

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3556	Date: July 1, 2016
	Change Request 9620

Transmittal 3509 dated April 29, 2016, is being rescinded and replaced by Transmittal 3556, dated July 1, 2016, to update BR 9620.2 to add clarifying language and identify the appropriate FISS responsibility. The transmittal also includes 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.

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	3/Table Of Contents
R	3/90.3/Stem Cell Transplantation
R	3/90.3.1/Billing for Stem Cell Transplantation
R	4/231.10/Billing for Autologous Stem Cell Transplants
R	4/231.11/Billing for Allogeneic Stem Cell Transplants
R	32/90/Stem Cell Transplantation

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. 100-04	Transmittal: 3556	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 of 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 August 4, 2010, through

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. 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							
9620.2	Effective for claims with dates of service specified herein, contractors shall pay claims with the following clarified ICD-9 and ICD-10 diagnosis codes for allogeneic HSCT for the treatment of Myelodysplastic Syndromes (MDS) in the context of a Medicare-approved clinical study meeting specific criteria pursuant to CED: For dates of service August 4, 2010, through September 30, 2015, ICD-9-CM diagnosis codes 238.72, 238.73, 238.74, or 238.75, (No editing changes by FISS shall be performed for claims with DOS prior to October 1, 2015) AND Clinical Trial ICD-9-CM diagnosis code V70.7. For dates of service on or after October 1, 2015, ICD-10-CM codes D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, or D46.9, D46.Z, AND Clinical Trial ICD-10-CM diagnosis code Z00.6.	X	X			X	X			

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	
9620.3	<p>Contractors shall pay inpatient hospital claims (TOB11X) with discharges on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease that contain the following required codes:</p> <ul style="list-style-type: none"> • HSCT-ICD-10-PCS procedure codes 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1,30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1,or 30263Y1; • Clinical Trial ICD-10-CM diagnosis code - Z00.6; • Condition Code 30 – Qualifying Clinical Trial; • Value Code D4 – Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website); <p>Along with the appropriate ICD-10 CM diagnosis code below: :</p> <p>Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02</p> <p>OR</p> <p>Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81</p> <p>OR</p> <p>Sickle Cell Disease- ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819</p>	X				X				
9620.3.1	Contractors shall pay outpatient hospital claims (TOBs	X				X				

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	
	<p>13X and 85x) with dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease that contain the following required codes:</p> <ul style="list-style-type: none"> • HSCT CPT code 38240; • Clinical Trial ICD-10-CM diagnosis code - Z00.6; • Condition Code 30 – Qualifying Clinical Trial; • Value Code D4 – Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website); <p>Along with the appropriate ICD-10 CM diagnosis code below:</p> <p>Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02</p> <p>OR</p> <p>Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81</p> <p>OR</p> <p>Sickle Cell Disease-ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819</p>									
9620.3.2	<p>For claims with dates of service on or after January 27, 2016, contractors shall pay practitioner claims billed by a Method II CAH on an 85X TOB with Revenue Codes 96X, 97X, or 98X for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease that contain the following required codes:</p>	X				X				

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	
	<ul style="list-style-type: none"> • HSCT CPT code 38240 • Clinical Trial ICD-10-CM diagnosis code - Z00.6; • Condition Code 30 – Qualifying Clinical Trial; • Value Code D4 – Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website); <p>Along with the appropriate ICD-10 CM diagnosis code below:</p> <p>Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02</p> <p>OR</p> <p>Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81</p> <p>OR</p> <p>Sickle Cell Disease- ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819</p>									
9620.4	<p>For claims with dates of service on or after January 27, 2016, contractors shall pay professional claims for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease that contain the following required codes:</p> <ul style="list-style-type: none"> • HSCT CPT code 38240; • Clinical Trial ICD-10-CM diagnosis code - Z00.6; 		X				X			

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	
	<ul style="list-style-type: none"> Q0 modifier <p>Along with the appropriate ICD-10 CM diagnosis code below:</p> <p>Multiple Myeloma ICD-10-CM diagnosis code C90.00, C90.01, or C90.02</p> <p>OR</p> <p>Myelofibrosis ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81</p> <p>OR</p> <p>Sickle Cell Disease ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819</p> <p>AND</p> <p>POS Code 19, 21, and 22</p>									
9620.5	<p>Contractors shall deny claims for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease that do not contain all of the coding included in BRs 9620.04.3, 9620.04.3.1, 9620.04.3.2, and 9620.04.4 using the following messages:</p> <p>CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a</p>	X	X							

