Subject: Hematopoietic Stem Cell Transplantation for Chronic Myelogenous Leukemia (CML)  

Guidance Number: MCG-187  

ORIGINAL EFFECTIVE DATE: 7/25/14

PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.gov/center/coverage.asp.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does have a NCD called Stem Cell Transplantation (110.8.1)1 and covers allogeneic hematopoietic stem cell transplantation (HSCT) for the treatment of leukemia and leukemia in remission effective for services performed on or after August 1, 1978.

INITIAL COVERAGE CRITERIA

All transplants must be approved by the Medical Director prior to authorization

Members must meet the criteria outlined below for transplantation and the diagnosis must be made by a Hematologist, Oncologist and/or transplant surgeon.

Pre-Transplant Evaluation:

1. General requirements for transplant evaluation include all of the following: 2 4 5 12 18
   - History and physical examination
   - Psychosocial evaluation and clearance: This must be completed and documentation submitted for review before any additional transplant work-up or testing is initiated.
   - Dietary consult and clearance for transplant
   - Disease evaluation may include all the following:
     - Bone marrow biopsy and/or bone marrow aspiration: must show adequate response to therapy
- CT scan
- PET scan

- Cardiac Echocardiogram: Ejection fraction > 50%
- EKG
- Chest X-ray

- Performance Status: [ONE]
  - *Karnofsky score 70-100%
  - **Eastern Cooperative Oncology Group (ECOG) grade 0-2

- Neurological exam and clearance for transplant: [ONE]
  - Normal exam by H&P
  - Abnormal neurological exam with positive findings: [ONE]
    - Lumbar puncture normal cytology
    - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance

- Pulmonary function testing: [ALL]
  - diffusion capacity (DLCO) >60%
  - forced expiratory volume (FEV) >60%
  - forced capacity (FVC) >60%

- Lab studies:
  - Complete blood cell count, liver function tests, kidney profile, coagulation profile (prothrombin time, partial thromboplastin time)
    - SGOT or SGPT >2x upper limit of normal
  - HIV testing
  - Hepatitis A (HAV), Hepatitis B (HBV), Hepatitis C (HCV), Hepatitis D, Ebstein-Barr virus (EBV), cytomegalovirus (CMV) serology, syphilis, toxoplasmosis, herpes simplex virus
  - HLA Antibody
  - Blood type
  - Serum creatinine: <1.5mg%
  - creatinine clearance: > 60 ml/min
  - Bilirubin < 2mg%²

Within the last 12 months the following is required:

- Colonoscopy (indicated > age 50 with removal of any polyps if applicable)
- Dental examination (contact plan for coverage criteria)
- GYN examination with Pap smear (indicated > age 18) with complete workup and treatment of abnormal results as indicated
- Mammogram (indicated > age 40) with complete workup and treatment of abnormal results as indicated
- Osteoporosis screening with DEXA scan: [ONE]
  - cholestatic disorders
  - prolonged corticosteroid therapy
postmenopausal women
- age > 65

### Karnofsky Performance Score

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<th>Description</th>
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<tr>
<td>100%</td>
<td>Able to carry on normal activity, no evidence of disease</td>
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<tr>
<td>90%</td>
<td>Able to carry on normal activity, minor signs or symptoms of disease</td>
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<tr>
<td>80%</td>
<td>Normal activity with effort, some signs and symptoms of disease</td>
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<td>70%</td>
<td>Cares for self, unable to carry on normal activity or to work</td>
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<td>60%</td>
<td>Requires occasional assistance from others but able to care for most needs</td>
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<td>50%</td>
<td>Requires considerable assistance from others and frequent medical care</td>
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<td>Severely disabled, hospitalization indicated, death not imminent</td>
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<td>20%</td>
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<td>Very sick, hospitalization indicated, active support treatment necessary</td>
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### Eastern Cooperative Oncology Group (ECOG) Scale

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<th>Score</th>
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<tr>
<td>0</td>
<td>Fully active, able to carry on all pre-disease performance without restriction</td>
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<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work</td>
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<tr>
<td>2</td>
<td>Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours</td>
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<td>3</td>
<td>Capable of only limited self-care, confined to bed or chair more than 50% of waking hours</td>
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<tr>
<td>4</td>
<td>Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair</td>
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<td>5</td>
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**Criteria for Hematopoietic Allogeneic Stem Cell transplantation (HSCT) Transplantation:**

