

## Medical Policy Manual

**Topic:** Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia

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**Section:** Transplant

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### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

#### **Hematopoietic Stem-Cell Transplantation**

Hematopoietic stem-cell transplantation (HSCT) refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HSCT) or from a donor (allogeneic HSCT). 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 “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD).

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HSCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic HSCT. 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.

#### **Conventional Preparative Conditioning for HSCT**

The conventional (“classical”) practice of allogeneic HSCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that develops after engraftment of allogeneic stem cells within the patient’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease without the use of pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allogeneic HSCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections.

The success of autologous HSCT is predicated on the ability 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 prior to undergoing bone marrow ablation. As a consequence, autologous HSCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HSCT are susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

### **Reduced-Intensity Conditioning for Allogeneic HSCT**

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in conventional full-dose myeloablative conditioning treatments. The goal of RIC is not only to reduce disease burden, but also to minimize as much as possible associated treatment-related morbidity and non-relapse mortality (NRM) in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of NRM and relapse due to residual disease. RIC regimens can be viewed as a continuum in effects, from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Patients who undergo RIC with allogeneic HSCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For the purposes of this Policy, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be non-myeloablative, as opposed to fully myeloablative (conventional) regimens.

### **Chronic Myelogenous Leukemia**

Chronic myelogenous 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 BCR-ABL, a tyrosine kinase (TK) that stimulates unregulated cell proliferation, inhibition of apoptosis, genetic instability, and perturbation of the interactions between CML cells and the bone marrow stroma only in malignant cells.

The natural history of the disease consists of an initial (indolent) chronic phase, lasting a median of 3 years, that typically transforms into an accelerated phase, followed by a "blast crisis," which is usually the terminal event. Conventional-dose regimens used for chronic-phase disease can induce multiple remissions and delay the onset of blast crisis to a median of 4–6 years. However, successive remissions are invariably shorter and more difficult to achieve than their predecessors.

Imatinib mesylate (Gleevec®), a selective inhibitor of the abnormal BCR-ABL TK protein, is considered the treatment of choice for newly diagnosed CML. While imatinib can be highly effective in suppressing CML in most patients, it is not curative and is ineffective in 20% to 30%, initially or due to development of BCR-ABL mutations that cause resistance to the drug. Two other TK inhibitors (TKIs; dasatinib, nilotinib) have received marketing approval from the U.S. Food and Drug Administration (FDA) to treat CML following failure or patient intolerance of imatinib. In any case, allogeneic HSCT remains the only treatment capable of inducing durable remissions or cure in CML patients.

## **MEDICAL POLICY CRITERIA**

### **I. Autologous HSCT**

Autologous hematopoietic stem-cell transplantation is considered **investigational** as a treatment of chronic myelogenous leukemia.

### **II. Allogeneic HSCT**

A. Allogeneic hemopoietic stem-cell transplantation using a *myeloablative conditioning* regimen may be considered **medically necessary** as a treatment of chronic myelogenous leukemia (see Policy Guidelines).

B. Allogeneic hemopoietic stem-cell transplantation with a *reduced-intensity conditioning (RIC)* regimen may be considered **medically necessary** as a treatment of chronic myelogenous leukemia in patients who meet clinical criteria for an allogeneic HSCT but who are not considered candidates for a *myeloablative conditioning* allogeneic HSCT (see policy guidelines).

## **POLICY GUIDELINES**

Patients who meet criteria for allogeneic HSCT but whose advanced age (typically older than 60 years) and existing comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude the use of a standard myeloablative conditioning regimen, may be considered candidates for *reduced-intensity conditioning (RIC)*.

