I. POLICY

It is the policy of MedStar Health, Inc. to cover autologous transplant of bone marrow or stem cell when medically necessary and covered under the member’s specific benefit plan.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health Medical Director (Medical Director).

II. DEFINITIONS

Bone Marrow or Peripheral Blood Stem Cell Transplantation (PSCT) - is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant.

High-Dose Chemotherapy (HDC) - involves the administration of cytotoxic agents for the treatment of cancer. It uses doses several times greater than the standard therapeutic dose. In some cases, whole body or localized radiotherapy is also given and is included in the term HDC. Some HDC protocols can be administered on an outpatient basis but prolonged hospitalization can occur due to complications of the therapy or when whole body radiation is used.

Stem Cell Transplantation - is a 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.

III. PURPOSE
The purpose of this policy is to define the criteria for Bone Marrow or Stem Cell, Autologous Transplant.

IV. SCOPE

This policy applies to various MedStar Health departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description

Autologous Bone Marrow Transplants (AuBMT) or peripheral stem cell transplants (PSCT) refer to transplants in which the recipient and the donor are the same person. These procedures are undertaken for the purpose of restoring bone marrow function. The marrow or stem cells are harvested, processed and stored (frozen). After high dose chemotherapy and/or radiation therapy has been administered, resulting in the elimination of bone marrow function, the stored cells are thawed and infused intravenously.

B. Specific Indications

Members requesting AuBMT or PSCT must meet the criteria for member characteristics, general transplant criteria, and specific transplant criteria.

Member Characteristics
The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with his ability to manage the sequelae of the transplant including complex medication regimens.

General Transplant Criteria
Members requesting AuBMT or PSCT must meet all of the following:
1. The member meets the institution’s selection criteria for AuBMT or PSCT
2. Further treatment with non-transplant therapy is not likely to achieve durable remission
3. The probability of achieving a remission is greater with transplant dose chemotherapy than with non-transplant dose chemotherapy and/or radiation
4. There is no concurrent condition that would jeopardize the achievement of a sustained complete remission following AuBMT or PSCT

Specific Transplant Criteria
AuBMT or PSCT are considered to be an accepted treatment for the following diagnoses. For some diagnoses, only certain stages of disease are appropriate for transplantation. (Inappropriate or not covered for transplantation stages of disease are listed below)

**Brain and Central Nervous System (CNS) Tumors**
- Neuroblastoma (recurrent or refractory)
- Recurrent or refractory Primitive Neuroectodermal Tumors (PNET) such as the following:
  - Medulloblastoma
  - Ependymoblastoma
  - Pinealoblastoma
- Not covered for:
  - Treatment of ependymoma (ependymomas have a more mature histological differentiation than ependymoblastomas and therefore, not considered to be a member of the PNET family)
  - Treatment of malignant astrocytomas and gliomas (gliomas include both glioblastoma multiforme and oligodendroglioma)

**Germ Cell Tumors**
Germ cell tumors can develop as testicular, ovarian, mediastinal and retroperitoneal tumors. Histologies include seminoma, embryonal carcinoma, teratoma, yolk sac tumor, choriocarcinoma, and mixed germ cell tumors
- Germ cell tumors that do not achieve complete remission
- Germ cell tumors in members in second complete remission or in second relapse
- Not covered for:
  - Initial treatment of poor risk germ cell tumors

**Hodgkin’s Lymphoma**
- Advanced Hodgkin’s disease in patients who have failed conventional therapy and have no matched human leukocyte antigens (HLA) donor
- Relapse after completion of initial course of chemotherapy (including those with recurrence after more than one year)
- Not covered for:
  - Initial therapy
  - Members in complete remission

**Leukemia**
- Acute leukemia in remission with high risk for relapse and with no leucocyte antigens (HLA)-matched donors.
- Not covered for:
  - Relapse of acute lymphocytic leukemia (ALL) or acute myelogenous leukemia (AML) after prior high dose chemotherapy (HDC) and autologous stem cell transplant
Multiple Myeloma

- Newly diagnosed or responsive multiple myeloma. This includes:
  - Those 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),
  - Those in responsive relapse

Autologous Bone Marrow transplants and Tandem Auto Bone marrow transplants are now considered the standard of care for members with myeloma. (There remains controversy over superiority of single versus tandem autologous transplantation for Multiple Myeloma)

Non-Hodgkin’s Lymphoma

- Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response therapy
- **Not covered for:**
  - Initial therapy

Primary Amyloidosis

- Two (2) or fewer organs involved
  - Left ventricular ejection fraction (EF) is greater than 45%
- **Not covered for:**
  - Non-primary Amyloidosis.

