

MEDICAL POLICY – 8.01.520

Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia

BCBSA Ref. Policy: 8.01.32

Effective Date: Apr. 1, 2026

Last Revised: Mar. 23, 2026

Replaces: 8.01.32

RELATED MEDICAL POLICIES:


8.01.01 Adoptive Immunotherapy

8.01.26 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia

8.01.30 Hematopoietic Cell Transplantation for Chronic Myeloid Leukemia

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Introduction

Acute lymphocytic leukemia (ALL) is a cancer that starts from a certain form of early white blood cells known as lymphocytes. One way of treating ALL is to do a hematopoietic stem cell transplant.

Hematopoietic stem cells are cells that form within the bone marrow and can become many different types of blood cells. In a hematopoietic stem cell transplant, stem cells can be taken from a donor or the patient before the patient receives high dose chemotherapy. The harvested stem cells are then given to the patient, just like in a transfusion. It is hoped that these new stem cells will then settle into the bone marrow and start producing normal blood cells. If the hematopoietic stem cells are harvested from another person, it is called an allogeneic transplant. If the cells come from the patient, it is called an autologous stem cell transplant. This policy discusses when different types of hematopoietic stem cell transplants might be medically necessary to treat ALL.

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

The use of donor leukocyte infusions to treat relapse after high-dose chemotherapy (HDC) with allogeneic HCT for either children or adults is addressed in a separate medical policy (see [Related Policies](#)).

| Service | Medical Necessity |
|---|---|
| <p>Autologous or allogeneic HCT for children</p> | <p>Autologous or allogeneic hematopoietic cell transplantation (HCT) may be considered medically necessary to treat childhood acute lymphoblastic leukemia (ALL) for ANY of the following:</p> <ul style="list-style-type: none"> • First complete remission (CR1) but at high risk of relapse (see Related Information for high-risk factors) <p>OR</p> <ul style="list-style-type: none"> • Second or greater remission (CR2 or greater than 2) <p>Allogeneic HCT may be considered medically necessary to treat relapsing ALL after a prior autologous HCT or prior chemotherapy.</p> |
| <p>Autologous or allogeneic HCT for adults</p> | <p>Autologous hematopoietic cell transplantation (HCT) may be considered medically necessary to treat adult acute lymphoblastic leukemia (ALL) in:</p> <ul style="list-style-type: none"> • First complete remission (CR1) for any relapse risk level (see Related Information for risk factors) <p>Allogeneic HCT may be considered medically necessary to treat adult ALL for ANY of the following:</p> <ul style="list-style-type: none"> • First complete remission (CR1) for any relapse risk level <p>OR</p> <ul style="list-style-type: none"> • Second or greater remission (CR2 or >) <p>OR</p> <ul style="list-style-type: none"> • Relapsing ALL after a prior autologous HCT or prior chemotherapy |



| Service | Medical Necessity |
|--|---|
| Reduced-intensity conditioning allogeneic HCT | Reduced-intensity conditioning (RIC) allogeneic HCT may be considered medically necessary as a treatment of ALL in individuals who are in complete marrow and extramedullary first or second remission (CR1 or 2), and who for medical reasons (see Related Information), would be unable to tolerate a standard myeloablative conditioning regimen. |

| Service | Investigational |
|----------------------------------|---|
| Autologous HCT for adults | <p>Autologous HCT is considered investigational to treat adult ALL for the following:</p> <ul style="list-style-type: none"> • Second or greater remission (CR2 or >) <p>OR</p> <ul style="list-style-type: none"> • Those with refractory disease |

| Documentation Requirements |
|--|
| <p>The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:</p> <ul style="list-style-type: none"> • Diagnosis/condition • History and physical examination documenting the severity of the condition • Number of remissions individual has had • Risk factors for relapse |

Coding

| Code | Description |
|--------------|---|
| CPT | |
| 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 | |



| Code | Description |
|-------|--|
| 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 service; and the number of days of pre- and post-transplant care in the global definition |

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Relapse Risk Prognostic Factors

