Hematopoietic Cell Transplantation from Chronic Myeloid Leukemia

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

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 from chronic myeloid leukemia.

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.

Chronic myeloid leukemia (CML) – A hematopoietic stem cell disorder characterized by the presence of a chromosomal abnormality called the Philadelphia chromosome, which results from a reciprocal translocation between the long arms of chromosomes 9 and 22. CML most often presents in a chronic phase from which it progresses to an accelerated and then a blast phase. Allogeneic hematopoietic cell transplantation (HCT) is a treatment option for CML.

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

A prior authorization is required.

Allogeneic HCT using a myeloablative conditioning regimen may be considered medically necessary as a treatment of CML.

Allogeneic HCT, using either a myeloablative or a reduced-intensity conditioning (RIC) regimen for CML, may be considered medically necessary for individuals who qualify based on clinical criteria:

- Clinical criteria for myeloablative or RIC regimen may include those individuals:
  - Whose age (typically greater than 60 years) precludes use of a standard myeloablative conditioning regimen; or
  - Whose comorbidities (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude use of a standard myeloablative conditioning regimen.

Allogeneic HCT not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Autologous HCT for CML is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

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.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

HCT for CML 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 codes	Description
38230	Bone marrow harvesting for transplantation.
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor.
38241	Hematopoietic progenitor cell (HPC); autologous transplantation.

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES 38230, 38240, 38241

Code	Description
C92.10	Chronic Myeloid Leukemia, BCR/ABL-positive, not having achieved remission.
C92.12	Chronic Myeloid Leukemia, BCR/ABL-positive, in relapse.

C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission.
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse

REIMBURSEMENT

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

POLICY SOURCES

National Comprehensive Cancer Network (NCCN) – 2021

Current NCCN guidelines (v.3.2021) recommend allogeneic hematopoietic cell transplantation (allo-HCT) as an alternative treatment only for high-risk settings or in patients with advanced phase chronic myeloid leukemia (CML). Relevant recommendations are:

- "Allogeneic HCT is no longer recommended as a first-line treatment option for CP [chronic phase] CML."
- "Allogeneic HCT is an appropriate treatment option for the very rare patients presenting with BP [blast phase]-CML at diagnosis, patients with disease that is resistant to TKIs, patients with progression to AP [accelerated phase]-CML or BP-CML while on TKI therapy, and for the rare patients intolerant to all TKIs"
- Evaluation for allogeneic HCT...is recommended for all patients with AP-CML or BP-CML"

The Network guidelines also state: "Non-myeloablative allogeneic HCT is a well-tolerated treatment option for patients with a matched donor and the selection of patients is based on their age and the presence of comorbidities."

Autologous HCT for CML is not addressed in these guidelines.

References

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POLICY UPDATE HISTORY

08/24/2022	Approved in Medical Policy Committee
09/13/2022	Approved by QI-UM
10/10/2022	Approved in Governance