POLICY AND PROCEDURE MANUAL

Policy Title: Hematopoietic Cell Transplantation in Hodgkin's Lymphoma	**Policy Number: F.28**
Primary Department: Medical Management **Affiliated Department(s): N/A**	**NCQA Standard: N/A** **URAC Standard: N/A**
Last Revision Date: 02/22/2019 **Revision Dates: 01/23/2015; 03/04/2016; 03/21/2017; 02/23/2018; 02/22/2019** **Effective Date: 03/27/2015**	**Next Review Date: 03/31/2020** **Review Dates: 03/27/2015; 03/25/2016; 03/31/2017; ; 03/20/2019**
Applicable Lines of Business: ☐MeridianCare ☒MeridianHealth ☐MeridianComplete ☒MeridianChoice	
Applicable States: ☐All ☒MI ☒IL ☐OH ☐_____ ☐_____	
Applicable Programs: ☒All ☐Other _____	
Policy is to be published: Internally Only ☐ Internally & Externally ☒	

Please see NCD 110.23 for Medicare coverage guidelines

Definitions:

Hodgkin's lymphoma (HL)	Malignancy which involves the lymph nodes and lymphatic system. There are two main types of lymphoma. Hodgkin lymphoma is defined by the presence of Reed- Sternberg (large, abnormal lymphocytes that have an "owl look") or related cells. Non-Hodgkin lymphoma includes all the other types of lymphoma. Hodgkin lymphoma.
Classical Hodgkin lymphoma	Consist of Reed- Sternberg cells and Hodgkin cells. Classical types include nodular sclerosis, mixed cellularity, lymphocyte-depleted, and lymphocyte-rich disease.
Stem cell transplantation	Process in which stem cells are harvested from either a patient's (autologous) or donor's allogeneic bone marrow or peripheral blood for intravenous infusion.
Autologous Hematopoietic cell transplantation	Utilizes the patient's own hematopoietic cells (from peripheral blood or bone marrow) to rescue hematopoiesis after preparative therapy for HCT.
Allogenic Hematopoietic cell transplantation	Utilizes hematopoietic cells from another individual for hematopoietic rescue

Policy:

Hodgkin's lymphoma (HL) is a malignancy which involves the lymph nodes and lymphatic system. There are two peaks in age of diagnosis as follows: between the ages of 15-30, followed by another peak in adults aged ~~and~~ 55 years and older. [3] Based upon the WHO classification there are two types of HL: nodular lymphocyte predominant Hodgkin lymphoma

(NLPHL) and classical Hodgkin lymphoma (CHL). The majority or 95% fall into the CHL category of which there are four subtypes: nodular sclerosis (NSCHL), mixed cellularity (MCCHL), lymphocyte depleted (LDCHL) and lymphocyte rich (LRCHL).

Hematopoietic cell transplantation (HCT) is an important component of treatment for relapsed and refractory classical Hodgkin lymphoma (HL). [6] The goal of HCT in relapsed or refractory HL is to achieve long-term disease control (ie, cure) when possible. For patients who do not achieve cure, HCT can prolong life, improve the quality of life, and/or alleviate symptoms. Goals of HCT are influenced by the status of disease (ie, primary refractory/first relapse versus subsequent relapses), response to salvage treatment, eligibility for autologous versus allogeneic HCT, and the patient's personal goals. **[6]**

Procedure:

Criteria for Coverage:

*Criteria for **Autologous** Hematopoietic Cell Transplantation:*

Meridian considers autologous hematopoietic cell transplantation medically necessary for the following members with:

- Early relapse (less than 12 months after treatment) or induction failure *or*
- Second relapse after conventional treatment for first relapse *or*
- Generalized systemic relapse even beyond 12 months.

The use of autologous HCT in high risk members with advanced disease in first remission is controversial and investigational. [6]

*Criteria for **Allogeneic** Hematopoietic Cell Transplantation:*

Meridian considers allogeneic hematopoietic cell transplantation medically necessary for the treatment of members with relapsed HL (including members who have relapsed or have had persistent disease from an autologous hematopoietic cell transplant) or primary refractory HL.

Members who relapse following high-dose therapy and autologous HCT have treatment options of single agent chemotherapy, local irradiation, repeat autologous HCT, or reduced intensity (nonmyeloablative or "mini-transplant") conditioning followed by allogeneic HCT.

Also, as consideration for hematopoietic stem cell transplantation these guidelines **MUST** be met:

1. The National Comprehensive Cancer Network guidelines must be met and will be reviewed by a Medical Director (http://www.nccn.org/index.asp/ https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf)
2. Staging of Hodgkin's Lymphoma must be included in clinical documentation submitted with request
3. Cardiac function evaluation:
    a. Left ventricular ejection fraction equal or greater than 40 %**[26]**
    b. If present, coronary artery disease and cardiac arrhythmias must me controlled/stable
4. Pulmonary function evaluation:
    a. Forced vital capacity (FVC)/forced expiratory volume in 1 second (FEV1)/diffusion capacity of the lung for carbon monoxide (DLCO) equal to or greater than 50 % predicted.
5. Renal function with a serum creatinine < 2 mg/dl of Cl_{cr} > 50 ml/min
6. Liver function studies indicate no frank cirrhosis.[26]
7. No active infection must be present including OR any active form of any ONE of the following:

    a. Human immunodeficiency virus (HIV)
    b. Hepatitis B virus (HBV)
    c. Hepatitis C virus (HCV)
    d. Human T-cell lymphotropic virus (HTLV)-1

8. Dental exam, x-rays, and treatment completed to eliminate sources of infection in the oral-cavity.
    a. Examples include, but are not limited to gum disease, tooth decay, tooth abscesses and poor oral hygiene.

