

Medical Necessity Guidelines: Hematopoietic Stem-Cell Transplantation (HSCT)

Effective: November 18, 2020

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Applies to:</p> <p>COMMERCIAL Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>TUFTS HEALTH PUBLIC PLANS Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p>SENIOR Products</p> <ul style="list-style-type: none"> • 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

Hematopoietic stem cell transplantation (HSCT) has become a well-established life-saving treatment procedure for many patients with hematological malignancies, inborn errors, or bone marrow failure syndromes. HSCT involves multiple steps, including stem cell mobilization and harvest, application of a conditioning regimen to partially or fully ablate the patient’s existing hematopoietic system, ex vivo graft manipulation and/or in vivo T cell depletion (in some protocols), infusion of the stem cell graft to repopulate the patient’s hematopoietic system with healthy cells, and post-transplant care and monitoring. There are two main types of stem cell transplantation, autologous and allogeneic. An **autologous** transplant uses a patient's own stem cells. Stem cells are collected from the patient and frozen in liquid nitrogen before transplant conditioning. Following conditioning treatment, the patient's stem cells are returned to the body to help it produce healthy red and white blood cells and platelets. An **allogeneic** transplant uses stem cells from a donor whose human leukocyte antigens (HLA) are acceptable matches to the patient's. The stem cell donor may be related to the patient or may be an unrelated volunteer found through a donor registry such as the National Marrow Donor Program. There are two main types of allogeneic transplants, myeloablative and non-myeloablative (or “reduced intensity”, or “mini” or “RIC”). A myeloablative transplant uses large doses of chemotherapy or a combination of chemotherapy and radiation to overcome resistance and eradicate a patient's malignancy. A reduced intensity or non-myeloablative allogeneic transplant uses a reduced amount of chemotherapy to suppress the patient's immune system enough so that the donor stem cells can take root. While the chemotherapy may kill some of the tumor cells, that is not the goal of the chemotherapy given prior to the transplant. With a reduction in the amount of cancerous tissue, the transplanted stem cells can produce high numbers of health white blood cells to attack the remaining cancer cells.

CLINICAL COVERAGE CRITERIA

Autologous HSCT

Tufts Health Plan may authorize coverage of autologous hematopoietic stem cell transplantation for the following indications, **when the specific criteria outlined below for each indication are met:**

- [Acute promyelocytic leukemia \(APL\)](#)
- [Amyloidosis](#)
- [Central nervous system tumors](#)
- [Hodgkin's Disease](#)
- [Multiple Myeloma and POEMS Syndrome](#)
- [Neuroblastoma](#)
- [Non-Hodgkin's lymphoma, adult](#)
- [Non-Hodgkin's lymphoma, pediatric](#)
- [Pediatric solid tumors](#)
- [Systemic Sclerosis](#)
- [Testicular cancer and malignant germ cell tumors](#)

Allogeneic HSCT

Tufts Health Plan may authorize coverage of allogeneic hematopoietic stem cell transplantation for the following indications, **when the specific criteria outlined below for each indication are met:**

- [Acute promyelocytic leukemia \(APL\)](#)
- [Acute lymphocytic/lymphoblastic leukemia, adult \(ALL\)](#)
- [Acute lymphocytic/lymphoblastic leukemia, pediatric \(ALL\)](#)
- [Acute myelogenous leukemia \(AML\)](#)
- [Aplastic anemia](#)
- [Chronic lymphocytic leukemia/small lymphocytic lymphoma \(CLL/SLL\)](#)
- [Chronic myelogenous leukemia \(CML\)](#)
- [Chronic myelomonocytic leukemia \(CMML\)/Juvenile myelomonocytic leukemia \(JML\)](#)
- [Fanconi anemia](#)
- [Hodgkin's Disease](#)
- [Inherited immunodeficiency disorder](#)
- [Inherited metabolic disorders](#)
- [Myelodysplastic syndrome](#)
- [Myelofibrosis](#)
- [Neuroblastoma](#)
- [Non-Hodgkin's lymphoma, adult](#)
- [Non-Hodgkin's lymphoma, pediatric](#)
- [Sickle cell disease](#)

CLINICAL COVERAGE CRITERIA BY INDICATION

Acute Lymphocytic Leukemia (ALL), Adult

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.

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:

- Uncontrolled central nervous system (CNS) involvement
- Advanced age defined as greater than 65 years old (allogeneic HSCT only)
- Active disease (autologous HSCT only)

Acute Lymphocytic Leukemia (ALL), Pediatric

Tufts Health Plan may authorize coverage of an allogeneic HSCT from a related HLA-matched donor for the treatment of ALL in children when **one** of the following criteria is met:

- Initial treatment of Philadelphia chromosome positive patients
- Failed induction therapy
- First remission for Members with high risk (as described above) of disease relapse
- Second or subsequent remission

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

Tufts Health Plan **does not cover** non-myeloablative allogeneic HSCT for this diagnosis.