Childhood Acute Lymphoblastic Leukemia (ALL)

Adverse prognostic factors in children include the following: age younger than one year or more than nine years, male sex, white blood cell count at presentation above 50,000/ μ L, hypodiploidy (<45 chromosomes), translocation involving chromosomes 9 and 22 (t[9;22]) or BCR/ABL fusion, translocation involving chromosomes 4 and 11 (t[4;11]) or MLL/AF4 fusion, and ProB or T-lineage immunophenotype. Several risk stratification schema exist, but, in general, the following findings help define children at high risk of relapse: (1) poor response to initial therapy including poor response to prednisone prophase defined as an absolute blast count of 1000/ μ L or greater, or poor treatment response to induction therapy at six weeks with high-risk having 1% or higher minimal residual disease measured by flow cytometry; (2) all children with T-cell phenotype and (3) individuals with either the t(9;22) or t(4;11) regardless of early response measures.

Adult Acute Lymphoblastic Leukemia (ALL)

Risk factors for relapse are less well-defined in adults, but an individual with any of the following may be considered at high risk for relapse: age older than 35 years, leukocytosis at presentation of greater than 30,000/ μ L (B-cell lineage) or greater than 100,000/ μ L (T-cell lineage), "poor prognosis" genetic abnormalities like the Philadelphia chromosome (t[9;22]), extramedullary disease, and time to attain complete remission longer than 4 weeks.



Reduced Intensity Conditioning

Some individuals for whom a conventional myeloablative allogeneic hematopoietic cell transplantation (HCT) could be curative may be considered candidates for reduced intensity conditioning (RIC) allogeneic HCT. Such individuals include those whose age (typically older than 60 years) or comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy including autologous or allogeneic HCT, low Karnofsky Performance Status) precludes use of a standard myeloablative conditioning regimen.

Note: Unless otherwise specified in the text of this Policy, it is assumed that the term “allogeneic HCT” refers to the use of a myeloablative pretransplant conditioning regimen and a non-self donor.

The ideal allogeneic donors are human leukocyte antigen (HLA)-identical siblings, matched at the HLA-A, -B and DR (antigen-D related) loci on each arm of the chromosome 6. Related donors mismatched at one locus are also considered suitable donors. A matched, unrelated donor identified through the National Marrow Donor Registry is typically the next option considered. Recently, there has been interest in haploidentical donors, typically a parent or a child of the patient, where usually there is sharing of only three of the six major histocompatibility antigens. Most individuals will have such a donor. The risk of morbidity (e.g., graft-versus-host disease) may be higher than with HLA-matched donors; however, as medical treatments improve, the risks of graft-versus-host disease with haploidentical donors are approaching those similar to HLA-matched donors.

Benefit Application

The following considerations may supersede this policy:

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



- Some contracts may include specific conditions in which autologous bone marrow transplantation would be considered eligible for coverage.

Evidence Review

Description

Acute lymphoblastic leukemia (ALL) is a heterogeneous disease with different genetic variations resulting in distinct biologic subtypes. Individuals are stratified to risk-adapted therapy according to certain clinical and genetic risk factors that predict an outcome. Therapy may include hematopoietic cell transplantation (HCT).

Background

Acute Lymphoblastic Leukemia

Acute lymphoblastic leukemia (ALL) is a heterogeneous disease with different genetic variations resulting in distinct biologic subtypes. Individuals are stratified by certain clinical and genetic risk factors that predict an outcome, with risk-adapted therapy tailoring treatment based on the predicted risk of relapse.¹ Two of the most important factors predictive of risk are patient age and white blood cell count at diagnosis.¹ Certain genetic characteristics of leukemic cells strongly influence prognosis. Clinical and biologic factors predicting clinical outcomes and relapse risk are summarized in the Policy Criteria section.²

Childhood Acute Lymphoblastic Leukemia

ALL is the most common cancer diagnosed in children; it represents nearly 25% of cancers in children younger than 15 years.³ Remission of disease is now typically achieved with pediatric chemotherapy regimens in 98% of children with ALL, with up to 85% long-term survival rates. Survival rates have improved with the identification of effective drugs and combination chemotherapy through large, randomized trials, integration of pre-symptomatic central nervous system prophylaxis, and intensification and risk-based stratification of treatment.² The prognosis after the first relapse is related to the length of the original remission. For example, leukemia-free survival is 40% to 50% for children whose first remission was longer than 3 years compared



with 10% to 15% for those who relapse less than 3 years after treatment. Thus, HCT may be a strong consideration in those with short remissions. At present, the comparative outcomes with autologous or allogeneic HCT (allo-HCT) are unknown.