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	
	<p>coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code - Patient Responsibility (PR) if</p> <p>ABN/HINN given, otherwise Contractual Obligation (CO)</p> <p>MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)</p> <p>MSN 15.20 – The following policies [NCD 110.23] were used when we made this decision. (Las siguientes políticas [NCD 110.23] fueron utilizadas cuando se tomó esta decisión.)</p>									
9620.6	For claims with dates of service prior to the implementation date of this CR, contractors shall perform necessary adjustments only when affected claims are brought to their attention.	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		
9620.7	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-	X	X			

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
	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 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): Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage and Analysis), Cheryl Gilbreath, 410-786-5919 or cheryl.gilbreath@cms.hhs.gov (Coverage and Analysis), Mark Baldwin, 410-786-8139 or Marl.Baldwin@cms.hhs.gov (Professional Claims), Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis), Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov (Institutional 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 Claims Processing Manual

Chapter 3 – Inpatient Hospital Billing

Table of Contents
(Rev.3556, 07-16)

90.3.1 – *Billing for Stem Cell Transplantation*

90.3 - Stem Cell Transplantation

(Rev. 3556, 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.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. Effective October 1, 1990, these cases were assigned to MS-DRG 009, Bone Marrow Transplant. The A/B MAC (A)'s Medicare Code Editor (MCE) will edit stem cell transplant procedure codes against diagnosis codes to determine which cases meet specified coverage criteria. Cases with a diagnosis code for a covered condition will pass (as covered) the MCE noncovered procedure edit. When a stem cell transplant case is selected for review based on the random selection of beneficiaries, the QIO will review the case on a post-payment basis to assure proper coverage decisions.

Bone marrow transplant codes that are reported with an ICD-9-CM that is "not otherwise specified" are returned to the hospital for a more specific procedure code. ICD-10-PCS codes are more precise and clearly identify autologous and nonautologous stem cells.

The A/B MAC (A) may choose to review if data analysis deems it a priority.

B. Nationally Covered Indications

I. Allogeneic *Hematopoietic* Stem Cell Transplantation (*HSCT*)

a. General

Allogeneic stem cell transplantation (*ICD-9-CM Procedure Codes 41.02, 41.03, 41.05, and 41.08;* *ICD-10-PCS codes 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, and 30263Y1*) is a procedure in which a portion of a healthy donor's stem cells are obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect. See Pub. 100-03, National Coverage Determinations (NCD) Manual, chapter 1, section *110.23, for further information about this policy, and Pub. 100-04, CPM, chapter 32, section 90, for information on coding.*

Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell, and ordinary follow-up care.

b. Covered Conditions

i. 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;

ii. 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;

iii. *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.

iv. *Effective for claims with dates of service on or after January 27, 2016:*

- 1. 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.*
- 2. 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.*
- 3. 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.*

II. Autologous Stem Cell Transplantation (AuSCT)

a. General

Autologous stem cell transplantation (ICD-9-CM Procedure Codes 41.01, 41.04, 41.07, and 41.09; ICD-10-PCS codes 30230AZ, 30230G0, 30230Y0, 30233G0, 30233Y0, 30240G0, 30240Y0, 30243G0, 30243Y0, 30250G0, 30250Y0, 30253G0, 30253Y0, 30260G0, 30260Y0, 30263G0, and 30263Y0) 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 (high dose chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy, and Pub. 100-04, CPM, chapter 32, section 90, for information on coding.

b. Covered Conditions

1. Effective for services performed on or after April 28, 1989:

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 HLA-matched donor.

2. Effective for services performed on or after 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.*

3. 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. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy, and Pub. 100-04, CPM, chapter 32, section 90, for information on coding.

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. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy, and Pub. 100-04, CPM, chapter 32, section 90, for information on coding.

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.

90.3.1 - Billing for Stem Cell Transplantation

(Rev. 3556, Issued: 07-01-16; Effective: 1-27-16; Implementation: 10-3-16)

A. - Billing for Allogeneic Stem Cell Transplants

1. Definition of Acquisition Charges for Allogeneic Stem Cell Transplants

Acquisition charges for allogeneic stem cell transplants include, but are not limited to, charges for the costs of the following services:

- *National Marrow Donor Program fees, if applicable, for stem cells from an unrelated donor;*
- *Tissue typing of donor and recipient;*
- *Donor evaluation;*
- *Physician pre-admission/pre-procedure donor evaluation services;*
- *Costs associated with harvesting procedure (e.g., general routine and special care services, procedure/operating room and other ancillary services, apheresis services, etc.);*
- *Post-operative/post-procedure evaluation of donor; and*
- *Preparation and processing of stem cells.*

Payment for these acquisition services is included in the MS-DRG payment for the allogeneic stem cell transplant when the transplant occurs in the inpatient setting, and in the OPPS APC payment for the allogeneic stem cell transplant when the transplant occurs in the outpatient setting. The Medicare contractor does not make separate payment for these acquisition services, because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Unlike the acquisition costs of solid organs for transplant (e.g., hearts and kidneys), which are paid on a reasonable cost basis, acquisition costs for allogeneic stem cells are included in prospective payment.

