MEDICAL POLICY

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Medical Policy Title	**Autologous Hematopoietic Stem Cell Transplantation (Auto-HSCT)**
Policy Number	**7.02.03**
Current Effective Date	**June 15, 2026**
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Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Autologous hematopoietic stem cell transplant (auto-HSCT) is considered **medically appropriate** when **ALL** of the following criteria are met:

A. Candidates have met the transplanting institution's selection criteria;

B. The multidisciplinary team has evaluated the individual and recommends treatment (see policy guidelines for required documentation); **and**

C. The individual meets the following indication-specific criteria:

Blood/Plasma Cancers

1. Acute Promyelocyte Leukemia
   a. Adult ≥ age 18; in the following disease state:
      i. CR2, in molecular remission
   b. Child ≤ age 17; in the following disease state:
      i. Relapse;
2. Multiple Myeloma
   a. Adult ≥ age 18; in any of the following disease states:
      i. Initial response;
      ii. Sensitive relapse;
      iii. Refractory;
3. Plasma Cell Leukemia
   a. Adult ≥ age 18;
4. Amyloid Light-chain Amyloidosis
   a. Adult ≥ age 18
5. POEMS Syndrome

a. Adult ≥ age 18

6. Relapse after Autologous Transplant
   a. Adult ≥ age 18
7. Hodgkin Lymphoma
   a. Adult ≥ age 18; in **any** of the following disease states:
      i. Primary refractory, sensitive;
      ii. First relapse, sensitive; **or**
      iii. Second or greater relapse
   b. Child ≤ age 17; in **any** of the following disease states:
      i. Primary refractory, sensitive;
      ii. First relapse, sensitive; **or**
      iii. Second or greater relapse;
8. Diffuse Large B-cell Lymphoma
   a. Child ≤ age 17; in **any** of the following disease states:
      i. Primary refractory, sensitive;
      ii. First relapse, sensitive; **or**
      iii. Second or greater relapse;
   b. Adult ≥ age 18; and in **any** of the following disease states
      iv. Primary refractory, sensitive;
      v. First relapse, sensitive; **or**
      vi. Second or greater relapse;
9. High-grade B cell Lymphoma, with MYC and BCL2 or BL6 rearrangements:
   a. Adult ≥ age 18; and in **any** of the following disease states
      i. CR1 (positron emission tomography negative);
      ii. Primary refractory, sensitive;
      iii. First relapse, sensitive; **or**
      iv. Second or greater relapse;
10. Primary Central Nervous System Lymphoma
    a. Adult ≥ age 18; in **either** of the following disease states:
       i. CR1/first partial remission (consolidation); **or**

ii. Relapse, sensitive;

11. Follicular Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. Primary refractory, sensitive;
        ii. First relapse, sensitive (including POD24);
        iii. Second or greater relapse; **or**
        iv. Transformation to high-grade lymphoma;
12. Mantle Cell Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. First partial remission;
        ii. Primary refractory, sensitive;
        iii. First relapse, sensitive; **or**
        iv. Second or greater relapse;
13. T-Cell non-Hodgkin Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. CR1/first partial remission;
        ii. Primary refractory, sensitive;
        iii. First relapse, sensitive; **or**
        iv. Second or greater relapse;
    b. Child ≤ age 17; in **any** of the following disease states:
        i. CR1, standard or high risk;
        ii. CR2; **or**
        iii. Third complete remission with additional therapy (CR3+);
14. Burkitt Lymphoma
    a. Adult ≥ age 18: in the following disease state:
        i. First or greater relapse, sensitive;
    b. Child ≤ age 17; in the following disease state:
        i. First or greater relapse, sensitive;
15. Cutaneous T Cell Lymphoma
    a. Adult ≥ age 18; in relapse;

16. Lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. Primary refractory, sensitive; **or**
        ii. First or greater relapse, sensitive;
17. Plasmablastic Lymphoma
    a. Adult ≥ age 18; in relapse;
18. Chronic Lymphocytic Leukemia
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. T cell prolymphocytic leukemia;
        ii. B cell, prolymphocytic leukemia; **or**
        iii. Transformation to high-grade lymphoma;

<u>Solid Tumors</u>

19. Germ cell tumors
    a. Adult ≥ age 18; in **either** of the following disease states:
        i. Relapse; **or**
        ii. Refractory;
    b. Child ≤ age 17; in **either** of the following disease states:
        i. Relapse; **or**
        ii. Refractory;
20. Neuroblastoma
    a. Child ≤ age 17; in **either** of the following disease states:
        i. High risk; **or**
        ii. Relapse;
21. Wilms Tumor
    a. Child ≤ age 17; in relapse;
22. Osteosarcoma
    a. Child ≤ age 17; in relapse;
23. Ewing's sarcoma
    a. Adult ≥ age 18; high risk;
    b. Child ≤ age 17; in **either** of the following disease states:

i. High risk; **or**

ii. Relapse;

24. Medulloblastoma
    a. Adult ≥ age 18; high risk or recurrent;
    b. Child ≤ age 17; high risk or recurrent;
25. Pediatric brain tumors when **both** of the following criteria are met:
    a. High risk (e.g. rhabdoid tumors); **and**
    b. The intent is to avoid craniospinal radiation therapy;

Non-Malignant Conditions

26. Multiple Sclerosis (MS)
    a. Adult ≥ age 18; and ≤ 45 years; when **all** of the following criteria are met:
        i. Individual has a diagnosis of relapsing-remitting or secondary progressive MS;
        ii. Two (2) or more clinical relapses or one (1) relapse and MRI gadolinium-enhancing lesion(s) at an independent time point in the previous 12 months;
        iii. Continued disease activity despite use of one or more FDA-approved disease-modifying therapies (e.g., interferons, glatiramer acetate natalizumab, fingolimod, dethyl fumarate); **and**
        iv. Expanded Disability Status Scale (EDSS) score between 2.0 and 5.5 or less;
27. Systemic Sclerosis
    a. Adult ≥ age 18 with **either** of the following:
        i. Pulmonary Involvement with **both**:
            a) Active interstitial lung disease (i.e., bronchoalveolar cell composition or ground-glass opacities on computed tomography of the chest); **and**
            b) Forced vital capacity or a diffusing capacity of the lung for carbon monoxide of less than 70% of the predicted value;

            OR

            c) Renal involvement with previous scleroderma-related renal disease;
    b. Child ≤ age 17
28. Juvenile Rheumatoid Arthritis;
    a. Child ≤ age 17.