1. **Hematopoietic Allogeneic stem-cell transplantation (HSCT) ablative or non-myeloablative** from a human leukocyte antigen (HLA)-matched donor (i.e., at least six out of eight match of the HLA-A, HLA-B, HLA-C and HLA-DRB1 markers) or from cord blood when there are no matched sibling or unrelated donors (i.e. at least four out of six match of the HLA-A, HLA-B and HLA-DRB-1 markers) may be authorized in adults and children for the treatment of chronic myelogenous leukemia (CML) when ANY of the following criteria are met:

- In adults who are ≥ 18 years with any of the following clinical indications:
  - No hematologic response* after 3 months of oral tyrosine kinase inhibitor (TKI) {imatinib, dasatinib, nilotinib} therapy:
*Note: Complete hematologic response (CHR) is defined by a white blood cell count <10,000/microL with no immature granulocytes and <5 percent basophils on differential; platelet count <450,000/microL; and spleen not palpable.

OR

- No cytogenetic response*:

*Note: Cytogenetic response is classified according to the percent Philadelphia chromosome positive cells into none (>95 percent), minimal (66 to 95 percent), minor (36 to 65 percent), major (1 to 35 percent), and complete (no Philadelphia chromosome positive cells). For patients with an inadequate number of metaphases, complete cytogenetic response can also be documented by FISH of blood interphase cell nuclei demonstrating <1 percent BCR-ABL1-positive nuclei of at least 200 nuclei.

OR

- Those in cytogenetic relapse at 6, 12, or 18 months, after achieving initial hematologic remission after 3 months of imatinib therapy; or
- Progressing on an oral tyrosine kinase inhibitor (TKI) to accelerated phase: Defined by one or more of the following: [ONE]
  - 10 to 19 percent blasts in the peripheral blood or bone marrow
  - Peripheral blood basophils ≥20 percent
  - Platelets <100,000/microL, unrelated to therapy
  - Platelets >1,000,000/microL, unresponsive to therapy
  - Progressive splenomegaly and increasing white cell count, unresponsive to therapy
  - Cytogenetic evolution (defined as the development of chromosomal abnormalities in addition to the Philadelphia chromosome)

OR

- Progressing on a TKI to Blast crisis (myeloid or lymphoid): Defined by any of the following: [ONE]
  - ≥20 percent peripheral blood or bone marrow blasts
  - Large foci or clusters of blasts on the bone marrow biopsy
  - Presence of extramedullary blastic infiltrates (eg, myeloid sarcoma, also known as granulocytic sarcoma or chloroma)

OR

- Intolerance to TKI

AND

- None of the following absolute contraindications are present: [NONE]
Active alcohol and/or other substance abuse including smoking (to remove as a contraindication there must be 6 months of documented abstinence through participation in a structured alcohol/substance abuse program with regular meeting attendance and negative random drug testing)

- Documented history of non-compliance or inability to follow through with medication adherence or office follow-up
- Irreversible brain damage or active central nervous system disease
- Significant or advanced heart, lung, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after transplantation
- No behavioral health disorder by history or psychosocial issues: [One]
  - if history of behavioral health disorder, no severe psychosis or personality disorder
  - mood/anxiety disorder must be excluded or treated
  - member has understanding of surgical risk and post procedure compliance and follow-up required

*Note: Patient’s need to understand the importance of adherence to medication schedules and follow-up appointments/noncompliance is a major cause of graft failure.

- No adequate social/family support

Criteria for Subsequent Hematopoietic Stem Cell Transplantation:

2. A second or repeat *Hematopoietic Allogeneic stem cell transplantation* (ablative or non-myeloablative) may be authorized only one time for members with CML who meet all of the above criteria for transplant and have any of the following: [ONE]

- primary graft failure indicated by no signs of engraftment* by 42 days after the transplant; or
- failure to engraft*

*Note: Engraftment is defined as the first 3 consecutive days on which the absolute neutrophil count (ANC) exceeds 5 x 10^9/L or > ANC500 at any time after transplantation.15

Criteria for Donor Lymphocyte Infusion (DLI):

3. *Donor lymphocyte infusion (DLI), collection and cryopreservation* may be authorized following a medically necessary allogeneic hematopoietic stem cell transplant:

- For incomplete chimerism and disease relapse in the setting of incomplete chimerism (defined as incomplete donor stem cell grafting in the recipient’s bone marrow); and
- Donor lymphocytes must be collected from the original hematopoietic stem cell donor
CONTINUATION OF THERAPY

A review for any stem cell transplantation procedure is valid for one year from the time the request was approved. Due to potential lengthy organ donor waiting time, an annual review of clinical information should be conducted to evaluate any changes in the member’s clinical status.

