

**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 01/03/23
LAST REVIEW DATE: 01/03/23
CURRENT EFFECTIVE DATE: 01/03/23
LAST CRITERIA REVISION DATE: 01/03/23
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 1ST QTR 2024

HEMATOPOIETIC CELL TRANSPLANTATION

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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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Description:

Hematopoietic Cell Transplantation (HCT):

Hematopoietic stem 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) or stem cell transplantation (SCT).

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.

Nonmyeloablative Chemotherapy With Allogeneic Cell Transplantation (HCT):

Nonmyeloablative or reduced-intensity conditioning (RIC) is the administration of a lower dose of chemotherapy that is sufficient to eradicate the hematopoietic cells but does not completely destroy the bone marrow. RIC regimens attempt to reduce adverse effects secondary to bone marrow toxicity and allow for relatively prompt hematopoietic recovery. Nonmyeloablative chemotherapy may also be referred to as RIC, "mini transplant" or "transplant lite".

Chronic Granulomatous Disease:

Chronic granulomatous disease (CGD) is a rare, inherited immunodeficiency that affects certain white blood cells. People with this condition have immune systems that do not function properly, leaving the body vulnerable to chronic inflammation and frequent bacterial and fungal infections. It is caused by changes in any one of five different genes and is usually inherited in an autosomal recessive or X-linked recessive manner.

Granulocytic Sarcoma:

Granulocytic sarcoma is a rare solid tumor of the myelogenous cells occurring in an extramedullary site. Granulocytic sarcoma is also known as myeloid sarcoma, chloroma, extramedullary myeloid tumor, and myeloblastoma.

HIV Associated Lymphoma:

Infection with HIV weakens the immune system and reduces the body's ability to fight viral infections that may lead to cancer. Individuals infected with HIV are at higher risk for developing certain types of cancer compared to uninfected individuals. HIV associated lymphomas include Hodgkin lymphoma, primary effusion lymphoma, and multicentric Castleman disease.

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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Description: (cont.)

Acute Promyelocytic Leukemia (APL):

Acute promyelocytic leukemia (APL) is an aggressive type of acute myeloid leukemia in which there are too many immature blood-forming cells (promyelocytes) in the blood and bone marrow. This build up of promyelocytes leads to a shortage of normal white and red blood cells and platelets in the body. The signs and symptoms of APL include an increased risk to both bleed and form blood clots. Individuals may also experience excessive tiredness, pain in affected areas, loss of appetite, and weight loss. It is caused by a genetic change that is acquired over a person's lifetime, usually involving a translocation between chromosomes 15 and 17.

Paroxysmal Nocturnal Hemoglobinuria (PNH):

Paroxysmal nocturnal hemoglobinuria (PNH) is an acquired disorder that leads to the premature death and impaired production of blood cells. It can occur at any age, but is usually diagnosed in young adulthood. People with PNH have recurring episodes of symptoms due to hemolysis, which may be triggered by stresses on the body such as infections or physical exertion. This results in a deficiency of various types of blood cells and can cause signs and symptoms such as fatigue, weakness, abnormally pale skin (pallor), shortness of breath, and an increased heart rate. People with PNH may also be prone to infections and abnormal blood clotting (thrombosis) or hemorrhage, and are at increased risk of developing leukemia. It is caused by acquired, rather than inherited, genetic changes in the PIGA gene; the condition is not passed down to children of affected individuals.

Performance Status Tables:

Eastern Cooperative Oncology Group (ECOG) Score (Also known as Zubrod Score):

0	Asymptomatic. Fully active, able to carry on all pre-disease performance without restriction.
1	Symptomatic, fully ambulatory. Restricted in physically strenuous activity but able to carry out work of a light or sedentary nature.
2	Symptomatic, in bed less than 50% of the day. Capable of all self-care but unable to carry out any work activities.
3	Symptomatic, in bed or chair more than 50% of the day but not bedridden. Capable of only limited self-care.
4	Bedridden. Cannot perform any self-care.
5	Dead

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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Description: (cont.)

Performance Status Tables: (cont.)

