

MEDICAL POLICY – 8.01.23

Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer

BCBSA Ref. Policy: 8.01.23

Effective Date: Apr. 1, 2025

Last Revised: Mar. 10, 2025

Replaces: N/A


RELATED MEDICAL POLICIES:

8.01.24 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

8.01.532 Hematopoietic Cell Transplantation in the Treatment of Germ Cell Tumors

Select a hyperlink below to be directed to that section.

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[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 stem cells are harvested from another person, it is called an allogeneic stem cell transplant. If the stem 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 epithelial ovarian cancer. These transplants are considered investigational. 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

Condition	Investigational
Advanced stage epithelial ovarian cancer	Autologous and allogeneic hematopoietic cell transplants are considered investigational to treat advanced stage epithelial ovarian 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

The use of hematopoietic cell transplantation (HCT) has been investigated to treat individuals with epithelial ovarian cancer. Hematopoietic stem cells are infused to restore bone marrow function after cytotoxic doses of chemotherapeutic agents with or without whole body radiotherapy.

Background

Epithelial Ovarian Cancer

Several types of malignancies can arise in the ovary; epithelial carcinoma is the most common. Epithelial ovarian cancer is the fifth most common cause of cancer death in women. New cases and deaths from ovarian cancer in the US for 2024 were estimated at 19,680 and 12,740, respectively.¹ Most ovarian cancer individuals present with widespread disease, and the National Cancer Institute Surveillance, Epidemiology and Results Program reported a 50.9% five-year survival for all cases between 2014 and 2020.²

Treatment

Current management for advanced epithelial ovarian cancer is cytoreductive surgery with chemotherapy. Approximately 75% of individuals present with International Federation of Gynecology and Obstetrics stage III to IV ovarian cancer and are treated with paclitaxel plus a

platinum analogue, (e.g. cisplatin), the preferred regimen for the newly diagnosed advanced disease.^{3,4} Use of platinum and taxanes has improved progression-free survival and overall survival in advanced disease to between 16 and 21 months and 32 and 57 months, respectively.³ However, cancer recurs in most women, and they die of the disease because chemotherapy drug resistance leads to uncontrolled cancer growth.⁴

Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer individuals who receive bone-marrow-toxic doses of drugs with or without whole body radiotherapy. Bone marrow stem cells may be obtained from the transplant recipient (autologous HCT) or a donor (allogeneic HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naive” and thus are associated with a lower incidence of rejection or graft-versus-host disease.

HCT is an established treatment for certain hematologic malignancies; however, its use in solid tumors in adults is largely experimental.

Summary of Evidence

For individuals who have advanced-stage epithelial ovarian cancer who receive HCT, the evidence includes randomized trials and data from case series and registries. The relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment related mortality and morbidity. Although some observational studies have reported longer survival in subsets of women with advanced epithelial ovarian cancer than in women treated with standard chemotherapy, none of the randomized trial evidence has shown a benefit from HCT in this population. Overall, the evidence has not shown that HCT improves health outcomes in treating epithelial ovarian cancer, including survival, compared with conventional standard doses of chemotherapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in December 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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 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.

National Comprehensive Cancer Network Guidelines

Current National Comprehensive Cancer Network (NCCN) guidelines on epithelial ovarian cancer including fallopian tube cancer and primary peritoneal cancer (v.3.2024) do not address hematopoietic cell transplantation (HCT) for epithelial ovarian cancer for patients either with newly diagnosed or with relapsed or refractory disease.¹⁰ However, use of high-dose chemotherapy with HCT received a category 2B recommendation for individuals with certain malignant germ cell tumors demonstrating abnormal tumor markers and definitive recurrent disease and a category 2A recommendation in those with persistently elevated markers and definitive residual disease. NCCN notes that "patients with potentially curable recurrent germ cell disease should be referred to a tertiary care institution for HCT consultation and potentially curative therapy."

Accordingly, NCCN guidelines on HCT (v.2.2024) only reference germ cell tumors as an indication for HCT.¹¹

Medicare National Coverage

The Centers for Medicare and Medicaid Services currently have the following national noncoverage decision on autologous stem cell transplantation [AuSCT]: "Insufficient data exist



to establish definite conclusions regarding the efficacy of AuSCT for the following condition[s]: Solid tumors (other than neuroblastoma).”¹²

Regulatory Status

The US Food and Drug Administration 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.