COVERAGE EXCLUSIONS

1. Allogeneic (ablative or non-myeloablative) stem cell transplantation when the above criteria are not met.
2. A second or repeat autologous or allogeneic (ablative or non-myeloablative) transplant due to persistent, progressive or relapsed disease.
3. Autologous stem cell transplantation
4. Hematopoietic stem cell collection, storage and freezing for a future unplanned transplant is not covered
5. The following absolute contraindications to stem cell transplantation are not covered:
   - Active alcohol and/or other substance abuse including smoking (to remove as a contraindication there must be 6 months of documented abstinence through participation in a structured alcohol/substance abuse program with regular meeting attendance and negative random drug testing)
   - Documented history of non-compliance or inability to follow through with medication adherence or office follow-up
   - Irreversible brain damage or active central nervous system disease
   - Significant or advanced heart, lung, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after transplantation
   - No behavioral health disorder by history or psychosocial issues: [One]
     - if history of behavioral health disorder, no severe psychosis or personality disorder
     - mood/anxiety disorder must be excluded or treated
     - member has understanding of surgical risk and post procedure compliance and follow-up required

   Note: Patient’s need to understand the importance of adherence to medication schedules and follow-up appointments/noncompliance is a major cause of graft failure.

   - No adequate social/family support

6. Relative contraindications to stem cell transplantation include all of the following:
   - poor cardiac function (ejection fraction < 50%)
   - poor liver function (bilirubin > 2.0mg/dl and transaminases greater than two times normal), unless related to AML
   - poor renal function (creatinine clearance < 60ml/min)
   - poor pulmonary function [diffusion capacity (DLCO) < 60% of predicted]
   - active central nervous system involvement
   - presence of human immunodeficiency virus (HIV)
   - an active infection with any ONE of the following:
     - hepatitis B virus (HBV)
     - hepatitis C virus (HCV)
     - human T-cell lymphotropic virus (HTLV)-1
Karnofsky rating <70% ; OR
Eastern Cooperative Oncology Group (ECOG) performance status >2

**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

*Chronic Myelogenous Leukemia*

Chronic myelogenous leukemia (also referred to as CML or chronic granulocytic leukemia or chronic myeloid leukemia) is a disease of both the bone marrow and blood. It most often occurs in middle-aged adults. CML is characterized by the fact that too many granulocytes (neutrophils, eosinophils, and basophils), and not enough red blood cells and platelets, develop from bone marrow myeloid stem cells. This can lead to anemia, infection, and increased bleeding from abrasions. Signs and symptoms of CML may include night sweats, fever, exhaustion, and weight loss. It is thought that CML is due to a non-inherited genetic mutation called the “Philadelphia chromosome”. The Philadelphia chromosome results in the enzyme tyrosine kinase being produced in the bone marrow, and it is this enzyme that causes too many of the myeloid stem cells to take the path of converting into granulocytes, rather than red blood cells or platelets. CML can occur at any age; however it most often appears in adults with a median age of 60-65 years. There are three phases of the disease that consist of an initial (indolent) chronic phase, lasting a median of 3 years, which typically transforms into an accelerated phase, followed by a blast phase or "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. However, allogeneic HSCT remains the only treatment capable of inducing durable remissions or cure in CML patients.

*Stem Cell Transplantation*

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) from a donor into a patient. HSCs are immature cells that can develop into any of the three types of blood cells (red cells, white cells or platelets). HSCs are created in the bone marrow and are found in the bone marrow and peripheral blood. There is also a high concentration of HSCs in umbilical-cord blood. Hematopoietic stem-cell transplantation (HSCT) can be either autologous (using the person’s own stem cells) or allogeneic (using stem cells from a donor). In allogeneic HSCT, it is preferable for donors to have a human leukocyte antigen (HLA) type that is identical to the recipient. Matching is performed on the basis of variability at three of more loci of the HLA gene (e.g., HLA-A, HLA-B, HLA-DRB1). As HLA variability increases, transplant-related morbidity and mortality, including graft rejection and graft-versus-host disease, also increase.

*Donor Lymphocyte Infusion*
Following an allogeneic hematopoietic stem cell transplant, donor lymphocyte infusion is a form of adoptive immunotherapy and may be requested to induce a graft versus leukemia, or graft versus tumor, response without requiring the recipient to undergo additional high-dose chemotherapy. Donor lymphocytes are collected from the original donor through leukapheresis. This collection is an outpatient procedure for the donor. The lymphocytes are then either infused via vein into the recipient or are frozen for a more clinically appropriate time.