Adult Acute Lymphoblastic Leukemia

In adults, ALL accounts for 20% of acute leukemias. Between 60% and 80% of adults with ALL can be expected to achieve a complete response after induction chemotherapy; however, individuals who experience a relapse after remission usually die within 1 year.⁴ Differences in the frequency of genetic abnormalities that characterize adult ALL vs childhood ALL help, in part, explain differences in outcomes between the two groups. For example, the “good prognosis” genetic abnormalities, such as hyperdiploidy and translocation of chromosomes 12 and 21, are seen much less commonly in adult ALL, whereas they are some of the most common in childhood ALL. Conversely, “poor prognosis” genetic abnormalities such as the Philadelphia chromosome (translocation of chromosomes 9 and 22) are seen in 25% to 30% of adult ALL but infrequently in childhood ALL. Other adverse prognostic factors in adult ALL include age greater than 35 years, poor performance status, male sex, and leukocytosis at presentation of greater than 30,000/ μ L (B-cell lineage) or greater than 100,000/ μ L (T-cell lineage).

Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in cancer patients who receive bone marrow-toxic doses of cytotoxic drugs with or without whole-body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or a donor (allo-HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allogeneic stem cell transplantation, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the gene complex expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. An acceptable donor will match the patient at all or most of the HLA loci.



Conditioning for Hematopoietic Cell Transplantation

Conventional Conditioning

The conventional (“classical”) practice of allo-HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to cause bone marrow ablation in the recipient. Intense conditioning regimens are limited to individuals whose health status is sufficient to tolerate the procedure of body irradiation at doses sufficient to cause bone marrow ablation in the recipient. The beneficial treatment effect of this procedure is due to a combination of the initial eradication of malignant cells and subsequent graft-versus-malignancy effect mediated by non-self-immunologic effector cells. While the slower graft-versus-malignancy effect is considered the potentially curative component, it may be overwhelmed by substantial adverse effects. These include opportunistic infections secondary to loss of endogenous bone marrow function and organ damage or failure caused by the cytotoxic drugs. Subsequent to graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease (GVHD), which increases susceptibility to opportunistic infections.

The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy, with or without radiotherapy, to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow with presumably normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the individual’s disease is in complete remission. Individuals who undergo autologous HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections prior to engraftment, but not GVHD.

Reduced Intensity Conditioning for Allogeneic HCT

RIC refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiotherapy than are used in conventional full-dose myeloablative conditioning treatments. Although the definition of RIC is variable, with numerous versions employed, all regimens seek to balance the competing effects of relapse due to residual disease and non-relapse mortality. The goal of RIC is to reduce disease burden and to minimize associated treatment-related morbidity and non-relapse mortality in the period during which the beneficial graft-versus-malignancy effect of allogeneic transplantation develops. These RIC regimens range from being nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific disease and patient condition. Individuals who undergo RIC with allogeneic



HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. For the purposes of this policy, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be non-myeloablative.

