Hematopoietic Cell Transplantation for Solid Tumors of Childhood Surgery

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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 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 solid tumors of childhood surgery.

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.

Hematopoietic Cell Transplantation (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.

Solid Tumors of Childhood – Arise from mesodermal, ectodermal, and endodermal cells of origin. Examples of some common solid tumors of childhood are neuroblastoma, Ewing sarcoma/Ewing sarcoma family of tumors (ESFT), Wilms tumor, rhabdomyosarcoma, osteosarcoma, and retinoblastoma.

PROCEDURES

A prior authorization is required.

Autologous HCT may be considered medically necessary for ANY ONE the following indications:

- Initial treatment of high-risk neuroblastoma:
    - High-risk neuroblastoma is characterized by (not an all-inclusive list):
        - Age older than one (1) year; and
        - Disseminated disease; and
        - MYCN oncogene amplification; and
        - Unfavorable histopathologic findings.
- Recurrent or refractory neuroblastoma; or
- Initial treatment of high-risk Ewing's sarcoma; or
- Recurrent or refractory Ewing's sarcoma; or
- Metastatic retinoblastoma.

Autologous HCT is considered experimental/investigational and, therefore non-covered because the safety/and/or effectiveness of this service cannot be established by the available published peer-reviewed literature for the following conditions:

- Initial treatment of low- or intermediate-risk neuroblastoma; or
- Initial treatment of low- or intermediate-risk Ewing's sarcoma; or
- Rhabdomyosarcoma; or
- Wilms tumor; or
- Osteosarcoma; or
- Retinoblastoma without metastasis.

A maximum of three (3) tandem autologous HCT's may be considered medically necessary for the treatment of high risk neuroblastoma when ALL of the following have been met:

- Individual does not have a concurrent condition/disease, which would seriously compromise the chance of attaining a durable complete remission with this therapy; and
- Individual has stem cell product that meets infusion criteria of viability and neuroblastoma stem cell contamination (less than one (1) neuroblastoma cell per 100,000 peripheral blood progenitor cells or less than 10 % morphological evidence bone marrow involvement) prior to transplant.

Tandem autologous 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.

Allogeneic (myeloablative or nonmyeloablative) HCT for the treatment of pediatric solid tumors 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.

Salvage allogeneic HCT for the treatment of pediatric solid tumors that relapse after autologous HCT or fail to respond 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 solid tumors of childhood 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
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 donor lymphocyte infusions.

COVERED DIAGNOSIS CODES

Codes						
C40.00	C40.01	C40.02	C40.10	C40.11	C40.12	C40.20
C40.21	C40.22	C40.30	C40.31	C40.32	C40.80	C40.81
C40.82	C40.90	C40.91	C40.92	C41.0	C41.1	C41.2
C41.3	C41.4	C41.9	C74.00	C74.01	C74.02	C74.10
C74.11	C74.12	C74.90	C74.91	C74.92		

REIMBURSEMENT

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

POLICY SOURCES

National Comprehensive Cancer Network

Bone Cancer (v.1.2022) – 2021

- Osteosarcoma- The safety and efficacy of HDT/HCT in patients with locally advanced, metastatic, or relapsed osteosarcoma have also been evaluated. In the Italian Sarcoma Group study, treatment with carboplatin and etoposide was followed by stem cell rescue, combined with

surgery-induced complete response in chemo sensitive disease. Transplant-related mortality was 3.1%. The 3-year OS and DFS rates were 20% and 12%, respectively. The efficacy of this approach in patients with high-risk disease is yet to be determined in prospective randomized studies.

- Ewing Sarcoma – High-dose therapy followed by stem cell transplant (HDT/SCT) has been evaluated in [individuals] with localized as well as metastatic disease. HDT/SCT has been associated with potential survival benefit in [individuals] with non-metastatic disease. However, studies that have evaluated HDT/SCT in [individuals] with primary metastatic disease have shown conflicting results.
- Rhabdomyosarcoma – HCT not addressed

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POLICY UPDATE HISTORY

10/08/2021	Approved in Medical Policy Committee
08/24/2022	Annual review; approved by Medical Policy Committee
09/13/2022	Approved by QI-UM
10/10/2022	Approved in Governance