## **SCIENTIFIC EVIDENCE**

The principal outcomes associated with treatment of hematologic malignancies are typically measured in units of survival past treatment: disease-free survival (DFS), a period of time following treatment where the disease is undetectable; progression-free survival (PFS), the duration of time after treatment before the advancement or progression of disease; and overall survival (OS), the period of time the patient

remains alive following treatment. Risk of graft-versus-host disease is another primary outcome among patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT). Ideally, in order to understand the impact of HSCT for treatment of chronic myelogenous leukemia, comparative clinical trials that compare this therapy to standard medical treatment, such as treatment with a TKI, or among patients not able to tolerate TKIs, or for whom TKIs fail, standard conditioning regimens, are needed. Further, for treatment of hematologic cancers, particularly those with a poor prognosis, an understanding of any adverse treatment effects must be carefully weighed against any benefits associated with treatment to understand the net treatment effect.

## **Allogeneic HSCT**

Allogeneic hematopoietic stem-cell transplantation (HSCT) is the only known potentially curative therapy for chronic myelogenous leukemia (CML). It became a standard of treatment for CML in the 1980's when the graft-versus-leukemia (GVL) effect was shown to be the critical factor for long-term disease control.<sup>[1]</sup> Studies in patients with chronic phase disease who received an HLA-matched sibling donor transplant had a 45%–75% probability of long-term disease-free survival, while those transplanted with more advanced disease had a 15%–40% long-term survival.<sup>[2]</sup> Young, good-risk patients who received transplants early in the chronic phase from HLA-matched but unrelated donors had a 40%–60% chance of long-term survival, which was lower than that of similar patients transplanted from matched sibling donors.<sup>[3,4]</sup>

Allogeneic HSCT was once commonly performed for the treatment of CML; with the advent of TKIs, this has changed. A retrospective analysis of data from the Center for International Blood and Marrow Transplant Research Center (CIBMTR) showed that transplantation for CML was in decline prior to U.S. Food and Drug Administration (FDA) approval of imatinib in 2001.<sup>[5]</sup> Subsequently, long-term follow-up results from the International Randomized Study of Interferon and STI 571 (IRIS) of imatinib mesylate, plus the availability of two additional approved TKI agents (nilotinib and dasatinib), have caused modification of the timing of application of allogeneic SCT.<sup>[6-8]</sup> This procedure now is typically delayed in patients with newly diagnosed CML, who will receive imatinib mesylate as front-line treatment. It also may only be used early when a complete molecular response to the drug fails or is not achieved soon after starting imatinib administration.

Allogeneic HSCT has continued to develop, with important advancements in the use of nonmyeloablative or reduced-intensity conditioning (RIC) preparative regimens. RIC regimens were initially conceptualized as a means to extend the use of allogeneic HSCT to CML patients who were ineligible for myeloablative conditioning regimens because of advanced age or comorbidities. The use of RIC and allogeneic HSCT is of particular interest for treatment of CML given the relatively pronounced susceptibility of this malignancy to the GVL effect of allogeneic hematopoietic progenitor cells following their engraftment in the host.

## Systematic Review

A 2012 comparative effectiveness review published by the Agency for Healthcare Research and Quality (AHRQ) on the use of HSCT in the pediatric population considered allogeneic HSCT for the treatment of CML.<sup>[9]</sup> The review cited the risk of disease relapse with interruption in TKI therapy, which complicates the decision to proceed to allogeneic HSCT. The review concluded that there is no evidence to inform the “decision and timing to proceed to allogeneic HSCT” following treatment with TKI therapy.

## Non-randomized Trials

Overall, among nine studies compiled in a recent, non-systematic review by Chakrabarti and colleagues, outcomes achieved with RIC allogeneic transplants have been similar to those with conventional allotransplants, with overall survival (OS) rates ranging from 35% at 2.5 years to 85% at 5 years among patients in chronic phase 1 at transplant.<sup>[10]</sup> Among the studies included in this review, treatment-related mortality or nonrelapse mortality (NRM) ranged from 0% at 1 year to 29% at 1 year. In the largest experience, a retrospective European Group for Blood and Marrow Transplantation (EMBT) study of 186 patients, overall survival (OS) was 54% at 3 years using a variety of RIC regimens in patients in chronic phase 1 (n=118), chronic phase 2 (n=26), acute phase (n=30), and blast crisis (n=12).<sup>[11]</sup> Among patients transplanted in the first chronic phase (CP1), OS was 69% at 3 years.

