

## MEDICAL POLICY – 8.01.542

# Hematopoietic Cell Transplantation for Acute Myeloid Leukemia

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### RELATED MEDICAL POLICIES:


8.01.24 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

8.01.30 Hematopoietic Cell Transplantation for Treatment of Chronic Myeloid Leukemia

8.01.520 Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia

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## Introduction

The bone marrow is filled with cells known as hematopoietic stem cells. These immature cells develop into different types of blood cells: white blood cells to fight infection, red blood cells to carry oxygen, and platelets to clot the blood. In some cases, treating cancer also means destroying the bone marrow’s natural ability to create healthy blood cells. Restoring this function means returning these immature cells — the hematopoietic stem cells — to the body. When the immature blood cells come from a donor it’s known as an allogeneic transplant. When the cells are collected from the individual, stored, and later given back to the same individual it’s called an autologous transplant (autologous means from the same person). This policy describes when these transplants may be considered medically necessary for acute myeloid leukemia.

**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

Treatment	Medical Necessity
<b>Allogeneic hematopoietic cell transplantation (HCT)</b>	<p><b>Allogeneic hematopoietic cell transplantation (HCT) using a myeloablative conditioning regimen may be considered medically necessary to treat:</b></p> <ul style="list-style-type: none"> <li>• Poor to intermediate risk acute myeloid leukemia (AML) in first complete remission (CR1) (see <a href="#">Table 1</a>)</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• AML that is refractory to standard induction chemotherapy but can be brought into CR with intensified induction chemotherapy</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• AML that relapses following chemotherapy-induced CR1 but can be brought into CR2 or beyond with intensified induction chemotherapy</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• AML in individuals who have relapsed following a prior autologous HCT, but can be brought into CR with intensified induction chemotherapy and are medically able to tolerate the procedure</li> </ul>
<b>Allogeneic HCT using a reduced-intensity conditioning regimen</b>	<p><b>Allogeneic HCT using a reduced-intensity conditioning regimen may be considered medically necessary as a treatment of AML in individuals who are in complete marrow and extramedullary remission (CR1 or beyond), and who for medical reasons would be unable to tolerate a myeloablative conditioning regimen.</b></p>
<b>Second allogeneic HCT</b>	<p><b>A second allogeneic HCT may be considered medically necessary as a treatment of relapsed AML after an initial allogeneic HCT in individuals who can be brought into CR and are medically able to tolerate the procedure.</b></p>
<b>Autologous HCT</b>	<p><b>Autologous HCT may be considered medically necessary to treat AML in CR1 or beyond, or relapsed AML, if responsive to intensified induction chemotherapy in individuals who are not candidates for allogeneic HCT.</b></p>



Treatment	Investigational
<b>Allogeneic and autologous HCT</b>	<b>Allogeneic and autologous HCT are investigational in individuals not meeting any of the above criteria.</b>

**Additional Information**

Primary refractory acute myeloid leukemia (AML) is defined as leukemia that does not achieve a complete remission after conventionally dosed (non-marrow ablative) chemotherapy.

In the French-American-British criteria, the classification of AML is solely based on morphology as determined by the degree of differentiation along different cell lines and the extent of cell maturation.

Clinical features that predict poor outcomes of AML therapy include, but are not limited to, the following:

- Treatment-related AML (secondary to prior chemotherapy and/or radiotherapy for another malignancy)
- AML with antecedent hematologic disease (e.g., myelodysplasia)
- Presence of circulating blasts at the time of diagnosis
- Difficulty in obtaining first complete remission with standard chemotherapy
- Leukemias with monocytoid differentiation (French-American-British classification M4 or M5)

The newer, currently preferred, World Health Organization (WHO) classification of AML incorporates and interrelates morphology, cytogenetics, molecular genetics, and immunologic markers. It attempts to construct a classification that is universally applicable and prognostically valid. The WHO system was adapted by National Comprehensive Cancer Network (NCCN) to estimate individual patient prognosis to guide management, as shown in [Table 1](#).

