Medical Necessity Guidelines: HSCT for the Treatment of Acute Myelogenous Leukemia (AML)

Effective: October 10, 2018

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

<table>
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<tr>
<th>Applies to:</th>
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<tbody>
<tr>
<td>COMMERCIAL Products</td>
</tr>
<tr>
<td>☒ Tufts Health Plan Commercial products; Fax: 617.972.9409</td>
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<tr>
<td>☒ Tufts Health Freedom Plan products; Fax: 617.972.9409</td>
</tr>
<tr>
<td>● CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</td>
</tr>
<tr>
<td>T UFTS HEALTH PUBLIC PLANS Products</td>
</tr>
<tr>
<td>☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055</td>
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<tr>
<td>☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</td>
</tr>
<tr>
<td>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
</tr>
<tr>
<td>☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 781.393.2607</td>
</tr>
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<td>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</td>
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<th>SENIOR Products</th>
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<tr>
<td>● Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List</td>
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<tr>
<td>● Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</td>
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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).

Acute myelogenous leukemia is a quickly progressing disease in which too many immature blood-forming cells are found in the blood and bone marrow. This is also called acute myeloid leukemia or acute nonlymphocytic leukemia (National Cancer Institute, 2007).

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

CLINICAL COVERAGE CRITERIA

A. Autologous HSCT
   Tufts Health Plan does not cover autologous HSCT for this diagnosis.

B. Allogeneic HSCT
   1. Tufts Health Plan may authorize coverage of an allogeneic HSCT from an HLA-matched or haploidentical (sharing a haplotype; having the same alleles at a set of closely linked genes on
one chromosome) cell donor for the treatment of adults and children with AML when one of the following criteria is met:
- First remission
- First relapse
- Second remission

2. Tufts Health Plan may authorize coverage of a second allogeneic HSCT from an HLA-matched donor for the treatment of adults and children with AML when all of the following criteria are met:
- Relapsed disease after first allogeneic HSCT
- No peripheral blood blasts
- ≤ 5% blasts in the bone marrow

C. Non-myeloablative Allogeneic (NMA) HSCT
Tufts Health Plan may authorize coverage of a NMA HSCT for adults with AML based on guidelines for ablative transplantation subject to the following indications; age greater than 50, and/or ineligibility for fully ablative transplantation (based on either concomitant medical conditions or prior autologous transplantation/high dose chemo within one year).

LIMITATIONS
Tufts Health Plan considers allogeneic HSCT for adults or children with AML contraindicated and thus not medically necessary when there is also the presence of any significant co-morbid medical or psychiatric illness which would significantly compromise the Member’s clinical care and chances of survival.

CODES
The following HCPCS/CPT codes require prior authorization:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>38204</td>
<td>Management of recipient hematopoietic progenitor cell donor search and cell acquisition</td>
</tr>
<tr>
<td>38205</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic</td>
</tr>
<tr>
<td>38207</td>
<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
</tr>
<tr>
<td>38230</td>
<td>Bone marrow harvesting for transplantation</td>
</tr>
<tr>
<td>38240</td>
<td>Bone marrow or blood-derived peripheral stem transplantation; allogeneic</td>
</tr>
<tr>
<td>38242</td>
<td>Bone marrow or blood-derived peripheral stem cell transplantation; 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>
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REFERENCES
7. NCCN Guidelines, AML 2.2014
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
- May 4, 2009: Reviewed and renewed without changes
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- December 2010: Reviewed at MSPAC. Autologous HCT coverage added for Members “who are ineligible or who do not wish to undergo allogeneic transplantation and who remain in remission following at least two cycles of consolidation chemotherapy” as per NCCN guidelines; Non related matched (6/6 HLA) donors added to Allogeneic guideline, bullet 2; Non myeloablative transplantation added to coverage for adults with AML based on guidelines for ablative transplantation.
- December 12, 2012: Reviewed by IMPAC, removed limitation of sibling donor to be consistent with the current NCCN guidelines.
- December 11, 2013: Reviewed by IMPAC, no changes.
- June 11, 2014: Reviewed by IMPAC for an October 1, 2014 effective date, Tufts Health Plan will no longer cover autologous HSCT for this diagnosis as it is no longer a standard of care, coding updated to reflect this change.
- December 10, 2014: Reviewed by IMPAC; added haploidentical cell donor as source of stem cell
- 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; age limitation removed, updated guidelines for second allogenic HSCT to include coverage regardless of time to relapse and for any HLA-matched donor; removed limitation for history of central nervous system involvement
- 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
- October, 2018: Template and disclaimer updated

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.

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.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline 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.