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MEDICAL POLICY – 8.01.15

Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

BCBSA Ref. Policy:	8.01.15	
Effective Date:	Apr. 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 9, 2026	8.01.529 Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas
Replaces:	8.01.514	

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Introduction

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are two types of cancer that affect the white blood cells and the bone marrow. Many individuals initially do not have any obvious symptoms of these diseases, and they may be discovered during an annual physical exam or by doing routine blood tests. Other individuals may have symptoms and go to their doctor because they are worried and don't feel well. A variety of medications can be used to treat these cancers, and the choice of treatment may depend on how bad a person's symptoms are and how aggressive their cancer is. In some cases, a hematopoietic cell transplant may be used to treat these diseases. This policy discusses when a hematopoietic cell transplant may be medically necessary to treat CLL and SLL.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Transplant	Medical Necessity
Allogeneic hematopoietic cell transplantation	**Allogeneic hematopoietic cell transplantation is considered medically necessary to treat chronic lymphocytic leukemia or small lymphocytic lymphoma in individuals with markers of poor-risk disease (see Table1 below).**

Transplant	Investigational
Autologous hematopoietic cell transplantation	**Autologous hematopoietic cell transplantation is considered investigational to treat chronic lymphocytic leukemia or small lymphocytic lymphoma.**

Additional Information

Staging and Prognosis of Chronic Lymphocytic Leukemia or Small Lymphocytic Leukemia

Two scoring systems are used to determine stage and prognosis of individuals with chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). As outlined in Table 1 below, the Rai and Binet staging systems classify individuals into three risk groups with different prognoses and are used to make therapeutic decisions.

Because prognosis of individuals varies within the different Rai and Binet classifications, other prognostic markers are used in conjunction with staging to determine clinical management.

The National Comprehensive Cancer Network guideline on CLL/SLL stated the following as unfavorable prognostic factors: DNA sequencing with TP53 aberrations [del(17p) or TP53 mutation; immunoglobulin heavy-chain variable (IGHV)-unmutated status (≤2% of mutation or ≥98% homology with germline gene sequence) in those treated with chemoimmunotherapy-based regimens; interphase cytogenetics with del17p or deletion of 11q (del11q); or complex karyotype (≥3 unrelated chromosome abnormalities in more than 1 cell on karyotype).

Table 1. Rai and Binet Classification for CLL or SLL

Rai Stage	Risk	Description	Median Survival, y	Binet Stage	Description	Median Survival, y
0	Low	Lymphocytosis	>10	A	≤3 lymphoid areas, normal hemoglobin and platelets	>10
I	Int	Lymphocytosis + lymphadenopathy	7 to 9	B	≥3 lymphoid areas, normal hemoglobin and platelets	7
II	Int	Lymphocytosis + splenomegaly ± lymphadenopathy	7 to 9			
III	High	Lymphocytosis + anemia ± lymphadenopathy or splenomegaly	1.5 to 5	C	Any number of lymphoid areas, anemia, thrombocytopenia	5
IV	High	Lymphocytosis + thrombocytopenia ± anemia, splenomegaly, or lymphadenopathy	1.5 to 5			

CLL: chronic lymphocytic leukemia; Int: Intermediate; SLL: small lymphocytic lymphoma.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include clinical documentation of the following:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Markers of poor-risk disease

Coding

Code	Description
CPT	

Code	Description
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
HCPCS	
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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Related Information

Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous hematopoietic bone marrow transplantation offered as part of clinical trials of autologous bone marrow transplantation approved by the National Institutes of Health.
- Some plans may participate in voluntary programs offering coverage for individuals participating in National Institutes of Health -approved clinical trials of cancer chemotherapies, including autologous hematopoietic bone marrow transplantation.

Evidence Review

Description

Risk stratification of individuals with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) guides therapy decisions, which may include hematopoietic cell transplantation (HCT) for those with poor-risk features.

Background

Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are neoplasms of hematopoietic origin characterized by the accumulation of lymphocytes with a mature, generally well-differentiated morphology. In CLL, these cells accumulate in blood, bone marrow, lymph nodes, and spleen; in SLL they are generally confined to lymph nodes. The Revised European-American/World Health Organization Classification of Lymphoid Neoplasms considers B-cell CLL and SLL a single disease entity.

CLL and SLL share many common features and are often referred to as blood and tissue counterparts of each other, respectively. Both tend to present as asymptomatic enlargement of the lymph nodes, tend to be indolent, but can undergo transformation to a more aggressive form of disease (e.g., Richter transformation). The median age at diagnosis of CLL is approximately 72 years, but it may present in younger individuals, often as poor-risk disease with significantly reduced life expectancy.