**Table 1. Risk Status of AML Based on Genetic Factors**

Risk Status	Genetic Abnormality
Favorable	t(8;21)(q22;q22.1); RUNX1-RUNX1T1 inv(16)(p13.1q22) or t(16;16)(p13.1;q22); CBFβ-MYH11 Biallelic mutated CEBPA Mutated NPM1 without FLT3-ITD or with FLT3-ITD <sup>low</sup>



Risk Status	Genetic Abnormality
Intermediate	Mutated NPM1 and FLT3-ITD <sup>high</sup> Wild-type NPM1 without FLT3-ITD or with FLT3-ITD <sup>low</sup> (without adverse-risk genetic lesions) t(9;11)(p21.3;q23.3); MLLT3-KMT2A Cytogenetic abnormalities not classified as favorable or adverse
Poor/Adverse	t(6;9)(p23;q34.1); DEK-NUP214 t(v;11q23.3); KMT2A rearranged t(9;22)(q34.1;q11.2); BCR-ABL1 inv(3)(q21.3q26.2) or t(3;3)(q21.3;q26.2); GATA2,MECOM(EV11) -5 or del(5q); -7; -17/abn(17p) Complex karyotype, monosomal karyotype Wild-type NPM1 and FLT3-ITD <sup>high</sup> Mutated RUNX1 (if not co-occurring with favorable-risk AML subtypes) Mutated ASXL1 (if not co-occurring with favorable-risk AML subtypes) Mutated TP53

AML: acute myeloid leukemia; ITD: internal tandem duplication.

## Documentation Requirements

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

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Prior treatment (if any) individual has received
- Any poor risk features
- History of remission(s) and relapse(s) (if any)

## Coding

Code	Description
<b>CPT</b>	
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



Code	Description
<b>HCPCS</b>	
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

**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

The relative importance of cytogenetic and molecular abnormalities in determining prognosis and guiding therapy is under investigation.

The ideal allogeneic donors are human leukocyte antigen (HLA) -identical siblings, matched at the HLA-A, -B, and -DR loci (6 of 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 individual, for which there usually is sharing of only 3 of the 6 major histocompatibility antigens. Most individuals will have such a donor; however, the risk of graft-versus-host disease (GVHD) and overall morbidity of the procedure may be severe, and experience with these donors is not as extensive as that with matched donors.

## Evidence Review

### Description

Acute myeloid leukemia (AML) refers to leukemias that arise from a myeloid precursor in the bone marrow. There is a high incidence of relapse, which has prompted research into various post-remission strategies using either allogeneic (allo-) or autologous hematopoietic cell



transplantation (HCT). HCT refers to a procedure that infuses hematopoietic stem cells to restore bone marrow function in individuals with cancer who receive bone-marrow-toxic doses of drugs with or without whole body radiotherapy.

## Background

### Acute Myeloid Leukemia

Acute myeloid leukemia (AML), also called acute nonlymphocytic leukemia, refers to a set of leukemias that arise from a myeloid precursor in the bone marrow. AML is characterized by proliferation of myeloblasts, coupled with low production of mature red blood cells, platelets, and often non-lymphocytic white blood cells (granulocytes, monocytes). Clinical signs and symptoms are associated with neutropenia, thrombocytopenia, and anemia. The incidence of AML increases with age, with a median of 67 years. Approximately 21,380 new cases are diagnosed annually.<sup>60</sup>

### Treatment

Complete remission can be achieved initially using induction therapy, consisting of conventional doses of combination chemotherapy. A complete response is achieved in 60% to 80% of adults younger than 60 years of age and 40% to 60% in individuals older than 60 years of age. However, the high incidence of disease relapse has prompted research into a variety of post-remission (consolidation) strategies, typically using high-dose chemotherapy with autologous hematopoietic cell transplantation (HCT) or high-dose or reduced-intensity chemotherapy with allogeneic HCT (allo-HCT). The two treatments - autologous HCT and allo-HCT - represent two different strategies. The first, autologous HCT, is a "rescue," but not a therapeutic procedure; the second, allo-HCT, is a "rescue" plus a therapeutic procedure.

### Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in individuals with cancer 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). These cells 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 allo-HCT, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLAs) 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 for HCT

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. The beneficial treatment effect of this procedure is due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that is mediated by non-self immunologic effector cells. While the slower GVM effect is considered the potentially curative component, it may be overwhelmed by existing disease in the absence of pretransplant conditioning. Intense conditioning regimens are limited to individuals who are sufficiently medically fit to tolerate substantial adverse events. 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 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 susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.



## Reduced-Intensity Conditioning for Allogeneic Hematopoietic Cell Transplantation

Reduced-Intensity Conditioning (RIC) refers to the pretransplant use of lower doses of cytotoxic drugs or less intense regimens of radiotherapy than are used in traditional 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. RIC regimens range from nearly total 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. In this review, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative.

A 2015 review in the *New England Journal of Medicine* summarized recent advances in the classification of AML, the genomics of AML and prognostic factors, and current and new treatments.<sup>1</sup> The National Comprehensive Cancer Network guidelines provide updated information on genetic markers for risk stratification, and additional recent reviews summarize information on novel therapies for AML.<sup>2,3,4</sup>

### Summary of Evidence

For individuals who have cytogenetic or molecular intermediate- or poor-risk acute myeloid leukemia (AML) in first complete remission (CR1) who receive allogeneic (allo)-hematopoietic cell transplant (HCT) with myeloablative conditioning (MAC), the evidence includes systematic reviews, randomized controlled trials (RCTs), and matched cohort studies. The relevant outcomes are overall survival (OS) and disease-specific survival (DSS). The majority of the evidence has revealed that allo-HCT is better at improving OS and DSS rates in individuals with AML in (CR1) than conventional chemotherapy. One RCT found no difference in OS between allo-HCT and high-dose cytarabine, although the study had many limitations. All trials employed natural randomization based on donor availability and intention-to-treat analysis. Survival rates appear to be associated with presence of minimal residual disease and risk category. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.



For individuals who have AML refractory to standard induction chemotherapy who receive allo-HCT with MAC, the evidence includes retrospective data compiled from individuals entered in phase 3 trials and registry data. The relevant outcomes are OS and DSS. The evidence suggests that allo-HCT improves OS and DSS rates in individuals who are refractory to induction chemotherapy better than conventional chemotherapy. While there are some limitations to the evidence, which include its retrospective nature, lack of rigorous randomization, and general pitfalls of registry data, these results may provide clinically meaningful benefit for such individuals who do not have other treatment options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have AML who relapsed after standard induction chemotherapy-induced CR1 who receive allo-HCT or autologous HCT with MAC, the evidence includes retrospective data compiled from individuals entered in phase 3 trials and registry data. The relevant outcomes are OS and DSS. The evidence has shown that allo-HCT improves OS rates in individuals with relapsed AML better than conventional chemotherapy. Limitations of the evidence include its retrospective nature, lack of rigorous randomization, and pitfalls of registry data. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cytogenetic or molecular intermediate -or poor- risk AML in CR1 and for medical reasons cannot tolerate MAC who receive allo-HCT with reduced-intensity conditioning (RIC), the evidence includes two RCTs, three meta-analyses and other comparative and noncomparative studies. The relevant outcomes are OS, DSS, and treatment-related morbidity. The RCTs compared RIC with MAC and reported similar rates in nonrelapse mortality, relapse, and OS though one of the trials was stopped prematurely due to a slow accrual of individuals. Two retrospective comparative studies found no difference in OS or leukemia-free survival between the conditioning regimens. It is unlikely that additional comparative evidence will be generated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have AML in CR1 or beyond without a suitable allo-HCT donor who receive autologous HCT, the evidence includes prospective cohort studies in which individuals with an available sibling donor were offered allo-HCT (biologic randomization) with random assignment of all others to autologous HCT or chemotherapy (or no further treatment); and randomized trials comparing autologous HCT with chemotherapy in all individuals. The relevant outcomes are OS and DSS. Compared with chemotherapy, individuals undergoing autologous HCT experienced reduced relapse and improved disease-free survival rates. The OS did not differ between the groups. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.



