



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 03/25/24
CURRENT EFFECTIVE DATE: 03/25/24
LAST CRITERIA REVISION DATE: 03/07/23
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NEXT ANNUAL REVIEW DATE: 1ST QTR 2025

HEMATOPOIETIC CELL TRANSPLANTATION FOR CENTRAL NERVOUS SYSTEM (CNS) EMBRYONAL TUMORS AND EPENDYMOMA

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

High-dose chemotherapy with hematopoietic cell transplantation (HCT) has been investigated as a possible therapy in pediatric individuals with brain tumors, particularly in those with high-risk disease. The use of HCT has allowed for a reduction in the dose of radiation needed to treat both average- and high-risk disease with a goal of preserving the quality of life and intellectual functioning.

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 tumors is not uncommon and, depending on which type of treatment the individual initially received, autologous hematopoietic cell transplantation (HCT) may be an option. For individuals 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 individuals and is primarily seen in individuals with a first relapse of localized disease at the time of the relapse.

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., age >3 years, without metastatic disease, and with total or near-total surgical resection [$<1.5 \text{ cm}^2$ residual tumor]) compared with conventional therapies.

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

Hematopoietic cell transplantation is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in cancer individuals 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.

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 recipient 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 recipient at all or most of the HLA loci.



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Definitions:

Allogeneic: From a third-party donor.

Autologous: From an individual's own bone marrow and/or circulating blood.

Consolidation therapy: Therapy administered to a cancer individual after the disease is in remission.

Induction therapy: The first major treatment or therapy administered to a cancer individual.

Tandem autologous: Two autologous transplants performed with a period of no more than six months.

Criteria:

Stem cell transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

Embryonal Tumors of the Central Nervous System:

Autologous Hematopoietic Cell Transplantation

- Autologous hematopoietic cell transplantation 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 is considered **medically necessary**.
- Autologous hematopoietic cell transplantation for the treatment of recurrent embryonal tumors of the CNS is considered **medically necessary**.
- Tandem autologous hematopoietic cell transplantation for the treatment of embryonal tumors of the CNS is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

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Allogeneic Hematopoietic Cell Transplantation

- Allogeneic hematopoietic cell transplantation for the treatment of embryonal tumors of the CNS is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Ependymoma:

- Autologous, tandem autologous, and allogeneic hematopoietic cell transplantation for the treatment of ependymoma is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 03/25/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 03/25/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Alsultan A, Alharbi M, Al-Dandan S, et al. High-dose Chemotherapy With Autologous Stem Cell Rescue in Saudi Children Less Than 3 Years of Age With Embryonal Brain Tumors. *J Pediatr Hematol Oncol*. Apr 2015;37(3):204-8. doi:10.1097/mpb.0000000000000301
2. Bergthold G, El Kababri M, Varlet P, et al. High-dose busulfan-thiotepa with autologous stem cell transplantation followed by posterior fossa irradiation in young children with classical or incompletely resected medulloblastoma. *Pediatr Blood Cancer*. May 2014;61(5):907-12. doi:10.1002/pbc.24954

