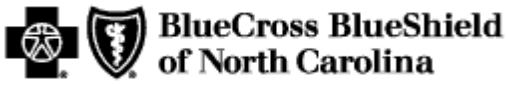

Medicare Part C Medical Coverage Policy

Transplant: Stem Cell

Origination: December 21, 2016
Review Date: September 6, 2022
Next Review: September, 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Stem Cells are used to repopulate the bone marrow of patients receiving high-dose chemotherapy/radiation therapy for a variety of neoplasms. Stem cells are also used to treat certain genetic diseases and anemias. The process involves harvesting stem cells from one of four sources: bone marrow, peripheral blood, embryonic/fetal or umbilical cord/placenta.

Autologous transplant is defined as cells that are harvested from and returned to the same member.

Allogenic transplant is defined as cells that are harvested from a healthy compatible donor and infused into a member.

The harvesting or banking of autologous bone marrow or stem cells for future use, when myeloablative high-dose chemotherapy may be a necessary treatment option, is eligible for coverage when the following criteria are met.

POLICY STATEMENT

Coverage will be provided for Stem Cell Transplant when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and

- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE

1. **Preauthorization by the Plan is required;**

   AND;

2. **Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) is eligible for coverage in the following:**
   - **a)** The treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary.

     OR

   - **b)** The treatment of severe combined immunodeficiency disease (SCID) and for the treatment of Wiskott-Aldrich syndrome.

     OR

   - **c)** Primary refractory or relapsed Hodgkin's and non-Hodgkin's lymphomas with B-cell or T-cell origin that are medically necessary in members for whom there are no other curative intent options

     OR

   - **d)** The treatment of the following, but only when participating in an approved clinical study meeting criteria under the Coverage with Evidence Development (CED) standard (See https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-HSCT or https://www.clinicaltrials.gov/ for approved Clinical Trials):
     1. Myelodysplastic Syndromes
     2. Multiple myeloma with Durie-Salmon Stage II or III disease, or International Staging System (ISS) Stage II or Stage III disease
     3. Myelofibrosis (MF) with Dynamic International Prognostic Scoring System (DIPSSplus) intermediate-2 or High primary or secondary disease; or
     4. Sickle cell disease (SCD) that is severe and symptomatic

3. **Autologous Stem Cell Transplantation (AuSCT) is eligible for coverage in the following**:

a) Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;

OR

b) Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;

OR

c) Recurrent or refractory neuroblastoma;

OR

d) Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

OR

e) The following requirements are only covered for Durie-Salmon Stage II or III and International Staging System Stage II or III members that fit in the next two categories:

1. Newly diagnosed or responsive multiple myeloma. This includes those members with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and
2. Adequate cardiac renal pulmonary, and hepatic function.

OR

f) High dose melphalan (HDM) together with AuSCT is reasonable and necessary for members with primary amyloid light chain (AL) amyloidosis who meet the following criteria:

1. Amyloid deposition in 2 or fewer organs; and,
2. Cardiac left ventricular ejection fraction (EF) greater than 45%

WHEN COVERAGE WILL NOT BE APPROVED

I. **Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)** is not covered as treatment for multiple myeloma.
II. **Autologous Stem Cell Transplantation (AuSCT)** is not considered reasonable and necessary and is not covered for the following conditions:
   a. Acute Leukemia not in remission;
   b. Chronic granulocytic leukemia
   c. Solid tumors (other than neuroblastoma);
   d. Tandem transplantation (multiple rounds of AuSCT) for memberss with multiple myeloma;
   e. Non primary AL amyloidosis

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 38204, 38205, 38206, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38230, 38232, 38240, 38241, 38242

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

For an approved Stem Cell transplant, services eligible for coverage include:

1. Preoperative Care, including prophylactic dental care, i.e., including periodontal care;
2. Transplant Care, facility and professional fees;
3. Bone Marrow and peripheral stem cells harvesting or donor fees;
4. Post-transplant care is covered as medical benefit, including immunosuppressant drugs;
5. A psychological evaluation by a trained psychologist is covered as a medical benefit as part of a transplant evaluation process;

SPECIAL NOTES

1. Immunosuppressive drugs are covered as a medical benefit (Part B) for members after a Medicare covered transplant procedure. See Medical Coverage Policy "Immunosuppressant Medications."

