

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 193	Date: July 1, 2016
	Change Request 9620

Transmittal 191 dated April 29, 2016, is being rescinded and replaced by Transmittal 193, dated July 1, 2016 to provide clarifying language for references to the Pub. 100-03 NCD manual, under Summary of Changes. All other information remains the same.

SUBJECT: Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after January 27, 2016, contractors shall be aware that the use of allogeneic HSCT for treatment of Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease is only covered by Medicare if provided in the context of a Medicare-approved clinical study meeting specific criteria under the CED paradigm. This CR also clarifies the ICD-9 and ICD-10 diagnosis codes for allogeneic HSCT for treatment of Myelodysplastic Syndromes in the context of a Medicare-approved, prospective clinical study under the CED paradigm. See Pub. 100-03, chapter 1, section 110.23, of the NCD Manual, for further information. Please note, chapter 1, section 110.8.1 has been removed from the NCD Manual and incorporated into chapter 1, section 110.23.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: January 27, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 3, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
D	1/110.8.1/Stem Cell Transplantation (Various Effective Dates Below)
N	1/110.23/Stem Cell Transplantation ⁹ Formerly 110.8.1)(Various Effective Dates Below)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 193	Date: July 1, 2016	Change Request: 9620
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SUBJECT: Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes

EFFECTIVE DATE: January 27, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 3, 2016

I. GENERAL INFORMATION

A. Background: Hematopoietic stem cell transplantation (HSCT) is a process that includes mobilization, harvesting, and transplant of stem cells and the administration of high dose chemotherapy and/or radiotherapy prior to the actual transplant. During the process stem cells are harvested from either the patient (autologous) or a donor (allogeneic) and subsequently administered by intravenous infusion to the patient.

Multiple myeloma is a neoplastic plasma-cell disorder. Myelofibrosis is a stem cell-derived hematologic disorder. Sickle cell disease is a group of inherited red blood cell disorders created by the presence of abnormal hemoglobin genes. On April 30, 2015, CMS accepted a formal request from the American Society for Blood and Marrow Transplantation (ASBMT) to reconsider its policy and expand coverage of allogeneic HSCT for sickle cell disease, myelofibrosis, multiple myeloma and rare diseases.

Myelodysplastic Syndrome (MDS) refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. On August 4, 2010, CMS issued a final decision stating that allogeneic HSCT for MDS is covered by Medicare only if provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). Change Request (CR) 7137 provides specific ICD-9 related coding and claims processing requirements regarding this particular coverage decision, and CRs 8197 and 8691 provide ICD-10 related coding requirements. On November 30, 2015, CMS accepted a formal request from the National Marrow Donor Program (NMDP) to clarify the list of ICD-9-CM and ICD-10-CM diagnosis codes covered for allogeneic HSCT for the treatment MDS in the context of a Medicare-approved clinical study under CED.

B. Policy: On January 27, 2016, CMS issued a final decision to expand national coverage of items and services necessary for research in an approved clinical study via Coverage with Evidence Development (CED) under §1862(a)(1)(E) of the Act for allogeneic hematopoietic stem cell transplantation (HSCT) for the following indications:

- Multiple Myeloma
- Myelofibrosis; and
- Sickle Cell Disease.

For claims of allogeneic HSCT for in the treatment of MDS in a Medicare approved study under CED, this CR also clarifies the list of appropriate ICD-9-CM codes for dates of service between August 4, 2010, and September 30, 2015, and the list of appropriate ICD-10-CM codes for dates of service on or after October 1,

2015.

Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for information regarding this NCD. Please note, chapter 1, section 110.8.1 has been removed from the NCD Manual and incorporated into chapter 1, section 110.23.

Refer to Pub. 100-02, Benefit Policy Manual chapter 14, section 50, Pub. 100-03, NCD Manual, chapter 1, section 310.1, and Pub. 100-04, Claims Processing Manual, chapter 32, sections 69 for further supporting information relative to processing clinical trial claims. In addition, there are further billing instructions specific to this NCD in the below business requirements.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
9620 -1	Effective for claims with dates of service on and after January 27, 2016, contractors shall be aware that the use of allogeneic HSCT for treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease is only covered by Medicare if provided in the context of a Medicare-approved clinical study meeting specific criteria under the CED paradigm. See Pub. 100-03, chapter 1, section 110.23, of the NCD Manual, and Pub. 100-04, chapter 3, section 90.3, and chapter 32, sections 69 and 90 of the Claims Processing Manual, for further information.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9620 -2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the	X	X			

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
	provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov (Institutional Claims), Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage and Analysis), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocato-simons@cms.hhs.gov (Coverage and Analysis), Mark Baldwin, 410-786-8139 or Mark.Baldwin@cms.hhs.gov (Professional Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Table of Contents
(Rev. 193, 07-16)

110.23 - Stem Cell Transplantation (Formerly 110.8.1) (Various Effective Dates Below)

110.23 - Stem Cell Transplantation (Formerly 110.8.1) (Various Effective Dates Below)
(Rev.193, Issued; 07-01-16, Effective: 1-27-16, Implementation: 10-3-16)

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.

