MEDICAL POLICY – 8.01.28
Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma

BCBSA Ref. Policy: 8.01.28
Effective Date: April 1, 2019
Last Revised: March 19, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.50 Placental and Umbilical Cord Blood as a Source of Stem Cells

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Some tumors form within the brain and spinal cord, which are both part of the central nervous system (CNS). Treatment for these tumors may include surgery, chemotherapy, and radiation. High dose chemotherapy may damage the person’s bone marrow, which is important in making different types of blood cells. In order to restore bone marrow function, a hematopoietic stem cell transplant may be done.

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 was delivered. The stem cells can also be harvested from the patient himself before he is given any high dose chemotherapy. In all of these cases, the harvested stem cells are then given to the patient, just like in a transfusion. It is hoped that these new stem cells will then settle into the bone marrow and start producing normal blood cells.

If the hematopoietic stem cells are harvested from another person, it is called an allogeneic transplant. If the cells come from the patient himself before his high dose chemotherapy is given, it is called an autologous stem cell transplant. This policy discusses when different types of hematopoietic stem cell transplants might be medically necessary to treat CNS tumors.
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

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Autologous hematopoietic cell transplantation</strong></td>
<td>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 Additional Information below). Autologous hematopoietic cell transplantation may be considered medically necessary to treat recurrent embryonal tumors of the CNS.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tandem autologous hematopoietic cell transplantation</strong></td>
<td>Tandem autologous hematopoietic cell transplant is investigational to treat embryonal tumors of the CNS.</td>
</tr>
<tr>
<td><strong>Allogeneic hematopoietic cell transplantation</strong></td>
<td>Allogeneic hematopoietic cell transplantation is investigational to treat embryonal tumors of the CNS.</td>
</tr>
<tr>
<td><strong>Autologous, tandem autologous, and allogeneic hematopoietic cell transplant</strong></td>
<td>Autologous, tandem autologous, and allogeneic hematopoietic cell transplant is investigational to treat ependymoma.</td>
</tr>
</tbody>
</table>

### Additional Information

In general, use of autologous hematopoietic cell transplantation for previously untreated medulloblastoma has shown no survival benefit for those patients considered to be at average risk (ie, patients older than 3 years of age, without metastatic disease, and with
**Additional Information**

Total or near total surgical resection (<1.5 cm² residual tumor) when compared with conventional therapies.

**Documentation Requirements**

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Prior treatment (if any) patient has received

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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</tr>
<tr>
<td>38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
</tr>
<tr>
<td>38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>S2150</td>
<td>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</td>
</tr>
</tbody>
</table>

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**Related Information**

N/A
Consideration of Age

The age stated in this policy for which autologous HSCT may be considered medically necessary as consolidation therapy for previously untreated embryonal tumors of the central nervous system that show partial or complete response to induction chemotherapy, or stable disease after induction therapy is age 3 or younger. This is based on scientific evidence that has shown no survival benefit for patients considered to be at average risk (older than 3 years) without metastatic disease and with total or near total surgical resection when compared with conventional therapies. The treatment protocols are based on risk stratification as average or high risk. The average-risk group at 3 years, without metastatic disease, and with tumors that are totally or near totally resected. The high-risk group includes children aged 3 years or younger, or with metastatic disease, and/or subtotal resection.

Benefit Application

The following considerations may supersede this policy:

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

- Some plans may participate in voluntary programs offering coverage for patients participating in National Institutes of Health-approved clinical trials of cancer chemotherapies, including autologous hematopoietic bone marrow transplantation.

- Some contracts or certificates of coverage may include specific conditions in which autologous hematopoietic bone marrow transplantation would be considered eligible for coverage.
Description

High-dose chemotherapy with hematopoietic cell transplantation (HCT) has been investigated as a possible therapy in pediatric patients with brain tumors, particularly in those with high risk disease. Moreover, the use of HCT has allowed for a reduction in the dose of radiation needed to treat both average and high-risk disease, all while preserving the quality of life and intellectual functioning and without compromising survival.

Background

**Central Nervous System Embryonal Tumors**

Classification of brain tumors is based on both histopathologic characteristics of the tumor and location in the brain. Central nervous system (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 tumor is 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, 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 in the first relapse with localized disease at the time of the relapse.1

**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 cells are infused to restore bone marrow function in cancer patients who receive bone marrow ablative doses of cytotoxic drugs. Bone marrow stem 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.

**HCT for Brain Tumors**

Autologous HCT allows for 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 allogeneic HCT for solid tumors does not rely on escalation of chemotherapy intensity and tumor reduction but rather on a graft-versus-tumor effect. Allogeneic HCT is not commonly used in solid tumors and may be used if an autologous source cannot be cleared of tumor or cannot be harvested.

