MEDICAL POLICY

POLICY TITLE	HEMATOPOIETIC CELL TRANSPLANTATION FOR CNS EMBRYONAL TUMORS AND EPENDYMOMA
POLICY NUMBER	MP 9.050

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	**5/1/2026**

POLICY

EMBRYONAL TUMORS OF THE CENTRAL NERVOUS SYSTEM

Autologous hematopoietic cell transplantation may be considered **medically necessary** as consolidation therapy for previously untreated embryonal tumors of the central nervous system (CNS) that show partial or complete response to induction chemotherapy, or stable disease after induction therapy (**see Policy Guidelines).**

Autologous hematopoietic cell transplantation may be considered **medically necessary** to treat recurrent embryonal tumors of the CNS.

The following are considered **investigational** to treat embryonal tumors of the CNS as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

- Tandem autologous hematopoietic cell transplant
- Allogeneic hematopoietic cell transplantation

EPENDYMOMA

Autologous, tandem autologous, and allogeneic hematopoietic cell transplantation are considered **investigational** to treat ependymoma. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

In general, use of autologous hematopoietic cell transplantation for previously untreated medulloblastoma has shown no survival benefit for those individuals considered to be at average risk (i.e., patient age older than 3 years, without metastatic disease, and with total or near total surgical resection [less than 1.5 cm^2 residual tumor]) when compared with conventional therapies.

Other central nervous system (CNS) tumors include astrocytoma, oligodendroglioma, and glioblastoma multiforme. These tumors arise from glial cells, not neuroepithelial cells.

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Due to their neuroepithelial origin, peripheral neuroblastoma and Ewing sarcoma may be considered primitive neuroectodermal tumors. These peripheral tumors are discussed in greater detail in policy **MP 9.054**.

Cross-References:
MP 9.042 Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas
MP 9.054 Hematopoietic Cell Transplantation for Solid Tumors of Childhood
MP 9.001 Placental/Umbilical Cord Blood as a Source of Stem Cells

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

Central Nervous System Embryonal Tumors

Classification of brain tumors is based on both histopathologic characteristics of the tumor and location in the brain. CNS embryonal tumors are more common in children and are the most common brain tumor in childhood. Medulloblastomas account for 20% of all childhood CNS tumors.

Recurrent childhood CNS embryonal tumors are not uncommon and, depending on which type of treatment the patient initially received, autologous hematopoietic cell transplantation (HCT) may be an option. For patients who receive high-dose chemotherapy and autologous HCT for recurrent embryonal tumors, the objective response is 50% to 75%; however, long-term disease control is obtained in fewer than 30% of patients and is primarily seen in patients with a first relapse of localized disease at the time of the relapse.

Ependymoma

Ependymoma is a neuroepithelial tumor that arises from the ependymal lining cell of the ventricles and is, therefore, usually contiguous with the ventricular system. An ependymoma tumor typically arises intracranially in children, while in adults a spinal cord location is more common. Ependymomas have access to the cerebrospinal fluid and may spread throughout the

entire neuroaxis. Ependymomas are distinct from ependymoblastomas due to their more mature histologic differentiation.

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]). These cells can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Cord blood is discussed in greater detail in policy **MP 9.001**.

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.

Conventional Conditioning for HCT

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 graft-versus-host disease.

Reduced-Intensity Conditioning Allogeneic HCT

Reduced-intensity conditioning (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. 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.

Autologous HCT allows for the escalation of chemotherapy doses above those limited by myeloablation and has been tried in patients with high-risk brain tumors in an attempt to eradicate residual tumor cells and improve cure rates. The use of allo-HCT for solid tumors does not rely on the escalation of chemotherapy intensity and tumor reduction but rather on a graft-versus-tumor effect. Allo-HCT is not commonly used in solid tumors and may be used if an autologous source cannot be cleared of a tumor or cannot be harvested.

REGULATORY STATUS

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 (CFR) Title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

RATIONALE

Summary of Evidence

For individuals who have newly diagnosed CNS embryonal tumors who receive autologous HCT, the evidence includes prospective and retrospective studies. Relevant outcomes are overall survival (OS), disease-specific survival (DSS), and treatment-related mortality and morbidity. For pediatric CNS embryonal tumors, an important consideration is whether the use of HCT may allow for a reduction in radiation dose. Data from single-arm studies using high-dose chemotherapy (HDC) with autologous HCT to treat newly diagnosed CNS embryonal tumors have shown comparable or improved survival (both event-free survival and overall survival) compared with historical controls treated with conventional therapy, with or without radiotherapy, particularly in patients with disease considered high risk. In a retrospective comparative study, survival in patients receiving HDC with HCT and delayed craniospinal irradiation (CSI) was comparable with survival in those receiving upfront CSI. Overall, data from

