**Medical Necessity Guidelines: Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Chronic Myelogenous Leukemia (CML)**

**Effective:** October 10, 2018

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Applies to:

- ☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409
- ☒ Tufts Health Public Plans products
  - ☒ Tufts Health Direct — Health Connector; Fax: 888.415.9055
  - ☒ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055
  - ☐ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607
  - ☒ Tufts Health RITogether — A Rhode Island Medicaid Plan; Fax: 857.304.6404
- ☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

**OVERVIEW**

Stem cells are cells in the bone marrow that give the body a constant source of blood cells. Stem cell transplants are used to resupply the bone marrow when it has been destroyed by disease, chemotherapy, or radiation. Depending on the source of the stem cells, this procedure may be called a bone marrow transplant, a peripheral blood stem cell transplant, or a cord blood transplant (American Cancer Society, 2007).

Hematopoietic stem cell transplantation (HSCT) is a rapidly evolving technique that offers a potential cure for hematologic cancers (leukemias, lymphomas, myeloma) and other hematologic disorders, e.g., primary immunodeficiency, aplastic anemia, myelodysplasia. HSCT may be autologous or allogeneic; bone marrow, peripheral blood, or umbilical cord stem cells may be used. Peripheral blood has largely replaced bone marrow as a source of stem cells, especially in autologous HSCT, because stem cell harvest is easier and neutrophil and platelet counts recover faster. Umbilical cord HSCT has been mainly restricted to children because the number of stem cells is low (Merck Manual, 2006).

Chronic myelogenous leukemia (CML) is also known as chronic myeloid leukemia. It is a type of cancer that starts in blood-forming cells of the bone marrow. It then invades the blood and can then spread to the lymph nodes, the spleen, liver, and other parts of the body. In contrast, other types of cancer can start in these organs and then spread to the bone marrow (or elsewhere). Those cancers are not leukemia.

CML can also change into a fast-growing acute leukemia that invades almost any organ in the body (American Cancer Society, 2007)

To initiate the prior authorization process, it is necessary to complete and submit the Stem Cell Transplant Request for Coverage Form.

**COVERAGE GUIDELINES**

**Autologous HSCT**

Tufts Health Plan does not cover an autologous HSCT for the treatment of CML.

**Allogeneic HSCT**

- Tufts Health Plan may authorize coverage of an allogeneic HSCT from an HLA-matched donor for the treatment of chronic myelogenous leukemia (CML) that is resistant to tyrosine kinase inhibitors.
- After allogeneic HSCT, Tufts Health Plan may authorize coverage of donor leukocyte infusion for the treatment of cytogenetic or molecular relapsed CML.
Non-myeloablative Allogeneic HSCT
Tufts Health Plan may authorize coverage of a non-myeloablative allogeneic HSCT for the treatment of CML only in the context of a clinical trial. Please refer to Medical Necessity Guidelines: Clinical Trials - Routine Costs

LIMITATIONS
None

CODES
The following HCPCS/CPT code(s) require prior authorization:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>38240</td>
<td>Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic</td>
</tr>
<tr>
<td>38241</td>
<td>Bone marrow or blood-derived peripheral stem cell transplantation; autologous</td>
</tr>
<tr>
<td>38242</td>
<td>allogeneic donor lymphocyte infusions</td>
</tr>
<tr>
<td>38243</td>
<td>Hematopoietic Progenitor cell (HPC; HPC boost)</td>
</tr>
<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
<tr>
<td>S2142</td>
<td>Cord blood-derived stem-cell transplantation, allogeneic</td>
</tr>
<tr>
<td>S2150</td>
<td>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</td>
</tr>
</tbody>
</table>

REFERENCES
1. American Cancer Society. What is chronic myeloid leukemia (CML)? Cancer Reference Information. Retrieved on January 22, 2007 from: cancer.org/docroot/CRI/content/CRI_2_2_1x_What_Is_Chronic_Myeloid_Leukemia.asp?

APPROVAL HISTORY
November 2006: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:
- March 16, 2007: New Format
- April 25, 2008: Reviewed and renewed without changes
- April 6, 2009: Reviewed and renewed without changes
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MSPAC, no changes
- November 28, 2012: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), renewed without changes.
- December 11, 2013: Reviewed by IMPAC, minor wording changes
Hematopoietic Stem Cell Transplantation (HSCT) for the Treatment of Chronic Myelogenous Leukemia (CML)

- December 10, 2014: Reviewed by IMPAC, approved for effective date April 1, 2015. Non-myoeloblastive allogeneic HSCT will no longer be covered, except in context of a clinical trial, per NCCN guidelines.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- October 14, 2015: Reviewed by IMPAC, renewed without changes
- July 20, 2016: Reviewed by IMPAC, renewed without changes
- November 9, 2016: Reviewed by IMPAC, renewed without changes
- November 23, 2016: Contact information updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- September 18, 2017: Administrative update
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- October 10, 2018: Reviewed by IMPAC, renewed without changes

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member's benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLinkSM Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of these guidelines is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

**Provider Services**