Hematopoietic Cell Transplantation for Hodgkin Lymphoma

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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 Hodgkin Lymphoma.

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.

Hodgkin lymphoma (HL) – Results from a clonal expansion of a B-cell lineage, characterized by the presence of Reed-Sternberg cells on pathology. Standard treatment is based on the stage at presentation and may involve chemotherapy with or without radiotherapy. Hematopoietic cell transplantation (HCT) has been used for HL, particularly in the setting of relapse or refractory disease.

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.

   The following HCT treatments may be considered medically necessary for individuals with primary refractory or relapsed HL:

   - Autologous HCT; or
   - Allogeneic HCT, using either:
     - Myeloablative; or
     - Reduced intensity conditioning regimens.

   Second autologous HCT for relapsed HL after a prior autologous HCT 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.

   Tandem autologous HCT may be considered medically necessary:

   - In individuals with primary refractory HL; or
   - In individuals with relapsed disease with poor risk features who do not attain a complete remission to cytoreductive chemotherapy prior to transplantation.

   HCT treatments, including, but not limited to the following are 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:

   - Initial therapy for newly diagnosed disease; or
   - To consolidate a first complete remission.

   HCT in individuals with HL not meeting the criteria as indicated in this policy are 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.

2. Lugano classification staging system for Hodgkin Lymphoma

   The staging system used for Hodgkin lymphoma is the Lugano classification. It has 4 stages, labeled I, II, III, and IV. For limited stage (I or II) HL that affects an organ outside of the lymph system, the letter E is added to the stage (for example, stage IE or IIE).

Stage	Area of Concern
I	Involvement of a single lymph node region (I) or localized involvement of a single extralymphatic organ or site (I_E).
II	Involvement of two or more lymph node regions on the same side of the diaphragm (II) or localized involvement of a single associated extralymphatic organ or site and its regional lymph node(s), with or without involvement of other lymph node regions on the same side of the diaphragm (II_E).
III	Involvement of lymph node regions on both sides of the diaphragm (III), which may also be accompanied by localized involvement of an associated extralymphatic organ or site (III_E), by involvement of the spleen (III_S), or by both (III_{E+S}).
IV	Disseminated (multifocal) involvement of one or more extralymphatic organs, with or without associated lymph node involvement, or isolated extralymphatic organ involvement with distant (nonregional) nodal involvement.

Note: The number of lymph node regions involved may be indicated by a subscript (e.g., II_3). Each stage may also be assigned a letter (A or B). B is added (stage IIIB, for example) if a person has ANY of these B symptoms:

- Loss of more than 10% of body weight over the previous 6 months (without dieting).
- Unexplained fever of at least 100.4°F (38°C).
- Drenching night sweats.

If a person has any B symptoms, it usually means the lymphoma is more advanced, and more intensive treatment is often recommended. If no B symptoms are present, the letter A is added to the stage.

3. PET 5-point scale (Deauville criteria)

Score		Area of Concern
Negative	1	No uptake.
	2	Uptake less than or equal to mediastinum.
	3	Uptake greater than mediastinum but less than or equal to liver.
Positive	4	Uptake moderately higher than liver and visually above adjacent background activity.
	5	Uptake markedly higher than liver and/or new lesions.
	X[a]	New areas of uptake unlikely to be related to lymphoma.

[a] Watchful waiting, biopsy, or additional imaging tests may be appropriate depending on clinical circumstances. Obtaining a second opinion/overread of the imaging may be beneficial.

4. 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.

5. Place of service: inpatient/outpatient

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

   HCT for HL 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.

COVERED DIAGNOSIS CODES

Codes						
C81.00	C81.01	C81.02	C81.03	C81.04	C81.05	C81.06
C81.07	C81.08	C81.09	C81.10	C81.11	C81.12	C81.13
C81.14	C81.15	C81.16	C81.17	C81.18	C81.19	C81.20
C81.21	C81.22	C81.23	C81.24	C81.25	C81.26	C81.27
C81.28	C81.29	C81.30	C81.31	C81.32	C81.33	C81.34
C81.35	C81.36	C81.37	C81.38	C81.39	C81.40	C81.41
C81.42	C81.43	C81.44	C81.45	C81.46	C81.47	C81.48
C81.49	C81.70	C81.71	C81.72	C81.73	C81.74	C81.75
C81.76	C81.77	C81.78	C81.79	C81.90	C81.91	C81.92
C81.93	C81.94	C81.95	C81.96	C81.97	C81.98	C81.99
C81.00	C81.01	C81.02	C81.03	C81.04	C81.05	C81.06
C81.07	C81.08	C81.09	C81.10	C81.11	C81.12	C81.13