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3. Bode U, Zimmermann M, Moser O, et al. Treatment of recurrent primitive neuroectodermal tumors (PNET) in children and adolescents with high-dose chemotherapy (HDC) and stem cell support: results of the HITREZ 97 multicentre trial. *J Neurooncol*. Dec 2014;120(3):635-42. doi:10.1007/s11060-014-1598-8
4. Chintagumpala M, Hassall T, Palmer S, et al. A pilot study of risk-adapted radiotherapy and chemotherapy in patients with supratentorial PNET. *Neuro Oncol*. Feb 2009;11(1):33-40. doi:10.1215/15228517-2008-079
5. Dhall G, Grodman H, Ji L, et al. Outcome of children less than three years old at diagnosis with non-metastatic medulloblastoma treated with chemotherapy on the "Head Start" I and II protocols. *Pediatr Blood Cancer*. Jun 2008;50(6):1169-75. doi:10.1002/pbc.21525
6. Dufour C, Foulon S, Geoffray A, et al. Prognostic relevance of clinical and molecular risk factors in children with high-risk medulloblastoma treated in the phase II trial PNET HR+5. *Neuro Oncol*. Jul 1 2021;23(7):1163-1172. doi:10.1093/neuonc/noaa301
7. Dufour C, Kieffer V, Varlet P, et al. Tandem high-dose chemotherapy and autologous stem cell rescue in children with newly diagnosed high-risk medulloblastoma or supratentorial primitive neuro-ectodermic tumors. *Pediatr Blood Cancer*. Aug 2014;61(8):1398-402. doi:10.1002/pbc.25009
8. Dunkel IJ, Boyett JM, Yates A, et al. High-dose carboplatin, thiotepa, and etoposide with autologous stem-cell rescue for patients with recurrent medulloblastoma. Children's Cancer Group. *J Clin Oncol*. Jan 1998;16(1):222-8. doi:10.1200/jco.1998.16.1.222
9. Dunkel IJ, Gardner SL, Garvin JH, Jr., Goldman S, Shi W, Finlay JL. High-dose carboplatin, thiotepa, and etoposide with autologous stem cell rescue for patients with previously irradiated recurrent medulloblastoma. *Neuro Oncol*. Mar 2010;12(3):297-303. doi:10.1093/neuonc/nop031
10. Egan G, Cervone KA, Philips PC, Belasco JB, Finlay JL, Gardner SL. Phase I study of temozolomide in combination with thiotepa and carboplatin with autologous hematopoietic cell rescue in patients with malignant brain tumors with minimal residual disease. *Bone Marrow Transplant*. Apr 2016;51(4):542-5. doi:10.1038/bmt.2015.313
11. Fangusaro J, Finlay J, Sposto R, et al. Intensive chemotherapy followed by consolidative myeloablative chemotherapy with autologous hematopoietic cell rescue (AuHCR) in young children with newly diagnosed supratentorial primitive neuroectodermal tumors (sPNETs): report of the Head Start I and II experience. *Pediatr Blood Cancer*. Feb 2008;50(2):312-8. doi:10.1002/pbc.21307
12. Friedrich C, von Bueren AO, von Hoff K, et al. Treatment of young children with CNS-primitive neuroectodermal tumors/pineoblastomas in the prospective multicenter trial HIT 2000 using different chemotherapy regimens and radiotherapy. *Neuro Oncol*. Feb 2013;15(2):224-34. doi:10.1093/neuonc/nos292

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13. Gajjar A, Chintagumpala M, Ashley D, et al. Risk-adapted craniospinal radiotherapy followed by high-dose chemotherapy and stem-cell rescue in children with newly diagnosed medulloblastoma (St Jude Medulloblastoma-96): long-term results from a prospective, multicentre trial. *Lancet Oncol*. Oct 2006;7(10):813-20. doi:10.1016/s1470-2045(06)70867-1
14. Geyer JR, Sposto R, Jennings M, et al. Multiagent chemotherapy and deferred radiotherapy in infants with malignant brain tumors: a report from the Children's Cancer Group. *J Clin Oncol*. Oct 20 2005;23(30):7621-31. doi:10.1200/jco.2005.09.095
15. Gill P, Litzow M, Buckner J, et al. High-dose chemotherapy with autologous stem cell transplantation in adults with recurrent embryonal tumors of the central nervous system. *Cancer*. Apr 15 2008;112(8):1805-11. doi:10.1002/cncr.23362
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17. Grodman H, Wolfe L, Kretschmar C. Outcome of patients with recurrent medulloblastoma or central nervous system germinoma treated with low dose continuous intravenous etoposide along with dose-intensive chemotherapy followed by autologous hematopoietic stem cell rescue. *Pediatr Blood Cancer*. Jul 2009;53(1):33-6. doi:10.1002/psc.21985
18. Kanate AS, Majhail NS, Savani BN, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy. *Biol Blood Marrow Transplant*. Jul 2020;26(7):1247-1256. doi:10.1016/j.bbmt.2020.03.002
19. Kim H, Kang HJ, Lee JW, et al. Irinotecan, vincristine, cisplatin, cyclophosphamide, and etoposide for refractory or relapsed medulloblastoma/PNET in pediatric patients. *Childs Nerv Syst*. Oct 2013;29(10):1851-8. doi:10.1007/s00381-013-2163-z
20. Kostaras X, Easaw JC. Management of recurrent medulloblastoma in adult patients: a systematic review and recommendations. *J Neurooncol*. Oct 2013;115(1):1-8. doi:10.1007/s11060-013-1206-3
21. Lee JY, Kim IK, Phi JH, et al. Atypical teratoid/rhabdoid tumors: the need for more active therapeutic measures in younger patients. *J Neurooncol*. Apr 2012;107(2):413-9. doi:10.1007/s11060-011-0769-0
22. Lester RA, Brown LC, Eckel LJ, et al. Clinical outcomes of children and adults with central nervous system primitive neuroectodermal tumor. *J Neurooncol*. Nov 2014;120(2):371-9. doi:10.1007/s11060-014-1561-8

