Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Hematopoietic Stem-Cell Transplantation (HSCT)

Effective: March 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care-- A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

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, including radiation injury. 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. The main types of allogeneic transplants are myeloablative, non-myeloablative, and reduced intensity ("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.

Poor graft function (PGF), a relevant complication following HSCT, is defined as frequent dependence on blood and/or platelet transfusions and/or growth factor support in the absence of other explanations, such as disease relapse, drugs, or infections, assuming that donor myeloid and lymphoid chimerism are within a desirable target level. The administration of donor CD34+ stem cell boost is a therapeutic option to improve PGF occurring after allogeneic stem cell transplant.

For Tuft's Health One Care
The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. For **Tuft's Health One Care** plan members the following is used for select indications: Stem Cell Transplantation NCD 110.23, while the criteria below is used for other indications.

- The Stem Cell Transplantation NCD 110.23 is used for the following indications: Leukemia, Aplastic Anemia, Amyloidosis, Hodgkin's Disease, Severe Combined Immunodeficiency (multiple types), Wiskott-Aldrich Syndrome, Multiple Myeloma, Myelodysplastic Syndrome, Myelofibrosis, Neuroblastoma, Non- Hodgkin's Lymphoma, and Sickle Cell Disease
- The below criteria is used for all other indication. The coverage of diagnoses and the supportive criteria are supported by National Cancer Comprehensive Network (NCCN) guidelines and the American Society for Transplantation and Cellular Therapy.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

Autologous HSCT

The 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:**

1. Acute promyelocytic leukemia (APL)
2. Amyloidosis
3. Central nervous system tumors
4. Hodgkin's Disease
5. Multiple Myeloma and POEMS Syndrome
6. Neuroblastoma
7. Non-Hodgkin's lymphoma, adult
8. Non-Hodgkin's lymphoma, pediatric
9. Pediatric solid tumors
10. Systemic Sclerosis
11. Testicular cancer and malignant germ cell tumors

Allogeneic HSCT

The 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**:

1. Acute promyelocytic leukemia (APL)
2. Acute lymphocytic/lymphoblastic leukemia, adult (ALL)
3. Acute lymphocytic/lymphoblastic leukemia, pediatric (ALL)
4. Acute myelogenous leukemia (AML)
5. Aplastic anemia
6. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
7. Chronic myeloid leukemia (CML)
8. Chronic myelomonocytic leukemia (CMML)/Juvenile myelomonocytic leukemia (JMML)
9. Fanconi anemia
10. Hodgkin's Disease

11. Inherited immunodeficiency disorder
12. Inherited metabolic disorders
13. Myelodysplastic syndrome
14. Myelofibrosis
15. Neuroblastoma
16. Non-Hodgkin's lymphoma, adult
17. Non-Hodgkin's lymphoma, pediatric
18. Paroxysmal nocturnal hemoglobinuria (PNH)
19. Sickle cell disease
20. Thalassemia

Repeat allogeneic stem cell transplant is appropriate for primary and secondary failure to engraft and for disease relapse.

CD34(+) stem cell boost:

The Plan may authorize CD34(+) selected stem cell boost when member has poor graft function following allogeneic HSCT.

Clinical Coverage Criteria by Indication

Acute Lymphocytic Leukemia (ALL), adult

The 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:

1. Failed induction therapy
2. Any patient in first remission, even those not considered high risk.
3. Second or subsequent remission

The 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: The 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:

1. Uncontrolled central nervous system (CNS) involvement

Acute Lymphocytic Leukemia (ALL), pediatric

The 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:

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

The 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.

Limitations: The 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)

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

The 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:

1. Failure to achieve second remission
2. PCR positivity in patients who achieve remission

Acute Myelogenous Leukemia (AML)

The 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:

1. First remission
2. First relapse
3. Second remission

The 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:

1. Relapsed disease after first allogeneic HSCT
2. No peripheral blood blasts
3. ≤ 5% blasts in the bone marrow

The 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

The 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:

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

Aplastic Anemia

The Plan may authorize coverage of allogeneic HSCT from an HLA-matched donor for Members who fail to respond to prior immunosuppressive therapy and/or are not deemed to be candidates for immunosuppressive therapy **and** who meet **ALL** of 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

Central Nervous System Tumors

The 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)

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

1. Members who have undergone transformation to a more aggressive histology
2. Members with relapsed disease

3. First remission for Members with del17/del11 CLL who have a complete/partial response to therapy

Chronic Myeloid Leukemia

The 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.

Note: After allogeneic HSCT, The Plan may authorize coverage of donor leukocyte infusion for the treatment of all malignant hematologic conditions.

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

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

Fanconi Anemia

The Plan may authorize coverage of an allogeneic HSCT with a suitable donor for the treatment of Fanconi anemia.

Hodgkin's Disease

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

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

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

1. A suitable 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

Inherited Immunodeficiency Disorder

The Plan may authorize coverage of allogeneic HSCT with a suitable human leukocyte antigen (HLA) matched donor for **ONE** of the following Inherited Immunodeficiency Disorders:

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

The Plan may authorize coverage of non-myleoablative 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

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

1. Hurler syndrome
2. Maroteaux-Lamy syndrome
3. Childhood-onset cerebral X-linked adrenoleukodystrophy

4. Gaucher disease Type 3 which has failed enzyme replacement therapy
5. Krabbe disease in asymptomatic newborns transplanted in the neonatal period
6. Late onset Krabbe disease
7. Late infantile and early juvenile metachromatic leukodystrophy (MLD) in asymptomatic Members
8. Late juvenile and early adult MLD in patients with adequate neuropsychological function and independence in activities of daily living

Multiple Myeloma and POEMS Syndrome

The 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

The 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.