Other Tumors of Childhood

- Initial treatment of high-risk neuroblastoma for members older than one (1) year of age.
- Primary refractory or recurrent neuroblastoma.
- Recurrent high-risk Wilms’ tumor.
- **Not covered for:**
  - Initial treatment of low or intermediate risk Ewing’s sarcoma
  - Retinoblastoma
  - Osteosarcoma
  - Rhabdomyosarcoma
  - Relapse after prior high dose chemotherapy (HDC) and autologous stem cell transplant

C. **Limitations**
1. Not Covered
   - Prophylactic collection and storage of umbilical cord blood for unspecified future use in autologous stem cell transplant in the original donor, or for specified future use as an allogeneic stem cell transplant in a related or unrelated recipient.
   - Tandem or sequential autologous bone marrow or stem cell transplants that are not medically necessary. Tandem transplants are two planned courses of HDC and stem cell support, typically administered at intervals of (2) two to six (6) months, contingent on recovery from prior toxicity.

2. Contraindications include the following:
   - Active systemic or localized infection
     (Recipients developing infections while on a waiting list may become temporarily inactive and return to active status if the infection resolves.)
   - Ongoing alcohol or drug abuse
     (Persons with history of drug or alcohol abuse must be abstinent for at least 6 months prior to consideration of transplant.)
   - Active smoking
     (Persons with a past smoking history or recent cessation should currently be enrolled in a smoking cessation program)
   - Irreversible multisystem organ failure
   - Untreatable vascular disease
   - Active malignancy (other than non-melanoma skin cancers) unless there has been definitive surgical and/or medical therapy with a small likelihood of recurrence. The follow-up period prior to eligibility is variable, and is a function of the specific type of cancer.
   - Morbid obesity evidenced by a body mass index (BMI) >40 or >35 with comorbid conditions.
   - Absent of appropriate social support group
   - Not up to date with all applicable preventive services recommended by U.S. Preventive Services Task Force guidelines (i.e. immunizations or screenings)
   - Current and/or history of non-compliance or psychiatric illness or psychological condition or lack of other resources of support which would make compliance with a disciplined medical regimen impossible for a member/minor

3. HIV+ Specific Contraindications include:
   - Documented history of progressive multifocal leukoencephalopathy (PML)
EBV (Epstein-Barr virus) and HHV8 (Human Herpes Virus 8) related lymphoproliferative disorders (lymphomas and multi-centric Castleman’s disease)
Persistent viremia despite Highly Active Antiretroviral Therapy (HAART) therapy
Kaposi’s Sarcoma or lymphomas
Demonstrated non-compliance with HAART therapy
Unwilling to comply with anti-fungal and antiviral prophylaxis as required
If co-infected with Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV), evidence of cirrhosis on liver biopsy

D. Information Required for Review

In order to assess medical necessity for bone marrow transplantation, adequate information must be furnished by the treating physician. Necessary documentation includes but is not limited to the following:
1. Member’s age, clinical history and physical and functional status
2. Documentation of diagnosis, staging, and treatment history including response
3. Detailed treatment plan/transplant protocol including medications, dosages
4. Definition of the use of hematopoietic stem cells
5. Current or past history of substance use disorder
6. Current or past history of smoking
7. Current or past history of any disease or condition
8. Documentation of any history of emotional instability or non-compliance with medical management
9. Results of pre-transplant testing, examinations and consultations including:
   bone marrow biopsies, laboratory tests, radiological evaluations and electrocardiogram (EKG).
10. Documentation for HIV + Members
    In addition to the above documentation, the following information should be furnished:

    - The member’s life expectancy
    - CD4 count for the last 6 months
    - Documentation to show absence of HIV viremia for 6 months
    - Indication that the member is treatable with HAART post-transplant
    - Demonstrated compliance with anti-fungal and HAART regimen for ≥ 6 months
    - Documentation to support the absence of Kaposi’s Sarcoma or lymphomas
    - If co-infected with HBV or HCV, there is no evidence of cirrhosis on liver biopsy

E. Review Process
1. The Medical Management ancillary service staff reviews the request according to the established criteria. If the case does not meet the established criteria, it is referred to a MedStar Health Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management ancillary service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member’s benefit plan.

F. Variations

For Commercial members in the State of Maryland:

Autologous and nonautologous bone marrow, cornea, kidney, liver, heart, lung, heart cornea, kidney, liver, heart, lung, heart/lung, pancreas, and pancreas/kidney transplants are covered as essential Health benefits.

Patient costs associated with an autologous bone marrow transplant normally considered experimental that are part of a clinical trial may be covered under the clinical trial mandate. (See MP.078.MH Clinical Trials)

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

**Applicable CPT Coding:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>38206</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous</td>
</tr>
<tr>
<td>38207</td>
<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
</tr>
<tr>
<td>38208</td>
<td>Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing per donor</td>
</tr>
</tbody>
</table>
38209 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing per donor
38210 Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38211 Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38212 Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213 Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214 Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38232 Bone marrow harvesting for transplantation, autologous
38241 Bone marrow or blood-derived peripheral stem cell transplantation; autologous

I. References

Medical Literature/Clinical Information:
   http://theoncologist.alphamedpress.org/content/6/3/247.full.pdf+html


Regulatory/Government Source:
   http://www.uspreventiveservicestaskforce.org/AdultRec.htm


3. Maryland Essential Health benefits: Autologous and Non Autologous Bone Marrow transplants: 