an individual themselves before high dose chemotherapy is given, it is called an autologous stem cell transplant.

Hematopoietic stem cell transplants are sometimes given to individuals who have cancers that are solid tumors. These transplants are considered investigational when used to treat solid tumors. This policy explains why it is considered to be investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Transplant	Investigational
Autologous or allogeneic hematopoietic cell transplant	Autologous or allogeneic hematopoietic cell transplantation is considered investigational for the following malignancies in adults: <ul style="list-style-type: none">• Cancer of the bile duct• Cancer of the fallopian tubes• Cervical cancer• Colon cancer• Esophageal cancer• Gall bladder cancer• Lung cancer, any histology• Malignant melanoma• Nasopharyngeal cancer• Neuroendocrine tumors• Pancreatic cancer• Paranasal sinus cancer• Prostate cancer• Rectal cancer• Renal cell cancer• Soft tissue sarcomas• Stomach cancer• Thyroid tumors• Tumors of the thymus• Tumors of unknown primary origin



Transplant	Investigational
	<ul style="list-style-type: none"> Uterine cancer

Coding

Code	Description
CPT	
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
HCPCS	
S2142	Cord blood-derived stem-cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous bone marrow transplantation offered as part of clinical trials of autologous bone marrow transplantation approved by the National Institutes of Health (NIH).

- Some plans may participate in voluntary programs offering coverage for individuals participating in NIH-approved clinical trials of cancer chemotherapies, including autologous bone marrow transplantation.

Evidence Review

Description

Hematopoietic cell transplantation (HCT) is an established treatment for certain hematologic malignancies and has been investigated for a variety of adult solid tumors. Interest continues in exploring nonmyeloablative allogeneic HCT (allo-HCT) for a graft-versus-tumor effect of donor-derived T-cells in metastatic solid tumors.

Background

Though cancer incidence along with overall mortality has been declining in the United States, certain population groups continue to have an increased risk of cancer progression and mortality due to social, economic, and environmental disadvantages.¹ The National Cancer Institute has published statistics on cancer disparities in relation to various criteria including specific racial and ethnic groups, gender, and geography. Some key incidence and mortality statistics in the United States are as follows: incidence rates of lung, colorectal, and cervical cancers are increased in rural Appalachia compared to urban areas; American Indians/Alaska Natives have increased mortality rates from kidney, liver, and intrahepatic bile duct cancer compared to other racial and ethnic groups; Black men are twice as likely to die of prostate cancer than White men.

Hematopoietic Cell Transplantation

Hematopoietic cell transplantation (HCT) is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or a

donor (allogeneic HCT [allo-HCT]). They can be harvested from bone marrow, peripheral blood, or from umbilical cord blood shortly after delivery of neonates.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allogeneic stem cell transplantation, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the gene complex expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. An acceptable donor will match the patient at all or most of the HLA loci.

Conditioning for Hematopoietic Cell Transplantation

Conventional Conditioning

The conventional ("classical") practice of allo-HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to cause bone marrow ablation in the recipient. The beneficial treatment effect of this procedure is due to a combination of the initial eradication of malignant cells and subsequent graft-versus-malignancy effect mediated by non-self-immunologic effector cells. While the slower graft-versus-malignancy effect is considered the potentially curative component, it may be overwhelmed by existing disease in the absence of pre-transplant conditioning. Intense conditioning regimens are limited to individuals who are sufficiently medically fit to tolerate substantial adverse effects. These include opportunistic infections secondary to loss of endogenous bone marrow function and organ damage or failure caused by cytotoxic drugs. After graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease (GVHD), which increases susceptibility to opportunistic infections.

The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy with or without radiotherapy, to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of the bone marrow with normal hematopoietic stem cells obtained from the individual before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the patient's disease is in complete remission. Individuals who undergo autologous HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.

Reduced-Intensity Conditioning for Allogeneic Hematopoietic Cell Transplantation

Reduced-intensity conditioning (RIC) refers to the pre-transplant use of lower doses of cytotoxic drugs or less intense regimens of radiotherapy than are used in traditional full-dose myeloablative conditioning treatments. Although the definition of RIC is variable, with numerous versions employed, all regimens seek to balance the competing effects of relapse due to residual disease and non-relapse mortality. The goal of RIC is to reduce disease burden but also to minimize associated treatment-related morbidity and non-relapse mortality in the period during which the beneficial graft-versus-malignancy effect of allogeneic transplantation develops. RIC regimens range from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Individuals who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. In this policy, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative.