Karnofsky Performance Score:

100%	Able to carry on normal activity, no evidence of disease.
90%	Able to carry on normal activity, minor signs or symptoms of disease.
80%	Normal activity with effort, some signs and symptoms of disease.
70%	Cares for self, unable to carry on normal activity or to work.
60%	Requires occasional assistance from others but able to care for most needs
50%	Requires considerable assistance from others and frequent medical care
40%	Disabled, requires special care and assistance.
30%	Severely disabled, hospitalization indicated, death not imminent.
20%	Very sick, hospitalization indicated, active support treatment necessary.
10%	Moribund
0%	Dead

Lansky Play Score (Also known as Lansky Play - Performance Scale):

100	Fully active, normal.
90	Minor restrictions in physically strenuous activity
80	Active, but tires more quickly.
70	Both greater restriction of and less time spent in play activity
60	Up and around, but minimal active play; keeps busy with quieter activities.
50	Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities.
40	Mostly in bed; participates in quiet activities.
30	In bed; needs assistance even for quiet play.
20	Often sleeping; play entirely limited to very passive activities.
10	No play; does not get out of bed.
0	Unresponsive

Donor Types:

- Allogeneic: From a third-party donor
- Autologous: From an individual's own bone marrow and/or circulating blood
- Syngeneic: From an identical twin

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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Definitions:

Refractory/Primary Refractory:

The disease is resistant to treatment and does not achieve a complete remission.

Relapse:

The recurrence of a disease or symptoms after apparent recovery.

Remission:

Period of time when cancer is responding to treatment or is under control. In complete remission, all signs and symptoms of the disease have disappeared.

Criteria:

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

Must meet both criteria A and B

A. Hematopoietic Cell Transplant:

Chronic Granulomatous Disease

- Nonmyeloablative reduced-intensity conditioning (RIC) with allogeneic stem cell transplantation for the treatment of chronic granulomatous disease is considered **medically necessary**.

Granulocytic Sarcoma

- High dose chemotherapy with allogeneic hematopoietic cell transplantation for the treatment of granulocytic sarcoma is considered **medically necessary** with documentation of **ANY** of the following:
 1. To induce remission
 2. Following first remission in chemoresponsive disease
- Nonmyeloablative reduced-intensity conditioning (RIC) with allogeneic hematopoietic cell transplantation for an individual who meets criteria for allogeneic hematopoietic cell transplantation but is medically unable to tolerate high dose chemotherapy is considered **medically necessary**.

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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Criteria: (cont.)

A. Hematopoietic Cell Transplant: (cont.)

Granulocytic Sarcoma (cont.)

- High dose chemotherapy with autologous hematopoietic cell transplantation for the treatment of granulocytic sarcoma is considered ***experimental or investigational***¹ 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.

HIV Associated Lymphoma

- High dose chemotherapy with autologous hematopoietic cell transplantation for the treatment of HIV associated lymphoma is considered ***medically necessary*** with documentation of **ALL** of the following:
 1. Current use of highly active antiretroviral therapy (HAART)
 2. Undetectable HIV viral load
 3. First remission or chemosensitive lymphoma in relapse
- High dose chemotherapy with allogeneic hematopoietic cell transplantation for the treatment of HIV associated lymphoma is considered ***experimental or investigational***¹ 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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HEMATOPOIETIC CELL TRANSPLANTATION (cont.)

Criteria: (cont.)

A. Hematopoietic Cell Transplant: (cont.)

Acute Promyelocytic Leukemia (APL)

- High dose chemotherapy with allogeneic or autologous hematopoietic cell transplantation for the treatment of acute promyelocytic leukemia is considered **medically necessary** with documentation of **ANY** of the following:
 1. 1st complete remission
 2. Primary refractory
 3. Relapsed
- High dose chemotherapy with allogeneic hematopoietic cell transplantation for relapse after a prior course of high dose chemotherapy with autologous hematopoietic cell transplantation if autologous hematopoietic cell transplantation was less than 6 months ago is considered **experimental or investigational**¹ 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.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- High dose chemotherapy with allogeneic or syngeneic hematopoietic cell transplantation for the treatment of paroxysmal nocturnal hemoglobinuria is considered **medically necessary** with documentation of **ANY** of the following:
 1. Refractory
 2. Life threatening complications (i.e., blood clots, progression to aplastic anemia or acute myelogenous leukemia)

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Criteria: (cont.)

B. Pretransplantation Evaluation:

- Human Leukocyte Antigen (HLA) typing and Matched Unrelated Donor (MUD) searches may be approved by the coordinator if the prior medical necessity criteria are met. HLA typing may use serologic tissue and/or DNA (gene) for more precise matching. The psychosocial criteria listed below must only be met prior to the actual transplant procedure.
- Pretransplantation evaluation with documentation of **ALL** of the following:
 1. Psychosocial screen with documentation of **ALL** of the following:
 - Drug/alcohol screen with documentation of **ONE** of the following:
 - No drug/alcohol abuse by history
 - Drug and alcohol free for a period greater than or equal to 6 months
 - Behavioral health disorder screening with documentation of **ONE** of the following:
 - No behavioral health disorder by history and physical exam
 - Behavioral health disorder treated
 2. Adequate social/family support
 3. Performance status with documentation of **ONE** of the following:
 - Karnofsky score greater than or equal to 70%
 - Eastern Cooperative Oncology Group (ECOG) score 0-2
 - For ages 10 or under: Lansky Play score greater than or equal to 70. A Lansky Play score less than 70 **will be reviewed by the medical director(s) and/or clinical advisor(s).**

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.

