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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

Description:

High-dose chemotherapy with hematopoietic cell transplantation (HCT) has been investigated as a possible therapy in pediatric individuals with brain tumors, particularly in individuals with disease that is considered high risk. In addition, the use of HCT has allowed for a reduction in the dose of radiation needed to treat both average and high-risk disease, with preservation of quality of life and intellectual functioning, without compromising survival.
HEMATOPOIETIC CELL TRANSPLANTATION FOR CENTRAL NERVOUS SYSTEM (CNS) EMBRYONAL TUMORS AND EPENDYMOMA (cont.)

Description: (cont.)

Embryonal tumors include, but are not limited to:

- Atypical teratoid/rhabdoid tumor
- Ependymoblastoma
- Ependymoma
- Medulloblastoma
- Medulloepithelioma
- Primitive neuroectodermal tumors (PNETs): neuroblastoma, ganglioneuroblastoma, pinealblastoma

Hematopoietic Cell Transplantation (HCT):
Hematopoietic cells form blood and immune cells. HCT is a procedure in which hematopoietic cells are infused into a recipient with deficient bone marrow function. 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 a delivery. HCT may also be referred to as bone marrow transplant (BMT).

High-Dose Chemotherapy (HDC):
HDC is the administration of myelotoxic agents at doses sufficient to cause bone marrow failure. Myeloablative chemotherapy eradicates cancerous cells from the blood and bone marrow and inhibits the immune response against the donor bone marrow. HDC may be given with or without total body radiation.

Donor Types:
- Allogeneic: From a third-party donor
- Autologous: From an individual’s own bone marrow and/or circulating blood

Definitions:

Tandem Transplant:
Two successive cycles of high-dose chemotherapy, each followed by infusion of autologous stem cells, whether or not there is evidence of persistent disease following the first treatment.
HEMATOPOIETIC CELL TRANSPLANTATION FOR CENTRAL NERVOUS SYSTEM (CNS) EMBRYONAL TUMORS AND EPENDYMOMA (cont.)

Criteria:

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

Embryonal Tumors of the CNS:

- HDC with autologous HCT for an individual with a previously untreated embryonal tumor of the CNS is considered **medically necessary** with documentation of **ANY** of the following:
  1. Partial or complete induction response to induction of chemotherapy
  2. Stable disease after induction therapy

- HDC with autologous HCT for an individual with a recurrent embryonal tumor of the CNS is **medically necessary**.

- HDC with autologous HCT for an individual with an embryonal tumor of the CNS for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- HDC with allogeneic HCT for an individual with an embryonal tumor of the CNS is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- Tandem autologous HCT for an individual with an embryonal tumor of the CNS is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
HEMATOPOIETIC CELL TRANSPLANTATION FOR CENTRAL NERVOUS SYSTEM (CNS) EMBRYONAL TUMORS AND EPENDYMOMA (cont.)

Criteria: (cont.)

Ependymoma:

- HDC with autologous, tandem autologous or allogeneic HCT for an individual with an ependymoma is considered experimental or investigational\(^1\) based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

\(^1\) Although specific transplantation procedures may be considered experimental or investigational and therefore not eligible for coverage under standard medical benefits, these procedures may be eligible for coverage based upon Arizona Revised Statutes §20-2326 concerning Cancer Clinical Trials.

Resources:

Literature reviewed 02/06/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 04/01/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

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

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, Office for Civil Rights, 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 nihilinígíí Blue Cross Blue Shield of Arizona haada ylt’ éego bina’dílhdídgo él doodago Háída bįį aniyyéediíłłí t’aadoo le’é yina’dílhdídgo beehaz’ ánníí hóół díí t’áa hazaad’ehí hák’ a’doodolgo bee haz’á doo baą́́h ilínígóó. Aта’ halné’ígíí koįj’ bích’į’ hodilíihí 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thành viên dịch viễn, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعدته سؤالًا بخصوص Blue Cross Blue Shield of Arizona، يمكنك الحصول على المساعدة والموارد الضرورية بلغتك من دون أي تكلفة. للتحدث مع متجر الحاصل ب. 877-475-4799.
HEMATOPOIETIC CELL TRANSPLANTATION FOR CENTRAL NERVOUS SYSTEM (CNS) EMBRYONAL TUMORS AND EPENDYMOMA (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinututulan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역어와 매개하기 위해서는 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète,appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dömitscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi: آگاه شما یا کسی که شما به آن کمک می کنید، سوال در مورد اطلاعات به زبان خود را به مدارک رایگان دریافت نمایید 877-475-4799.

Assyrian: Blue Cross Blue Shield of Arizona ئاین گەرەکەی ئاینەدە، ئایتە کە ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان ئاینەشەکان، ئاینەشەکان 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besporeno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณหรือคุณและผู้ที่คุณช่วยเหลือเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับข้อมูลและคำแนะนำภาษา ของคุณโดยไม่มีค่าใช้จ่าย โปรดโทรหมายเลข โทร 877-475-4799.