Medical Necessity Guidelines: Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Acute Lymphocytic/Lymphoblastic Leukemia (ALL) and Acute Promyelocytic Leukemia (APL), Adult

Effective: October 10, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Yes ☒ No ☐</th>
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<tbody>
<tr>
<td>If REQUIRED, submit supporting clinical documentation pertinent to service request.</td>
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### Applies to:

**COMMERCIAL Products**
- Tufts Health Plan Commercial products; Fax: 617.972.9409
- Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink™ – Refer to [CareLink Procedures, Services and Items Requiring Prior Authorization](#)

**TUFTS HEALTH PUBLIC PLANS Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
- Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 781.393.2607

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**SENIOR Products**
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the [Tufts Health Plan SCO Prior Authorization List](#)
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the [Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List](#)

### 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 lymphocytic leukemia (ALL), also called acute lymphoblastic leukemia, is a type of cancer that starts from white blood cells in the bone marrow (the soft inner part of the bones) called lymphocytes. In most cases it quickly moves into the blood. It can then spread to other parts of the body including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testes. “Acute” means that the leukemia develops quickly; ‘lymphocytic or lymphoblastic” means it develops from cells called lymphocytes or lymphoblasts (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](#).
CLINICAL COVERAGE CRITERIA

I. ACUTE LYMPHOCYTIC/LYMPHOBLASTIC LEUKEMIA (ALL)

A. Autologous HSCT
Tufts Health Plan does not cover autologous hematopoietic stem-cell transplantation (HSCT) for the treatment of ALL in adult Members.

B. Allogeneic HSCT
Tufts Health Plan may authorize coverage of an allogeneic HSCT from a human leukocyte antigen (HLA)-matched donor for the treatment of ALL in adults when one of the following criteria is met:
- Failed induction therapy
- Any patient in first remission, even those not considered high risk.
- Second or subsequent remission

Tufts Health Plan may authorize coverage of a second allogeneic HSCT from HLA-matched donor for the treatment of ALL in adults when relapsed disease occurs after first allogeneic HSCT.

C. Non-myeloablative (NMA) allogeneic HSCT
Tufts Health Plan does not cover NMA allogeneic HSCT for this diagnosis.

II. ACUTE PROMYELOCYTIC LEUKEMIA (APL)

A. Autologous HSCT
- Tufts Health Plan may authorize coverage of autologous HSCT for second remission only

B. Allogenic HSCT
Tufts Health Plan may authorize coverage of an allogenic HSCT from a human leukocyte antigen (HLA)-matched donor for the treatment of APL in adults when one of the following criteria is met:
- Failure to achieve second remission
- PCR positivity in patients who achieve remission

LIMITATIONS
Tufts Health Plan does not cover HSCT for the treatment of ALL in adults with any of the following conditions because it is considered not medically necessary (this list may not be all inclusive):
- Uncontrolled central nervous system (CNS) involvement
- Presence of any significant co-morbid medical or psychiatric illness, which would significantly compromise the patient’s clinical care and chances of survival
- Advanced age defined as greater than 65 years old (allogeneic HSCT only)
- Active disease (autologous HSCT only)

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; allogenic</td>
</tr>
<tr>
<td>38206</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous</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, allogenic</td>
</tr>
<tr>
<td>38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>38240</td>
<td>Bone marrow or blood-derived peripheral stem transplantation; allogeneic</td>
</tr>
<tr>
<td>38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</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>
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HSCT for the Treatment of ALL and APL, Adult

<table>
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<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

6. NCCN Guidelines, ALL, 1.2014.
8. NCCN Guidelines, AML 2.2014.

APPROVAL HISTORY

November 1, 2006: Reviewed by the Clinical Coverage Criteria Committee.

Subsequent endorsement date(s) and changes made:
- April 25, 2008: Reviewed and renewed without changes.
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- December 2010: Reviewed by MSPAC. Under Allogeneic HSCT coverage expanded to “Any patient in first remission, even those not considered high risk”.
- December 12, 2012: Reviewed by IMPAC, donor source information added per current NCCN guidelines, coding updated.
- December 11, 2013: Reviewed by IMPAC, renewed without changes.
- December 10, 2014: Reviewed by IMPAC, accepted for effective date of April 1, 2015. Changed definition of advanced age to greater than 65 years old per National Accepted Standards re; use of HSCT, added coverage guidelines for Acute Promyelocytic Leukemia (APL), a sub-form of ALL, per NCCN guidelines and added associated codes 38206, 38232 and 38241.
- 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; criteria for ALL updated to include coverage for any HLA-matched donor and for second HSCT irrespective of time to failure from first allogenic HSCT; effective 4/1/2016, criteria for APL updated to include guidelines for coverage of allogenic HSCT.
- 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.

**Provider Services**

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