II. Autologous HSCT is considered **investigational** for all other indications.

RELATED POLICIES

Corporate Medical Policy

7.02.02 Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

7.02.11 Chimeric Antigen Receptor T-cell (CAR-T) Therapy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Each individual considered for autologous stem cell transplant will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

I. Required documentation from the multidisciplinary team that includes the individual's eligibility and risk for autologous stem cell transplant should include:
   A. Clinical Evaluation
      1. Confirmation of diagnosis;
      2. Identification of co-morbidities;
      3. Current assessment of co-morbidities;
      4. Management of co-morbidities;
      5. Consult notes (if applicable);
   B. Psycho-Social Evaluation:
      1. Identification of stressors (e.g., family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse).
   C. Performance Status:
      1. Karnofsky performance score;
      2. Palliative Performance Scale (PPS) score;
      3. Eastern Cooperative Oncology Group (ECOG) performance status; or
      4. Lansky Play-Performance Scale (for age 1 to 16 years)
   D. Oral Health Evaluation
   E. Lab Tests:
      1. CBC;
      2. Metabolic profile;
   F. Cardiac Assessment:
      1. 12 Lead EKG;
      2. Echo or Muga Scan

G. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);

H. Age-Appropriate Screening Tests:

1. Please refer to the U.S. Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. https://uspreventiveservicestaskforce.org/uspstf/ [accessed 2025 Nov 24]

DESCRIPTION

In auto-HCT a portion of the patient's own stem cells are re-infused intravenously to rescue the patient by re-establishing his/her bone marrow which has been eradicated after high dose chemotherapy and/or total body irradiation has been given to destroy the malignant cells. Utilization of one's own cells avoids immunologic incompatibilities that can be seen with allogeneic stem cell transplants. This also permits subsequent engraftment and repopulation of the bone marrow with normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, auto-HCT is typically performed as consolidation therapy when the patient's disease is in complete remission. Patients who undergo auto-HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment.

Disability Scores

I. The Karnofsky performance status score describes a patient's functional status as a comprehensive 11-point scale correlating to percentage values ranging from 100% (no evidence of disease, no symptoms) to 0% (death). Adapted from Peus, et al 2013:

A: Able to carry on normal activity and to work. No special care is needed.	100	Normal, no complaints, no evidence of disease.
	90	Able to carry on normal activity, minor signs or symptoms of disease.
	80	Normal activity with effort, some signs, or symptoms of disease.
B: Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	70	Cares for self, unable to carry on normal activity or to do active work.
	60	Requires occasional assistance but is able to care for most of personal needs.
	50	Requires considerable assistance and frequent medical care.

C: Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled, requires special care and assistance. [In bed more than 50% of the time]
	30	Severely disabled, hospitalization is indicated although death not imminent. [Almost completely bedfast]
	20	Very ill, hospitalization and active supportive treatment necessary. [Totally bedfast and requiring extensive nursing care by professionals and/or family]
	10	Moribund, fatal processes progressing rapidly. [Comatose or barely arousable]
	0	Dead.

II. Palliative Performance Scale (PPS) score; adapted from Fast Facts and Concepts (Wilner and Arnold 2004):

Percentage	Ambulation	Activity Level/Evidence of Disease	Self-Care	Intake	Level of Consciousness
100	Full	Normal No Disease	Full	Normal	Full
90	Full	Normal Some Disease	Full	Normal	Full
80	Full	Normal with Effort Some Disease	Full	Normal or Reduced	Full
70	Reduced	Can't do normal job or work Some Disease	Full	As above	Full
60	Reduced	Can't do hobbies or housework Significant Disease	Occasional Assistance Needed	As above	Full or confusion

50	Mainly sit/lie	Can't do any work Extensive Disease	Considerable Assistance Needed	As above	Full or Confusion
40	Mainly in bed	As above	Mainly Assistance	As above	Full or Drowsy or Confusion
30	Bed Bound	As above	Total Care	Reduced	As above
20	Bed Bound	As above	As above	Minimal	As above
10	Bed Bound	As above	As above	Mouth care only	Drowsy or coma
0	Death	-	-	-	-

III. Eastern Cooperative Oncology Group (ECOG) performance status; adapted from ECOG-ACRIN Cancer Research group:

Grade	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

IV. Lansky Play-Performance Scale (for age 1 to 16 years)

The Lansky play-performance scale is used for children aged 1-16 with any type of malignancy. It is typically rated by parents based on their child's activity over the past week. Adapted from: Performance status | HemOnc.org - A Hematology Oncology Wiki [accessed 2025 Nov 24]:

Rating	Description
100	Fully active, normal
90	Minor restrictions with strenuous physical activity
80	Active, but gets tired quickly
70	Both greater restriction of, and less time spent in, active play
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Lying around much of the day, but gets dressed; no active play; participates in all quiet play activities
40	Mostly in bed; participates in quiet activities
30	Stuck in bed; needs help even for quiet play
20	Often sleeping; play is entirely limited to very passive activities
10	Does not play or get out of bed
0	Unresponsive

V. Kurtzke Expanded Disability Status Scale (EDSS)

The EDSS is one of the most widely used assessment instruments in MS. It is a clinical rating scale ranging from 0 (normal neurological examination) to 10 (death due to MS) in half point increments. It is used in conjunction with the Kurtzke Functional System Scores, observation, information concerning gait and use of assistive devices in order to rate the EDSS. The guidelines recommend that patients with an EDSS of 2.0-5.5 could be considered for auto-HSCT, with 2.0 defined as minimal disability in one functional system (FS) score, and 5.5 defined as ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities.

SUPPORTIVE LITERATURE

Blood Plasma Cancers

Acute Myeloid Leukemia

A meta-analysis published by Nathan et al (2004) compared survival outcomes for auto-HCT in CR1 with standard chemotherapy or no further treatment in AML patients ages 15 to 55 years. Two types of studies were eligible: (1) prospective cohort studies in which patients with an available sibling donor were offered allogeneic hematopoietic stem cell transplantation (allo-HCT) (biologic randomization) with random assignment of all others to auto-HCT or chemotherapy (or no further treatment); and (2) randomized trials that compared auto-HCT with chemotherapy in all patients.