Treatment regimens used for CLL are generally the same as those used for SLL, and treatment outcomes are comparable for both diseases. Both low- and intermediate-risk CLL and SLL demonstrate relatively good prognoses, with median survivals of six to 10 years; however, the median survival of high-risk CLL or SLL may only be two years. Although typically responsive to initial therapy, CLL and SLL are rarely cured by conventional therapy, and nearly all individuals ultimately die of their disease. This natural disease history prompted investigation of HCT as a possible curative regimen.

Hematopoietic Cell Transplantation

Hematopoietic cell transplantation (HCT) is a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer individuals who receive bone-marrow–toxic doses of drugs with or without whole body radiotherapy. Hematopoietic stem cells may be

obtained from the transplant recipient (autologous HCT) or a donor (allogeneic HCT [allo-HCT]). These cells can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after the delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically "naive" and thus are associated with a lower incidence of rejection or graft-versus-host disease.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. However, immunologic compatibility between donor and individual is critical for achieving a good outcome of allo-HCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA-A, -B, and -DR loci on each arm of chromosome 6. Depending on the disease being treated, an acceptable donor will match the individual at all or most of the HLA loci.

Conditioning for HCT

Conventional Conditioning for HCT

The conventional practice of allo-HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy effect that develops after engraftment of allogeneic stem cells within the individual's bone marrow space. The slower graft-versus-malignancy effect is considered the potentially curative component, but it may be overwhelmed by extant disease without the use of pretransplant conditioning. However, intense conditioning regimens are limited to individuals who are sufficiently fit medically to tolerate substantial adverse events that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease, which also increases the susceptibility of the individual to opportunistic infections.

The success of autologous HCT is predicated on the ability of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the individual before undergoing bone marrow ablation. As a consequence, autologous HCT is typically performed as consolidation therapy when the individual's disease is in complete remission. Individuals who undergo autologous HCT

are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not graft-versus-host disease.

Reduced-Intensity Conditioning for Allo-HCT

Use of a myeloablative or reduced-intensity pretransplant conditioning regimen, should be individualized based on factors that include age, the presence of comorbidities, and disease burden.

Some individuals for whom a conventional myeloablative allotransplant could be curative may be considered candidates for reduced-intensity conditioning (RIC) allogeneic hematopoietic cell transplantation (allo-HCT). These include those individuals whose age (typically >60 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status score) preclude use of a standard myeloablative conditioning regimen. An individual who relapses following a conventional myeloablative allo-HCT could undergo a second myeloablative procedure if a suitable donor is available and his or her medical status would permit it. However, this type of individual would likely undergo RIC before a second allo-HCT if complete remission could be reinduced with chemotherapy.

The ideal allogeneic donors are human leukocyte antigen (HLA)-identical siblings, matched at the HLA-A, -B, and -DR loci on each arm of chromosome 6. Related donors mismatched at a single locus are also considered suitable donors. A matched, unrelated donor identified through the National Marrow Donor Registry is typically the next option considered. Recently, haploidentical donors—typically a parent or a child of the individual—with whom there is usually sharing of only three of the six major histocompatibility antigens, have been under investigation as a stem cell source. Most individuals will have such a donor; however, the risk of graft-versus-host disease and overall morbidity of the procedure may be severe, and experience with these donors is not as extensive as that with matched donors.

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in conventional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden but also to minimize as much as possible associated treatment-related morbidity and nonrelapse mortality in the period during which the beneficial graft-versus-malignancy effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of nonrelapse mortality and relapse due to residual disease. RIC regimens can be viewed as a continuum in effects, from near

totally myeloablative to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and an individual's condition. Individuals who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For this policy, the term "reduced-intensity conditioning" will refer to all conditioning regimens intended to be non-myeloablative, as opposed to fully myeloablative (conventional) regimens.

Summary of Evidence

For individuals who have chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and markers of poor-risk disease who receive allogeneic HCT (allo-HCT), the evidence includes single-arm prospective and registry-based studies. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related mortality and morbidity. Data have suggested that allo-HCT can provide long-term disease control and overall survival in individuals with poor-risk CLL/SLL. High rates of treatment-related morbidity discourage this approach in lower risk disease, particularly among older individuals whose health status typically precludes the use of myeloablative conditioning. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have CLL/SLL who receive autologous HCT, the evidence includes randomized controlled trials and a systematic review. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related mortality and morbidity. Autologous HCT is feasible in younger individuals but is not curative, particularly in those with poor-risk CLL. Studies of autologous HCT published to date have not shown improvement in overall survival in individuals with CLL/SLL, and results must be considered in the context of improved outcomes with the use of newer chemoimmunotherapy agents. Furthermore, evidence from the European Intergroup randomized controlled trial has suggested quality of life issues are important in selecting individuals for autologous HCT and may dictate the management course for individuals who are otherwise candidates for this approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in December 2025 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society for Transplantation and Cellular Therapy

In 2025, the American Society for Transplantation and Cellular Therapy (ASTCT) updated guidelines on the role of HCT and chimeric antigen receptor T-cell therapy (CAR T).[17] The updated guidelines include reduced recommendations for allogeneic HCT compared with earlier guideline versions in favor of CAR T-cell therapy for several indications.

