



Cigna Medical Coverage Policy

Subject Stem-Cell Transplantation for Chronic Myelomonocytic Leukemia (CMML) and Juvenile Myelomonocytic Leukemia (JMML)

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Coverage Policy

Cigna covers allogeneic hematopoietic stem-cell transplantation (HSCT) as medically necessary for the treatment of chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML) when an appropriately-matched human leukocyte antigen (HLA) donor is available.

Cigna does not cover autologous HSCT for the treatment of CMML or JMML because it is considered experimental, investigational or unproven.

General Background

Chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML) are clonal disorders characterized by both dysplastic and proliferative features. They are classified by the World Health Organization as myelodysplastic/myeloproliferative neoplasms (MDS/MPD) (National Cancer Institute [NCI], 2012).

CMML is primarily a disorder of older age adults with a median age of 65 to 70 years, with 75% over age 60. Median survival for CMML ranges from 12–24 months, with a progression to acute leukemia in 15%–20% of cases (NCI, 2012). Conversely, the median age for JMML is 1.8 years. Prognosis is poor and the disorder is resistant to standard dose chemotherapy. The median survival is 10 months to four years; prognosis is related

to the age at diagnosis (National Cancer Institute [NCI], 2012). Children less than one year at diagnosis have a better prognosis than children at other ages.

For both chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML) various standard-dose chemotherapy regimens have been used with only modest success; responses achieved are usually of short duration (NCI, 2012). Approximately 10% to 20% of children will progress to a blast-like phase consistent with acute myelogenous leukemia (Smith, 2008). Bone marrow transplantation or hematopoietic stem-cell transplantation (HSCT) seem to offer the best chance of cure (NCI, 2012; Smith, 2008).

Stem-Cell Transplantation

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) 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). Hematopoietic stem-cell transplantation (HSCT) can be either autologous (i.e., using the patient's own stem cells), or allogeneic (i.e., using stem cells from a donor).

The selection of an appropriately-matched allogeneic donor source is dependent on several variables including the availability of a human leukocyte antigen (HLA)-identical sibling donor, and stage of disease. It is preferable for donors to have an HLA type that is identical to the recipient due to the potential for increased complications such as graft rejection and graft-versus-host disease; however, only about one-third of individuals who might otherwise be eligible for allogeneic HSCT have an HLA-matched sibling donor. Especially for individuals with high-risk disease, additional appropriate donor sources may include HLA-matched unrelated and HLA partially-matched related donors.

A boost of hematopoietic progenitor or stem cells, also referred to as a hematopoietic stem-cell infusion (HSCI) may be used to facilitate more rapid hematopoietic recovery, graft loss, or loss of chimerism following HSCT. The cell product used for a boost may be a previously cryopreserved cell product that contains stem cells or may alternatively require the donor to undergo additional evaluation, mobilization, and harvest. A boost is not preceded by a preparative regimen, and may be required when additional conventional chemotherapy is given to treat relapse and reestablish remission after transplantation. Prolonged cytopenias and immunosuppression may result, requiring additional HSCI which is typically given days to weeks after reinduction chemotherapy (LeMaistre, 2013).

Allogeneic HSCT: There are limited options for successful treatment of CMML and JMML. Allogeneic HSCT is noted to be a component of the standard of care for treatment of selected individuals with CMML and JMML. The National Cancer Institute ([NCI], 2012) notes that this treatment appears to be the only current treatment that alters the natural history of CMML. Allogeneic HSCT is generally considered in younger, healthy patients with appropriate donor matches. Age and performance status are critical factors that may influence ability to tolerate intensive therapies.

Although disease relapse, treatment-related mortality and graft-versus-host disease remain issues associated with allogeneic HSCT for CMML, this treatment option offers the best chance for cure. Data from randomized controlled clinical trials are lacking; however, several retrospective studies have demonstrated improved overall survival (OS) with myeloablative allogeneic HSCT with estimated OS rates of 10%–41% at two- to five years (Elliot, 2006; Karrabul, 2005; Kroger, 2002; Arnold, 1998).

Allogeneic HSCT also offers the best chance of cure for JMML (NCI, 2012; Smith, 2008; Hasle, 2007). Several retrospective reviews have demonstrated three- and five-year OS of 50% and 32%–64%, respectively (Yoshima, 2007; Locatelli, 2005). In a review of outcomes of 183 patients registered in the prospective and retrospective studies of the European Working Group on Myelodysplastic Syndrome in Childhood involving second allogeneic transplantation of 24 children with JMML, Yoshima (2007) noted an event-free survival of 52% at five years, however, relapse rates were 33%-40% with a five-year cumulative incidence of mortality of 27%.