Warlick and colleagues recently reported outcomes of 306 patients with CML treated with myeloablative or RIC preparative regimens before allogeneic HSCT at the Center for International Blood and Marrow Transplant Research.<sup>[12]</sup> Although age, disease status, prior treatment (including TKI and autologous transplant), and strength of donor match differed between the treatment groups, a statistical model indicated a potential association between use of RIC preparatory regimen and increased survival (when compared with traditional myeloablative regimens). However, the lack of randomization to treatment group limits the interpretation of these findings as treatment imbalances between groups may have accounted for the differences seen in survival rates.

RIC regimens have many of the same limitations as standard-intensity conditioning: relapse, graft-versus-host disease (GVHD; particularly chronic GVHD), and mortality from treatment-related causes other than myelotoxicity. However, in the absence of prospective, comparative, randomized trials, only indirect comparisons can be made between the relative clinical benefits and harms associated with myeloablative and RIC regimens with allogeneic HSCT. Comparison of study results is further compromised by heterogeneity among patients, treatments, and outcome measures. Nonetheless, clinical evidence suggests outcomes in CML are similar with myeloablative and RIC allogeneic HSCT.<sup>[8,10,11]</sup>

However, the advent of TKI therapy has altered the treatment paradigm for CML such that the majority of patients are treated initially with a TKI until disease progresses. While progression may occur within months of starting a TKI, this may be delayed for years, as shown by the results of the IRIS trial<sup>[6]</sup> and other studies.<sup>[7,8]</sup> With the addition of two other TKIs (dasatinib and nilotinib) plus the possibility of effective dose escalation with imatinib to override resistance, it is possible to maintain a typical CML patient past the upper age limit (usually 50–55 years) at which a myeloablative allogeneic HSCT is considered an option.<sup>[6,13,14]</sup> In such cases, RIC allogeneic SCT would be considered a viable choice because it harnesses the potent GVL effect of allogeneic SCT with substantially reduced treatment-related morbidity and mortality compared to myeloablative allogeneic SCT.

### **Autologous HSCT**

A major limitation in the use of autologous HSCT in patients with CML is the risk that leukemic cells will be re-infused. However, it is recognized that many CML patients still have normal marrow stem cells. Techniques used to isolate and expand this normal clone of cells have included ex vivo purging, long-term culture, and immunophenotype selection.<sup>[15]</sup> Even without such techniques, there have been isolated case reports of partial cytogenetic remissions after autologous HSCT, and one study has suggested that patients undergoing such therapy may have improved survival compared with historical controls.<sup>[2]</sup>

Another article summarized the results of 200 consecutive autologous transplants using purged or unpurged marrow from 8 different transplant centers.<sup>[16]</sup> Of the 200 patients studied, 125 were alive at a median follow-up of 42 months. Of the 142 transplanted in chronic phase, the median survival had not been reached at the time of publication, while the median survival was 35.9 months for those transplanted during an accelerated phase. Other data consist of small, single institution case series using a variety of techniques to enrich the population of normal stem cells among the harvested cells.<sup>[2]</sup> Additional reports of small, uncontrolled studies with a total of 182 patients (range: 15–41 patients) given autotransplants for CML included patient populations that varied across the studies. Some focused on newly diagnosed patients or those in the first year since diagnosis.<sup>[17,18]</sup> Others focused on patients who did not respond to or relapsed after initial treatment using interferon alfa,<sup>[19,20]</sup> or who received interferon alfa as maintenance therapy following autologous HSCT.<sup>[21]</sup> Finally, some focused on patients transplanted in the late chronic phase<sup>[22]</sup> or after transformation to accelerated phase or blast crisis.<sup>[23]</sup> Although some patients achieved complete or partial molecular remissions and long-term disease-free survival, these studies do not permit conclusions free from the influence of patient selection bias. Note also that all autotransplanted patients included in these reports were treated before imatinib mesylate or newer TKIs became available. Since these agents have been shown to induce major hematologic and, less often, cytogenetic remissions, even among patients in accelerated phase and blast crisis, future studies of autotransplants for CML may focus on patients who fail or become resistant to imatinib mesylate. Alternatively, it may be incorporated into combination regimens used for high-dose therapy.<sup>[24]</sup>