Hematopoietic Cell Transplantation in Solid Tumors in Adults

HCT is an established treatment for certain hematologic malignancies. Its use in solid tumors is less well established, although it has been investigated for a variety of solid tumors. With the advent of nonmyeloablative 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.²

HCT as a treatment of ovarian cancer, germ cell tumors, ependymoma, or malignant glioma is addressed in separate policies (see [Related Policies](#)). HCT as a treatment for breast cancer is not addressed. This policy collectively addresses other solid tumors of adults for which HCT has been investigated, including lung cancer; malignant melanoma; tumors of the gastrointestinal tract (affecting the colon, rectum, pancreas, stomach, esophagus, gallbladder, or bile duct); male and female genitourinary systems (e.g., renal cell carcinoma, prostate cancer, cervical cancer, uterine cancer, fallopian tube cancer); tumors of the head and neck; soft tissue sarcoma; thyroid tumors; tumors of the thymus; and tumors of unknown primary origin.

Summary of Evidence

Autologous Hematopoietic Cell Transplantation

For individuals who have adult soft tissue sarcomas who receive autologous HCT, the evidence includes two randomized controlled trials (RCTs), phase 2 single-arm studies (some of which have been summarized in a systematic review), and a retrospective registry study. The relevant outcomes are overall survival (OS), disease-specific survival, and treatment-related mortality and morbidity. Although a phase 2 RCT reported longer survival for individuals treated with autologous HCT than with standard chemotherapy, this trial did not show an overall survival benefit with HCT. An RCT from 2019 also showed no survival benefits with autologous HCT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have small cell lung cancer (SCLC) who receive autologous HCT, the evidence includes several RCTs, and systematic reviews of these studies. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Studies have not reported increased overall survival for individuals with small cell lung cancer treated with autologous HCT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Allogeneic Hematopoietic Cell Transplantation

For individuals who have renal cell carcinoma (RCC), colorectal cancer (CRC), pancreatic cancer, or nasopharyngeal cancer who receive allo-HCT, the evidence includes small single-arm series. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The evidence for allo-HCT to treat renal cell carcinoma, colorectal cancer, pancreatic cancer, and nasopharyngeal cancer has been limited to small case series. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04937842	Efficacy and Safety of Radiotherapy or Chemotherapy Combined with Microtransplantation in the Treatment of Advanced and Relapsed Solid Tumors	60	June 2025
Unpublished			
NCT01505569	Alkylator-Intense Conditioning Followed by Autologous Transplantation for Patients with High Risk or Relapsed Solid or CNS Tumors	44	Feb 2024

NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society for Blood and Marrow Transplantation

In 2015, the American Society for Blood and Marrow Transplantation (now referred to as the American Society for Transplantation and Cellular Therapy) issued guidelines related to indications for autologous and allogeneic HCT.³² The guidelines were updated in 2020.³³ The tumors addressed herein for which the Society has provided recommendations are as listed in [Table 2](#).



Table 2. Recommendations for Use of Autologous and Allogeneic Hematopoietic Cell Transplantation

Condition	Treatment Option	2015 Recommendation	2020 Recommendation
Ewing sarcoma, high risk	Allogeneic HCT	Not generally recommended	Developmental
	Autologous HCT	Standard of care, clinical evidence available	Standard of care, clinical evidence available
Renal cancer, metastatic	Allogeneic HCT	Developmental	Developmental
	Autologous HCT	Not generally recommended	Not generally recommended

HCT: hematopoietic cell transplantation.

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (NCCN) guidelines on the tumors addressed in this policy do not discuss hematopoietic cell transplantation (HCT) as a treatment option and these tumors are also not addressed in the NCCN HCT guideline.^{34,35}

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have the following national noncoverage decision on autologous stem cell transplantation: "Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT [autologous stem cell transplantation] for the following condition[s]: Solid tumors (other than neuroblastoma)."³⁶