References

1. American Cancer Society. Cancer Facts & Figures 2024. Atlanta, GA: American Cancer Society; 2024; <https://www.cancer.org/cancer/types/ovarian-cancer.html>. Accessed February 6, 2025.
2. National Cancer Institute, Surveillance Epidemiology and End Results Program. Cancer Stat Facts: Ovarian Cancer. n.d.; <https://seer.cancer.gov/statfacts/html/ovary.html>. Accessed February 6, 2025.
3. Möbus V, Wandt H, Frickhofen N, et al. Phase III trial of high-dose sequential chemotherapy with peripheral blood stem cell support compared with standard dose chemotherapy for first-line treatment of advanced ovarian cancer: intergroup trial of the AGO-Ovar/AIO and EBMT. *J Clin Oncol*. Sep 20 2007; 25(27): 4187-93. PMID 17698804
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11. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation (HCT). Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed February 6, 2025.
12. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Stem Cell Transplantation (110.23, formerly 110.8.1). 2024: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=366>. Accessed February 6, 2025.

History

Date	Comments
02/01/00	Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on HDC for miscellaneous malignancies. However, policy statement is unchanged.
02/26/01	Replace Policy - Policy revised no criteria changes.
05/13/03	Replace Policy - Policy updated, references added; no change in policy statement. CPT codes updated.
08/12/03	Replace Policy - Reviewed and recommended for adoption without any changes by Company Oncology Advisory Panel 7/22/03
12/14/04	Replace Policy - Policy reviewed with literature search; references added. Policy statement unchanged.
01/10/06	Replace Policy - Policy reviewed with literature search; NCI and NCCN information updated; no change to policy statement. Reviewed by OAP 04/21/05.
06/02/06	Disclaimer and Scope updates - No other changes.
03/13/07	Replace Policy - Policy updated with literature review; policy statement unchanged. Reviewed and recommended by OAP February 22, 2007.
10/09/07	Cross References Updated - No other changes.
04/08/08	Replace Policy - Policy updated with literature search; no change to the policy statement. Reviewed and recommended for adoption by the Oncology Advisory Panel, February 21, 2008.
05/13/08	Cross Reference Update - No other changes
02/10/09	Replace Policy - Policy updated with literature search; no change to the policy statement. Rational section extensively revised. HDC removed from title and reflected on the body of the policy. References added.
01/12/10	Replace Policy - Policy updated with literature search. Minor addition to the policy statement "hematopoietic" added; no other changes.
02/09/10	Code Update - New 2010 codes added.



Date	Comments
01/11/11	Replace Policy - Policy updated with literature review; references 1 and 11 updated. No change in policy statement. Reviewed and recommended for adoption by Oncology Advisory Panel, May 20, 2010.
12/06/11	Related Policy Titles Updated.
01/06/12	Replace Policy – Policy updated with literature review; no new references added; no change in policy statement. ICD-10 codes added to policy.
01/24/12	Code 38232 added.
02/10/12	The CPT code 38204 was removed from the policy.
06/20/12	Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.
07/31/12	Updates to Related Policy titles: 8.01.17, 8.01.30, 8.01.31, 8.01.35, and 8.01.520. Removed 8.01.38 as it was archived.
10/08/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
01/29/13	Replace policy. Policy updated with literature review; no new references added; no change in policy statement. Codes 38220 and 38221 removed; they do not apply to this policy. Change title to 8.01.21 in Related Policies section.
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 8.01.31.
10/18/13	Update Related Policies. Change title to 8.01.17.
01/21/14	Replace policy. Policy updated with literature review through August 2013. Reference 11 added; references 1, 2, and 12 updated. No change in policy statement.
03/21/14	Update Related Policies. Delete 8.01.514.
04/18/14	Update Related Policies. Remove 8.01.20, 8.01.35 and 8.01.54, then add 8.01.529, 8.01.531 and 8.01.532.
12/03/14	Update Related Policies. Remove 8.01.17.
01/28/15	Annual Review. Policy updated with literature review through October 20, 2014; no new references added; references 1-2 and 12 updated. No change in policy statement. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in policy adjudication.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through December 18, 2015; no references added; references 1-2 updated. Policy statement unchanged.
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 9, 2016; reference 12 added. Policy statement unchanged.



Date	Comments
	Changed "hematopoietic stem cell transplantation" to "hematopoietic cell transplantation" per NCCN terminology change.
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; reference 2 added; references 1 and 3 updated. Policy statement revised to add "advanced stage" associated with epithelial ovarian cancer; intent of the policy is unchanged.
4/01/19	Annual Review, approved March 5, 2019. Policy updated with literature review through December 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 9, 2020; no references added. Policy statement unchanged.
05/01/21	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 November 22, 2021; no references added. Policy statement unchanged.
10/01/22	Coding update. Removed HCPC code S2140.
04/01/23	Annual Review, approved March 6, 2023. Policy updated with literature review through October 17, 2022; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/24	Annual Review, approved March 11, 2024. Policy updated with literature review through December 29, 2023; no references added. Policy statement unchanged.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through December 6, 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.



