Medical Necessity Guidelines: Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Myelodysplastic Syndrome

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).

Myelodysplastic (myelo - bone marrow, dysplastic – abnormal growth) syndromes are a group of conditions caused by abnormal blood-forming cells of the bone marrow. In myelodysplastic syndromes (MDS), the bone marrow cannot produce blood cells effectively. Many of the blood cells formed are defective. These abnormal blood cells are usually destroyed before they leave the bone marrow or shortly after entering the bloodstream. As a result, patients have shortages of blood cells, which are reflected in their low blood counts.

Although MDS has not been considered cancer in the past, most hematologists (specialists in diseases of the blood) now consider it a form of cancer. The major reason is that MDS is a clonal disease, which means that there is a large population of abnormal cells that all came from a single, abnormal cell. These abnormal cells are exactly alike (just like identical twins), and they share abnormal growth properties. Clonal growth is typically seen in cancer where all the cells appear to have started from an original abnormal cell. Although MDS is a clonal disorder, there are many different forms.

A second reason MDS is considered a form of cancer is that in about 30% of MDS cases, the abnormal bone marrow cells eventually progress into acute myeloid leukemia, a rapidly growing cancer of bone marrow cells. Some doctors think MDS is an early form of leukemia, although it often does not progress into leukemia. In the past, myelodysplastic syndromes were called pre-leukemia or smoldering leukemia (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 to the following address:

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

COVERAGE GUIDELINES

A. Autologous HSCT
Tufts Health Plan does not cover an autologous HSCT for the treatment of myelodysplastic syndrome.

B. Allogeneic HSCT
1. Tufts Health Plan may authorize coverage of allogeneic hematopoietic HSCT for the treatment of Members with low-risk myelodysplastic syndrome, defined as having an International Prognostic Scoring System (IPSS-R) score of >1.5-3, who have an available HLA matched donor and have had failure/intolerance to hypomethylating agents.

2. Tufts Health Plan may authorize coverage of allogeneic hematopoietic HSCT for the treatment of Members with intermediate or high-risk myelodysplastic syndrome, defined as having an IPSS-R score of >3-4.5 (intermediate) or >4.5 (high/very high) who have an available HLA matched donor.

C. Non-myeloablative Allogeneic HSCT
1. Tufts Health Plan may authorize coverage of non-myeloablative allogeneic HSCT for the treatment of low-risk myelodysplastic syndrome, defined as having an IPSS-R score of >1.5-3, when all of the following criteria are met:
   a. The Member has had failure/intolerance to hypomethylating agents.
   b. The member is not a candidate for high-dose chemotherapy followed by allogeneic transplantation.
   c. A suitable HLA-matched donor has been identified and is available.

2. Tufts Health Plan may authorize coverage of non-myeloablative allogeneic HSCT for the treatment of intermediate or high-risk myelodysplastic syndrome, defined as having an IPSS-R score of >3-4.5 (intermediate) or >4.5 (high/very high), when both of the following criteria are met:
   a. The member is not a candidate for high-dose chemotherapy followed by allogeneic transplantation.
   b. A suitable HLA-matched donor has been identified and is available.

Note: Risk stratification is according to the International Prognostic Scoring System (IPSS). This score is available at [www.mds-foundation.org/ipss-r-calculator/](http://www.mds-foundation.org/ipss-r-calculator/).

LIMITATIONS
None

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>
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Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Myelodysplastic Syndrome

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<tr>
<th>Code</th>
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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

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

Subsequent endorsement date(s) and changes made:
- April 28, 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.
- December 2010: Reviewed by MCMC recommendation to remove autologous transplantation for MDS as there is limited efficacy for this diagnosis, as per NCCN. Effective July 2011.
- December 12, 2012: Reviewed by IMPAC, removed restriction to allow matched, non-sibling donors for allogeneic HSCT per current NCCN guidelines, coding updated.
- December 11, 2013: Reviewed by IMPAC, definition of intermediate to high-risk disease clarified with use of the IPSS.
- 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, criteria for low-risk patients added to "Allogenic HSCT” and “Non-myeloablative Allogenic HSCT” sections effective April 1, 2016.
- 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.