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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Bone Marrow Transplant Donor Policy

Indication/Usage:

Marrow or blood cell transplantation is a life-saving treatment for numerous blood diseases, such as leukemia, lymphoma, sickle-cell disease, multiple myeloma and myelofibrosis. This type of transplantation replaces the individual's unhealthy blood cells and healthy blood-forming cells from a donor. Three sources of blood forming cells include marrow, blood-forming cells collected from the blood (called peripheral-blood stem-cell donation [PBSC]) and umbilical cord blood. Transplantation involving the use of the individual's own cells is referred to as an autologous transplant. During this procedure, cells are collected from the patient's blood or, less frequently, marrow, and stored for a transplant. Using transplantation cells from a family member, an unrelated donor, or cord blood is referred to as an allogeneic transplant. Syngeneic transplantation is a transplantation method using cells from an identical twin.

Bone-Marrow Donor: Bone marrow donation involves a minor surgical procedure, which is performed under local or general anesthetic.

Peripheral Blood Stem Cell (PBSC) Donor: PBSC donation requires the donor to receive medication, such as growth factor (e.g., filgrastim), for several days to increase the number of stem cells released from the bone marrow into the bloodstream.

Umbilical Cord Blood Stem Cell Donor: Umbilical cord blood contains large numbers of stem cells. After a baby's birth, blood is collected from the placenta and umbilical cord. There is no physical effect on the mother or infant.

The selection of a donor is a critical element contributing to the success of hematopoietic cell transplantation (HCT). There are several possible sources for these cells:

- An identical twin
- A sibling, relative, or unrelated donor
- Umbilical cord blood
- The patient

Matching donor and recipient for human leukocyte antigen (HLA) class I (-A, -B, and –C) and class II (-DRB1 and –DQB1) haplotypes is a key part of successful allogeneic cell transplantation.

Outcomes following allogeneic hematopoietic cell transplantation (HCT) depend upon the underlying disease (reason for transplant), the timing of the transplant (early versus late, patient comorbidities (including CMV seropositivity), and the choice of donor. The search for an appropriate donor must consider the urgency of the procedure and potential risks of postponing transplant. All patients likely to require an allogeneic HCT should undergo high resolution HLA typing for HLA-A, -B, -C, and – DR soon after diagnosis to allow for the timely identification of an appropriate donor. Performing these tests early in the course of treatment is often critical so that the donor search can be initiated and time is not lost later.

Medical Indications for Authorization
Commercial Members

SummaCare will cover typing of Bone Marrow Donors from approved sources up to 6 times without prior authorization. After typing of 6 potential donors any additional typing of potential donors will require prior authorization.

Medicare Members

CGS LCD ID L39434 Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin

Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

Background

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. Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells. AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cells or bone marrow is obtained and prepared for intravenous infusion.

Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cells or bone marrow is obtained and prepared for intravenous infusion. Hematopoietic stem cells are multi-potent cells that give rise to all the blood cell types; these stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis - a process by which cells that are unneeded or detrimental will self-destruct.

The Centers for Medicare & Medicaid Services (CMS) has clarified that bone marrow and peripheral blood stem cell transplantation 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. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage.

NCD 110.23 Stem Cell Transplantation includes for allogenic transplantation:

- Leukemia
- Aplastic Anemia
- Severe Combined Immunodeficiency disease (SCID)
- Wiskott-Aldrich Syndrome

Allogeneic HSCT is covered only for Medicare beneficiaries with the following indications when participating in an approved prospective clinical study meeting specific criteria under the Coverage with Evidence Development (CED) paradigm:

- Myelodysplastic Syndrome
- Multiple myeloma only for beneficiaries with Durie-Salmon Stage II or III multiple myeloma, or International Staging System (ISS) Stage II or Stage III multiple myeloma
- Myelofibrosis (MF) only for beneficiaries with Dynamic International Prognostic

Scoring System (DIPSSplus) intermediate-2 or High primary or secondary MF; or

- Sickle cell disease (SCD) only for beneficiaries with severe, symptomatic SCD who participate in an approved prospective clinical study meeting specific criteria under the CED Paradigm. (Please refer to CMS Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, §110.23)

Per the NCD, "All other indications for stem cell transplantation not otherwise noted above as covered or non-covered remain at local Medicare Administrative Contractor discretion."