Summary of Evidence

For individuals who have childhood ALL in first complete remission (CR1) at high risk of relapse, remission, or refractory ALL who receive autologous HCT, the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. For children with high risk ALL in first complete remission (CR1) or with relapsed ALL, studies have suggested that HCT is associated with fewer relapses but higher death rates due to treatment-related toxicity. However, for a subset of high-risk individuals in second complete remission or beyond or with relapsed disease, autologous HCT is a treatment option. This conclusion is supported by an evidence-based systematic review and position statement from the American Society for Blood and Marrow Transplantation (ASBMT). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have childhood ALL in CR1 at high-risk of relapse, remission, or refractory ALL who receive allogeneic HCT (allo-HCT), the evidence includes RCTs and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. For children with high-risk ALL in CR1 or with relapsed ALL, studies have suggested that allo-HCT is associated with fewer relapses but higher death rates due to treatment-related toxicity. However, for a subset of these high-risk individuals in second complete remission or beyond or with relapsed disease, allo-HCT is a treatment option. This conclusion is further supported by an evidence-based systematic review and position statement from the ASBMT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have adult ALL in CR1, subsequent remission, or refractory ALL who receive autologous HCT, the evidence includes RCTs and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Current evidence supports the use of autologous HCT for adults with high-risk ALL in CR1, whose health status is sufficient to tolerate the procedure. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.



For individuals who have adult ALL in first complete remission or subsequent remission, or refractory ALL who receive allo-HCT, the evidence includes RCTs, systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Current evidence supports the use of myeloablative allogeneic HCT (allo-HCT) for adults with any risk level ALL, whose health status is sufficient to tolerate the procedure. RIC allo-HCT may be considered for individuals who demonstrate complete marrow and extramedullary first or second remission and who could be expected to benefit from a myeloablative allo-HCT, but for medical reasons would not tolerate a myeloablative conditioning regimen. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have relapsed after a prior autologous HCT for adult or childhood ALL who receive allo-HCT, the evidence includes case series. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Evidence reviews have identified only small case series with short term follow-up which was considered inadequate evidence of benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|-----------------------------|--|--------------------|-----------------|
| Ongoing | | | |
| NCT03314974 | Myeloablative Allogeneic Hematopoietic Cell Transplantation Using a Related or Unrelated Donor for the Treatment of Hematological Diseases | 300 | Jun 2027 |
| NCT01949129 | Allogeneic Stem Cell Transplantation for Children and Adolescents With Acute Lymphoblastic Leukaemia | 1800 | Apr 2030 |
| NCT04232241 | Matched Unrelated vs Haploidentical Donor for Allogeneic Stem Cell Transplantation in Patients With Acute Leukemia With Identical GVHD Prophylaxis - A Randomized Prospective European Trial | 167 | Nov 2026 |



| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|--------------------|---|--------------------|-----------------|
| NCT05031897 | A 2 Step Approach to Haploidentical Transplant Using Radiation-Based Reduced-Intensity Conditioning | 63 | Apr 2032 |
| Unpublished | | | |
| NCT01700946 | A Phase II Study of Therapy for Pediatric Relapsed or Refractory Precursor B-Cell Acute Lymphoblastic Leukemia and Lymphoma | 80 | Jul 2021 |

NCT: national clinical trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013 Input

In response to requests, input was received from one medical society, two academic medical centers, and three physicians from Blue Distinction Centers while this policy was under review in 2013. In general, input supported most existing policy statements. However, most reviewers disagreed that allogeneic hematopoietic cell transplantation (allo-HCT) is considered investigational to treat relapsing acute lymphoblastic leukemia (ALL) after a prior autologous HCT in either children or adults. Given a scarcity of evidence on this topic, with no substantial trials likely to be forthcoming, that allo-HCT after failed autologous HCT has been shown to be of clinical benefit in other hematologic malignancies and is potentially curative, and that RIC allo-HCT is considered medically necessary to treat relapsed or refractory ALL following failure of an auto-HCT, the policy statements were revised to medical necessity for this indication in children and adults.



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.

The American Society for Transplantation and Cellular Therapy

In 2020, the guidelines from the American Society for Transplantation and Cellular Therapy (previously known as the American Society for Blood and Marrow Transplantation) were published on indications for autologous and allo-HCT. Recommendations were intended to describe the current consensus on the use of HCT in and out of the clinical trial setting.²⁸ Recommendations on ALL are listed in [Table 2](#).