Limitations: Tufts Health Plan does not cover HSCT for children with ALL when there is central nervous system (CNS) involvement, as it is considered not medically necessary.

Acute Promyelocytic Leukemia (APL)

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

Tufts Health Plan may authorize coverage of an allogeneic 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

Acute Myelogenous Leukemia (AML)

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:
 - a. First remission
 - b. First relapse
 - c. 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:
 - a. Relapsed disease after first allogeneic HSCT
 - b. No peripheral blood blasts
 - c. $\leq 5\%$ blasts in the bone marrow
3. Tufts Health Plan may authorize coverage of a non-myeloablative (NMA) allogeneic 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).

Amyloidosis

Tufts Health Plan may authorize coverage of an autologous HSCT for the treatment of primary systemic amyloidosis (i.e., amyloid light-chain or AL) when **all** of the following criteria are met:

- Biopsy proven Amyloid
- Eastern Cooperative Oncology Group (ECOG) performance status 0-3 (refer to ECOG Performance Status)
- Single-organ involvement, or two-organ involvement with ECOG performance 0-1 (refer to ECOG Performance Status)
- Absence of Multiple Myeloma
- Cardiac interventricular septal thickness is less than or equal to 15 mm
- Left ventricular ejection fraction is greater than 55%
- Serum creatinine is less than or equal to 2.0 mg/dl
- Adequate pulmonary function with normal oxygen saturation on room air
- Adequate liver function as defined as total bilirubin less than 2.0 mg/dl and transaminases less than two times normal

Aplastic Anemia

Tufts Health Plan may authorize coverage of allogeneic HSCT from an HLA-matched donor for Members who fail to respond to prior immunosuppressive therapy or who relapse following primary immunosuppressive therapy **and** who meet the following criteria:

1. Bone marrow biopsy demonstrates one of the following:
 - a. Less than 25% of normal cellularity
 - b. Less than 50% of normal cellularity, with less than 30% of the cells hematopoietic

AND

2. Testing must demonstrate **two** of the following:
 - a. Absolute reticulocyte count less than 40,000/microL
 - b. Absolute neutrophil count less than 500/microL
 - c. Platelet count less than 20,000/microL

Tufts Health Plan **does not cover** non-myeloablative allogeneic HSCT for aplastic anemia.

Central Nervous System Tumors

Tufts Health Plan may authorize coverage of autologous HSCT for the treatment of recurrent medulloblastoma or supratentorial primitive neuroectodermal tumors in children.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

Tufts Health Plan may authorize coverage of allogeneic HSCT (myeloablative or non-myeloablative) from an HLA-matched donor for the treatment of CLL/SLL for any of the following indications:

- Members who have undergone transformation to a more aggressive histology
- Members with relapsed disease
- First remission for Members with del17/del11 CLL who have a complete/partial response to therapy

Chronic Myelogenous Leukemia

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.

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](#)

Chronic Myelomonocytic Leukemia (CMML)/Juvenile Myelomonocytic Leukemia (JML)

Tufts Health Plan may authorize coverage of allogeneic HSCT (myeloablative or non-myeloablative) for the treatment of CMML or JML from a suitable HLA matched donor.

Fanconi Anemia

Tufts Health Plan may authorize coverage of an allogeneic HSCT with an HLA-matched donor for the treatment of Fanconi anemia for Members who have failed conventional medical management.

Hodgkin's Disease

Tufts Health Plan may authorize coverage of an autologous HSCT following high-dose chemotherapy when **either** of the following criteria is met:

1. Primary refractory Hodgkin's disease
2. Relapse after primary therapy

Tufts Health Plan may authorize coverage of an allogeneic HSCT following high-dose chemotherapy when **all** of the following criteria are met:

1. A suitable human leukocyte antigen (HLA) matched donor has been identified and is available
2. The Member's disease can be categorized as one of the following:
 - a. Primary refractory Hodgkin's disease
 - b. Relapse after autologous HSCT

Tufts Health Plan **does not cover** non-myeloablative allogeneic HSCT for the treatment of this diagnosis.

Inherited Immunodeficiency Disorder

Tufts Health Plan may authorize coverage of allogeneic HSCT with a suitable human leukocyte antigen (HLA) matched 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

Tufts Health Plan may authorize coverage of non-myeoablative 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.