For individuals who have relapsed AML who receive a second HCT, the evidence includes clinical trials, and retrospective registry studies, In all studies, the mortality was high (25 to 50%), but in a select number of individuals, the leukemia-free survival rate at three to five years ranged from 11 to 42 percent. A second allograft may provide a chance at long-term survival for a select subset of individuals who may have no other alternative treatment options.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in [Table 2](#).

**Table 2. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT06643195</a>	Immediate Allogeneic Hematopoietic Stem Cell Transplantation Versus Re-treatment for Patients With High-Risk Acute Myeloid Leukemia: <sup>a</sup> Randomised, Open-label, Phase 2 Clinical Trial.	358	Sep 2027

NCT: national clinical trial. <sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## 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 2020, the American Society for Transplantation and Cellular Therapy published expert panel recommendations on the role of hematopoietic cell transplant (HCT) in newly-diagnosed adult AML.<sup>55</sup> Recommendations were generated based on findings from a systematic review and graded based on prespecified criteria. Expert panel recommendations regarding allogeneic HCT (allo-HCT) and autologous HCT and the grades of the recommendations are as follows:

- Individuals with unfavorable-risk in CR1 should undergo allo-HCT. (Grade A)
- Individuals with intermediate-risk in CR1 should undergo allo-HCT. (Grade B)
- Individuals with favorable-risk in CR1 should not undergo allo-HCT. (Grade C)
- The role of secondary mutational abnormalities in selecting an individual for allo-HCT is unclear. (Grade N/A [not applicable])
- The presence of measurable residual disease at the end of induction therapy should be considered an indication to offer allo-HCT. (Grade C)
- The role of allo-HCT is unclear in individuals with induction failure. (Grade N/A)
- Individuals with secondary AML in CR1 should undergo allo-HCT. (Grade D)
- Individuals with therapy-related AML in CR1 should undergo allo-HCT. (Grade D)
- Individuals  $\geq 60$  years in CR1 should undergo allo-HCT. (Grade B).
- Autologous HCT is a good alternative to chemotherapy consolidation in individuals who are not eligible for allo-HCT. (Grade B)
- MAC should be the preferred type of conditioning in individuals who are fit for MAC, but RIC is an acceptable alternative in unfit individuals. (Grade D)

In 2015, the American Society for Transplantation and Cellular Therapy (formerly The American Society for Blood and Marrow Transplantation) published guidelines on indications for autologous HCT and allo-HCT.<sup>56</sup> An updated guideline was published in 2020.<sup>57</sup> **Table 3** summarizes recommendations for HCT in AML from the most recent guideline iteration.



**Table 3. Recommendations for the Use of Hematopoietic Cell Transplantation to Treat Acute Myeloid Leukemia**

<b>Indication</b>	<b>Allo-HCT<sup>a</sup></b>	<b>Autologous HCT<sup>a</sup></b>
<b>AML, Age less than 18 Years</b>		
First CR, low risk	N	N
First CR, intermediate risk	C	N
First CR, high risk	S	N
Second or greater CR	S	N
Not in remission	S	N
<b>AML, Age greater or equal than 18 Years</b>		
First CR, low risk	N	C
First CR, intermediate risk	S	C
First CR, high risk	S	N
Second CR	S	C
Third or greater CR	S	N
Not in remission	S	N

a Recommendations were classified as follows: S, standard of care (well-defined and generally supported by evidence in the form of high quality clinical trials and/or observational studies); C, standard of care, clinical evidence available (large clinical trials are not available; however, sufficiently large cohort studies have shown efficacy with acceptable risk of morbidity and mortality); N, not generally recommended

allo-HCT: allogeneic hematopoietic cell transplantation; AML: acute myeloid leukemia; CR: complete response; HCT: hematopoietic cell transplantation