**Summary of Evidence**

For individuals who have newly diagnosed CNS embryonal tumors who receive autologous HCT, the evidence includes prospective and retrospective studies. The relevant outcomes are overall survival, disease-specific survival, 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 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 was comparable with survival in those receiving upfront craniospinal irradiation. Overall, data from these observational studies have suggested HCT may allow reduced doses of craniospinal irradiation 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. The relevant outcomes are overall survival, disease-specific survival, 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 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 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 (eg, 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. The relevant outcomes are overall survival, disease-specific survival, 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 overall survival 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. The relevant outcomes are overall survival, disease-specific survival, 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 overall survival, disease-specific survival, 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.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00085202</td>
<td>Treatment of Patients With Newly Diagnosed Medulloblastoma, Supratentorial</td>
<td>416</td>
<td>Sep 2018</td>
</tr>
<tr>
<td></td>
<td>Primitive Neuroectodermal Tumor, or Atypical Teratoid Rhabdoid Tumor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02653196</td>
<td>A Multi-Institutional Phase II Feasibility Study of Allogeneic Hematopoietic</td>
<td>30</td>
<td>Jul 2019</td>
</tr>
<tr>
<td></td>
<td>Stem Cell Transplantation for Patients With Malignant Neuro-Epithelial and</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other Solid Tumors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00653068</td>
<td>Treatment of Atypical Teratoid/Rhabdoid Tumors (AT/RT) of the Central</td>
<td>70</td>
<td>Apr 2015</td>
</tr>
<tr>
<td></td>
<td>Nervous System With Surgery, Intensive Chemotherapy, and 3-D Conformal</td>
<td></td>
<td>(completed)</td>
</tr>
<tr>
<td></td>
<td>Radiation</td>
<td></td>
<td></td>
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<tr>
<td>NCT00336024</td>
<td>A Phase III Randomized Trial for the Treatment of Newly Diagnosed</td>
<td>96</td>
<td>Dec 2016</td>
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<tr>
<td></td>
<td>Supratentorial PNET and High Risk Medulloblastoma in Children &lt; 36 Months</td>
<td></td>
<td>(completed)</td>
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<tr>
<td></td>
<td>Old With Intensive Induction Chemotherapy With Methotrexate Followed by</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Consolidation With Stem Cell Rescue Versus the Same Therapy Without</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methotrexate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines on treating central nervous system tumors (v.2.2018) make the following recommendations about hematopoietic cell transplant (HCT) 36:
For medulloblastoma and supratentorial primitive neuroectodermal tumor, autologous HCT for localized recurrent disease with maximum safe resection is a category 2A recommendation.

American Society for Blood and Marrow Transplantation

The American Society for Blood and Marrow Transplantation (2015) published consensus guidelines on the use of HCT to treat specific conditions, in both clinical trial and clinical practice settings. Per this review, clinical evidence is available to support autologous HCT in pediatric patients (<18 years) with medulloblastoma. Stem cell transplantation is not generally recommended using allogeneic HCT for medulloblastomas. The guidelines did not address HCT in treating ependymomas.

Medicare National Coverage

There is no national coverage determination.

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

References


<p>| Date       | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |</p>
<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search. No references added; no change in policy statements. ICD-10 codes added.</td>
</tr>
<tr>
<td>01/24/12</td>
<td>Code 38232 added.</td>
</tr>
<tr>
<td>02/10/12</td>
<td>The CPT code 38204 was removed from the policy.</td>
</tr>
<tr>
<td>06/20/12</td>
<td>Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.</td>
</tr>
<tr>
<td>07/30/12</td>
<td>Related Policy title updates to: 8.01.17, 8.01.22, 8.01.31, 8.01.35 and 8.01.520. Deleted 8.01.38 as it was archived.</td>
</tr>
<tr>
<td>10/08/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature search. References 7, 8, 13 and 18 added; no change in policy statements. Removed CPT codes 38220 and 38221; they do not apply to this policy. Change title to Related Policy 8.01.21.</td>
</tr>
<tr>
<td>03/20/13</td>
<td>The following codes were removed from the policy, as they were not suspending and just informational: HCPCS J9000-J9999 and Q0083 – Q0085.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change policy title to 8.01.31.</td>
</tr>
<tr>
<td>10/18/13</td>
<td>Update Related Policies. Change title to policy 8.01.17.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Replace policy. Policy updated with literature search through October 8, 2013. References 13 and 14 added, references 3 and 24 updated; no change in policy statements. Remove CPT code 38230; it does not apply to this policy.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Remove 801.514 as it was deleted.</td>
</tr>
<tr>
<td>04/18/14</td>
<td>Update Related Policies. Remove 8.01.20 and replace with 8.01.529.</td>
</tr>
<tr>
<td>06/24/14</td>
<td>Update Related Policies. Remove 8.01.35, 8.01.42 and 8.01.54, then add 8.01.530, 8.01.531 and 8.01.532.</td>
</tr>
<tr>
<td>12/03/14</td>
<td>Update Related Policies. Remove 8.01.17 and 8.01.26.</td>
</tr>
<tr>
<td>01/28/15</td>
<td>Annual Review. Policy updated with literature review through September 30, 2014. References 5-6, 9, 15, and 17-19 added. Policy statements unchanged. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy updated with literature review through October 27, 2015; references 4-6 and 9 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>11/04/16</td>
<td>Coding update. Removed codes that are transplant benefit related.</td>
</tr>
<tr>
<td>04/01/17</td>
<td>Annual Review, approved March 14, 2017. Policy updated with literature review through November 7, 2016; references 6, and 22-23 added. Changed “hematopoietic stem cell transplantation” to “hematopoietic cell transplantation” per NCCN terminology change. Policy statements unchanged.</td>
</tr>
<tr>
<td>11/10/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>09/01/18</td>
<td>Minor update. Re-added Consideration of Age information, which was inadvertently removed during a previous update.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Annual Review, approved March 19, 2019. Policy updated with literature review through December 2018; no references added; reference 36 updated. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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يتم تضمين هذه المعلومات في هذا الإشعار. قد تحتاج إلقاء نظرة على تفويض مهنة للحصول على تلبية مطالعات الصحة والمساهمة في دفع أسعار التأمين. يُعادل كل المعلومات على هذه المعلومات والمساهمة بذلك دون تكبد أي ألغام.

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**Oromo (Cushite):**


Lakkoofsa bibibila 800-722-1471 (TTY: 800-842-5357) tii bibibila.

**Italiano (Italian):**


037338 (07-2016)
This notification can contain important information. This notification may contain important information. This notification may contain important information. This notification may contain important information.

Premera Blue Cross (TTY: 800-842-5357).

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You have the right to receive this information and assistance in any language without cost. Call 800-722-1471 (TTY: 800-842-5357).

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