Among a total of 4058 patients included in 6 studies, 2989 (74%) achieved CR1; 1044 (26%) were randomized to HCT (n=524) or to chemotherapy (n=520). Of the 5 studies for which overall survival (OS) data were available, outcomes with auto-HCT were better in three, and outcomes with chemotherapy were better in two. None of the differences were statistically significant, nor was the pooled estimate (fixed-effects model survival probability ratio, 1.01; 95% CI, 0.89 to 1.15; p=.86). In all six studies, disease free survival (DFS) was numerically superior using auto-HCT compared with chemotherapy (or no further treatment), but only one reported a statistically significant DFS probability associated with auto-HCT. The pooled estimate for DFS showed a statistically significant probability in favor of auto-HCT at 48 months posttransplant (fixed-effects model survival probability ratio, 1.24; 95% CI, 1.06 to 1.44; p=.006). This review comprised studies performed between 1984 and 1995, during which transplant protocols and patient management evolved significantly, particularly compared with current care.

A second meta-analysis, published by Wang et al (2010), evaluated auto-HCT plus further chemotherapy or no further treatment for patients with AML in CR1. A total of nine randomized trials involving 1104 adults who underwent auto-HCT and 1118 patients who received additional chemotherapy or no additional treatment were identified. Analyses suggested that auto-HCT in CR1 is associated with a statistically significant reduction of relapse risk (relative risk, 0.56; 95% CI, 0.44 to 0.71; p=.001) and significant improvement in DFS (HR, 0.89; 95% CI, 0.80 to 0.98), but at the cost of an increased non-relapse mortality rate (relative risk, 1.90; 95% CI, 1.34 to 2.70; p=.23). There were more deaths during the first remission among patients assigned to auto-HCT than among the chemotherapy recipients or further untreated patients. As a consequence of the increased non-relapse mortality rate, no statistical difference in OS (HR, 1.05; 95% CI, 0.91 to 1.21) was associated with the use of auto-HCT, compared with further chemotherapy or no further therapy. These results are concordant with the earlier meta-analysis.

A prospective, randomized phase 3 trial by Vellenga et al (2011) compared auto-HCT with intensive consolidation chemotherapy among patients (range, 16 to 60 years) with newly diagnosed AML of similar risk profiles in CR1. After two cycles of intensive chemotherapy (etoposide and mitoxantrone), patients in CR1 who were not a candidate for allo-HCT were randomized to a third consolidation cycle of the same chemotherapy (n=259) or auto-HCT (n=258). The HCT group experienced an upward trend toward superior regression free survival (RFS) (38%) compared with the chemotherapy group at five years (29%; p=.065). The HCT patients also had a lower relapse rate at five years (58%) compared with chemotherapy recipients (70%; p=.02). The OS did not differ between the HCT group (44%) and the chemotherapy group (41%; p=.86). Non-relapse mortality rates were higher in the auto-HCT group (4%) than in the chemotherapy consolidation group (1%; p=.02). Despite this difference in non-relapse mortality, the relative equality of OS rates was attributed by the investigators to a higher proportion of successful salvage treatments (second-line chemotherapy, autologous or allo-HCT) in the chemotherapy consolidation recipients that were not available to the auto-HCT patients. This large trial has shown an advantage for post-remission auto-HCT in reducing relapse, but similar OS rates secondary to better salvage of chemotherapy-consolidated patients.

Miyamoto et al (2018) reported results of a randomized, multicenter phase 3 trial conducted in 24 centers in Japan from 2003 to 2011 that compared auto-HCT versus HiDAC consolidation as post-remission therapy in AML. This trial enrolled 240 patients between 15 and 64 years of age with newly

diagnosed favorable- and intermediate-risk AML and Eastern Cooperative Oncology Group (ECOG) performance status of <3; 87 of those who achieved CR1 were randomized to auto-HCT or HiDAC. The study was powered to include 122 patients with 5 years of accrual and 3 years of post-accrual follow-up to detect a difference in DFS at 3 years of 40% versus 65%. Approximately one-third of the patients had favorable risk AML, and the remaining two-thirds had intermediate-risk AML. The median age was 48 years. Median follow-up was approximately 4.5 to 5 years. Three-year DFS rate was 41% (95% CI, 27% to 55%) in the HiDAC group and 55% (95% CI, 38% to 68%) in the auto-HCT group (p=.25). Three-year OS was 77% (95% CI, 61% to 87%) versus 68% (95% CI, 52% to 80%) (p=.67). Cumulative incidence of relapse was 54% versus 41% (p=.22). There were no differences between the HiDAC and auto-HCT groups in the incidence of liver or renal dysfunction. The incidence of life-threatening infectious complications (p=.003) and mucositis/diarrhea (p=.002) was significantly higher in the auto-HCT group.

Multiple Myeloma

Chakraborty et al (2022) conducted a meta-analysis investigating the impact of high-dose therapy (HDT) consolidation on survival outcomes in patients with newly diagnosed multiple myeloma, focusing on differences between those with standard-risk and high-risk cytogenetics. Researchers reviewed randomized controlled trials from 2000 to 2021 comparing HDT to standard-dose therapy (SDT). Six trials were included for progression-free survival (PFS) analysis and four for OS, with follow-ups ranging from 3.1 to 7.8 years. The results showed that HDT significantly improved OS in high-risk patients (HR 0.66) compared to standard-risk patients (HR 0.90), with a statistically significant interaction (P = .03). For PFS, HDT also showed benefits in both groups, but the difference between them was not statistically significant (P = .25). Overall, the study concluded that the survival benefit of HDT is influenced by cytogenetic risk, supporting the use of upfront HDT consolidation particularly in high-risk patients.