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Resources:

Literature reviewed 01/03/23. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 01/31/22 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Ambinder RF, Wu J, Logan B, et al. Allogeneic Hematopoietic Cell Transplant for HIV Patients with Hematologic Malignancies: The BMT CTN-0903/AMC-080 Trial. *Biology of blood and marrow transplantation : journal of the American Society for Blood and Marrow Transplantation*. Nov 2019;25(11):2160-2166. doi:10.1016/j.bbmt.2019.06.033
2. Brodsky RA. Treatment and prognosis of paroxysmal nocturnal hemoglobinuria. In: Rosmarin AG, ed. *UpToDate*. UpToDate; 2022. Accessed December 9, 2022. <https://www.uptodate.com/contents/treatment-and-prognosis-of-paroxysmal-nocturnal-hemoglobinuria>
3. Burt R. Cyclophosphamide and rATG With Hematopoietic Stem Cell Support in Systemic Scleroderma. NIH U.S. National Library of Medicine ClinicalTrials.gov. Updated April 30, 2014. Accessed December 13, 2022. <http://www.clinicaltrials.gov/ct2/show/NCT00278525?term=cyclophosphamide+and+ratg+systemic+scleroderma&rank=1>
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9. Genetic and Rare Diseases Information Center. NIH National Center for Advancing Translational Sciences. 2022. Updated November 8, 2021. Accessed December 12, 2022. <https://rarediseases.info.nih.gov/diseases/>
10. Hashmi H, Nishihori T. Role of hematopoietic cell transplantation in relapsed acute promyelocytic leukemia. *Clin Transplant*. Sep 2020;34(9):e14009. doi:10.1111/ctr.14009

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Resources: (cont.)

11. HIV Infection and Cancer Risk. NIH National Cancer Institute. 2022. Updated September 14, 2017. Accessed December 13, 2022. <https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hiv-fact-sheet>
12. Holter Chakrabarty JL, Rubinger M, Le-Rademacher J, et al. Autologous is superior to allogeneic hematopoietic cell transplantation for acute promyelocytic leukemia in second complete remission. *Biology of blood and marrow transplantation : journal of the American Society for Blood and Marrow Transplantation*. Jul 2014;20(7):1021-5. 24691221. doi:10.1016/j.bbmt.2014.03.025
13. Hunter NB, Vogt S, Ambinder RF. Treatment of HIV-Associated Lymphomas: The Latest Approaches for Optimizing Outcomes. *Oncology (Williston Park)*. Dec 15 2017;31(12):872-7, 884.
14. Kaplan LD, Ai W. HIV-related lymphomas: Treatment of systemic lymphoma. In: Rosmarin AG, ed. *UpToDate*. UpToDate; 2022. Accessed December 9, 2022. <https://www.uptodate.com/contents/hiv-related-lymphomas-treatment-of-systemic-lymphoma>
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19. Min GJ, Cho BS, Park SS, et al. Treatment for relapsed acute promyelocytic leukemia: what is the best post-remission treatment? *Blood Res*. Sep 30 2022;57(3):197-206. doi:10.5045/br.2022.2022060
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Resources: (cont.)

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23. Yamamoto S, Tomizawa D, Kudo K, et al. Hematopoietic stem cell transplantation for pediatric acute promyelocytic leukemia in Japan. *Pediatr Blood Cancer.* May 2020;67(5):e28181. doi:10.1002/pbc.28181
24. Yanada M. Treatment for relapsed acute promyelocytic leukemia. *Ann Hematol.* Dec 2022;101(12):2575-2582. doi:10.1007/s00277-022-04954-0
25. Yanada M, Matsuda K, Ishii H, et al. Allogeneic Hematopoietic Cell Transplantation for Patients with Relapsed Acute Promyelocytic Leukemia. *Transplant Cell Ther.* Dec 2022;28(12):847.e1-847.e8. doi:10.1016/j.jtct.2022.09.021

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,
 HCPCS: S2140, S2142, S2150

History:

Date:

Activity:

Medical Policy Panel	01/03/23	Approved guideline
Legal Division	12/14/22	Review with no revisions
Medical Director (Dr. Deering)	12/02/22	Review with revisions
Pediatric Subspecialty Advisory Sub-Committee	11/30/22	Review with no revisions

Policy Revisions:



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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 nílínígíí Blue Cross Blue Shield of Arizona haada yit'éego bína'idíílkidgo éí doodago Háida bíjá anílyeedígíí t'áadoo le'é yína'idíílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ílínígóó. Ata' halne'ígíí kojí' bich'í' hodíílnih 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.



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