### **Clinical Practice Guidelines**

The NCCN recommends allogeneic stem cell transplant as an alternative treatment option only for high risk settings<sup>[25]</sup> and includes:

- Patients who do not achieve complete hematologic remission after 3 months of imatinib therapy;
- Patients with no cytogenetic response at 6, 12 months, or 18 months, after achieving initial hematologic remission after 3 months of imatinib therapy;
- Patients progressing on a TKI to accelerated phase or blast crisis;
- Patient unable to tolerate any TKI inhibitor.

The NCCN guidelines state that nonmyeloablative HSCT is under investigation and should be performed only in the context of a clinical trial.

The NCCN guidelines are silent on autologous bone marrow transplant for CML.

### **Summary**

Among patients with chronic myelogenous leukemia who fail to respond, develop resistance, or are unable to tolerate treatment with an available TKI agent, allogeneic hematopoietic stem-cell transplantation (HSCT) represents the only potentially curative option. Thus, myeloablative conditioning followed by allogeneic HSCT may be considered medically necessary for these patients. Among patients who are not candidates for a myeloablative conditioning regimen, allogeneic HSCT with a reduced-intensity conditioning (RIC) regimen may also be considered medically necessary.

Given the successes seen with tyrosine kinase inhibitors (TKIs) in chronic myelogenous leukemia (CML), and the risks associated with myeloablative autologous hematopoietic stem-cell transplantation

(HSCT), evidence does not support the use of autologous HSCT in patients with CML. Therefore, such use is considered investigational.

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26. BlueCross BlueShield Association Medical Policy Reference Manual "Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia." Policy No. 8.01.30

## CROSS REFERENCES

[Donor Lymphocyte Infusion for Malignancies Treated with an Allogeneic Hematopoietic Stem-Cell Transplant](#), Transplant, Policy No. 45.03

[Placental and Umbilical Cord Blood as a Source of Stem Cells](#), Transplant, Policy No. 45.16

[Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms](#), Transplant, Policy No. 45.24

CODES	NUMBER	DESCRIPTION
CPT	38204	Management of recipient hematopoietic cell donor search and cell acquisition



CODES	NUMBER	DESCRIPTION
	38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogeneic
	38206	;autologous
	38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
	38208	;thawing of previously frozen harvest, without washing, per donor
	38209	;thawing of previously frozen harvest with washing, per donor
	38210	;specific cell depletion with harvest, T cell depletion
	38211	;tumor cell depletion
	38212	;red blood cell removal
	38213	;platelet depletion
	38214	;plasma (volume) depletion
	38215	;cell concentration in plasma, mononuclear, or buffy coat layer
	38220	Bone marrow; aspiration only
	38221	Bone marrow; biopsy, needle or trocar
	38230	Bone marrow harvesting for transplantation; allogeneic
	38232	Bone marrow harvesting for transplantation; autologous
	38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
	38241	;autologous transplantation
	38243	;HPC boost
	38242	Allogeneic lymphocyte infusions
HCPCS	J9000– J9999	Chemotherapy drugs code range
	Q0083– Q0085	Chemotherapy administration code range
	S2140	Cord blood harvesting for transplantation; allogeneic
	S2142	Cord blood derived stem-cell transplantation, allogeneic

CODES	NUMBER	DESCRIPTION
	S2150	Bone marrow or blood-derived peripheral stem-cell harvesting and transplantation, allogeneic or autologous, including pheresis, high-dose chemotherapy, and the number of days of post-transplant care in the global definition (including drugs; hospitalization; medical surgical, diagnostic and emergency services)