MEDICAL POLICY

POLICY TITLE	HEMATOPOIETIC CELL TRANSPLANTATION FOR CHRONIC MYELOID LEUKEMIA
POLICY NUMBER	MP 9.039

Effective Date:	5/1/2023

I. POLICY

Allogeneic hematopoietic cell transplantation (HCT) using a myeloablative conditioning regimen may be considered **medically necessary** as a treatment of chronic myelogenous leukemia.

Allogeneic HCT using a reduced-intensity conditioning regimen may be considered **medically necessary** as a treatment of chronic myeloid leukemia in members who meet clinical criteria for an allogeneic HCT but who are not considered candidates for a myeloablative conditioning allogeneic HCT.

Autologous HCT is **investigational** as a treatment of chronic myeloid leukemia. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

Policy Guidelines

Some members for whom a conventional myeloablative allotransplant could be curative may be considered candidates for reduced-intensity conditioning allogeneic HCT. These include those members whose age (typically greater than 60 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status score) preclude use of a standard myeloablative conditioning regimen.

For members who qualify for a myeloablative allogeneic HCT on the basis of clinical status, either a myeloablative or reduced-intensity conditioning regimen may be considered medically necessary.

Cross-references:

MP 9.001 Placental/Umbilical Cord Blood as a Source of Stem Cells.
MP 9.038 Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
MP 9.040 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia

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MP 9.041 Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia
MP 9.042 Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas
MP 9.043 Hematopoietic Cell Transplantation for Hodgkin Lymphoma
MP 9.044 Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome
MP 9.045 Hematopoietic Cell Transplantation for Primary Amyloidosis
MP 9.046 Hematopoietic Cell Transplantation for Waldenstrom Macroglobulinemia
MP 9.047 Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer
MP 9.048 Hematopoietic Cell Transplantation Miscellaneous Solid Tumors in Adults
MP 9.050 Hematopoietic Cell Transplantation for CNS Embryonal Tumors and Ependymoma
MP 9.052 Hematopoietic Cell Transplantation in the Treatment of Germ-Cell Tumors
MP 9.053 Hematopoietic Cell Transplantation for Autoimmune Diseases
MP 9.054 Hematopoietic Cell Transplantation for Solid Tumors of Childhood
MP 9.055 Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias
MP 9.056 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO
Note: The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services. The FEP Medical Policy manual can be found at: https://www.fepblue.org/legal/policies-guidelines

III. DESCRIPTION/BACKGROUND

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CHRONIC MYELOID LEUKEMIA
Chronic myeloid leukemia (CML) is a hematopoietic stem cell disorder characterized by the presence of a chromosomal abnormality called the Philadelphia chromosome, which results from a reciprocal translocation between the long arms of chromosomes 9 and 22. This cytogenetic change results in constitutive activation of BCR-ABL, a tyrosine kinase that stimulates unregulated cell proliferation, inhibits cell apoptosis, creates genetic instability, and upsets interactions between CML cells and the bone marrow stroma only in malignant cells. CML accounts for about 15% of newly diagnosed cases of leukemia in adults and occurs in 1 to 2 cases per 100,000 adults.[1]

The natural history of the disease consists of an initial (indolent) chronic phase, lasting a median of 3 years, which typically transforms into an accelerated phase, followed by a “blast crisis,”

which is usually the terminal event. Most patients present in chronic phase, often with nonspecific symptoms secondary to anemia and splenomegaly. CML diagnosis is based on the presence of the Philadelphia chromosome abnormality by routine cytogenetics, or by detection of abnormal BCR-ABL products by fluorescence in situ hybridization or molecular studies, in the setting of persistent unexplained leukocytosis. Conventional-dose chemotherapy regimens used for chronic phase disease can induce multiple remissions and delay the onset of blast crisis to a median of 4 to 6 years. However, successive remissions are invariably shorter and more difficult to achieve than their predecessors.

Treatment

Historically, the only curative therapy for CML in blast phase has been allogeneic HCT (allo-HCT), which was used more widely earlier in the disease process given the lack of other therapies for chronic phase CML. Drug therapies for chronic phase CML were limited to nonspecific agents including busulfan, hydroxyurea, and interferon-α.[1]

Imatinib mesylate (Gleevec®), a selective inhibitor of the abnormal BCR-ABL tyrosine kinase protein, is considered the treatment of choice for newly diagnosed CML. While imatinib can be highly effective in suppressing CML, it is not curative and is ineffective in 20% to 30% of patients, initially or due to development of *BCR-ABL* variants that cause resistance to the drug. Even so, the overall survival of patients who present in chronic phase is greater than 95% at 2 years and 80% to 90% at 5 years.[2]

For CML, two other tyrosine kinase inhibitors ([TKIs]; dasatinib, nilotinib) have received marketing approval from the U.S. Food and Drug Administration as first-line therapies or following failure or patient intolerance of imatinib. Two additional TKIs (bosutinib, ponatinib) have been approved for use in patients resistant or intolerant to prior therapy.

For patients on imatinib who have disease progression, the therapeutic options include increasing the imatinib dose, changing to another TKI, or allo-HCT. Detection of *BCR-ABL* variants may be important in determining an alternative TKI; the presence of the *T315I* variant is associated with resistance to all TKIs and should indicate the need for allo-HCT or experimental therapy. TKIs have been associated with long-term remissions; however, if disease progression occurs on TKI therapy, allo-HCT is generally indicated and offers the potential for cure.

Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of drugs with or without whole body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or a donor (allo-HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naive” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD). Cord blood is discussed in detail in medical policy 9.001, Placental/Umbilical Cord Blood as a Source of Stem Cells.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allo-HCT, immunologic compatibility between donor and patient is a

critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLAs) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. 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 (eg, 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 initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that is mediated by non-self-immunologic effector cells. While the slower GVM 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 and failure caused by the cytotoxic drugs. Subsequent to graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and GVHD, which also increase susceptibility to opportunistic infections.

The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed when the patient's disease is in complete remission. Patients who undergo autologous HCT are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.

Reduced-Intensity Conditioning for Allo-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 GVM 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. For this evidence review, RIC will refer to all conditioning regimens intended to be nonmyeloablative.

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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have CML who receive allo-HCT, the evidence includes systematic reviews, randomized controlled trials, and multiple prospective and retrospective series. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The introduction of TKIs has significantly changed the clinical use of HCT for CML. TKIs have replaced HCT as initial therapy for patients with chronic phase CML. However, a significant proportion of cases fail to respond to TKIs, develops resistance to them, or cannot tolerate TKIs and proceed to allo-HCT. Also, allo-HCT represents the only potentially curative option for those patients in the accelerated or blast phase CML. Currently, available evidence has suggested that TKI pretreatment does not lead to worse outcomes if HCT is needed. Myeloablative conditioning regimens before HCT are used in younger (less than 60 years of age) patients without significant comorbidities. However, for patients with more comorbidities and/or more advanced age for whom myeloablative conditioning regimens would be prohibitively high-risk, evidence has suggested that reasonable outcomes can be obtained after HCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have CML who receive autologous HCT, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. In the largest series (n=200 patients), median survival was 36 months for patients transplanted during an accelerated phase; median survival data were not available for patients transplanted in chronic phase. Controlled studies are needed to permit conclusions on the impact of autologous HCT on health outcomes in patients with CML. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ALLOGENEIC refers to having a different genetic constitution but belonging to the same species, i.e., involves a donor and a recipient. These cells are harvested from a donor, after verifying the donor and the recipient are well matched with respect to human leukocyte antigens (HLA). Allogeneic cells provide two (2) theoretical advantages: the lack of tumor contamination associated with autologous stem cells, and the possibility of a beneficial graft-versus-tumor effect. Their disadvantage is the risk of graft-versus host disease (GVHD), which increases with great HLA disparity and recipient age.

AUTOLOGOUS refers to originating within an individual, i.e., self-donation. These stem cells are harvested from patients prior to myeloablative therapy.

HEMATOPOIETIC CELL TRANSPLANT (HCT) is the intravenous infusion of autologous (from one's self) or allogeneic (from a matched donor) stem cells (immature cells within the bone

marrow that give rise to most cells within the blood) in order to reestablish hematopoietic function in patients with damaged or defective bone marrow or immune systems.

KARNOFSKY INDEX is a tool to estimate clinically a patient's physical state, performance, and prognosis. The scale is from 100%, perfectly well and active, to 0%, completely inactive, or dead. It has been used in studying cancer and chronic illness. Lower Karnofsky scores are generally associated with poorer treatment response and prognosis.

MYELOABLATIVE CONDITIONING REGIMEN is a combination of agents expected to produce profound pancytopenia and myeloablation within 1–3 weeks from administration. Pancytopenia is long lasting, usually irreversible, and in most instances fatal unless hematopoiesis is restored by hemopoietic stem cell infusion.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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.

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Investigational; therefore not covered:

Procedure Codes							
38206	38232	38241					

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Covered when medically necessary:

Procedure Codes								
38204	38205	38207	38208	38209	38210	38211	38212	38213
38214	38215	38230	38240	S2140	S2142	S2150		

ICD-10-CM Diagnosis Codes	Description
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse

IX. REFERENCES

TOP

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X. POLICY HISTORY

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MP 9.039	**CAC 5/20/14 Minor**. Information related to HSCT for Chronic Myelogenous Leukemia extracted from MP 9.037 Autologous and Allogeneic Stem Cell Transplantation and this separate policy created. No change to policy statements. Policy guidelines added. References updated.
	CAC 6/2/15 Consensus. No change to policy statements. References and rationale updated. Coding reviewed.
	CAC 5/31/16 Consensus. No change to policy statements. References and rationale updated. Coding reviewed**.**
	1/1/17 Administrative Update Variation reformatting
	CAC 7/25/17 Consensus. Clarification as follows: • "Hematopoietic stem cell transplantation" changed to "hematopoietic cell transplantation" per NCCN terminology change (title and policy language revised as appropriate). • "Myelogenous" changed to "myeloid" (title and policy language revised as appropriate). Cross References, Description/Background, Rationale, and Reference sections updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	4/4/18 Consensus review. Background and references reviewed. Rationale condensed to include only the evidence summary.
	3/7/19 Consensus review. Policy statement unchanged. References updated. Coding reviewed and updated.
	4/9/20 Consensus review. Policy criteria unchanged, minor revisions under Description/Background section, references updated. Coding reviewed.
	5/26/21 Consensus review. Policy unchanged references and coding reviewed.
	2/8/22 Consensus review. NCCN statement added, no changes to current criteria. No references added.
	2/3/23 Consensus review. No changes to policy statement. References reviewed and updated. Coding reviewed.

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