POEMS Syndrome

For individuals who have POEMS syndrome (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal gammopathy, and Skin abnormalities Syndrome) who receive HCT, the evidence includes retrospective cohort studies, case reports, and case series. Relevant outcomes are OS and treatment-related morbidity. No RCTs of HCT of any type have been performed in patients with POEMS syndrome of any severity, nor is it likely such studies will be performed because of the rarity of this condition. Available case reports and series are subject to selection bias and are heterogeneous concerning treatment approaches and peritransplant support. However, for patients with disseminated POEMS syndrome, a chain of evidence and contextual factors related to the disease and multiple myeloma would suggest improvement in health outcomes with auto-HCT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Hodgkin Lymphoma (HL)

A systematic review and meta-analysis of the available RCTs on HCT for patients with relapsed or refractory HL were published by Rancea et al (2014). Reviewers included three RCTs, 2 (1993, 2002) of which compared HDC plus auto-HCT with conventional treatment. Both trials were judged to be at moderate risk of bias using the Cochrane criteria. Combined analysis for the outcome of OS

demonstrated a hazard ratio of 0.67 for patients treated with auto-HCT, which was not statistically significant (95% CI, 0.41 to 1.07). For the outcome of progression-free survival (PFS), there was a significant improvement for auto-HCT treatment, with a hazard ratio of 0.55 (95% CI, 0.35 to 0.86).

A retrospective observational cohort study by Merryman et al (2021) evaluated auto-HCT after anti-programmed death-1 (PD-1) therapy for patients with relapsed or refractory HL. A total of seventy-eight patients who were identified underwent auto-HCT as a third-line (or later) treatment; 74% of patients underwent auto-HCT after anti-PD-1 treatment and 26% of patients received anti-PD-1 treatment along with additional therapy prior to auto-HCT. The 18-month PFS and OS after auto-HCT were 81% (95% CI, 69 to 89) and 96% (95% CI, 87 to 99), respectively. Favorable outcomes were reported for patients who had received greater than four systemic therapies before auto-HCT (18-month PFS, 73%), who were refractory to two consecutive therapies immediately prior to anti-PD-1 treatment (18-month PFS, 78%), and who had positive pre-HCT positron emission tomography (PET) (18-month PFS, 75%); patients who were non-responders to anti-PD-1 treatment had inferior outcomes (18-month PFS, 51%).

Diffuse Large B-Cell Lymphoma (DLBCL)

Results of a phase 3 multicenter randomized trial, Chemoradiotherapy and Peripheral Stem Cell Transplantation Compared with Combination Chemotherapy in Treating Patients with Non-Hodgkin's Lymphoma (SWOG-9704) of auto-HCT as consolidation for aggressive (high-intermediate or high-risk) DLBCL were published in 2013 (Stiff et al). In this trial, 253 patients received five cycles of induction chemotherapy (CHOP with [n=156 (47%)] or without rituximab). Those who had at least a PR to five cycles of induction therapy were randomized to three additional cycles of CHOP (n=128) or one additional cycle of CHOP followed by auto-HCT (n=125). The primary efficacy endpoints of the trial were 2-year PFS and OS. Two-year PFS rates were 69% and 55% in the HCT and control group, respectively (HR control vs. HCT, 1.72; 95% CI, 1.18 to 2.51; p=.005). The 2-year OS rates in the HCT and control group were 74% and 71%, respectively (HR, 1.26; 95% CI, 0.82 to 1.94; p=.30). Unplanned exploratory analyses showed a differential treatment effect by disease risk level. Among high-risk patients, the 2-year OS rate was 82% in the HCT group and 64% in the control group (p=.01). The main results of this trial are consistent with earlier study results in not discerning a significant effect of early auto-HCT on OS among a group of patients with high-, intermediate-, and high-risk diffuse B-cell NHL. However, the survival curve appeared to plateau among the high-risk HCT patients out to 10 years after study registration. Although this evidence was from exploratory subset analysis, it further supports the efficacy of this approach in such cases compared with nontransplant strategies.

The pivotal trial that established the superiority of auto-HCT for relapsed DLBCL is the Autologous Bone Marrow Transplantation as Compared with Salvage Chemotherapy in Relapses of Chemotherapy-Sensitive Non-Hodgkin's Lymphoma (PARMA) (Philip et al 1995), a prospective randomized study in which 215 patients with chemosensitive disease in first or second relapse of aggressive lymphoma were given two courses of conventional chemotherapy. A total of 109 patients responded and were randomized to four courses of chemotherapy plus radiotherapy (n=54) or radiotherapy plus intensive chemotherapy and auto-HCT (n=55). The groups did not differ in baseline characteristics. Median follow-up was 63 months. The response rate was 84% in the HCT group and

44% in the nontransplant group. The event free survival (EFS) rate for the transplant group was 46% and 12% in the nontransplant group (p=.001); the OS rate was 53% in the transplant group and 32% in the nontransplant group (p=.038).

Follicular Lymphoma (FL)

Follicular lymphoma is the most common indolent Non-Hodgkin Lymphoma (NHL) (70% to 80% of cases), and often the terms indolent lymphoma and FL are used synonymously. Also included in the indolent NHL are small lymphocytic lymphoma/chronic lymphocytic lymphoma, lymphoplasmacytic lymphoma, marginal zone lymphomas, and cutaneous T-cell lymphoma.

Schaaf et al (2012) performed a systematic review of RCTs comparing auto-HCT with chemotherapy or immunochemotherapy in patients with previously untreated or relapsed FL concerning OS, PFS, treatment-related mortality, adverse events, and secondary malignancies. Five RCTs involving 1093 patients were included, with four trials in previously untreated patients and one in relapsed patients. The quality of the five trials was judged to be moderate. There was a statistically significant increase in PFS in previously untreated FL patients in the HCT arm (hazard ratio [HR], 0.42; 95% confidence interval [CI], 0.33 to 0.54; p<.001). However, there was no statistically significant OS advantage (HR, 0.97; 95% CI, 0.76 to 1.24; p=.81). In the four trials in previously untreated patients, there were no statistically significant differences between HCT and the control arm in terms of treatment-related mortality (relative risk [RR], 1.28; 95% CI, 0.25 to 6.61; p=.77), secondary acute myeloid leukemia/myelodysplastic syndromes (RR, 2.87; 95% CI, 0.7 to 11.75; p=.14), or solid cancers (RR, 1.20; 95% CI, 0.25 to 5.77; p=.82). Adverse events were rarely reported but were more frequent in patients who underwent HCT. For patients with relapsed FL, there was some evidence from one trial with 70 patients that HCT was advantageous regarding PFS (HR, 0.30; 95% CI, 0.15 to 0.61) and OS (HR, 0.40; 95% CI, 0.18 to 0.89). No results were reported from this trial for treatment-related mortality, adverse events, or secondary cancers.