Allogeneic hematopoietic cell transplantation, (HCT) has been increasingly used for a variety of hematologic neoplasm and non-malignant marrow disorders. Eligibility for Allogeneic HCT varies among institutions and is usually based on a case-by-case basis dependent upon a risk benefit assessment, and the needs and wishes of the patient.[1]

Although historically allogeneic HCT was offered to patients who had exhausted all other treatment modalities, currently the decision to perform a transplant is dependent upon an assessment if the transplant will offer an outcome superior to other treatment options.[1]

The CMS National Coverage Determination (NCD 110.23) for Stem Cell Transplantation describes nationally covered indications for stem cell transplant, the details of which will not be repeated within this policy. This policy describes additional locally covered indications for Allogeneic stem cell for primary refractory or relapsed Hodgkin's and non-Hodgkin's lymphoma with B-cell or T-cell origin, for whom there are no other curative intent options, and are medically necessary.

Multiple other disorders are under investigation as part of clinical trials and are not covered unless the clinical trial meets the criteria of NCD 310.1 Routine Costs in Clinical Trials.

This policy describes additional locally covered indications for Allogeneic stem cell for primary refractory or relapsed Hodgkin's and non-Hodgkin's lymphoma with B-cell or T-cell origin, for whom there are no other curative intent options, and are medically necessary.

Coverage Indications, Limitations, and/or Medical Necessity

Allogenic hematopoietic cell transplant is considered reasonable and necessary when:

1. Patient has primary refractory or relapse of Hodgkin's or non-Hodgkin's lymphoma with B-cell or T-cell origin
2. Pre-transplantation assessment indicates good function status, low-comorbidities and patient is candidate for transplantation based on risk assessment
3. There are no other treatment options available with curative intent

NCD ID 110.23 Stem Cell Transplantation

Item/Service Description

A. General

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. Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells. AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion. Allogeneic HSCT may be used to restore function in recipients having an inherited or acquired deficiency or defect. Hematopoietic stem cells are multi-potent stem cells that give rise to all the blood cell types; these stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis - a process by which cells that are unneeded or detrimental will self-destruct.

The Centers for Medicare & Medicaid Services (CMS) is clarifying that bone marrow and peripheral blood stem cell transplantation 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. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Indications and Limitations of Coverage

A. Nationally Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

a. Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary,
b. Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) and for the treatment of Wiskott-Aldrich syndrome.
c. Effective for services performed on or after March 6, 2024, allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with myelodysplastic syndromes who have prognostic risk scores of:

- ≥ 1.5 (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or
- ≥ 4.5 (high or very high) using the International Prognostic Scoring System - Revised (IPSS-R), or ≥ 0.5 (high or very high) using the Molecular International Prognostic Scoring System (IPSS-M).

d. MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical

characteristics, cytologic and pathologic features, and cytogenetics. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow.

e. Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for multiple myeloma is covered by Medicare only for beneficiaries with Durie-Salmon Stage II or III multiple myeloma, or International Staging System (ISS) Stage II or Stage III multiple myeloma, and participating in an approved prospective clinical study that meets the criteria below. There must be appropriate statistical techniques to control for selection bias and confounding by age, duration of diagnosis, disease classification, International Myeloma Working Group (IMWG) classification, ISS stage, comorbid conditions, type of preparative/conditioning regimen, graft vs. host disease (GVHD) prophylaxis, donor type and cell source.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for multiple myeloma pursuant to CED must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with multiple myeloma who receive allogeneic HSCT have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic);
- Other transplant-related adverse events;
- Overall survival; and (optional) Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population as listed in section g.

f. Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for myelofibrosis (MF) is covered by Medicare only for beneficiaries with Dynamic International Prognostic Scoring System (DIPSSplus) Intermediate-2 or High primary or secondary MF and participating in an approved prospective clinical study. All Medicare approved studies must use appropriate statistical techniques in the analysis to control for selection bias and potential confounding by age, duration of diagnosis, disease classification, DIPSSplus score, comorbid conditions, type of preparative/conditioning regimen, graft vs. host disease (GVHD) prophylaxis, donor type and cell source.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for myelofibrosis pursuant to Coverage with Evidence Development (CED) must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with MF who receive allogeneic HSCT transplantation have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic);
- Other transplant-related adverse events; overall survival; and (optional) – Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population as listed in section g.

g. Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for sickle cell disease (SCD) is covered by Medicare only for beneficiaries with severe, symptomatic SCD who participate in an approved prospective clinical study.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for sickle cell disease pursuant to Coverage with Evidence Development (CED) must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with SCD who receive allogeneic HSCT have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic),
- Other transplant-related adverse events: Overall survival: and (optional) – Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population listed in section g.