2. Transportation and Lodging Expenses: When the Plan pre-authorizes a **HMO** member to receive transplant services at a facility located outside of the Plan's service area (out of the state of North Carolina), the Plan will cover reasonable expenses for transportation to and lodging at the distant location for the member and a companion. When transplant services are provided by a facility located inside the Plan's service area (within the state of North Carolina), transportation and lodging expenses are not

covered by the Plan. Lodging must be approved in advance and arranged through the transplant coordinator at the transplant center or the Plan. (See Authorization Entry Guidelines).

When a **PPO** Member should chooses to have a transplant outside the Plan's service area (outside the state of North Carolina), when services are available inside the Plan's service area (within the state of North Carolina), Transportation and Lodging Expenses are not covered even though the transplant itself didn't require prior authorization.

References: (Arial 10)

1. Medicare National Coverage Determination (NCD) for Stem Cell Transplantation (ID#110.23); Effective date: 01/27/2016; accessed via Internet site http://www.cms.gov on 9/6/2022.
2. Medicare Managed Care Manual- Chapter 4- Benefits and Beneficiary Protections; Reviewed on 6/3/19; Section 10.11; Transportation Benefits. Accessed via internet site on 9/6/2022.
3. Transplant Certification and Compliance; accessed via Internet site www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp#TopOfPage on 6/3/19 (old reference).
4. Medicare basic information about Transplant programs viewed online at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Transplant.html; viewed on 9/6/2022.
5. MLN Matters: Office of Inspector General Report: Stem Cell Transplantation: SE1624, Article release date 11/22/16. Accessed via internet site 05/17/17.
6. Medicare Local Coverage Determination (LCD) for Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (ID# L39270); Effective 09/04/2022; accessed via internet site http://cms.gov on 9/6/2022

Policy Implementation/Update Information:

Revision Date: February 15, 2017: Indications for Coverage: #3. e) "and International Staging System Stage II or III" Special Notes, #3. Rephrased for staff clarification to read "**Stem cell transplants are typically performed in the outpatient setting.** If Inpatient Level of Care is requested for the procedure, then it will require Medical Director Review."
Revision Date: May 17, 2017: Indications for Coverage: 2.C-Updated hyperlinks to clinical trials and CED information at CMS as they didn't redirect correctly.
Revision Date: May 17, 2017: Special Notes: #3 Added "The documentation in the medical record must support that an inpatient admission is necessary, and is subject to medical review."
Revision Date: June 21, 2017: Special Notes: #3 Removed.
Revision Date: January 17, 2018: Only updated Transportation and lodging verbiage for staff clarification to read: 2.**Transportation and Lodging Expenses**: When the Plan pre-authorizes a **HMO** member to receive transplant services at a facility located outside of the Plan's service area (out of the state of North Carolina), the Plan will cover reasonable expenses for transportation to and lodging at the distant location for the member and a companion. When transplant services are provided by a facility located inside the Plan's service area (within the state of North Carolina), transportation and lodging expenses are not covered by the Plan. Lodging must be approved in advance and arranged through the transplant coordinator at the transplant center or the Plan. (See Authorization Entry Guidelines). When a **PPO** Member should choose to have a transplant outside the Plan's service area (outside the state of North Carolina), when services are available inside the Plan's service area (within the state of North Carolina), Transportation and Lodging Expenses are not covered even though the transplant itself didn't require prior authorization.
Revision Date: June 19, 2019; Annual Review. No CMS Updates to Criteria. Minor Revisions Only.
Revision Date: June 16, 2021; Annual Review; No CMS Updates. Minor Revisions Only.
Revision Date: September 6, 2022; Additional coverage indications for Allogeneic Hematopoietic Stem Cell Transplantation added per new LCD L39270.

Approval Dates:

Medical Coverage Policy Committee: September 17, 2022

Policy Owner: Beth Sell, RN, BSN
Medical Policy Coordinator