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# MEDICAL POLICY – 8.01.30

# Hematopoietic Cell Transplantation for Chronic Myeloid Leukemia

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|---|---|
| BCBSA Ref. Policy: | 8.01.30 |
| Effective Date: | Apr. 1, 2025 |
| Last Revised: | Mar. 10, 2025 |
| Replaces: | N/A |

RELATED MEDICAL POLICIES:

| | |
|---|---|
| 8.01.26 | Hematopoietic Cell Transplantation for Acute Myeloid Leukemia |
| 8.01.520 | Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia |
| 8.01.529 | Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas |
| 8.01.539 | Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms |

**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

Chronic myeloid leukemia (CML) is a type of cancer that starts in certain blood-forming cells within the bone marrow. These blood-forming calls are called "hematopoietic" cells. When a person has CML, they make too many white blood cells. Different types of treatment have been used against CML, including chemotherapy and other medications. Another common type of treatment is a hematopoietic cell transplant. In a hematopoietic cell transplant, hematopoietic cells are taken from a donor's bone marrow and are given to the person with CML, just like in a transfusion. It is hoped that these new cells will then settle into the bone marrow and start producing normal blood cells, and the person will no longer have CML.

When the hematopoietic cells are harvested from another person, it is called an allogeneic transplant. When the cells come from the individual himself, it is called an autologous cell transplant. This policy discusses when an allogeneic hematopoietic cell transplant would be medically necessary to treat CML.

**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

| Transplant | Medical Necessity |
|---|---|
| **Allogeneic hematopoietic cell transplantation (HCT)** | **Allogeneic hematopoietic cell transplantation (HCT) using a myeloablative conditioning regimen may be considered medically necessary as a treatment of chronic myeloid leukemia.**<br><br>**Allogeneic HCT using a reduced-intensity conditioning regimen may be considered medically necessary as a treatment of chronic myeloid leukemia in individuals who meet clinical criteria for an allogeneic HCT but who are not considered candidates for a myeloablative conditioning allogeneic HCT.** |

| Transplant | Investigational |
|---|---|
| **Autologous HCT** | **Autologous HCT is investigational as a treatment of chronic myeloid leukemia.** |

### Additional Information

- Some individuals for whom a conventional myeloablative allotransplant could be curative may be considered candidates for reduced-intensity conditioning allogeneic hematopoietic stem-cell transplantation (HCT). These include those individuals whose age (typically >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 individuals 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**.

## Documentation Requirements

**The individual'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

# Coding

| Code | Description |
|---|---|
| **CPT** | |
| 38241 | Hematopoietic progenitor cell (HPC); autologous transplantation |

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

# Related Information

## Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous 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 individuals participating in National Institutes of Health-approved clinical trials of cancer chemotherapies, including autologous bone marrow transplantation.
- Some contracts or certificates of coverage may include specific conditions in which autologous bone marrow transplantation would be considered eligible for coverage.

# Evidence Review

## Description

Chronic myeloid leukemia (CML) is a hematopoietic stem cell disorder that is characterized by the presence of a chromosomal abnormality called the Philadelphia chromosome, which results from reciprocal translocation between the long arms of chromosomes 9 and 22. CML most often presents in a chronic phase from which it progresses to an accelerated and then a blast phase. Allogeneic hematopoietic cell transplantation (allo-HCT) is a treatment option for CML.

## Background

## Chronic Myeloid Leukemia

Chronic myeloid leukemia (CML) is a hematopoietic stem-cell disorder that is characterized by the presence of a chromosomal abnormality called the Philadelphia chromosome, which results from reciprocal translocation between the long arms of chromosomes 9 and 22. This cytogenetic change results in constitutive activation of the fusion gene 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 about 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 three years, which typically transforms into an accelerated phase, followed by a "blast crisis," which is usually the terminal event. Most individuals present in chronic phase, often with nonspecific symptoms that are secondary to anemia and splenomegaly. CML is diagnosed 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 four to six years. However, successive remissions are usually shorter and more difficult to achieve than their predecessors.

**Treatment**

Historically, the only curative therapy for CML in blast phase has been allogeneic hematopoietic cell transplantation (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 usually not curative and is ineffective in 20% to 30% of individuals, initially or due to development of *BCR-ABL* variants that cause resistance to the drug. Even so, the overall survival of individuals who present in the 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 US Food and Drug Administration (FDA) as first-line therapies or following failure or individual intolerance of imatinib. Two additional TKIs (bosutinib, ponatinib) have been approved for use in individuals resistant or intolerant to prior therapy.

For individuals 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 T315I variant is associated with resistance to all TKIs, except Ponatinib (3rd generation TKI), and should indicate the need for allo-HCT or an 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 intravenously 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 (allogeneic HCT). They 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 allo-HCT, immunologic compatibility between donor and patient is critical 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 loci on each arm of chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci.

## Conditioning for Hematopoietic Cell Transplantation

### Conventional Conditioning

The conventional ("classical") practice of allogeneic HCT involves administration of cytotoxic agents (e.g., 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 individuals 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 graft-versus-host disease (GVHD), which increases susceptibility to opportunistic infections.