these observational studies have suggested HCT may allow reduced doses of CSI without worsening survival outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have recurrent or relapsed CNS embryonal tumors who receive autologous HCT, the evidence includes prospective and retrospective single-arm studies and a systematic review of these studies. Relevant outcomes are OS, DSS, and treatment-related mortality and morbidity. For recurrent/relapsed CNS embryonal tumors, survival outcomes after HCT vary, and survival is generally very poor for tumors other than medulloblastoma. Data from some single-arm studies using autologous HCT to treat recurrent CNS embryonal tumors have shown comparable or improved survival compared with historical controls treated with conventional therapy for certain patients. The results of a 2012 systematic review of observational studies in patients with relapsed supratentorial primitive neuroectodermal tumor (PNET) suggested that a subgroup of infants with chemosensitive disease might benefit from autologous HCT, achieving survival without the use of radiotherapy, whereas outcomes in older children and/or in the pineal location are poor with this modality. However, a relatively large prospective multicenter study has reported that HCT was not associated with improved survival outcomes in patients who had a good response to therapy. Overall, data from these single-arm studies have suggested HCT may be associated with improved survival outcomes in select patients, although data for some tumor types are limited (e.g., atypical teratoid/rhabdoid tumors). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have CNS embryonal tumors who receive tandem autologous HCT, the evidence includes prospective and retrospective single-arm studies. Relevant outcomes are OS, DSS, and treatment-related mortality and morbidity. Less evidence specifically addresses the use of tandem autologous HCT for CNS embryonal tumors. The available single-arm studies are very small but appear to report OS and event-free survival rates comparable with single autologous HCT. Tandem transplants might allow reduced doses of craniospinal irradiation, with the goal of avoiding long-term radiation damage. However, most studies used standard-dose irradiation, making the relative benefit of tandem autologous HCT uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have CNS embryonal tumors who receive allogeneic HCT, the evidence includes case reports. Relevant outcomes are OS, DSS, and treatment-related mortality and morbidity. The available evidence is limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have ependymoma who receive autologous HCT, the evidence includes relatively small case series. Relevant outcomes are OS, DSS, and treatment-related mortality and morbidity. The available case series do not report higher survival rates for patients with

ependymoma treated with HCT compared with standard therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

DEFINITIONS

NA

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered for treatment of embryonal tumors of the CNS

Procedure Codes								
38205	38230	38240	38242					

Covered when medically necessary:

Procedure Codes								
38204	38206	38207	38208	38209	38210	38211	38212	38213
38214	38215	38232	38241	S2150				

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ICD-10-CM Diagnosis Code	Description
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of Cerebral ventricles
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C72.0	Malignant neoplasm of spinal cord
C75.1	Malignant neoplasm of pituitary gland
C75.3	Malignant neoplasm of pineal gland

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POLICY HISTORY

MP 9.050	**04/03/2020 Consensus Review.** No change to the policy statements. Language under Product Variations: FEP PPO, Description/Background sections, and References updated. Coding reviewed.
	03/30/2021 Minor Review. Changed title from HCT for CNS Embryonal Tumors and Ependymoma to HCT for CNS Embryonal Tumors, CNS Germ Cell Tumors, and Ependymoma. Added MN criteria for HCT for adult medulloblastoma. Added MN criteria for childhood CNS germ cell tumors.

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	Clarified if a statement is for childhood or adult tumors. Added information about pineoblastoma to policy guidelines. Added NCCN statement. Updated cross references. Updated description/background and summary of evidence. Added ICD-10 codes: C72.0, C75.1, and C75.3. Updated references.
	05/03/2021 Consensus Review. Added expanded NCCN statement as it was approved at 4/27/2021 CAC.
	02/16/2022 Consensus Review. No change to policy statement. References updated.
	02/28/2023 Consensus Review. No change to policy statements. References reviewed and updated. Coding reviewed.
	03/05/2024 Consensus Review. No change to policy statement. References reviewed and updated. Coding reviewed. No coding changes.
	11/19/2024 Administrative Update. Removed NCCN statement.
	01/22/2025 Minor Review. Changed title from HCT for CNS Embryonal Tumors, CNS Germ Cell Tumors, and Ependymoma to HCT for CNS Embryonal Tumors and Ependymoma. Deleted MN criteria for HCT for adult medulloblastoma. Deleted MN criteria for childhood CNS germ cell tumors. Deleted information about pineoblastoma to policy guidelines. Updated description/background and summary of evidence. Updated references.
	01/27/2026 Consensus Review. No changes to policy statement. Removed benefit variations. Updated policy formatting, cross-references, product variations, background, disclaimer, and references. No coding changes.