Allogeneic HCT is recommended:

- If CLL is relapsed and/or refractory to CAR T-cell therapy when an objective response is demonstrated prior to the allograft.
- In patients with clonally-related Richter transformation (RT) after demonstrating an objective response to front-line chemoimmunotherapy or other treatments.

The guidelines are uncertain about recommending autologous HCT in patients with RT that achieve an objective response to chemoimmunotherapy.

National Comprehensive Cancer Network Guidelines

Current National Comprehensive Cancer Network (NCCN) guidelines (v.1.2026) for CLL and small lymphocytic lymphoma (SLL) state the following regarding HCT:[18]

- "Given the favorable outcome of patients with del(17p) or TP53 mutation treated with covalent BTKi as first-line therapy and the availability of venetoclax as an effective treatment option for relapsed or refractory CLL, allogeneic HCT is not considered as a reasonable treatment option for relapsed/refractory CLL after initial purine analogue-based therapy."
- "Allogeneic HCT can be considered for CLL/SLL refractory to small-molecule therapy in individuals without significant comorbidities."
- In individuals with histologic transformation (Richter's) and progression, allogeneic HCT can be considered for certain individuals with disease responding to initial chemoimmunotherapy. In addition, "autologous HCT may also be appropriate for individuals with disease responding to initial therapy but who are not candidates for allogeneic HCT due to age, comorbidities, or lack of a suitable donor."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under the Code of Federal Regulation title 21, parts 1270 and 1271. Hematopoietic cells are included in these regulations.

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History

Date	Comments
03/10/14	New Policy. Policy replaces 8.01.514. Policy updated with literature review through December, 2013; reference 11 added. In new policy, policy statement regarding autologous HCT changed from medically necessary to investigational. Policy statement regarding allogeneic HCT changed to medically necessary only in patients with markers of poor-risk disease as defined in Policy Guidelines.
04/18/14	Update Related Policies. Delete 8.01.20 and replace with 8.01.529.
06/27/14	Update Related Policies. Remove 8.01.35 and add 8.01.532.
12/03/14	Update Related Policies. Remove 8.01.17.
03/10/15	Annual Review. Policy updated with literature review through December 22, 2014; no new references added; no change to policy statements. ICD-9 and ICD-10 diagnosis codes removed; not utilized in adjudication. HCPCS Q and J code ranges removed.
07/01/16	Annual Review, approved June 14, 2016. Literature review. No change to policy statement.
11/04/16	Coding update. Removed codes that are transplant benefit related.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 9, 2016; references 22-23 added. Policy statements unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
04/01/18	Annual Review, approved March 13, 2018. Policy updated with literature review through November 2017; Note added that American Society for Blood and Marrow Transplantation guidelines were updated - allo-HSCT no longer recommended for high-risk CLL as consolidation in first remission or immune-chemotherapy sensitive first relapse. No references added; reference 24 updated. Policy statements unchanged.
04/01/19	Annual Review, approved March 5, 2019. Policy updated with literature review through December 2018, reference 24 updated, Policy statements unchanged.

Date	Comments
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020 and replaced with InterQual criteria for dates of service on or after July 2, 2020. Removed CPT code 38242 effective April 1, 2020; code does not match criteria.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
08/01/20	Annual Review, approved July 2, 2020. Policy updated with literature review through November 1, 2019, no references added, Policy statements unchanged.
09/01/20	Coding update. Removed CPT codes 38232, 38241 and HCPCS S2140, S2142 and S2150.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through November 17, 2020; no references added. Policy statements unchanged.
5/1/21	Update Related Policies. Removed policy 7.01.50 as it was archived.
04/01/22	Annual Review, approved March 7, 2022. Policy updated with literature review through November 29, 2021; no references added. Policy statements unchanged.
04/01/23	Annual Review, approved March 6, 2023. Policy updated with literature review through December 2, 2022; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/24	Annual Review, approved March 25, 2024. Policy updated with literature review through November 27, 2023; references added. Policy statements unchanged.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 25, 2024; no references added. Policy statements unchanged.
04/01/26	Annual Review, approved March 9, 2026. Policy updated with literature review through December 3, 2025; reference added. Policy statements updated for clarity and concordance with current guidelines. Coding update. Adding CPT codes 38231 and 38241; and HCPCS codes S2142 and S2150 as they apply to this criteria.

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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.