Policy: Aplastic anemia is characterized by pancytopenia due to the bone marrow’s failure to produce blood cells. In most patients the etiology is unknown (idiopathic) or can be due to infections, drugs, or toxins as well as hereditary such as in Fanconi’s anemia or Diamond-Blackfan syndrome. Hematopoietic cell transplantation (HCT) with an HLA-identical sibling currently is the treatment of choice for a child with SAA because it offers a cure by restoration of normal hematopoiesis and is associated with low mortality and morbidity.

General Guidelines:
Criteria for Allogeneic Hematopoietic Cell Transplantation
Meridian considers allogeneic hematopoietic cell transplantation medically necessary when the member meets the criteria for severe aplastic anemia (SAA) as follows:
- A marrow biopsy showing less than 25 percent of normal cellularity, or
- A marrow showing less than 50 percent normal cellularity in which fewer than 30 percent of the cells are hematopoietic and at least two of the following are present: absolute reticulocyte count below 40,000/microL; absolute neutrophil count (ANC) less than 500/microL; or platelet count below 20,000/microL.

Meridian considers allogeneic hematopoietic cell transplantation medically necessary for Fanconi’s Anemia when the member has:
- Severe aplastic anemia (see criteria above for severe aplastic anemia) or
- Myelodysplastic syndrome or
- Acute Myelogenous Leukemia
Meridian considers allogeneic hematopoietic cell transplantation medically necessary for Diamond-Blackfan Anemia when the member has been:

- Refractory to corticosteroids

Meridian considers allogeneic hematopoietic cell transplantation medically necessary for Paroxysmal Nocturnal Hemoglobinuria when the member has:

- Severe aplastic anemia (see criteria above for SAA)
- Ongoing transfusion requirements and
- HLA-matched donor or
- Has Myelodysplastic syndrome

A second or repeat allogeneic (ablative or non-myeloablative) hematopoietic stem cell transplant due to persistent, progressive or relapsed disease is considered investigational and not medically necessary.

**Criteria for Autologous Hematopoietic Cell Transplantation**

Meridian considers autologous hematopoietic cell transplantation experimental for the treatment of severe aplastic anemia, Diamond-Blackfan Anemia, Fanconi’s Anemia, and Paroxysmal Nocturnal Hemoglobinuria as its effectiveness has not been recognized.

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

1. The member meets selection criteria requirements regarding organ function. The following values should be used: cardiac function (left ventricular ejection fraction equal or greater than 45%); pulmonary function [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]; Renal function with a serum creatinine < 2 mg/dl of Clcr > 50 ml/min; Liver function no frank cirrhosis.
2. Emotional and psychiatric stability, including a strong family or alternative support network (documented by formal social work evaluation)
3. Ability to understand the risks of the procedures
4. Karnofsky performance score or Lansky score of 70% or greater or Southwestern Oncology Group (SWOG)/Eastern 6. Cooperative Oncology Group (ECOG) score of 0 to 2
5. No active infection including but not limited to HIV, hepatitis B, hepatitis C, or potential oral sources
6. No persistent or active substance or alcohol abuse
7. Absence of psychiatric disease that would interfere with the member’s ability to comply with the pre- or post-transplant therapeutic regimen
8. No significant history of medical noncompliance as defined by Meridian Health Plan Policy I.07

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

**Special Instructions:** N/A

**Line of Business Applicability:**

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](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--.00.html)), the Illinois Medicaid Fee Schedule (located at: [http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx](http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx)), or the Iowa Medicaid Fee Schedule (located at: [http://dhs.iowa.gov/ime/providers/csrp/fee-schedule](http://dhs.iowa.gov/ime/providers/csrp/fee-schedule)). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located

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For Medicare members, coverage is determined by the Centers for Medicare and Medicaid Services (CMS). If a coverage determination has not been adopted by CMS, this policy applies. Medicare Fee Schedules can be found on the CMS website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html).

For Exchange members, please refer to the Meridian Choice Certificate of Coverage located here: https://share13.mhplan.com/sites/communications/Bronson%20Healthcare/MCH%20Certificate%20of%20Coverage%202016.pdf. If there is a discrepancy between this policy and the Certificate of Coverage for Meridian Choice, the Certificate will govern.

References:
4. Hematopoietic cell transplantation for Diamond-Blackfan anemia and the myelodysplastic syndromes in children and adolescents Up to Date. Shaklia Khan, MD

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