In most patients with FL relapse, and with relapsed disease, a cure is unlikely, with a median survival of 4.5 years after recurrence. In the European CUP trial (Schouten et al 2004), 89 patients with relapsed, non-transformed FL with PR or CR after standard induction chemotherapy were randomized to one of three arms: three additional cycles of conventional chemotherapy (n=24), high-dose chemotherapy and unpurged auto-HCT (n=33), or high-dose chemotherapy with purged auto-HCT (n=32). The OS rates at 4 years for chemotherapy versus unpurged versus purged arms were 46%, 71%, and 77%, respectively. Two-year PFS rates were 26%, 58%, and 55%, respectively. No difference was found between the auto-HCT arms. Although several studies have consistently shown improved DFS with auto-HCT for relapsed FL, this study was the first to show a difference in OS benefit.

Mantle Cell Lymphoma (MCL)

Zoellner et al (2021) conducted a post-hoc analysis of an open-label, multicenter, randomized phase 3 trial on previously untreated MCL patients. A total of 269 patients were randomized to receive myeloablative radiochemotherapy followed by auto-HCT (n=134) or interferon alfa maintenance after completion of a CHOP-like induction therapy (n=135) with or without rituximab. The median follow-up period was 14 years, with the intention-to-treat population consisting of 174 patients (93 in the

auto-HCT group and 81 in the interferon alfa maintenance group) who responded to induction therapy. The median PFS in the auto-HCT group was 3.3 years (95% CI, 2.5 to 4.3 years) compared to 1.5 years (95% CI, 1.2 to 2.0 years) in the interferon alfa group (log-rank p<.0001; adjusted HR, 0.5 [95% CI, 0.36-0.69]). The median OS in the auto-HCT group was 7.5 years (95% CI, 5.7 to 12.0 years) and 4.8 years (95% CI, 4.0 to 6.6 years) in the interferon alfa group (log-rank p=.019; adjusted HR, 0.66 [95% CI, 0.46-0.95]). For patients treated with a rituximab-containing induction regimen, neither PFS nor OS was significantly different between the 2 groups.

Metzner et al (2023) reported long-term outcomes for a series of 65 individuals with MCL who received auto-HCT. 54 (83%) received first-line auto-HCT, 10 (15%) received second-line auto-HCT. The 10-year OS and PFS after first-line HCT were 64% and 52%, respectively. 10-year OS and PFS after second-line HCT was 50% and 20%. Treatment-related mortality 3 months after HCT was 1.5%. At the time of publication, 26 of the individuals who received first-line HCT remained in complete remission up to 19 years following HCT.

Dreyling et al (2024) conducted an RCT evaluating the impact of adding ibrutinib to standard immunochemotherapy in younger patients (aged ≤65 years) with MCL. The TRIANGLE study assessed whether ibrutinib-enhanced regimens could improve clinical outcomes compared to standard treatment involving auto-HCT or to an ibrutinib-containing regimen without auto-HCT. The trial included 870 patients with untreated stage II to IV MCL who were randomized 1:1:1 to a control group receiving alternative R-CHOP and rituximab, dexamethasone, cytosine-arabinoside, and platinum (R-DHAP) followed by auto-HCT (group A), an experimental group receiving the same regimen with added ibrutinib during induction and as maintenance therapy post- auto-HCT (group A+I), or another experimental group receiving ibrutinib without auto-HCT (group I). The primary outcome was failure-free survival (FFS). After a median follow-up of 31 months, group A+I demonstrated superior FFS compared to group A, with 3-year FFS rates of 88% vs 72%, respectively (HR, 0.52; 98.3% CI, 0 to 0.86; p=.0008). However, the superiority of group A over group I was not shown, with 3-year FFS rates of 72% vs 86%, respectively (HR, 1.77; 98.3% CI, 0 to 3.76; p=.9979). The comparison between groups A+I and I is ongoing. During maintenance or follow-up, grade 3 to 5 hematological adverse events occurred in 50% of patients in group A+I, 28% in group I, and 21% in group A. Infections were reported in 25% of patients in group A+I, 19% in group I, and 13% in group A. The results of this study demonstrate that Auto-HSCT is no longer clearly superior to ibrutinib-containing immunochemotherapy without ASCT in first complete remission.

Peripheral T-Cell Lymphoma (PTCL)

Schmitz et al (2021) conducted a randomized, prospective phase 3 trial of autologous versus allo-HCT as part of first-line therapy in patients with PTCL. There were 104 patients enrolled, age 18 to 60 years, who were randomized to four cycles of CHOP without etoposide (CHOEP) and 1 cycle of DHAP followed by high-dose therapy and auto-HCT (n=54) or myeloablative conditioning and allo-HCT (n=49). A few study patients were unable to proceed with transplantation due to disease progression, toxicity, or other reasons, so the final patient population consisted of 41 patients who underwent auto-HCT and 26 patients who underwent allo-HCT. The median follow-up period was 42 months and the 3-year EFS was 38% (95% CI, 25% to 52%) in the auto-HCT group versus 43%

(95% CI, 29% to 57%) in the allo-HCT group. The 3-year OS was 70% (95% CI, 57% to 82 %) in the auto-HCT group versus 57% (95% CI, 43% to 71%) in the allo-HCT group.

Girard et al (2024) published a meta-analysis including 17 studies (N=1798) that compared upfront auto-HCT in patients with PTCL achieving first CR post-chemotherapy, with chemotherapy treatment alone. Histological subtypes included in the studies were heterogeneous, though the majority of patients had nodal PTCL. Results demonstrated that among transplant-eligible patients in CR after chemotherapy, auto-HCT provided significant benefits in both PFS (9 studies; HR, 0.61; 95% CI, 0.47 to 0.81) and OS (3 studies; HR, 0.59; 95% CI, 0.36 to 0.95). Subgroup analysis showed that angioimmunoblastic T-cell lymphoma patients in CR derived a significant PFS benefit from auto-HCT (3 studies; HR, 0.43; 95% CI, 0.20 to 0.94), though no significant OS advantage was noted.

