Medical Necessity Guidelines: Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Inherited Immunodeficiency Disorder

Effective: November 9, 2016

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<tr>
<td>☒ Applies to:</td>
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<tr>
<td>☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409</td>
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<tr>
<td>☒ Tufts Health Public Plans products</td>
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<tr>
<td>☒ Tufts Health Direct — Health Connector; Fax: 888.415.9055</td>
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<tr>
<td>☒ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055</td>
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<tr>
<td>☐ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607</td>
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<tr>
<td>☒ Tufts Health RITogether — A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
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<tr>
<td>☒ Tufts Health Freedom Plan products; Fax: 617.972.9409</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 re-supply 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).

Immune system disorders occur when the immune response is inappropriate (excessive or lacking). Immunodeficiency disorders occur when the immune system fails to fight tumors or invading substances.

Immunodeficiency causes persistent or recurrent infections, severe infections by organisms that are normally mild, incomplete recovery from illness or poor response to treatment, and an increased incidence of cancer and other tumors. Opportunistic infections are widespread infections by microorganisms that are usually controllable.

Immunodeficiency disorders may affect any part of the immune system. Most commonly, this involves decreased functioning of T or B lymphocytes (or both), or deficient antibody production. The causes include congenital (inherited) defects and acquired immunodeficiency caused by a disease that affects the immune system (US National Library of Medicine, 2007).

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

Medical Management Intake Services, Tufts Health Plan, 705 Mount Auburn Street, Watertown, MA 02471. Fax: 888.415.9055

COVERAGE GUIDELINES

Autologous HSCT
Tufts Health Plan does not cover an autologous HSCT for Inherited Immunodeficiency Disorders.
Allogeneic HSCT
Tufts Health Plan may authorize coverage of allogeneic HSCT with a matched sibling donor, a matched unrelated donor, or a mismatched related donor for any of the following Inherited Immunodeficiency Disorders:

- Severe combined immunodeficiency (multiple types)
- Wiskott-Aldrich Syndrome
- X-linked hyper IgM syndrome (CD4 IgM deficiency)
- AID and UNG deficiencies (autosomal recessive hyper IgM syndromes)
- CD40 deficiency (autosomal recessive hyper IgM syndrome)
- X-linked lymphoproliferative disease
- Interferon gamma receptor defects
- NF kappa B essential modifier (NEMO) deficiency
- Chronic granulomatous disease
- Leukocyte adhesion deficiency type 1
- Griscelli syndrome

Non-myeloablative Allogeneic HSCT
Tufts Health Plan may authorize coverage of non-myeloablative allogeneic HSCT with a matched sibling donor, a matched unrelated donor, or a mismatched related donor for any of the Inherited Immunodeficiency Disorders listed above.

LIMITATIONS
Tufts Health Plan does not cover in utero transplantation for these conditions.

CODES
The following HCPCS/CPT codes require prior authorization:

<table>
<thead>
<tr>
<th>Code</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>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</td>
</tr>
<tr>
<td>38240</td>
<td>Bone marrow or blood-derived peripheral stem 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>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

**APPROVAL HISTORY**

November 2006: Reviewed by the Clinical Coverage Criteria Committee.

Subsequent endorsement date(s) and changes made:
- April 25, 2008: Reviewed and renewed without changes.
- May 4, 2009: Diagnosis of severe combined immunodeficiency added to coverage criteria for a non-myeloablative allogeneic HSCT.
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MSPAC, no changes.
- December 12, 2012: Reviewed by IMPAC, coding updated.
- December 11, 2013: reviewed by IMPAC, no changes.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- 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

**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 the 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 CareLink™ 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.