Regulatory Status

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



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History

Date	Comments
02/01/00	Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on high-dose chemotherapy for miscellaneous malignancies. However, policy statement is unchanged.
03/11/03	Replace policy - Policy updated; new references; no change in policy statement.
05/13/03	Replace policy - Update CPT codes only.
08/12/03	Replace policy - Reviewed by OAP on 7/22/03. Recommended that investigational statement be more inclusive.
10/12/04	Replace policy - Policy updated with literature review; no change to policy statement. Approved by OAP 10/29/04, no need to back to MPC.
10/11/05	Replace policy - Policy updated with literature review; no clinical trial publications found. No change to policy statement.
06/02/06	Disclaimer and Scope updates - No other changes.
11/14/06	Replace policy - Policy updated with literature review; policy statement unchanged.
02/22/07	Update References - Policy reviewed and recommended by OAP on February 22, 2007.
11/13/07	Replace policy - Policy updated with literature review; policy statement unchanged. References added.
11/11/08	Replace policy - Policy updated with literature search; no change to the policy statement. Description and rationale updated. Title changed to delete "HDC" and added "Transplant" after "Stem Cell". References and codes added. Policy reviewed and recommended by OAP on May 22, 2008.
12/08/09	Replace policy - Policy updated with literature search; no change to the policy statement. References added. Policy reviewed and recommended by OAP on November 19, 2009.
02/09/10	Code Update - New 2010 codes added.
12/14/10	Replace policy - Policy updated with literature review using MEDLINE through July 2010; reference number 22 added and number 23 updated. Policy statements remain unchanged. Reviewed and recommended by OAP in November 2010.
10/11/11	Replace policy – Policy updated with literature review using MEDLINE through July 2011; reference numbers 9 and 22 added; reference 6 removed; references renumbered. Policy statements unchanged. ICD-10 codes added. Codes 38220 and 38221 removed from policy.
01/24/12	Code 38232 added.
02/10/12	The CPT code 38204 was removed from the policy.



Date	Comments
06/20/12	Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.
07/31/12	Update Related Policy titles: 8.01.17, 8.01.21, 8.01.26, 8.01.27, 8.01.29, 8.01.30, 8.01.31, and 8.01.35. Removed Policy 8.01.507 as it was renamed to 8.01.17.
12/19/12	Replace policy. Policy updated with literature review using MEDLINE through September 2012; no references added. Policy statement unchanged. Updated Related Policy 7.01.540, now replaced with 7.01.95.
02/01/13	Update Related Policies, change title of policy 8.01.21.
03/20/13	The following codes were removed from the policy, as they were not suspending and just informational: HCPCS J9000-J9999 and Q0083 – Q0085.
09/30/13	Update Related Policies. Change title to policy 8.01.31.
10/18/13	Update Related Policies. Change title to policy 8.01.17.
12/09/13	Replace policy. Policy updated with literature review using MEDLINE through September 26 2013; no references added. Policy statement unchanged.
01/20/14	Update Related Policies. Change title to 8.01.21.
03/21/14	Update Related Policies. Delete 8.01.514.
04/18/14	Update Related Policies. Remove 8.01.20 and add 8.01.529.
06/24/14	Update Related Policies. Remove 8.01.35 and 8.01.42, then add 8.01.530 and 8.01.532.
12/17/14	Annual Review. Policy updated with literature review through September 30, 2014. References 9-10, 12, and 26 added. Policy statement unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication.
02/03/15	Update Related Policies. Remove 8.01.23, 8.01.28 and 8.01.30.
12/08/15	Annual Review. Literature review performed; no change to policy statements.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through October 27, 2015; references 2, 6, 18, and 22 added. Policy statement unchanged.
09/01/16	Update Related Policies. Remove 8.01.27 as it was archived.
11/04/16	Coding update. Removed codes that are transplant benefit related.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 10, 2016; references 20 and 29-30 added. Policy statement unchanged. Changed “hematopoietic stem cell transplantation” to “hematopoietic cell transplantation” per NCCN terminology change.
08/01/17	Updated title of Related Policy 8.01.511.
11/10/17	Policy moved to new format, no changes to policy statement.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through November 2017; references 8-9 and 28 added. Policy statement unchanged.



Date	Comments
04/01/19	Annual Review, approved March 5, 2019. Policy updated with literature review through November 2018; no references added. Policy statement unchanged.
04/01/20	Annual Review, approved March 19, 2020. Policy updated with literature review through November 2019; no references added. Policy statement unchanged. Removed CPT code 38242, does not match criteria.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through December 1, 2020; references added. Policy statement unchanged. Update Related Policies, removed reference to 8.01.22 and replaced with 8.01.538.
5/01/21	Update Related Policies. Removed policy 7.01.50 as it was archived.
04/01/22	Annual Review, approved March 7, 2022. Policy updated with literature review through December 1, 2021; references added. Policy statement unchanged.
10/01/22	Coding update. Removed HCPCS code S2140.
04/01/23	Annual Review, approved March 6, 2023. Policy updated with literature review through December 6, 2022; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/24	Annual Review, approved March 12, 2024. Policy updated with literature review through November 15, 2023; reference added. Policy statement unchanged. Updated Related Policy section; 8.01.21 was replaced by 8.01.539 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 19, 2024; no references added. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