Solid Tumors

Matthay et al (1999) randomized 129 children with high-risk neuroblastoma to a combination of myeloablative chemotherapy, total body irradiation, and transplantation of autologous bone marrow and compared their outcomes with those of 150 children randomized to intensive nonmyeloablative chemotherapy; both groups underwent a second randomization to subsequent 13-cis-retinoic acid (cis-RA) or no further therapy. The 3-year event free survival (EFS) rate among patients assigned to transplantation was 43% and 27% among those assigned to continuation chemotherapy (p=.027). However, OS rates for both groups did not differ significantly, with 3-year estimates of 43% or 44% for those assigned to transplant and continued chemotherapy, respectively (p=.87). Long-term results from this trial were reported in 2009 after a median follow-up of 7.7 years (range, 130 days to 12.8 years). The 5-year EFS rate for patients who underwent auto-HCT was 30% and 19% for those who underwent nonmyeloablative chemotherapy (p=.04). Five-year OS rates from the second randomization of patients who underwent both random assignments were 59% for autologous transplant/cis-RA, 41% for auto-HCT/no cis-RA, and, for nonmyeloablative chemotherapy, 38% and 36% with and without cis-RA. Authors concluded that myeloablative chemotherapy and auto-HCT resulted in significantly better 5-year EFS and OS rates.

A systematic review by Żebrowska et al (2024) evaluated the survival benefits of myeloablative therapy (MAT) combined with auto-HCT in high-risk neuroblastoma. Analysis of RCTs revealed significant improvements in event-free survival (HR, 0.78; 95% CI, 0.67 to 0.91; p=.001) and a trend toward OS benefit (HR, 0.86; 95% CI, 0.73 to 1.00; p=.05) with MAT+ auto-HCT compared to conventional chemotherapy or no further treatment. Tandem MAT+ auto-HCT demonstrated superior event-free survival and OS compared to single auto-HCT, particularly when followed by anti-disialoganglioside 2 immunotherapies. Limited evidence suggested an increased risk of relapse when MAT+ auto-HCT was omitted prior to anti-GD2 therapy, while MAT+ auto-HCT also appeared to improve OS in relapsed patients, though data were sparse.

Non- Malignant Conditions

Multiple Sclerosis

Ruiz-Argüelles et al (2019) conducted a single-center, prospective study of 617 consecutive patients with multiple sclerosis (MS) referred for autologous hematopoietic stem cell transplantation (HSCT) between June 2015 and March 2019. The goal was to assess the safety and efficacy of the “Mexican

method," which uses a conditioning regimen based on cyclophosphamide and rituximab. Eligible patients included those with relapsing-remitting MS (RRMS), secondary progressive MS (SPMS), or primary progressive MS (PPMS), provided they had a Karnofsky performance status above 70% and an Expanded Disability Status Scale (EDSS) score of 8 or lower within two weeks prior to transplant. All patients underwent a washout period of at least three months from other immunosuppressive agents. Follow-up ranged from 3 to 42 months (median: 12 months). Primary endpoints were recovery of granulocyte and platelet counts and transplant-related mortality (TRM). Secondary endpoints included overall survival (OS) and clinical response, defined as improvement or stabilization of the self-reported EDSS score. Of the 617 participants, 216 were male (35%) and 401 female (65%), with a median age of 46 years (range: 18–73). MS subtypes included 259 RRMS (42%), 228 SPMS (37%), and 130 PPMS (21%). The median EDSS score was 5.5 (range: 0–8; interquartile range: 4–6.5). All transplants were performed on an outpatient basis; 32 patients required brief hospitalization (15 for neutropenic fever, six for MS flare, four for pneumothorax requiring chest tube). Eleven patients required red blood cell transfusions, and six needed platelet transfusions. Thirty-month survival was 100%. At 12 months, 78% of patients reported improvement or stabilization of EDSS scores, with the best outcomes in RRMS (83%). Disability progression-free survival was 82% overall. A limitation of the study was that MRI was not systematically used to confirm self-reported improvements. The authors concluded that HSCT is safe and effective, particularly for RRMS.

Nabizadeh et al (2022) reviewed 50 studies involving 4,831 patients to assess the safety and effectiveness of autologous hematopoietic stem cell transplantation (AHSCT) for multiple sclerosis (MS). The analysis found that AHSCT significantly improved disability scores and reduced relapse rates compared to pre-treatment. After transplantation, 73% of patients remained progression-free, 81% were relapse-free, and 63% had no disease-related events. MRI activity-free survival was 89%, with only 8% developing new lesions. Additionally, 68% achieved no evidence of disease activity (NEDA), and overall survival was high at 94%. However, transplant-related mortality was 4%, indicating some risk despite the generally favorable outcomes.

Scleroderma

An open-label, randomized, controlled phase 2 trial (Trial of High Dose Cyclophosphamide and Rabbit Antithymocyte Globulin [rATG] With Hematopoietic Stem Cell Support in Patients with Systemic Scleroderma: A Randomized Trial [ASSIST]; Burt et al 2011) evaluated the safety and efficacy of autologous nonmyeloablative HCT compared with standard cyclophosphamide therapy. The primary outcome was improvement at 12 months, defined as either a decrease in modified Rodnan skin score (mRSS) of at least 25% for patients with an initial mRSS >14, or an increase in forced vital capacity (FVC) of more than 10%. Patients in the control group who experienced disease progression (>25% increase in mRSS or >10% decrease in FVC) despite cyclophosphamide could switch to HCT after 12 months. Patients assigned to HCT (n=10) improved at or before the 12-month follow-up, compared with none of the nine patients assigned to cyclophosphamide ($p<.001$). Treatment failure (disease progression without improvement) occurred in eight of nine controls but in none of the HCT patients ($p<.001$). After a mean follow-up of 2.6 years, all but two HCT patients had sustained improvement in mRSS and FVC, with the longest follow-up reaching 60 months. Seven patients from the cyclophosphamide group switched to HCT at a mean of 14 months after enrollment and all improved

without complications. Among four of these patients followed for at least one year, mRSS decreased from a mean of 27 (SD=15.5) to 15 (SD=7.4), FVC increased from 65% (SD=20.6%) to 76% (SD=26.5%), and total lung capacity rose from 81% (SD=14.0%) to 88% (SD=13.9%). Data for 11 patients with two years of follow-up after HCT suggested that improvements in mRSS ($p<.001$) and FVC ($p<.03$) persisted.