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25. Mason WP, Goldman S, Yates AJ, Boyett J, Li H, Finlay JL. Survival following intensive chemotherapy with bone marrow reconstitution for children with recurrent intracranial ependymoma--a report of the Children's Cancer Group. *J Neurooncol.* Apr 1998;37(2):135-43. doi:10.1023/a:1005980206723
26. Massimino M, Gandola L, Biassoni V, et al. Evolving of therapeutic strategies for CNS-PNET. *Pediatr Blood Cancer.* Dec 2013;60(12):2031-5. doi:10.1002/pbc.24540
27. Matsuda Y, Hara J, Osugi Y, et al. Allogeneic peripheral stem cell transplantation using positively selected CD34+ cells from HLA-mismatched donors. *Bone Marrow Transplant.* Feb 1998;21(4):355-60. doi:10.1038/sj.bmt.1701095
28. Mueller S, Chang S. Pediatric brain tumors: current treatment strategies and future therapeutic approaches. *Neurotherapeutics.* Jul 2009;6(3):570-86. doi:10.1016/j.nurt.2009.04.006
29. National Cancer Institute Physician Data Query (PDQ). Childhood Medulloblastoma and Other Central Nervous System Embryonal Tumors Treatment. Updated April 12, 2023. Accessed December 4, 2023. <https://www.cancer.gov/types/brain/hp/child-cns-embryonal-treatment-pdq>
30. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: central nervous system cancers. Version 2.2022. Accessed December 4, 2023. https://www.nccn.org/professionals/physician_gls/PDF/cns.pdf
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33. Raghuram CP, Moreno L, Zacharoulis S. Is there a role for high dose chemotherapy with hematopoietic stem cell rescue in patients with relapsed supratentorial PNET? *J Neurooncol.* Feb 2012;106(3):441-7. doi:10.1007/s11060-011-0690-6

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35. Reddy AT, Strother DR, Judkins AR, et al. Efficacy of High-Dose Chemotherapy and Three-Dimensional Conformal Radiation for Atypical Teratoid/Rhabdoid Tumor: A Report From the Children's Oncology Group Trial ACNS0333. *J Clin Oncol*. Apr 10 2020;38(11):1175-1185. doi:10.1200/jco.19.01776
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37. Sung KW, Lim DH, Lee SH, et al. Tandem high-dose chemotherapy and autologous stem cell transplantation for anaplastic ependymoma in children younger than 3 years of age. *J Neurooncol*. Apr 2012;107(2):335-42. doi:10.1007/s11060-011-0745-8
38. Sung KW, Lim DH, Son MH, et al. Reduced-dose craniospinal radiotherapy followed by tandem high-dose chemotherapy and autologous stem cell transplantation in patients with high-risk medulloblastoma. *Neuro Oncol*. Mar 2013;15(3):352-9. doi:10.1093/neuonc/nos304
39. Sung KW, Lim DH, Yi ES, et al. Tandem High-Dose Chemotherapy and Autologous Stem Cell Transplantation for Atypical Teratoid/Rhabdoid Tumor. *Cancer Res Treat*. Oct 2016;48(4):1408-1419. doi:10.4143/crt.2015.347
40. Sung KW, Yoo KH, Cho EJ, et al. High-dose chemotherapy and autologous stem cell rescue in children with newly diagnosed high-risk or relapsed medulloblastoma or supratentorial primitive neuroectodermal tumor. *Pediatr Blood Cancer*. Apr 2007;48(4):408-15. doi:10.1002/pbc.21064
41. Zacharoulis S, Levy A, Chi SN, et al. Outcome for young children newly diagnosed with ependymoma, treated with intensive induction chemotherapy followed by myeloablative chemotherapy and autologous stem cell rescue. *Pediatr Blood Cancer*. Jul 2007;49(1):34-40. doi:10.1002/pbc.20935
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Coding:

CPT: 38204, 38205, 38206, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38220, 38230, 38232, 38240, 38241, 38242, 38243, 86812, 86813, 86816, 86817, 86821



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HCPCS: S2140, S2142, S2150

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Pane (ad hoc)	03/25/24	Review with revisions
Pediatric Subspecialty Advisory Sub-Committee	11/16/23	Review with no revisions
Medical Policy Panel	03/07/23	Review with revisions
Pediatric Subspecialty Advisory Sub-Committee	11/30/22	Review with no revisions
Medical Policy Panel	08/02/22	Approved guideline (Effective 9/19/22)

Policy Revisions:

03/25/24	Updated:	Resources section
03/07/23	Added:	“Insufficient evidence to support improvement of the net health outcome; or”, and “Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or” to experimental or investigational criteria bullets
03/07/23	Revised:	“Insufficient evidence to support improvement outside the investigational setting” from #3 to #5 in experimental or investigational criteria bullets
03/07/23	Removed:	HCPCS codes: J9000-J9999, Q0083, Q0084, Q0085
03/07/23	Updated:	Description section; Resources section



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