Table 2. Guidelines for Autologous and Allogeneic HCT in ALL

| Indication | Children (Age <18 Years) | | Adults (Age ≥18 Years) | |
|--|--------------------------|----------------|------------------------|----------------|
| | Allogeneic HCT | Autologous HCT | Allogeneic HCT | Autologous HCT |
| First complete response, standard-risk | N | N | S | N |
| First complete response, high-risk | S | N | S | N |
| Second complete response | S | N | S | N |
| At least third complete response | C | N | S | N |
| Not in remission | C | N | S | N |

ALL: acute lymphoblastic leukemia; C: clinical evidence available; HCT: hematopoietic cell transplantation; N: not generally recommended; S: standard of care.



National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines (v.2.2025) for ALL indicate allo-HCT is appropriate for consolidation treatment of most poor-risk (e.g., the Philadelphia chromosome-positive, relapsed or refractory) individuals with ALL.²⁹ The guidelines state that for appropriately fit older adults with ALL who are achieving remission, "consideration of autologous or reduced-intensity allogeneic stem cell transplantation may be appropriate." In addition, the guidelines note that chronologic age is not a good surrogate for fitness for therapy and that patient should be evaluated on an individual basis.

Current National Comprehensive Cancer Network guidelines (v.1.2026) for pediatric ALL say that "Allogeneic HSCT has demonstrated improved clinical outcomes in pediatric ALL patients with evidence of certain high-risk features and/or persistent disease. In addition, survival rates appear to be comparable regardless of the stem cell source (matched related, matched unrelated, cord blood, or haploidentical donor)". The guidelines state that the benefit of allo-HCT in infants is still controversial.³⁰

Medicare National Coverage

There is a national coverage determination for stem cell transplantation (110.23; formerly 110.81),³¹ portions of which are highlighted below:

Nationally Covered Indications

- I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
 - a. Effective ... 1978, for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary,
- II. Autologous Stem Cell Transplantation (AuSCT)
 - a. Effective ... 1989, AuSCT is considered reasonable and necessary ... for the following conditions and is covered under Medicare for patients with:
 1. Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;



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 Code of Federal Regulation Title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

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History

| Date | Comments |
|----------|---|
| 06/27/00 | Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on HDC for miscellaneous malignancies. However, policy statement is unchanged. |
| 12/21/00 | Replace Policy - Policy statement revised to state that allogeneic transplant after a prior failed autotransplant is considered investigational, based on 2000 Tec Assessment. |
| 06/17/03 | Replace Policy - Policy updated w/expanded rationale and new references; policy statement unchanged. |
| 08/12/03 | Replace Policy - Reviewed and recommended for adoption without any changes by Company Oncology Advisory Panel July 22, 2003. |
| 12/14/04 | Replace Policy - Policy reviewed w/literature search; update added on clinical trials and NCCN guidelines; policy statement unchanged. |
| 01/10/06 | Replace Policy - Policy reviewed with literature search; no change to policy statement. |
| 06/02/06 | Disclaimer and Scope update - No other changes |
| 10/09/07 | Replace Policy - Policy reviewed with BCBSA literature update through March 2007. NCI clinical trials updated; NCCN guidelines information unchanged. New references added; Policy statement unchanged. |
| 11/12/07 | Code updated - CPT code 86817 removed as directed by RPIW. |
| 05/13/08 | New PR status - Policy statement regarding HDC and allogeneic SCT to treat relapsing ALL after a prior course of HDC and autologous SCT changed from investigational to medically necessary for children and adults. Reviewed and recommended by the OAP on February 21, 2008. Replaces BC.8.01.32, status changed from BC to PR. |