Sullivan et al (2018) conducted an RCT comparing auto-HCT with cyclophosphamide for the treatment of scleroderma (SCOT – A Randomized, Open-Label, Phase II Multicenter Study of High-Dose Immunosuppressive Therapy Using Total Body Irradiation, Cyclophosphamide, ATGAM, and Autologous Transplantation with Auto-CD34+HPC Versus Intravenous Pulse Cyclophosphamide for the Treatment of Severe Systemic Sclerosis [SCSSc-01]). The trial was originally designed for 226 patients, but due to low enrollment, 75 patients participated. Of the 36 patients randomized to HCT, 27 completed the trial per protocol (3 died and 6 withdrew early). Of the 39 patients randomized to cyclophosphamide alone, 19 completed per protocol (11 died and 9 withdrew early). The primary outcome was a global rank composite score, which does not measure disease activity directly but compares outcomes in pairs based on death, EFS, FVC, Disability Index of the Health Assessment Questionnaire, and mRSS. At 4 and 4.5 years of follow-up, more pairwise comparisons favored HCT over cyclophosphamide. Disease progression events were significantly higher in the cyclophosphamide group for initiating disease-modifying antirheumatic drugs, congestive heart failure requiring treatment, and pulmonary arterial hypertension. Events such as arrhythmia, pericardial effusion, renal crisis, and myositis did not differ significantly between groups.

PROFESSIONAL GUIDELINE(S)

In 2019, Cohen and colleagues published a position statement from the American Society for Blood and Marrow Transplantation (ASBMT) addressing the use of auto-HCT in treatment-refractory relapsing MS. The position statement is as follows:

“The ASBMT Task Force recommends revising the recommended indication for AHCT in MS to “standard of care, clinical evidence available”, for patients with relapsing forms of MS (RRMS or progressive MS with superimposed activity) who have prognostic factors that indicate a high risk of future disability, including ongoing clinical relapse or MRI lesion activity despite treatment with available DMTs, especially if disease activity continues despite treatment with high-efficacy DMTs and/or worsening disability.”

In 2020, the American Society of Transplantation and Cellular Therapy (ASTCT) convened a guideline committee to make recommendations for the use of hematopoietic cell transplantation and immune effector cell therapy. Indications were categorized as (1) Standard of care, where indication is well defined and supported by evidence; (2) Standard of care, clinical evidence available, where large clinical trials and observational studies are not available but have shown to be effective therapy; (3) Standard of care, rare indication, for rare diseases where demonstrated effectiveness exists but large clinical trials and observational studies are not feasible; (4) Developmental, for diseases where preclinical or early-phase clinical studies show promising results, and (5) not generally recommended, where available evidence does not support the routine use of hematopoietic stem cell transplantation.

The following indications have auto-HCT categorized as standard of care for pediatric patients under the age of 18:

- Hodgkin lymphoma, first relapse, sensitive;
- Ewing sarcoma, high risk or relapse;
- Neuroblastoma, high risk or relapse.

The following indications have auto-HCT categorized as standard of care for adult patients:

- Hodgkin lymphoma, first relapse (sensitive);
- Ewing sarcoma, high risk or relapse;
- Neuroblastoma, high risk or relapse;
- Acute promyelocytic leukemia, CR2, molecular remission;
- Myeloma, initial response, or sensitive relapse;
- Amyloid light-chain amyloidosis;
- Hodgkin lymphoma, primary refractory (sensitive), first relapse (sensitive), or second or greater relapse;
- Diffuse Large B cell lymphoma, primary refractory (sensitive); first relapse (sensitive), or second or greater relapse;
- Follicular lymphoma, primary refractory (sensitive), second or greater relapse, or transformation to high grade lymphoma;
- Mantle cell lymphoma, CR1, first partial remission, primary refractory (sensitive) first relapse (sensitive), or second or greater relapse;
- T cell lymphoma, CR1/first partial remission, primary refractory (sensitive), first relapse (sensitive);
- Lymphoplasmocytic lymphoma/Waldenstrom macroglobulinemia, first or greater relapse (sensitive);
- Chronic lymphocytic leukemia, transformation to high-grade lymphoma;
- Germ cell tumor, relapse, or refractory; and
- Systemic sclerosis.

In 2021, the ASTCT, Center of International Blood and Marrow Transplant Research (CIBMTR), and the European Society for Blood and Marrow Transplantation (EBMT) formulated consensus recommendations regarding auto-HCT, allo-HCT, and chimeric antigen receptor (CAR) T-cell therapy for patients with MCL (Munshi et al). The panel of experts, consisting of physicians and investigators, recommended the use of auto-HCT as consolidation therapy in newly diagnosed MCL patients (without TP53 mutation or bi-allelic deletion) who are in complete or partial remission after first-line therapies.

The ASTCT Committee on Practice Guidelines published guidance on transplantation and cellular therapies in DLBCL in 2023 (Epperla et al). The committee made the following recommendations:

- "The panel does not recommend auto-HCT in DLBCL (regardless of IPI score) as consolidation in complete remission after first-line (R-CHOP or similar) therapy." (Grading: A)
- "Autologous HCT may be considered for eligible patients with DLBCL with secondary CNS involvement at diagnosis achieving complete remission and with undetectable CNS disease after first-line therapy." (Grading: C)
- "The panel recommends consolidation with autologous HCT for eligible primary CNS lymphoma patients in CR1."(Grading: A)
- "In DLBCL patients with early relapse who achieve a complete remission with salvage therapy, the panel considers autologous HCT an acceptable consolidation therapy in eligible patients."(Grading: B)
- "In DLBCL patients with early relapse who achieve a partial remission with salvage therapy, the panel considers autologous HCT an acceptable consolidation therapy in eligible patients." (Grading: B)
- "In DLBCL patients with late relapse, the panel recommends autologous HCT consolidation therapy in eligible patients who have achieved a complete or partial remission after second-line therapies." (Grading: A)
- "The panel recommends allogeneic HCT in eligible DLBCL patients relapsing/progressing after CAR-T therapy if they achieve a complete or partial remission with subsequent antilymphoma therapies." (Grading: C)
- "The panel recommends allogeneic HCT in eligible relapsed or refractory DLBCL patients after autologous HCT failure in regions without access to CAR-T therapy, and in those with CAR T cell manufacturing failure, ideally after achieving a complete or partial remission with subsequent antilymphoma therapies." (Grading: C)

Grading of recommendations:

- A- There is good research-based evidence to support the recommendation;
- B- There is fair research-based evidence to support the recommendation;
- C- The recommendation is based on expert opinion and panel consensus;
- X- There is evidence of harm from this intervention.