Acquisition charges for stem cell transplants apply only to allogeneic transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient himself or herself), because autologous transplants involve services provided to the beneficiary only (and not to a donor), for which the hospital may bill and receive payment (see Pub. 100-04, chapter 4, §231.10 and paragraph B of this section for information regarding billing for autologous stem cell transplants).

2. Billing for Acquisition Services

The hospital bills and shows acquisition charges for allogeneic stem cell transplants based on the status of the patient (i.e., inpatient or outpatient) when the transplant is furnished. See Pub. 100-04, chapter 4, §231.11 for instructions regarding billing for acquisition services for allogeneic stem cell transplants that are performed in the outpatient setting.

When the allogeneic stem cell transplant occurs in the inpatient setting, the hospital identifies stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately by using revenue code 0819 (Other Organ Acquisition). Revenue code 0819 charges should include all services required to acquire stem cells from a donor, as defined above.

On the recipient's transplant bill, the hospital reports the acquisition charges, cost report days, and utilization days for the donor's hospital stay (if applicable) and/or charges for other encounters in which the stem cells were obtained from the donor. The donor is covered for medically necessary inpatient hospital days of care or outpatient care provided in connection with the allogeneic stem cell transplant under Part A. Expenses incurred for complications are paid only if they are directly and immediately attributable to the stem cell donation procedure. The hospital reports the acquisition charges on the billing form for the recipient, as described in the first paragraph of this section. It does not charge the donor's days of care against the recipient's utilization record. For cost reporting purposes, it includes the covered donor days and charges as Medicare days and charges.

The transplant hospital keeps an itemized statement that identifies the services furnished, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges will be reflected in the transplant hospital's stem cell/bone marrow acquisition cost center. For allogeneic stem cell acquisition services in cases that do not result in transplant, due to death of the intended recipient or other causes, hospitals include the costs associated with the acquisition services on the Medicare cost report.

The hospital shows charges for the transplant itself in revenue center code 0362 or another appropriate cost center. Selection of the cost center is up to the hospital.

B. - Billing for Autologous Stem Cell Transplants

The hospital bills and shows all charges for autologous stem cell harvesting, processing, and transplant procedures based on the status of the patient (i.e., inpatient or outpatient) when the services are furnished. It shows charges for the actual transplant, in revenue center code 0362 or another appropriate cost center. ICD-9-CM or ICD-10-PCS codes are used to identify inpatient procedures.

The HCPCS codes describing autologous stem cell harvesting procedures may be billed and are separately payable under the OPSS when provided in the hospital outpatient setting of care. Autologous harvesting procedures are distinct from the acquisition services described in Pub. 100-04, chapter 4, §231.11 and section A. above for allogeneic stem cell transplants, which include services provided when stem cells are obtained from a donor and not from the patient undergoing the stem cell transplant. The HCPCS codes describing autologous stem cell processing procedures also may be billed and are separately payable under the OPSS when provided to hospital outpatients.

Payment for autologous stem cell harvesting procedures performed in the hospital inpatient setting of care, with transplant also occurring in the inpatient setting of care, is included in the MS-DRG payment for the autologous stem cell transplant.

Medicare Claims Processing Manual

Chapter 4 - Part B Hospital

(Including Inpatient Hospital Part B and OPPS)

231.10 - Billing for Autologous Stem Cell Transplants

(Rev.3556, Issued: 07-01-2016; Effective: 1-27-16; Implementation: 10-3-16)

The hospital bills and shows all charges for autologous stem cell harvesting, processing, and transplant procedures based on the status of the patient (i.e., inpatient or outpatient) when the services are furnished. It shows charges for the actual transplant, described by the appropriate ICD procedure or CPT codes in Revenue Center 0362 (Operating Room Services; Organ Transplant, Other than Kidney) or another appropriate cost center.