**Pretransplant Evaluation**

The goal of the pretransplant evaluation is to assess the ability of a patient to tolerate the surgery, post-operative immunosuppression, and transplant care. An extensive cardiopulmonary evaluation, screening for occult infection or cancer, and psychosocial evaluation is standard. Specific testing varies depending upon the patient’s age, medical history, and transplant center practice. In addition, while a certain battery of tests may initiate the work up, more testing may be indicated depending upon the condition of the patient or the initial test results. In addition to a standard medical evaluation the initial assessment should include a psychological and social support evaluation to identify issues that may impair a successful outcome after transplantation. These include a lack of information about the nature of the transplant procedure and post-transplant care, drug or alcohol dependence, compliance with complex medical and behavior regimens. The assessment includes education of the family and the support network of the patient because compliance with complex medical and behavior treatment is critical after any organ transplant procedure. Recipients must be able to incorporate complicated medications, follow-up appointments, and frequent laboratory visits into their schedules. Having an adequate support network aware of these requirements will encourage patient compliance and long-term success.

**GENERAL INFORMATION**

**Summary of Medical Evidence**

The published, peer-reviewed scientific literature supports the safety and effectiveness of allogeneic HSCT for the treatment of CML in selected individuals. However, improved outcomes have not been demonstrated for autologous HSCT compared with conventional chemotherapy in individuals with CML therefore the role of autologous HSCT for this indication has not been established. A summary of the most relevant medical evidence is outlined below.

Saussele et al (2010) from the German CML study group presented overall survival data of a prospective multiarm trial (n=84) of first line treatment with allogeneic stem cell transplantation in selected low-risk CML patients, advanced disease, or as planned second-line therapy after imatinib failure. Excellent outcomes were achieved with a 3-year projected overall survival of 91% after allogeneic transplantation in chronic phase. 59% achieved OS in advanced disease. 88% achieved complete molecular remission and, when a matched-pair analysis was performed of transplanted CML patients in first chronic phase versus matched non-transplantation patients derived from the imatinib-responsive group, 3-year survivals were equivalent. 16

In a retrospective study by Hehlman (2007) patients with Philadelphia chromosome negative, and/or breakpoint cluster-Abelson (BCR-ABL) positive chronic phase chronic myelogenous leukemia (CML) were randomized to hematopoietic stem-cell transplantation (HSCT) as first-line therapy (n=135) or best available drug treatment (n=219). Survival was superior for patients who received drug treatment compared to HSCT (p=.049), with outcomes most pronounced in low-risk patients (p=.032). 20
Results of several case series and retrospective clinical studies involving adult patients suggest that stable engraftment can occur and that treatment-related mortality is decreased with the use of non-myeloablative or reduced-intensity conditioning with allogeneic HSCT.\(^{21-26}\) Disease-free survival (DFS) ranges from 40% to 85% at three-to-five years. Graft-versus-host disease (GVHD) remains the most significant concern after non-myeloablative HSCT; morbidity and mortality from this complication can be reduced by careful patient selection.\(^{27}\) Additionally, nine studies compiled in a recent, non-systematic review indicates that 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.\(^{29}\)

Warlick et al. (2012) 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. 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). Relapse and disease-free survival were similar across age cohorts.\(^{30}\)

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. 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 evidence demonstrating benefit or harm of HSCT versus standard therapies or disease natural history was insufficient for most pediatric indications.\(^{28}\)

**Professional Organizations**

**National Comprehensive Cancer Network (NCCN):** The 2014 NCCN guidelines (v3.2014) recommend allogeneic bone marrow transplant as an alternative treatment option only for high-risk settings that include the following:\(^{14}\)

- patients who do not achieve hematologic remission after 3 months of TKI (imatinib, dasatinib, nilotinib) therapy
- patients with no cytogenetic response or those in cytogenetic relapse at 6, 12, 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
- patients unable to tolerate any TKI inhibitor

Nonmyeloablative allogeneic HSCT is recommended only within a clinical trial and autologous bone marrow transplant for CML is not addressed in the NCCN guidelines.

**Toronto (ON) Cancer Care Ontario Program Advisory Panel on Bone Marrow and Stem Cell Transplantation, and the Hematology Disease Site Group:** Stem Cell Transplantation for adults with CML is recommended for the following subsets:\(^{11}\)

- Allogeneic stem cell transplantation is an option for patients with CML for whom medical therapy has failed, as well as those in accelerated phase or blast crisis.
- Autologous stem cell transplantation is not recommended for patients with CML.
**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
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### RESOURCE REFERENCES


30. Warlick, E, Ahn, KW, Pedersen, TL, et al. Reduced intensity conditioning is superior to nonmyeloablative conditioning for older chronic myelogenous leukemia patients undergoing hematopoietic cell transplant during the tyrosine kinase inhibitor era. Blood. 2012 Apr 26;119(17):4083-90. PMID: 22408257

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