Hematopoietic Cell Transplantation for Acute Myeloid

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Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary hematopoietic cell transplantation for acute myeloid.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Acute myeloid leukemia (AML) – 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 or autologous hematopoietic cell transplantation (HCT).

HCT – Involves the intravenous (IV) infusion of allogeneic (donor) or autologous stem cells to reestablish hematopoietic function in individuals whose bone marrow or immune system is damaged or defective. They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates.

PROCEDURES

1. A prior authorization is required.

   Allogeneic HCT using a myeloablative conditioning regimen may be considered medically necessary to treat ANY of the following conditions:

   - Poor- to intermediate-risk AML in first complete remission CR1 (see table below); or
   - AML that is refractory to standard induction chemotherapy, but can be brought into CR with intensified induction therapy; or
   - AML that relapses following chemotherapy-induced CR1 but can be brought into CR1 or beyond with intensified induction chemotherapy; or
   - 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.

   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 and beyond), and who for medical reasons would be unable to tolerate a myeloablative conditioning regimen.

   In individuals who are not candidates for allogenic HCT, autologous HCT may be considered medically necessary to treat AML in CR1 or beyond, or relapsed AML, if responsive to intensified induction chemotherapy.

   The use of allogeneic or autologous HCT in individuals not meeting the criteria as indicated in this policy is considered not medically necessary.

2. Risk status of AML based on genetic factors

   The newer, currently preferred, World Health Organization 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 World Health Organization system was adapted by National Comprehensive Cancer Network to estimate individual patient prognosis to guide management, as shown in the below table.

Risk Status	Genetic Abnormalities
Favorable	t(8;21)(q22;q22.1); RUNX1-RUNX1T1. inv(16)(p13.1q22) or t(16;16)(p13.1;q22); CBFB-MYH11. Biallelic mutated CEBPA. Mutated NPM1 without FLT3-ITD or with FLT3-ITD^{low}.
Intermediate	Mutated NPM1 and FLT3-ITD^{high}. Wild-type NPM1 without FLT3-ITD or with FLT3-ITD^{low} (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(EVI1). -5 or del(5q); -7; -17/abn(17p). Complex karyotype, monosomal karyotype. Wild-type NPM1 and FLT3-ITD^{high}.

	Mutated RUNX1 (if not cooccurring with favorable-risk AML subtypes). Mutated ASXL1 (if not cooccurring with favorable-risk AML subtypes). Mutated TP53.

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

3. Post-payment audit statement

   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

4. Place of service: inpatient/outpatient

   Hematopoietic cell transplantation for acute myeloid leukemia is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous.
38230	Bone marrow harvesting for transplantation.
38232	Bone marrow harvesting for transplantation; autologous.
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor.
38241	Hematopoietic progenitor cell (HPC); autologous transplantation.
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic done lymphocyte infusions.

COVERED DIAGNOSIS CODES

Codes						
C92.00	C92.01	C92.02	C92.40	C92.41	C92.42	C92.50
C92.51	C92.52	C92.60	C92.61	C92.62	C92.A0	C92.A1
C92.A2	C93.00	C93.01	C93.02	C94.00	C94.01	C94.02
C94.20	C94.21	C94.22				

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

National Comprehensive Cancer Network – 2021

The National Comprehensive Cancer Network clinical guidelines (v.3.2021), for acute myeloid leukemia state that allogeneic HCT is recommended for [individuals] aged less than 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.

Allogeneic HCT is identified as a "reasonable option" for patients aged greater than or equal to 60 years after standard-dose cytarabine induction with residual disease or induction failure or following complete response (preferably in a clinical trial). In addition, allogeneic HCT is recommended for relapsed or refractory disease.

According to the guidelines, the role of autologous HCT is diminishing due to improvements in allogeneic HCT that have expanded the pool of potential donors outside the family setting. Autologous HCT should not be a recommended consolidation therapy outside the setting of a clinical trial.

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POLICY UPDATE HISTORY

<Date>	<Event>