| Date | Comments |
|----------|---|
| 05/12/09 | Replace Policy - Policy revised with literature search. Clinical input received. New policy statement added that RIC allogeneic SCT may be considered medically necessary in select patients in complete remission. Policy titles changed to: "Hematopoietic Stem Cell Transplantation for Acute Lymphocytic Leukemia". Reviewed and recommended by the OAP on February 19, 2009. |
| 12/08/09 | Code Update - 86817 added back to the policy. |
| 02/09/10 | Code Update - New 2010 codes added. |
| 11/09/10 | Replace Policy - Policy statement updated. Allogeneic HCT considered medically necessary for any risk level in first complete remission. Updated with literature review and references. References added. Reviewed by the OAP on August 19, 2010. |
| 09/15/11 | Replace Policy – Policy updated with literature review; no change in policy statement. |
| 03/23/12 | Replace policy. Policy updated with literature review; no change in policy statement. References added, removed and reordered. Reviewed and recommended by OAP on February 16, 2012. |
| 08/01/12 | Update Related Policies Titles: 8.01.21, 8.01.22, 8.01.29, 8.01.30, 8.01.31, 8.01.35, 8.01.514. Policy 8.01.507 was changed to 8.01.17. |
| 02/01/13 | Update Related Policies, change title of policy 8.01.21. |
| 03/20/13 | The following codes were removed from the policy, as they were not suspending and just informational: HCPCS J9000-J9999 and Q0083 – Q0085. |
| 07/24/13 | Replace policy. Policy statements formatted for readability. References 13,22,34,28 added; others renumbered/removed. Policy statement unchanged. |
| 09/30/13 | Update Related Policies. Change title to policy 8.01.31. |
| 10/18/13 | Update Related Policies. Change title to policy 8.01.17. |
| 12/03/13 | Coding Update. Add ICD-10 codes. |
| 02/27/14 | Update Related Policies. Change title to 8.01.30. |
| 03/21/14 | Update Related Policies. Remove 8.01.514 as it was deleted. |
| 04/18/14 | Update Related Policies. Delete 8.01.20 and replace with 8.01.529. |
| 07/31/14 | Annual Review. Policy updated with literature review; no change in policy statements. Related Policies updated; only those related to leukemia remain; all others removed. |
| 03/13/15 | Update Related Policies. Add 8.01.01 |
| 07/14/15 | Annual Review. Policy updated with literature search; no change to policy statement. References updated. ICD-9 and ICD-10 procedure codes removed; they were listed for informational purposes only. |
| 07/01/16 | Annual Review, approved June 14, 2016. Literature review. No change to policy statement. Discussion wording updated. Clinical trial reviews updated. |



| Date | Comments |
|----------|--|
| 09/30/16 | Coding Update. Remove CPT 86817 from coding section. |
| 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 28-29 and 32 added. Policy statements unchanged. |
| 06/09/17 | Coding update; updated description for CPT codes 38230, 38240, and 38241. |
| 11/10/17 | Policy moved into new format; no change to policy statements. |
| 05/01/18 | Annual Review, approved April 3, 2018. Policy updated with literature review through November 2017; references updated. Reference 35* added. Policy statements unchanged. |
| 05/01/19 | Annual Review, approved April 18, 2019. Policy updated with literature review through November 2018; no references added. Policy statements unchanged. |
| 05/01/20 | Annual Review, approved April 23, 2020. Policy updated with literature review through November 2019; no references added; reference on NCCN guidelines updated. Policy statements unchanged. |
| 04/01/21 | Annual Review, approved March 18, 2021. Policy updated with literature review through November 13, 2020; references on NCCN guidelines updated. Minor edits to 2013 Clinical Input summary to increase consistency with Supplemental Information section; intent unchanged. Policy statements unchanged. |
| 04/01/22 | Annual Review, approved March 8, 2022. Policy updated with literature review through November 29, 2021; reference added and NCCN guidelines updated. Policy statements unchanged. |
| 10/01/22 | Coding update. Removed HCPCS code S2140. |
| 04/01/23 | Annual Review, approved March 20, 2023. Policy updated with literature review through November 29, 2022; one reference 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 17, 2023; no references added. Policy statements unchanged. |
| 04/01/25 | Annual Review, approved March 10, 2025. Policy updated with literature review through November 15, 2024; no references added. Policy statements unchanged. |
| 04/01/26 | Annual Review, approved March 23, 2026. Policy updated with literature review through November 24, 2025; reference added. Policy statements unchanged. Added CPT code 38232. |

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and



local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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.