9. Karnofsky performance score of 70% or greater or Eastern 6 Cooperative Oncology Group (ECOG) score of 0 to 2.
10. Documentation of member's ability to understand the risks of the procedures.
11. Emotional and psychiatric stability, including a strong family or alternative support network (documented by formal social work evaluation)
12. Absence of psychiatric disease that would interfere with the member's ability to comply with the pre- or post-transplant therapeutic regimen

Absolute Contraindications:
Tandem transplants (sequential within 6 months) are experimental/investigational for the treatment of Hodgkin's lymphoma because of insufficient evidence of it safety and effectiveness.
Nonmyeloablative allogeneic HSCT for any other indication is considered experimental and investigational.

Facilities performing stem cell transplants must be accredited by the Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee and compliant with the FACT_JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration manual.

Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above):

1. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
2. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.
3. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

Line of Business Applicability:
This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual plans.

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html), or the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), or the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx) the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

State specific special instructions:

None: ☒
MI:
IL:
OH:

References:

1. Adult Hodgkin Lymphoma Treatment- for health professionals, National Cancer Institute (NIH) http://www.cancer.gov/cancertopics/pdq/treatment/adulthodgkins/HealthProfessional/page9. Updated February 7th, 2019. Accessed 2/13/2019.
2. Leukemia. Indications and relative indications for stem cell transplantation in non-Hodgkin's lymphoma.1993 Jul; 7(7):1091-4. Stewart FM.
3. National Comprehensive Cancer Network (NCCN) Guidelines: Hodgkin Lymphoma Accessed 2/13/2019
4. Ansell, SM. Hodgkin lymphoma: 2018 update on diagnosis, risk-stratification, and management. Am J Hematol. 2018 May; 93(5) 704-715. Accessed 2/13/2019.
5. Moskowitz, Craig. Hematopoietic cell transplantation in classical Hodgkin lymphoma. UpToDate.com. Accessed 2/14/2018.
6. Canellos, George. Overview of the treatment of classical Hodgkin lymphoma in adults. UpToDate.com. Accessed 2/19/2018.
7. Homberg, Leona, Deeg, Joachim. Determining eligibility for autologous hematopoietic cell transplantation. UpToDate.com. Accessed 2/13/2019.
8. Illinoi Department of Healthcare and Family Services. Chapter H-200. Section 254.11 Covered Transplant Procedures, page 33 https://www.illinois.gov/hfs/SiteCollectionDocuments/h200.pdf **.** Issued September 2014. Accessed 2/13/19.
9. Michigan Medicaid Provider Manual. Chapter: Billing & Reimbursement for Institutional Providers, Section 6.6. Version date: January 1, 2019. Accessed 2/13/19.
10. UpToDate. Hematopoietic cell transplantation in classic Hodgkin lymphoma. https://www.uptodate.com/contents/hematopoietic-cell-transplantation-in-classic-hodgkin-lymphoma . Last updated January 9, 2019. Accessed 2/14/2019.

State Letters/Bulletins					
CMS National/Local Coverage Determination (NCD/LCD)	NCD 110.23				
Medicare Managed Care Manual:					
Medicaid CFR:					
State Administrative Codes:					
Contract Requirements:					
Related Policies:					

Appendix A:

Definitions of Stages in Hodgkin's Disease [8]
Stage I: Involvement of a single lymph node region (I) or localized involvement of a single extralymphatic organ or site (IE)
Stage 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 (IIE).

Note: The number of lymph node regions involved may be indicated by a subscript (eg. II3)

Stage 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 (IIIE), by involvement of the spleen (IIIS) or by both (IIIE+S)

Stage IV: Disseminated (multifocal) involvement of one or more extralymphatic organs, with or without associated lymph node involvement, or isolated extralymphatic organ with distant (nonregional) nodal involvement.

A. No Systemic Symptoms Present
B. Unexplained fevers >38 degrees C; drenching night sweats; or weight loss 10% of body weight (within 6 months prior to diagnosis)

Appendix – Karnofsky Performance Scale (KPS) and The Eastern Cooperative Oncology Group (ECOG):

Karnofsky Performance Scale (KPS): One tool that assesses a patient's performance status is the Karnofsky Performance Scale. The scale ranges from 0 to 100%, with 100% representing patients without evidence of disease and 0% being dead. A status score of 70% denotes those patients that are able to care for themselves but may not be able to effectively work, shop, drive, or care for family members; patients with an irreversible score or less the 70% generally have a poor prognosis.

100%	Normal, no complaints, no signs of disease
90%	Capable of normal activity, few symptoms or signs of disease
80%	Normal activity with some difficulty, some symptoms or signs
70%	Caring for self, not capable of normal activity or work
60%	Requiring some help, can take care of most personal requirements
50%	Requires help often, requires frequent medical care
40%	Disabled, requires special care and help
30%	Severely disabled, hospital admission indicated but no risk of death
20%	Very ill, urgently requiring admission, requires supportive measures or treatment
10%	Moribund, rapidly progressive fatal disease processes
0%	Death

The Eastern Cooperative Oncology Group (ECOG) developed a performance status tool. This tool assesses the patient's disease progression, the impact of the disease on daily living, and provides information used to determine proper treatment and prognosis. Patients are classified based on the following information:

0	Asymptomatic (Fully active, able to carry on all predisease activities without restriction)
1	Symptomatic but completely ambulatory (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature. For example, light housework, office work)
2	Symptomatic, <50% in bed during the day (Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours)
3	Symptomatic, >50% in bed, but not bedbound (Capable of only limited self-care, confined to bed or chair 50% or more of waking hours)
4	Bedbound (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)
5	Death