The 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.

The Plan may authorize coverage of reduced intensity 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:

1. The Member has had failure/intolerance to hypomethylating agents.
2. The member is not a candidate for high-dose chemotherapy followed by allogeneic transplantation.
3. A suitable HLA-matched donor has been identified and is available.

The Plan may authorize coverage of reduced intensity 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 **ALL** of the following criteria are met:

1. The Member is not a candidate for high-dose chemotherapy followed by allogeneic transplantation.
2. 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 (Primary and Secondary)

The 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

The Plan may authorize coverage of a maximum of three tandem autologous HSCT for the treatment of high-risk neuroblastoma.

The 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.

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

Non-Hodgkin's Lymphoma, Adult

The Plan may authorize coverage of an autologous/allogeneic HSCT when the Member meets **ONE** of the following criteria:

1. 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.
2. Refractory indolent disease.
3. Recurrent indolent disease if relapse is within 12 months of initial remission.
4. Indolent disease transformation to aggressive disease.

In addition, the 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:

1. Relapsed after autologous transplant
2. Relapsed after CAR-T therapy.

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

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

Non-Hodgkin's Lymphoma, Pediatric

The 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.

The 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.

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

Pediatric Solid Tumors

The Plan may authorize coverage of high-dose chemotherapy followed by autologous HSCT for the treatment of **ONE** of the following:

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

Paroxysmal nocturnal hemoglobinuria (PNH)

The Plan may authorize allogeneic HSCT for treatment of PNH with co-existent severe bone marrow failure.

Sickle Cell Disease

The 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 related donor for the treatment of severe sickle cell disease characterized by **ONE** of the following:

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

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

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

1. Cord blood or peripheral blood

2. Matched unrelated donors

Systemic Sclerosis/Scleroderma

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

1. The Member is <65 years of age; **AND**
2. Duration of condition of 5 years or less; **AND**
3. Modified Rodnan skin score of 15 or higher; **AND**
4. 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**
5. There is no known presence of neoplasm(s) in the Member; **AND**
6. None of the organ involvement exclusion criteria below are met

Testicular Cancer and Metastatic Germ Cell Tumors

The 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.

Thalassemia

The Plan may authorize coverage of allogeneic HSCT for transfusion dependent thalassemia when donor is an HLA matched sibling. NOTE: HSCT offers no survival benefit over medical therapy.

Limitations: The Plan does not cover allogeneic HSCT if member has severe organ damage as a result of iron overload.

Organ Involvement Exclusion Criteria

Individuals with internal organ involvement indicated by the following measurements **should not be considered for allogeneic HSCT:**

- 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

Limitations

The Plan considers hematopoietic stem cell transplantation (HSCT) contraindicated and thus not medically necessary when there is also the presence of any significant co-morbid conditions which would significantly compromise the Member's clinical care and chances of survival.
The Plan considers HSCT investigational and, therefore, not medically necessary for any indication other than those listed above in these guidelines.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

*Codes are applicable to Tufts Health Plan members

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

Code	Description
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38243	Hematopoietic progenitor cell (HPC); HPC boost

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Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- November 4, 2020: Fax number for Unify updated
- November 18, 2020: Reviewed at IMPAC. Clarification of blood testing criterion for aplastic anemia
- August 18, 2021: Reviewed at IMPAC. Update to Sickle Cell Disease criteria: removal of non-sibling family donors limitation. HLA matched related donors allowed.
- February 16, 2022: Reviewed at Medical Policy Approval Committee (MPAC). For effective date February 16, 2022, criteria for CD34+ boost added.
- July 20, 2022: Reviewed by Medical Policy Approval Committee (MPAC) for integration
- purposes with Harvard Pilgrim Health Care. For effective date of April 1, 2023, added criteria for paroxysmal nocturnal hemoglobinuria (PNH), thalassemia, repeat allogeneic HSCT. Limitations removed from ALL criteria. CPT codes added to PA requirement: CPT 38208-38215, 38242.
- December 21, 2022: Reviewed by MPAC, renewed without changes pending Integrated policy effective 4/1/23
- November 16, 2023: Reviewed by MPAC, renewed without criteria changes, the following codes were removed from the policy and will continue to not require PA – 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38242; the following codes were removed from the policy and are no longer covered – S2140, S2142, S2150 effective January 1, 2024
- November 2023: Rebranded Unify to One Care and updated overview effective January 1, 2024
- December 1, 2023: Reviewed and approved by UM Committee
- November 21, 2024: Reviewed by MPAC, with the following changes: Removed non-myeloablative restriction of HSCT from several indications. Aplastic anemia-removed requirement member first receive immunosuppressive. For CML-Removed non-myeloablative restriction and Broadened donor leukocyte infusion criteria, For Fanconi Anemia and Hodgkin's Disease-removed HLA-matched donor requirement and Revised Non-Hodgkin's Lymphoma criteria to allow after relapse transplant and CAR-T; references updated. All effective March 1, 2025.
- December 13, 2024: Reviewed and approved by the UM Committee effective January 1, 2025

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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.