The National Comprehensive Cancer Network (NCCN) V.2.2025 clinical practice guidelines for pediatric aggressive mature B-cell lymphomas recommends HSCT for the treatment of relapsed or refractory disease, and that “the decision regarding the type of HSCT [autologous versus allogeneic] should be based upon donor availability and physician preference.” However, it is recommended that patients with a complete response to second-line therapy (e.g., rituximab, dexamethasone, cytarabine, and cisplatin) are better suited for an autologous HSCT.

In 2024, ASTCT and EBMT formulated consensus recommendations for HCT and cellular therapies in

follicular lymphoma (Iqbal et al). The following consensus statements regarding auto-HCT were made:

"Front-line setting (i.e., HCT following first-line chemotherapy):

- The panel does not recommend autologous or allogeneic HCT as consolidation therapy in eligible follicular lymphoma patients in complete or partial remission after first-line therapies."

"Early first relapse/progression (i.e., first relapse occurred on or within 24 months from receiving front-line chemoimmunotherapy (post-operative day [POD] 24) and without evidence of histological transformation):

- The panel recommends autologous HCT as an option for consolidation therapy in eligible, relapsed POD24 follicular lymphoma patients who have achieved complete or partial remission after second-line therapies.
- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who do not achieve complete or partial remission after second or subsequent line therapies.

"Late first relapse, second relapse, and beyond settings:

- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who did not achieve complete or partial remission after second or subsequent line therapies.
- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who have relapsed after CAR T-cell therapy and did not achieve complete or partial remission to the most recent anti-lymphoma treatment."

In 2023, Fraint and colleagues published a report from the ASTCT Committee on practice guidelines for the evaluation of children with malignancies for blood and marrow transplantation. ASTCT states, "Children with malignancy who require HCT for cure have a unique set of psychosocial needs, physical comorbidities, and disease risk features that differentiate them from adults. Given the inability for some of the important pre-HCT risk indices developed for adults to be applied to children, a specialized approach is needed, ideally with harmonization among centers." Although rigorous data on physiologic differences and randomized trials on management are lacking for children, the recommendations provided are meant to serve as a guide for pre-HCT preparations.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: Vaccines, Blood & Biologics | FDA [accessed 2025 Nov 24]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2025 Nov 24]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38210	Transplant preparation of hematopoietic progenitor cells; Specific cell depletion within harvest, T-cell depletion
38211	tumor cell depletion
38212	red blood cell removal
38213	platelet depletion
38232	Bone marrow harvesting for transplantation, autologous
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

HCPCS Codes

Code	Description
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

ICD10 Codes

Code	Description
C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs (code range)
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung (code range)

Code	Description
C38.1-C38.8	Malignant neoplasm of heart, mediastinum and pleura (code range)
C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system (code range)
C48.0	Malignant neoplasm of retroperitoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue (code range)
C50.011-C50.919	Malignant neoplasm of breast (code range)
C62.00-C62.92	Malignant neoplasm of testis (code range)
C71.0-C71.9	Malignant neoplasm of brain (code range)
C81.00-C81.99	Hodgkin lymphoma (code range)
C82.00-C82.99	Follicular lymphoma (code range)
C83.00-C83.09	Non-follicular lymphoma (code range)
C83.10-C83.19	Mantle cell lymphoma (code range)
C83.30-C83.39	Diffuse large B-cell lymphoma (code range)
C83.50-C83.59	Lymphoblastic (diffuse) lymphoma (code range)
C83.70-C83.79	Burkitt lymphoma (code range)
C83.80-C83.99	Other non-follicular lymphoma (code range)
C84.60-C84.79	Anaplastic large cell lymphoma, ALK-positive or ALK-negative (code range)
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.2-C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas (code range)

Code	Description
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms (code range)
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type (code range)
E85.0-E85.9	Amyloidosis (code range)
G35	Multiple sclerosis
M05.00-M05.09	Felty's syndrome (code range)
M05.20-M05.29	Rheumatoid vasculitis with rheumatoid arthritis (code range)
M05.30-M05.39	Rheumatoid heart disease with rheumatoid arthritis (code range)
M05.40-M05.59	Rheumatoid myopathy with rheumatoid arthritis (code range)
M05.60-M06.09	Rheumatoid arthritis with involvement of other organs and systems (code range)
M06.1	Adult-onset Still's disease
M06.4	Inflammatory polyarthropathy
M06.80-M06.9	Other specified rheumatoid arthritis (code range)
M08.00-M08.99	Juvenile arthritis (code range)
M12.00-M12.09	Other and unspecified arthropathy (code range)
M32.0-M32.9	Systemic lupus erythematosus (SLE) (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)

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SEARCH TERMS

Bone marrow transplant, BMT, peripheral blood stem cell transplant, PBCT, autogenous/autogenic transplant, high-dose chemotherapy with stem cell rescue

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Stem Cell Transplantation (Formerly 110.8.1) (NCD 110.23) [accessed 2025 Nov 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/25/99, 01/18/01, 03/21/02, 06/19/03, 06/17/04, 05/18/05, 03/16/06, 05/17/07, 07/17/08, 10/29/09, 10/28/10, 12/15/11, 10/18/12, 10/17/13, 10/16/14, 10/15/15, 10/20/16, 11/16/17, 11/15/18, 02/20/20, 02/18/21, 12/22/22, 12/21/23, 12/19/24, 02/19/26

Date	Summary of Changes

02/19/26	• Annual review, updates to indications and criteria to align with the American Society for Transplantation and Cellular Therapy guidelines.
01/01/25	• Summary of changes tracking implemented.
10/25/99	• Original effective date