



Louisiana

Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

Policy # 00059

Original Effective Date: 01/28/2002

Current Effective Date: 06/08/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer is addressed separately in medical policy 00054.

Note: Hematopoietic Cell Transplantation in the Treatment of Germ Cell Tumors is addressed separately in medical policy 00056.

Note: Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma is addressed separately in medical policy 00063.

Note: Hematopoietic Cell Transplantation for Solid Tumors of Childhood is addressed separately in medical policy 00064.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers autologous or allogeneic hematopoietic cell transplant (HCT) for miscellaneous solid tumors in adults including, but not limited to, the following malignancies to be **investigational**.*

- Lung cancer, any histology
- Colon cancer
- Rectal cancer
- Pancreas cancer
- Stomach cancer
- Esophageal cancer
- Gall bladder cancer

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- Cancer of the bile duct
- Renal cell cancer
- Cervical cancer
- Uterine cancer
- Cancer of the fallopian tubes
- Prostate cancer
- Nasopharyngeal cancer
- Paranasal sinus cancer
- Neuroendocrine tumors
- Soft tissue sarcomas
- Thyroid tumors
- Tumors of the thymus
- Tumors of unknown primary origin
- Malignant melanoma

Background/Overview

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 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 six. An acceptable donor will match the patient at all or most of the HLA loci.

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Conditioning for HCT

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 pretransplant conditioning. Intense conditioning regimens are limited to patients 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. Subsequent to graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease, 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 presumably normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVH disease.

Reduced-Intensity Conditioning Allo-HCT

RIC refers to the pretransplant 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 and 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 total myeloablative to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition.

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Patients 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 review, the term *reduced-intensity conditioning* will refer to all conditioning regimens intended to be nonmyeloablative.

HCT 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.¹

HCT as a treatment for ovarian cancer, germ cell tumors, ependymoma, or malignant glioma is addressed separately (medical policies 00054, 00056, and 00063, respectively). HCT as a treatment for breast cancer is not addressed. This evidence review 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 (eg, 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. 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.

Rationale/Source

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.

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Autologous HCT

For individuals who have adult soft tissue sarcomas who receive autologous HCT, the evidence includes two TEC Assessments, a randomized controlled trial, and a number of phase 2 single-arm studies, some of which have been summarized in a systematic review. The relevant outcomes are overall survival (OS), disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on autologous HCT as primary and salvage therapy for a variety of solid tumors, found that the available evidence did not permit conclusions about the effect of HCT on patient survival. Although a small phase 2 randomized controlled trial reported longer survival for patients treated with autologous HCT than with standard chemotherapy, this trial did not show a survival benefit with HCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have small cell lung cancer who receive autologous HCT, the evidence includes two TEC Assessments, several randomized controlled trials, and systematic reviews of these studies. The relevant outcomes are OS, disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on autologous HCT as primary and salvage therapy for a variety of solid tumors, found that the available evidence did not permit conclusions about the effect of HCT on patient survival. Studies published since the TEC Assessments have not reported increased OS for patients with small cell lung cancer treated with autologous HCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

Allo-HCT

For individuals who have renal cell carcinoma, colorectal cancer, pancreatic cancer, or nasopharyngeal cancer who receive allo-HCT, the evidence includes a TEC Assessment and small single-arm series. The relevant outcomes are OS, disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on allo-HCT as primary and salvage therapy for a variety of solid tumors, found that the available evidence did not permit conclusions about the effect of allo-HCT on patient survival. Since the publication of the TEC Assessments, 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 the effects of the technology on health outcomes.

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Supplemental Information

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines (2019) on the tumors addressed in this evidence review do not discuss hematopoietic cell transplantation (HCT) as a treatment option.

American Society for Blood and Marrow Transplantation

The American Society for Blood and Marrow Transplantation (2015) issued guidelines related to indications for autologous and allogeneic HCT. The tumors addressed herein for which the Society has provided recommendations are listed in Table 1.

Table 1. Recommendations for Use of Autologous and Allogeneic HCT

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

HCT: hematopoietic cell transplantation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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).”

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.



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Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03236883	Phase I Study of Nonmyeloablative Allogeneic Hematopoietic Stem Cell Transplantation in the Treatment of Pancreatic Cancer	30	Apr 2019 (Last update posted 08/02/17)

NCT: national clinical trial.

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|------------|--|
| 12/06/2001 | Medical Policy Committee review |
| 01/28/2002 | Managed Care Advisory Council approval |
| 03/31/2004 | Medical Director review |
| 05/07/2004 | Medical Director review |
| 05/18/2004 | Medical Policy Committee review. Format revision. High-Dose Chemotherapy and Hematopoietic Stem Cell Support for Miscellaneous Solid Tumors in Adults policy developed separately from current HDC with Hematopoietic Stem Cell Support policy. No substance change to policy. |
| 06/28/2004 | Managed Care Advisory Council approval |
| 07/12/2006 | Medical Director review |
| 07/19/2006 | Medical Policy Committee approval. Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility is unchanged. |
| 06/04/2008 | Medical Director review |
| 06/18/2008 | Medical Policy Committee approval. Coverage eligibility is unchanged. |

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06/04/2009	Medical Director review
06/17/2009	Medical Policy Committee approval. Changed title from “High-Dose Chemotherapy and Hematopoietic Stem Cell Support for Miscellaneous Solid Tumors in Adults” to “High-Dose Chemotherapy and Hematopoietic Stem Cell Transplantation for Miscellaneous Solid Tumors in Adults.” Coverage eligibility is unchanged.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. Changed title from “High-Dose Chemotherapy and Hematopoietic Stem Cell Transplantation for Miscellaneous Solid Tumors in Adults.” to “Hematopoietic Stem Cell Transplantation for Miscellaneous Solid Tumors in Adults.” Changed the wording of the investigational statement from, “high-dose chemotherapy (HDC) with autologous or allogeneic stem cell support (SCS) for miscellaneous solid tumors” to “autologous or allogeneic stem cell transplant (SCT) for miscellaneous solid tumors.” Coverage eligibility unchanged.
06/02/2011	Medical Policy Committee review
06/15/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding updated
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2014	Medical Policy Committee review
12/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review

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- 12/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 12/07/2017 Medical Policy Committee review
- 12/20/2017 Medical Policy Implementation Committee approval. “Stem” removed from title and policy. HSCT changed to HCT in policy text. Coverage eligibility unchanged.
- 12/06/2018 Medical Policy Committee review
- 12/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/05/2019 Medical Policy Committee review
- 12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/07/2020 Medical Policy Committee review
- 05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2021

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HCPCS	S2140, S2142, S2150
ICD-10 Diagnosis	All related diagnosis

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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