In 2022, the American Society of Transplantation and Cellular Therapy published guidance on the role of HCT in pediatric AML and myelodysplastic syndrome.<sup>58</sup> The guidelines state that HCT is recommended for individuals in CR1 with unfavorable mutations/cytomolecular abnormalities but not for individuals with favorable-risk lesions. HCT should also be considered for individuals with primary induction failure, refractory disease after 2 to 3 cycles of chemotherapy, and relapse.



## The National Comprehensive Cancer Network

The National Comprehensive Cancer Network clinical guidelines (v.3.2026)<sup>2</sup> for acute myeloid leukemia state that HCT is recommended for individuals aged <60 years after standard-dose cytarabine induction with induction failure or significant residual disease without a hypocellular marrow. It is also recommended after high-dose cytarabine induction with induction failure, or as post-remission therapy in those with intermediate-risk or poor-risk cytogenetics. Allo-HCT is identified as a "reasonable option" for individuals aged ≥60 years after standard-dose cytarabine induction with residual disease or induction failure or following complete response (preferably in a clinical trial). In addition, allo-HCT is recommended for relapsed or refractory disease. Autologous HCT is recommended as another option in patients with AML after standard induction chemotherapy-induced first complete remission, although allo-HCT is preferred.

In patients with acute promyelocytic leukemia, a subtype of AML, patients who achieve a molecular remission after second-line therapy should be considered for autologous HCT if they do not have contraindications to high-dose therapy. Allogeneic HCT should be reserved for patients who have persistent disease despite therapy for relapsed disease.

## Medicare National Coverage

The Centers for Medicare & Medicaid Services have the following national coverage determination on use of autologous cell transplantation for AML<sup>59</sup>:

- Allogeneic: "...for the treatment of leukemia, leukemia in remission..."
- Autologous: "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
02/01/00	Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on HDC for miscellaneous malignancies. However, policy statement is unchanged.



Date	Comments
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.
05/13/03	Replace Policy - Policy updated, references added; no change in policy statement. Updated CPT codes.
08/12/03	Replace Policy - Policy reviewed and recommended for approval by OAP July 22, 2003; no change in policy statement.
12/14/04	Replace Policy - Policy updated with references, NCCN guidelines, and NCI clinical trials information. Policy statement unchanged.
01/10/06	Replace Policy - Policy updated with literature search; NCI information updated; no change to policy statement.
06/02/06	Disclaimer and Scope update - No other changes
06/12/07	Replace Policy - Policy updated with literature review; references added. No change in policy statement. Reviewed by OAP on May 24, 2007.
10/09/07	Cross References Updated - No other changes.
11/11/08	Replace Policy - Policy extensively updated with literature search. Policy statement updated to remove "HDC" from statement and replaced with "cell transplantation". This update also reflected in the title and throughout the policy. Investigational statement was added to include Allogeneic SCT to treat AML relapsing after prior therapy. Reviewed by OAP on May 22, 2008.
09/15/09	Replace Policy - Policy extensively updated with literature search. Policy statements updated to include allogeneic HCT used in patients with poor to intermediate risk AML in remission and that allogeneic HCT may be used after failed autologous HCT. References added. Reviewed by OAP on August 20, 2009.
02/09/10	Code Update - New 2010 codes added.
09/14/10	Replace Policy - Policy updated with literature review; references 10, 21-23 added. No change in policy statements.
10/11/11	Replace Policy - Policy updated with literature search; reference 12 added. No change to policy statements. ICD-9 and HCPCS codes updated; ICD-10 codes added. Title changed from "myelogenous" to "myeloid" leukemia. Codes 38220 and 38221 removed from policy.
01/24/12	Code 38232 added.
02/10/12	The CPT code 38204 was removed from the policy, as it is not specific to transplant.
06/20/12	Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.
07/30/12	Related Policies title updates: 8.01.21, 8.01.22, 8.01.29, 8.01.30, 8.01.31, 8.01.35, 8.01.514, and 8.01.520