Inherited Metabolic Disorders

Tufts Health Plan may authorize coverage of allogeneic HSCT (myeloablative or non-myeloablative) from an HLA-matched donor for any of the following inherited metabolic disorders:

- Hurler syndrome
- Maroteaux-Lamy syndrome
- Childhood-onset cerebral X-linked adrenoleukodystrophy
- Gaucher disease Type 3 which has failed enzyme replacement therapy
- Krabbe disease in asymptomatic newborns transplanted in the neonatal period
- Late onset Krabbe disease
- Late infantile and early juvenile metachromatic leukodystrophy (MLD) in asymptomatic Members
- Late juvenile and early adult MLD in patients with adequate neuropsychological function and independence in activities of daily living

Multiple Myeloma and POEMS Syndrome

Tufts Health Plan may authorize the coverage of a single or tandem autologous stem-cell transplantation following high dose chemotherapy for multiple myeloma and POEMS syndrome.

Myelodysplastic Syndrome

- 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.
- 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.
- 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.
- 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 mds-foundation.org/ipss-r-calculator.

Myelofibrosis

Tufts Health Plan may authorize the coverage of allogeneic HSCT (myeloablative or non-myeloablative) for the treatment of myelofibrosis for symptoms that persist or worsen despite standard supportive care.

Neuroblastoma

- Tufts Health Plan may authorize coverage of a maximum of three tandem autologous HSCT for the treatment of high-risk neuroblastoma.
- Tufts Health Plan may authorize coverage of an allogeneic HSCT from an HLA-matched donor (at least five of six HLA-match) for the treatment of high-risk neuroblastoma when the patient is not a candidate for autologous HSCT.
- Tufts Health Plan **does not cover** non-myeloablative allogeneic HSCT for this diagnosis.

Non-Hodgkin's Lymphoma, Adult

Tufts Health Plan may authorize coverage of an autologous HSCT when the Member meets **one** of the following criteria:

- Recurrent, or refractory aggressive, or highly aggressive advanced stage disease (Stage III or IV) when Member responds to high dose chemotherapy. Purging is not covered.
- Refractory indolent disease.
- Recurrent indolent disease if relapse is within 12 months of initial remission.
- Indolent disease transformation to aggressive disease.

Tufts Health Plan may authorize coverage of allogeneic HSCT when the Member has a matched sibling or unrelated donor and **one** of the following criteria is met:

- Refractory indolent disease.
- Recurrent indolent disease if relapse is within 12 months of the initial remission.

Tufts Health Plan will cover non-myeloablative allogeneic HSCT for Members with low grade lymphoma and who are unable to undergo fully ablative transplantation.

Tufts Health Plan **does not cover** tandem autologous or allogeneic HSCT for this diagnosis.

Non-Hodgkin's Lymphoma, Pediatric

Tufts Health Plan may authorize coverage of an autologous or an allogeneic HSCT for the treatment of pediatric Members with non-Hodgkin's lymphoma with chemo sensitive disease in second remission.

Tufts Health Plan may authorize coverage of a non-myeloablative allogeneic stem cell transplantation for relapsed disease following an autologous HSCT, and for high-risk Members who cannot receive an ablative allogeneic HSCT.

Tufts Health Plan **does not cover** tandem autologous or allogeneic HSCT for this diagnosis.

Pediatric Solid Tumors

Tufts Health Plan may authorize coverage of high-dose chemotherapy followed by autologous HSCT for the treatment of the following:

- Relapsed Wilms' tumor
- Metastatic retinoblastoma
- Relapsed Ewing's sarcoma, not responsive to other therapies.
- Relapsed Peripheral Neuroectodermal Tumor (PNET): primary metastatic or bulky disease, not responsive to other therapies.
- Relapsed Rhabdomyosarcoma, not responsive to other therapies.
- Relapsed Desmoplastic small round cell tumor, not responsive to other therapies.
- Hepatoblastoma: Primary metastatic or recurrent.

Sickle Cell Disease

Tufts Health Plan may authorize coverage of an allogeneic HSCT in children, adolescents or young adults (under age 40) using bone marrow from a human leukocyte antigen (HLA)-matched donor sibling for the treatment of severe sickle cell disease characterized by **one or more** of the following:

- History of stroke or central nervous system event
- Recurrent acute chest syndrome, vaso-occlusive crises, or priapism
- Chronic transfusions (Member requires transfusions on a regular and ongoing basis, e.g., every 3-4 weeks)
- Abnormal transcranial Doppler study
- Impaired neuropsychological function combined with abnormal cerebral magnetic resonance imaging
- Sickle lung disease
- Sickle nephropathy
- Bilateral proliferative retinopathy and major visual impairment

- Osteonecrosis
- Red cell allo-immunization

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

Limitations: Tufts Health Plan **does not cover** HSCT for the treatment of sickle cell disease using stem cells derived from:

- Cord blood or peripheral blood
- Matched unrelated donors
- Non-sibling family donors

Systemic Sclerosis/Scleroderma

Tufts Health Plan may authorize coverage of an autologous HSCT for the treatment of systemic sclerosis/scleroderma when **ALL** of the following are met:

- The Member is <65 years of age; **AND**
- Duration of condition of 5 years or less; **AND**
- Modified Rodnan skin score of 15 or higher; **AND**
- The Member has rapidly progressing disease with evidence of internal organ involvement, including but not limited to pulmonary complications (e.g. interstitial lung disease, pulmonary hypertension), cardiac complications (e.g. heart failure, arrhythmia, angina/atypical chest pain), and renal complications (e.g. impaired renal function, scleroderma renal crisis), **AND**
- There is no known presence of neoplasm(s) in the Member; **AND**
- None of the organ involvement exclusion criteria below are met

Organ Involvement Exclusion Criteria

Patients with internal organ involvement indicated by the following measurements **should not be considered** for autologous HCT:

- Cardiac: left ventricular ejection fraction <45%, mean pulmonary artery pressure >25 mm Hg, pulmonary artery systolic pressure >40 mm Hg,
- Pulmonary: DLCo (diffusing capacity) <40% of predicted value, forced vital capacity (FVC) <65% of predicted value
- Renal: creatinine clearance <40 ml/minute

Testicular Cancer and Malignant Germ Cell Tumors

Tufts Health Plan may authorize coverage of a single or tandem high-dose chemotherapy followed by autologous HSCT for relapsed or refractory nonseminomatous testicular cancer, as well as relapsed or refractory germ cell cancer of the mediastinum or female genital tract.

GENERAL LIMITATIONS

Tufts Health Plan considers hematopoietic stem cell transplantation (HSCT) 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.

Tufts Health Plan considers HSCT investigational and, therefore, not medically necessary for any indication other than those listed above in these guidelines.

CODES

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

Table 1: CPT/HCPCS Codes

Code	Description
38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor

Code	Description
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38243	Hematopoietic progenitor cell (HPC); HPC boost
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem-cell transplantation, allogeneic
S2150	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

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10. Hayes, Inc. Health Technology Assessment. High-Dose Chemotherapy with Autologous Stem Cell Support, Treatment for Non-CNS Pediatric Solid Tumors Other Than Neuroblastoma. Annual review, October 8, 2006.
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APPROVAL HISTORY

September 18, 2019: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC); code 38242 removed from Table 1; multiple Hematopoietic Stem-Cell Transplantation (HSCT) Medical Necessity Guidelines for various indications were combined into this one Medical Necessity Guideline. As a result, the following Medical Necessity Guidelines were retired:

- Hematopoietic Stem Cell Transplantation: Acute Lymphocytic/Lymphoblastic Leukemia (ALL): Adult
- Hematopoietic Stem Cell Transplantation: Acute Lymphocytic/Lymphoblastic Leukemia (ALL): Pediatric
- Hematopoietic Stem Cell Transplantation: Acute Myelogenous Leukemia (AML)
- Hematopoietic Stem Cell Transplantation: Amyloidosis

- Hematopoietic Stem Cell Transplantation: Aplastic Anemia
- Hematopoietic Stem Cell Transplantation: Central Nervous System Tumors
- Hematopoietic Stem Cell Transplantation: Chronic Lymphocytic Leukemia (CLL/SLL)
- Hematopoietic Stem Cell Transplantation: Chronic Myelogenous Leukemia (CML)
- Hematopoietic Stem Cell Transplantation: Chronic Myelomonocytic Leukemia (CMML) And Juvenile Myelomonocytic Leukemia
- Hematopoietic Stem Cell Transplantation: Fanconi Anemia
- Hematopoietic Stem Cell Transplantation: for the Treatment of Sickle Cell Disease
- Hematopoietic Stem Cell Transplantation: Hodgkin's Disease
- Hematopoietic Stem Cell Transplantation: Inherited Immunodeficiency Disorder
- Hematopoietic Stem Cell Transplantation: Inherited Metabolic Disorders
- Hematopoietic Stem Cell Transplantation: Multiple Myeloma and Poems Syndrome
- Hematopoietic Stem Cell Transplantation: Myelodysplastic Syndrome
- Hematopoietic Stem Cell Transplantation: Myelofibrosis
- Hematopoietic Stem Cell Transplantation: Neuroblastoma
- Hematopoietic Stem Cell Transplantation: Non-Hodgkin's Lymphoma: Adult
- Hematopoietic Stem Cell Transplantation: Non-Hodgkin's Lymphoma: Pediatric
- Hematopoietic Stem Cell Transplantation: Pediatric Solid Tumors
- Hematopoietic Stem-Cell Transplantation (HSCT) for the Treatment of Testicular Cancer and Malignant Germ Cell Tumors
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- January 15, 2020: Reviewed by IMPAC, criteria added for HSCT for the indication of systemic sclerosis/scleroderma
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- November 4, 2020: Fax number for Unify updated
- November 18, 2020: Reviewed at IMPAC. Clarification of blood testing criterion for aplastic anemia

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](#)