B. 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 August 4, 2010, for the treatment of Myelodysplastic Syndromes (MDS) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.*

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

Medicare payment for these beneficiaries will be restricted to patients enrolled in an approved clinical study. In accordance with the Stem Cell Therapeutic and Research Act of 2005 (US Public Law 109-129) a standard dataset is collected for all allogeneic transplant patients in the United States by the Center for International Blood and Marrow Transplant Research. The elements in this dataset, comprised of two mandatory forms plus one additional form, encompass the information we require for a study under CED.

A prospective clinical study seeking Medicare payment for treating a beneficiary with allogeneic HSCT for MDS pursuant to CED must meet one or more aspects of the following questions:

1. *Prospectively, compared to Medicare beneficiaries with MDS who do not receive HSCT, do Medicare beneficiaries with MDS who receive HSCT have improved outcomes as indicated by:*
 - *Relapse-free mortality,*
 - *progression free survival,*
 - *relapse, and*
 - *overall survival?*

2. *Prospectively, in Medicare beneficiaries with MDS who receive HSCT, how do International Prognostic Scoring System (IPSS) scores, patient age, cytopenias, and comorbidities predict the following outcomes:*
 - *Relapse-free mortality,*
 - *progression free survival,*
 - *relapse, and*
 - *overall survival?*

3. *Prospectively, in Medicare beneficiaries with MDS who receive HSCT, what treatment facility characteristics predict meaningful clinical improvement in the following outcomes:*
 - *Relapse-free mortality,*
 - *progression free survival,*
 - *relapse, and*
 - *overall survival?*

In addition, the clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. *The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.*
- b. *The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.*
- c. *The research study does not unjustifiably duplicate existing studies.*
- d. *The research study design is appropriate to answer the research question being asked in the study.*
- e. *The research study is sponsored by an organization or individual capable of executing the proposed study successfully.*
- f. *The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.*
- g. *All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).*
- h. *The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.*
- i. *The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard 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.*
- j. *The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.*
- k. *The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal*

Editors (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than 3 years after the end of data collection.

- l. The research study protocol must explicitly discuss subpopulations affected by the treatment 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 on 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.*
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. 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 Social Security Act, the Agency for Health Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The clinical research study should also have the following features:

- It should be a prospective, longitudinal study with clinical information from the period before HSCT and short- and long-term follow-up information.*
- Outcomes should be measured and compared among pre-specified subgroups within the cohort.*
- The study should be powered to make inferences in subgroup analyses.*
- Risk stratification methods should be used to control for selection bias. Data elements to be used in risk stratification models should include:*

Patient selection:

- Patient Age at diagnosis of MDS and at transplantation*
- Date of onset of MDS*
- Disease classification (specific MDS subtype at diagnosis prior to preparative/conditioning regimen using World Health Organization (WHO) classifications). Include presence/absence of refractory cytopenias*
- Comorbid conditions*
- IPSS score (and WHO-adapted Prognostic Scoring System (WPSS) score, if applicable) at diagnosis and prior to transplantation*
- Score immediately prior to transplantation and one year post-transplantation*
- Disease assessment at diagnosis at start of preparative regimen and last assessment prior to preparative regimen Subtype of MDS (refractory anemia with or without blasts, degree of blasts, etc.)*
- Type of preparative/conditioning regimen administered (myeloablative, non-myeloablative, reduced-intensity conditioning)*
- Donor type*
- Cell Source*

Facilities must submit the required transplant essential data to the Stem Cell Therapeutics Outcomes Database.

- d) 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.

- e) 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.

- f) 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:

- g) 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:*
- a. 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.*
 - b. The rationale for the study is well supported by available scientific and medical evidence.*
 - c. The study results are not anticipated to unjustifiably duplicate existing knowledge.*
 - d. 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.*
 - e. The study is sponsored by an organization or individual capable of completing it successfully.*
 - f. 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.*
 - g. All aspects of the study are conducted according to appropriate standards of scientific integrity.*
 - h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.*
 - i. 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.*
 - j. 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).*
 - k. 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 accessible 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).*
 - l. 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.*
 - m. 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)

- a) *Effective for services performed on or after April 28, 1989, AuSCT is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:*
1. *Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;*
 2. *Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;*
 3. *Recurrent or refractory neuroblastoma; or,*
 4. *Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.*
- b) *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.*
- c) *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 §1862(a)(1)(A) of the Act and is not covered under Medicare.

D. Other

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

(This NCD last reviewed January 2016.)