Date	Comments
10/26/12	Replace policy. Policy updated with literature search; reference 14 added. No change in policy statements.
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.
10/14/13	Replace policy. Rationale updated based on a literature review through July 1, 2013. Reference 27 added; others renumbered/removed. Policy statements unchanged. Code 38204 removed; this is not reviewed.
12/06/13	Update Related Policies. Remove 8.01.31 as it was archived.
03/21/14	Update Related Policies. Remove 8.01.514 as it was deleted.
04/18/14	Update Related Policies. Remove 8.01.20 and add 8.01.529.
06/24/14	Update Related Policies. Remove 8.01.35 and 8.01.42, then add 8.01.530 and 8.01.532.
11/20/14	Annual Review. Policy updated with literature review through June 18, 2014; references 13, and 35-36 added. No change to policy statements. ICD-9 and ICD-10 diagnosis and procedure codes removed; they do not relate to adjudication of the policy.
11/10/15	Annual Review. Policy updated with literature review through July 9, 2015; no references added. Policy statements updated with clarifying information and to align with other HCT policies, but the intent remains unchanged.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through December 13, 2015; references 2-3 and 35 added. Policy statements unchanged.
11/04/16	Coding update. Removed codes that are transplant benefit related.
06/09/17	Coding update. Updated description for CPT codes 38240 and 38241.
10/01/17	Annual Review, approved September 5, 2017. Moved to new format. Policy updated with literature review through June 2, 2017; references 13, 19, 33, 39, and 41 added. "Stem" removed from title and policy. HSCT changed to HCT in Policy and Policy Guidelines. Policy statements otherwise unchanged.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through November 2017; references 16-17 and 49-51 added. Policy statements unchanged.
04/01/19	Annual Review, approved March 5, 2019. Policy updated with literature review through October 2018; reference 48 added. Policy statement regarding medical necessity for auto-HCT changed to clarify that it applies to patients that are not candidates for allo-HCT. Investigational statements added for patients not meeting medical necessity criteria.
04/01/20	Annual Review, approved March 19, 2020. Policy updated with literature review through November 2019; no references added; reference on NCCN guidelines updated. Policy statements unchanged. Removed CPT code 38242, does not match criteria.



Date	Comments
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.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through December 1, 2020; references added. 2009 Clinical Input removed as a subsequent body of evidence emerged (2012-2016) that provided sufficient support for medically necessary policy statement for use of RIC allo-HCT in patients who are in complete marrow and extramedullary first or second remission, and who for medical reasons, would be unable to tolerate a MAC regimen (Indication #4) and supplanted the utility of the clinical input. Policy statements unchanged.
05/01/21	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; references added. Policy statements unchanged.
10/01/22	Coding update. Removed HCPC code S2140.
04/01/23	Annual Review, approved March 20, 2023. Policy updated with literature review through December 5, 2022; 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 December 5, 2023; references added. Policy statements unchanged.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 27, 2024; no references added. Policy statements unchanged.
04/01/26	Annual Review, approved March 9, 2026. Policy updated with literature review through December 2, 2025; no references added. Policy statements unchanged.
05/01/26	Policy 8.01.542 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia replaced 8.01.26 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia, approved April 14, 2026. Added policy statement that second HCT for relapsed AML after initial HCT may be considered medically necessary when criteria are met. References added.

**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.

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