Although data are not robust, non-myeloablative chemotherapy with allogeneic HSCT is also an accepted treatment option for individuals with CMML and JMML. Outcomes are similar to those seen with myelodysplastic syndromes (MDS) as these disorders share dysplastic characteristics. Laporte et al. (2008) reported outcomes of 148 individuals with myelodysplastic syndromes and myeloproliferative disorders, including seven with

CMML, who underwent allogeneic HSCT with nonmyeloablative conditioning. Three-year relapse-free and overall survival rates in the individuals with CMML were 43% and 43%, respectively.

Autologous Hematopoietic Stem-Cell Transplantation (HSCT): Although autologous HSCT may occasionally be used in an investigational setting for the treatment of CMML and JMML, data are lacking in the peer-reviewed published scientific literature regarding improved health outcomes. At this time the role of this therapy has not been established for these indications.

Contraindications

Many factors affect the outcome of a tissue transplant; the selection process is designed to obtain the best result for each individual. The presence of any significant comorbid conditions which would significantly compromise clinical care and chances of survival is a contraindication to transplant. Advanced age in the setting of myeloablative chemotherapy may limit survival; greater age is associated with a higher incidence of post-transplantation complications. Relative contraindications to HSCT include, but are not limited to:

- poor cardiac function (ejection fraction less than 45%)
- poor liver function (bilirubin greater than 2.0 mg/dL and transaminases greater than two times normal), unless related to acute myelogenous leukemia
- poor renal function (creatinine clearance less than 50 mL/min)
- poor pulmonary function (diffusion capacity less than 60% of predicted)
- presence of human immunodeficiency virus or an active form of hepatitis B, hepatitis C or human T-cell lymphotropic virus (HTLV-1)
- Karnofsky rating less than 60% and/or Eastern Cooperative Oncology Group (ECOG) performance status greater than 2

Professional Societies/Organizations

Leukemia and Lymphoma Society: The Society publishes a fact sheet regarding CMML and JMML (FS-17, 2008) which notes “Allogeneic stem cell transplantation is the only known curative option for JMML patients. This treatment has been noted to achieve long-term survival in up to 50% of patients but relapses are known to occur in up to 30% to 40% of patients after transplantation. Nonetheless allogeneic HSCT remains the only known cure for JMML. Second transplants have been beneficial for some patients.” The Society also notes that allogeneic stem cell transplantation has been used to treat and sometimes cure CMML patients; however, it is associated with a relatively high mortality risk that increases with patient age. “It is an option for a small number of patients—generally, younger patients with an advanced disease, who have either failed to respond to or are no longer responding to other treatment and who have an appropriate stem cell donor.”

National Cancer Institute (NCI): The NCI (2012) notes “Bone marrow/stem-cell transplantation appears to be the only current treatment that alters the natural history of chronic myelomonocytic leukemia (CMML). Regarding juvenile myelomonocytic leukemia (JMML) the NCI (2012) notes that “No consistently effective therapy is available for JMML.” “Bone marrow transplantation seems to offer the best chance for a cure.”

National Comprehensive Cancer Network™ (NCCN™): NCCN (2013) Clinical Practice Guidelines in Oncology for Myelodysplastic Syndromes notes “Allogeneic HSCT from an HLA-matched sibling donor is a preferred approach for treating a portion of patients with MDS, particularly those with high-risk disease. High-dose conditioning is typically used for younger patients, whereas the approach using reduced/low intensity (RIC) for HSCT is generally the strategy in older individuals.”

Summary

Allogeneic hematopoietic stem-cell transplantation (HSCT) is the only potentially curative treatment for juvenile myelomonocytic leukemia (JMML) and chronic myelomonocytic leukemia (CMML). The published, peer-reviewed scientific literature supports the safety and effectiveness of this treatment for selected individuals. Data are lacking regarding the safety and effectiveness of autologous HSCT for the treatment of CMML and JMML. At this time the role of autologous HSCT for this indication has not been established.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered when medically necessary when used to report allogeneic bone-marrow or blood-derived stem cell procedures:

CPT[®]* Codes	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38230	Bone marrow harvesting for transplantation, allogeneic
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation, per donor
38242	Allogeneic lymphocyte infusions

HCPCS Codes	Description
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem-cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including pheresis and cell preparation/storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre-and post-transplant care in the global definition

Experimental/Investigational/Unproven/Not Covered when used to report autologous bone marrow or blood-derived stem cell procedures:

CPT* Codes	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38232	Bone marrow harvesting for transplantation, autologous
38241	Hematopoietic progenitor cell (HPC); autologous

HCPCS Codes	Description
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including pheresis and cell preparation/storage; marrow ablative therapy; drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre-and post-

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