The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy, with or without radiotherapy, 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 individual before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the individual's disease is in complete remission. Individuals 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 clinical 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 graft-versus-malignancy effect of allogeneic transplantation develops. RIC regimens range from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and individual condition. Individuals who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. In this policy, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative.

## Summary of Evidence

For individuals who have CML who receive allo-HCT, the evidence includes systematic reviews, randomized controlled trials (RCTs), and multiple prospective and retrospective series. The relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The introduction of tyrosine kinase inhibitors (TKIs) has significantly changed the clinical use of HCT for CML. TKIs have replaced HCT as initial therapy for individuals 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 individuals 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 (<60 years) individuals without significant comorbidities. However, for individuals 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. The relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. In the largest series (N=200 individuals), median survival was 36 months for individuals transplanted during an accelerated phase; median survival data were not available for individuals transplanted in chronic phase. Controlled studies are needed to permit conclusions on the impact of autologous HCT on health outcomes in individuals with CML. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Ongoing and Unpublished Clinical Trials

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

## Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| NCT03314974 | Myeloablative Allogeneic Hematopoietic Cell Transplantation Using a Related or Unrelated Donor for the Treatment of Hematological Diseases | 300 | Nov 2025 |
| **Unpublished** | | | |
| NCT01760655 | A Two Step Approach to Reduced Intensity Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Hematologic Malignancies | 62 | Dec 2022 |

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American Society for Transplantation and Cellular Therapy

In 2020, the guidelines by the American Society for Transplantation and Cellular Therapy (formerly the American Society for Blood and Marrow Transplantation) addressed indications for autologous and allo-HCT for CML.[29] Recommendations are listed in **Table 2**.

## Table 2. Recommendations on Allogeneic and Autologous HCT for CML

| Indications | Allogeneic HCT | Autologous HCT |
|---|---|---|
| **Pediatric** | | |
| Chronic phase | C | N |
| Accelerated phase | C | N |
| Blast phase | C | N |
| **Adult** | | |
| Chronic phase, TKI intolerant | C | N |
| Chronic phase, TKI refractory | C | N |
| Chronic phase 2+ | S | N |
| Accelerated phase | S | N |
| Blast phase | S | N |

C: Standard of care, clinical evidence available, CML: chronic myeloid leukemia; HCT: hematopoietic cell transplantation; N: Not generally recommended; S: standard of care.

## National Comprehensive Cancer Network

National Comprehensive Cancer Network CML guidelines (v.3.2025) recommend allo-HCT as an alternative treatment only for high-risk settings or in patients with advanced-phase CML.[30] Relevant recommendations are:

- "Allogeneic HCT is no longer recommended as a first-line treatment option for CP [chronic phase] CML."
- "Allogeneic HCT is an appropriate first-line treatment option for the very rare patients presenting with blast phase at diagnosis, patients with T315I and other BCR-ABL1 variants that are resistant to all TKIs [tyrosine kinase inhibitors], and for the rare patients intolerant to all TKIs."
- "Evaluation for allogeneic HCT….is recommended for all patients with AP [accelerated phase] CML or BP [blast phase] CML"

Autologous HCT for CML is not addressed in these guidelines.

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

The FDA 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


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## History

| Date | Comments |
|---|---|
| 02/01/00 | Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on high-dose chemotherapy for miscellaneous malignancies. However, policy statement is unchanged. |
| 01/14/03 | Replace Policy - Policy updated, new references added; no change in policy statement. |
| 06/17/03 | Replace Policy - Update CPT codes only. |
| 08/12/03 | Replace Policy - Reviewed and recommended for adoption without any changes by Company Oncology Advisory Panel July 22, 2003. |
| 10/12/04 | Replace Policy - Policy reviewed with literature search; no change in policy statement. Approved by OAP 10/29/04, returning to MPC. |
| 01/10/06 | Replace Policy - Policy reviewed with literature search; no change to policy statement. |
| 06/02/06 | Disclaimer and Scope updates - No other changes. |
| 11/14/06 | Replace Policy - Policy reviewed and recommended by OAP 10/26/06 without changes. |
| 10/09/07 | Replace Policy - BCBSA updated; Policy reviewed with literature search; policy statement unchanged; new references added. |
| 10/14/08 | Replace Policy - Policy updated with literature search; no change to the policy statement. References added. |
| 11/11/08 | Replace Policy - Policy extensively updated with literature search. Policy statement updated to remove “HDC” and replaced with “SCT”, this is reflected within the title and |