REIMBURSEMENT

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

POLICY SOURCES

National Comprehensive Cancer Network Guidelines – 2021

Current National Comprehensive Cancer Network guidelines for HL (v.2.2020), include a recommendation for autologous or allogeneic HCT in patients with biopsy-proven refractory disease who have undergone second-line systemic therapy and are Deauville stage 5 according to restaging based on findings from positron emission tomography or computed tomography. Additionally, in patients with biopsy-proven refractory disease who have undergone second-line systemic therapy and are Deauville stage 1-3 according to restaging based on findings from positron emission tomography or computed tomography, high-dose therapy and autologous stem cell rescue plus either observation or brentuximab vendotin for 1 year is recommended for patients with high-risk of relapse.

References

Adult Hodgkin Lymphoma Treatment (PDQÂ®)-Health Professional Version. 2017. Accessed February 14, 2020.

American Cancer Society. High-dose Chemotherapy and Stem Cell Transplant for Hodgkin Lymphoma. 2017.

Bair SM, Strelec L, Nagle SJ, et al. Outcomes of patients with relapsed/refractory Hodgkin lymphoma progressing after autologous stem cell transplant in the current era of novel therapeutics: A retrospective analysis. Am J Hematol. 2017;92(9):879-884.

Gao L, Xiang X, Zhang C, et al. Upfront autologous hematopoietic stem cell transplantation in patients with high-risk stage III to IV Hodgkin lymphoma: A multicenter retrospective cohort study. Hematology. 2019; 24(1):225-231.

Hodgkin Lymphoma Stages. Accessed February 14, 2020.

InterQual® Level of Care Criteria 2019. Acute Care Adult. McKesson Health Solutions, LLC.

Martínez C, Gayoso J, Canals C, et al. Post-transplantation cyclophosphamide-based haploidentical transplantation as alternative to matched sibling or unrelated donor transplantation for Hodgkin lymphoma: A registry study of the Lymphoma Working Party of the European Society for Blood and Marrow Transplantation. J Clin Oncol. 2017; 35(30):3425-3432.

Moskowitz CH, Walewski J, Nademanee A, et al. Five-year PFS from the AETHERA trial of brentuximab vedotin for Hodgkin lymphoma at high risk of progression or relapse. Blood. 2018;132(25): 2639-2642.

National Cancer Institute (NCI). Adult Hodgkin Lymphoma Treatment (PDQ) - Health Professional Version. Updated January 14, 2021.

NCCN Clinical Practice Guidelines in Oncology: Hodgkin disease/lymphoma. Version 3.2021. Accessed March 16, 2021.

Rashidi A, Ebadi M, Cashen AF. Allogeneic hematopoietic stem cell transplantation in Hodgkin lymphoma: A systematic review and meta-analysis. Bone Marrow Transplant. 2016; 51(4):521- 528.

Sibon D, Morschhauser F, Resche-Rigon M, et al. Single or tandem autologous stem-cell transplantation for first-relapsed or refractory Hodgkin lymphoma: 10-year follow-up of the prospective H96 trial by the LYSA/SFGM-TC study group. Haematologica. 2016;101(4):474-481.

Smith EP, Li H, Friedberg JW, et al. Tandem autologous hematopoietic cell transplantation for patients with primary progressive or recurrent Hodgkin lymphoma: A SWOG and Blood and Marrow Transplant Clinical Trials Network Phase II Trial (SWOG S0410/BMT CTN 0703). Biol Blood Marrow Transplant. 2018;24(4):700-707.

Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. Blood. 2016;127(20):2375-2390.

Winkfield KM, Advani RH, Ballas LK, et al. ACR Appropriateness Criteria(R) recurrent Hodgkin lymphoma. Oncology (Williston Park). 2016; 30(12):1099-1103, 1106-1098.

POLICY UPDATE HISTORY

<Date>	<Event>