a. All CMS-approved clinical studies and registries in sections d, e and f must adhere to the below listed standards of scientific integrity and relevance to the Medicare population:
b. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
c. The rationale for the study is well supported by available scientific and medical evidence.
d. The study results are not anticipated to unjustifiably duplicate existing knowledge.
e. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
f. The study is sponsored by an organization or individual capable of completing it successfully.
g. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
h. All aspects of the study are conducted according to appropriate standards of scientific integrity.
i. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
j. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being

studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

k. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
l. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
m. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
n. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

II. Autologous Stem Cell Transplantation (AuSCT)

- Effective for services performed on or after April 28, 1989, AuSCT is considered reasonable and necessary under §l862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:
- Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma; or,
- Advanced Hodgkin's disease who have failed conventional therapy and have no HLAmatched donor.

- Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients that fit the following requirements:

    - Newly diagnosed or responsive multiple myeloma. This includes those patients 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
    - Adequate cardiac, renal, pulmonary, and hepatic function. ○ Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high dose melphalan (HDM) together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria: ○ Amyloid deposition in 2 or fewer organs; and, ○ Cardiac left ventricular ejection fraction (EF) greater than 45%.

C. Nationally Non-Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Effective for claims with dates of service on or after May 24, 1996, through January 26, 2016, allogeneic HSCT is not covered as treatment for multiple myeloma.

II. Autologous Stem Cell Transplantation (AuSCT)

Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT for the following conditions:

a. Acute leukemia not in remission;
b. Chronic granulocytic leukemia;
c. Solid tumors (other than neuroblastoma);
d. Up to October 1, 2000, multiple myeloma;
e. Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma;
f. Effective October 1, 2000, non-primary AL amyloidosis; and,
g. Effective October 1, 2000, through March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, AuSCT is not considered reasonable and necessary within the meaning of §l862 (a) (1) (A) of the Act and in not covered under Medicare.

D. Other

Coverage of all other indications for stem cell transplantation not otherwise specified above as covered or non-covered will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A).

Limitations

A donor must have adequate cardiac, pulmonary, hepatic, and renal functions. If being considered for bone marrow collection, the donor must be able to tolerate anesthesia (either general or regional). Pediatric donors are only utilized for autologous collection or donation to siblings. Donors with ongoing malignancies or a history of a malignant condition other than minor skin cancers (e.g., basal cell carcinomas) are generally excluded for further consideration. For sibling donors with a history of a malignant condition, a five-year disease-free period without recurrence usually considered adequate for subsequent collection.

Donors must be negative for both anti-HIV antibodies and HIV RNA. Serologic tests for hepatitis B and C are also required at most transplant centers. Donors with active viral hepatitis are usually excluded, although exceptions are occasionally made with sibling donors, depending upon the clinical urgency. In certain circumstances, antiviral therapy may be considered if time permits for an adequate course. Testing for sickle cell disease, exposure to syphilis, West Nile virus, and other potential pathogens are required by some state and regions.

CPT Codes

38204 Management of recipient hematopoietic progenitor cell donor search and cell acquisition
38205 Blood-hyphen derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic
38206 autologous
38207 Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208 thawing of previously frozen harvest, without washing
38209 thawing of previously frozen harvest, with washing
38210 specific cell depletion within harvest, T-hyphencell depletion
38211 tumor cell depletion
38212 red blood cell removal
38213 platelet depletion
38214 plasma (volume) depletion
38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38230 Bone marrow harvesting for transplantation
38240 Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38243 Hematopoietic progenitor cell (HPC); HPC boost
59012 Cordocentesis (intrauterine), any method
86813 HLA typing; A, B, or C, multiple antigens
86817 DR/DQ, multiple antigens

86821 lymphocyte culture, mixed (MLC)
86920 Compatibility test each unit; immediate spin technique
86921 incubation technique
86922 antiglobulin technique
86923 electronic
S2140 Cord blood harvesting for transplantation, allogeneic
S2142 Cord blood-hyphenderived stem-hyphencell transplantation, allogeneic
S2150 Bone marrow or blood-hyphenderived stem-hyphencells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-hyphenup; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre-hyphenand post-hyphentransplant care in the global definition

This list is not all inclusive

Coverage Decisions
Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy
Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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CMS Stem Cell Transplantation
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