| Date | Comments |
|---|---|
| | body of the policy. Investigational statement added to include Autologous SCT as a treatment of chronic myelogenous leukemia. References added. Reviewed and recommended for approval by the Oncology Advisory Panel, February 21, 2008. |
| 01/12/10 | Replace Policy - Policy updated extensively with literature review. Policy statements revised to consider RIC allogeneic SCT as medically necessary in specific conditions. References added. |
| 02/09/10 | Code Update - New 2010 codes added. |
| 08/09/11 | Replace Policy – Policy updated with literature search; no change to policy statements. References 11-14 added; reference 23 updated. ICD-10 codes added to policy. Related Policy titles updated. |
| 10/19/11 | Related Policies updated; codes 38220 and 38221 removed. |
| 02/14/12 | Replace Policy – Policy updated with literature search; no change to policy statements. References 15-17 added. Code 38232 added; code 38204 listed as Medicare Status B, non-reimbursable. |
| 06/20/12 | Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012. |
| 07/30/12 | Update Related Policies titles for: 8.01.17, 8.01.22, 8.01.29, 8.01.31, and 8.01.514. |
| 10/09/12 | Update Coding Section – ICD-10 codes are now effective 10/01/2014. |
| 02/13/13 | Replace policy. A literature review through October 2012 did not prompt any changes to the rationale section. Clarifications added to the practice guidelines and position statements. No new references added. Policy statement unchanged. Update title to Related Policy 8.01.21. |
| 03/20/13 | The following codes were removed from the policy, as they were not suspending and just informational: CPT 38204, HCPCS J9000-J9999 and Q0083-Q0085. |
| 07/25/13 | Update Related Policies. Change title to 8.01.35. |
| 09/30/13 | Update Related Policies. Change title to 8.01.31. |
| 12/06/13 | Update Related Policies. Remove 8.01.31 as it was archived. |
| 02/10/14 | Replace policy. Deleted the word “treatment” from the title. Policy Guidelines reworded for readability. Rationale updated with literature search through November 8, 2013. Reference 13,26updated, reference 27 added Policy statements unchanged. |
| 03/21/14 | Update Related Policies. Remove 8.01.514 as it was deleted. |
| 04/18/14 | Update Related Policies. Remove 8.01.20 and add 8.01.529. |
| 06/24/14 | Update Related Policies. Remove 8.01.35, and 8.01.42, then add 8.01.530 and 8.01.532. |
| 12/03/14 | Update Related Policies. Remove 8.01.17. |
| 02/10/15 | Annual Review. Policy updated with literature review through November 3, 2014. References 1 and 15-18 added. Policy statements unchanged. Clarification made to |

| Date | Comments |
|---|---|
| | wording in the Policy Guidelines section for improved readability; no change in intent. ICD-9 and ICD-10 diagnosis and procedure codes removed. |
| 04/12/16 | Annual Review. Policy updated with literature review through October 27, 2015; references 3, 8, 18, and 20-22 added. Policy statements unchanged. |
| 11/04/16 | Coding update. Removed codes that are transplant benefit related. |
| 04/01/17 | Annual Review, approved March 14, 2017. Policy updated with literature review through November 9, 2016; references 11 and 30 added. In title and policy statements, "stem" removed and "myelogenous" changed to "myeloid". |
| 11/10/17 | Policy moved to new format, no changes to policy statement. |
| 06/01/18 | Annual Review, approved May 3, 2018. Policy updated with literature review through December 2017; no reference added, reference 29 updated. Policy statements unchanged. |
| 04/01/19 | Minor update, added Documentation Requirements section. |
| 05/01/19 | Annual Review, approved April 2, 2019. Policy updated with literature review through December 2018; no references added, reference 29 updated. Policy statements unchanged. |
| 04/01/20 | Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020. Approved March 19, 2020, policy updated with literature review through November 2019; no references added, reference on NCCN guidelines updated. Policy statements unchanged. Removed CPT code 38242, does not match criteria. |
| 06/10/20 | Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020. |
| 08/01/20 | Annual Review, approved July 2, 2020. Policy updated with literature review through November 11, 2019; no references added, reference on NCCN guidelines updated. Policy statements unchanged |
| 09/01/20 | Coding update. Removed CPT codes 38230, 38232 and HCPCS S2140, S2142 and S2150. Title updated, "myeloid" replaced with "myelogenous". |
| 04/01/21 | Annual Review, approved March 2, 2021. Policy updated with literature review through December 9, 2020; references updated on NCCN guidelines and American Society for Transplantation and Cellular Therapy. Policy statements unchanged. |
| 05/01/21 | Update Related Policies. Removed policy 7.01.50 as it was archived. |
| 04/01/22 | Annual Review, approved March 21, 2022. Policy updated with literature review through November 29, 2021; no references added. Policy statements unchanged. |
| 04/01/23 | Annual Review, approved March 20, 2023. Policy updated with literature review through November 15, 2022; no references added. Minor editorial refinements to |



| Date | Comments |
|---|---|
| | policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 04/01/24 | Annual Review, approved March 25, 2024. Policy updated with literature review through November 20, 2023; no references added. Policy statements unchanged. Updated Related Policy from 8.01.21 to 8.01.539 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms. |
| 04/01/25 | Annual Review, approved March 10, 2025. Policy updated with literature review through December 9, 2024; no references added. Policy statements unchanged. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.