The CPT codes describing autologous stem cell harvesting procedures may be billed and are separately payable under the Outpatient Prospective Payment System (OPPS) when provided in the hospital outpatient setting of care. Autologous harvesting procedures are distinct from the acquisition services described in Pub. 100-04, Chapter 3, §90.3.1 and §231.11 of this chapter for allogeneic stem cell transplants, which include services provided when stem cells are obtained from a donor and not from the patient undergoing the stem cell transplant.

The CPT codes describing autologous stem cell processing procedures also may be billed and are separately payable under the OPSS when provided to hospital outpatients.

231.11 - Billing for Allogeneic Stem Cell Transplants

(Rev.3556, Issued: 07-01-2016; Effective: 1-27-16; Implementation: 10-3-16)

1. Definition of Acquisition Charges for Allogeneic Stem Cell Transplants

Acquisition charges for allogeneic stem cell transplants include, but are not limited to, charges for the costs of the following services:

- National Marrow Donor Program fees, if applicable, for stem cells from an unrelated donor;
- Tissue typing of donor and recipient;
- Donor evaluation;
- Physician pre-procedure donor evaluation services;
- Costs associated with harvesting procedure (e.g., general routine and special care services, procedure/operating room and other ancillary services, apheresis services, etc.);
- Post-operative/post-procedure evaluation of donor; and
- Preparation and processing of stem cells.

Payment for these acquisition services is included in the OPSS APC payment for the allogeneic stem cell transplant when the transplant occurs in the hospital outpatient setting, and in the MS-DRG payment for the allogeneic stem cell transplant when the transplant occurs in the inpatient setting. The Medicare contractor does not make separate payment for these acquisition services, because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Unlike the acquisition costs of solid organs for transplant (e.g., hearts and kidneys), which are paid on a reasonable cost basis, acquisition costs for allogeneic stem cells are included in prospective

payment. Recurring update notifications describing changes to and billing instructions for various payment policies implemented in the OPSS are issued annually.

Acquisition charges for stem cell transplants apply only to allogeneic transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient himself or herself), because autologous transplants involve services provided to the beneficiary only (and not to a donor), for which the hospital may bill and receive payment (see Pub. 100-04, chapter 3, §90.3.1 and §231.10 of this chapter for information regarding billing for autologous stem cell transplants).

2. Billing for Acquisition Services

The hospital bills and shows acquisition charges for allogeneic stem cell transplants based on the status of the patient (i.e., inpatient or outpatient) when the transplant is furnished. See Pub. 100-04, chapter 3, §90.3.1 for instructions regarding billing for acquisition services for allogeneic stem cell transplants that are performed in the inpatient setting.

When the allogeneic stem cell transplant occurs in the outpatient setting, the hospital identifies stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in FL 42 of Form CMS-1450 (or electronic equivalent) by using revenue code 0819 (Other Organ Acquisition). Revenue code 0819 charges should include all services required to acquire stem cells from a donor, as defined above, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.

The transplant hospital keeps an itemized statement that identifies the services furnished, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges will be reflected in the transplant hospital's stem cell/bone marrow acquisition cost center. For allogeneic stem cell acquisition services in cases that do not result in transplant, due to death of the intended recipient or other causes, hospitals include the costs associated with the acquisition services on the Medicare cost report.

In the case of an allogeneic transplant in the hospital outpatient setting, the hospital reports the transplant itself with the appropriate CPT code, and a charge under revenue center code 0362 or another appropriate cost center. Selection of the cost center is up to the hospital.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

90 - Stem Cell Transplantation

(Rev.3556, Issued: 07-01-2016; 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.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.23, for a complete description of covered and noncovered conditions. For Part A hospital inpatient claims processing instructions, refer to Pub. 100-04, Chapter 3, section 90. The following sections contain claims processing instructions for all other claims.

B. Nationally Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

HCPCS Code 38240

ICD-9-CM Procedure Codes 41.02, 41.03, 41.05, and 41.08

ICD-10-PCS Procedure Codes 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, and 30263Y1

a. *Effective for services performed on or after August 1, 1978:*

- i. For the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91; see table below for ICD-10-CM codes)*

ICD-10	Description
<i>C91.01</i>	<i>Acute lymphoblastic leukemia, in remission</i>
<i>C91.11</i>	<i>Chronic lymphocytic leukemia of B-cell type in remission</i>
<i>C91.31</i>	<i>Prolymphocytic leukemia of B-cell type, in remission</i>
<i>C91.51</i>	<i>Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission</i>
<i>C91.61</i>	<i>Prolymphocytic leukemia of T-cell type, in remission</i>
<i>C91.91</i>	<i>Lymphoid leukemia, unspecified, in remission</i>
<i>C91.A1</i>	<i>Mature B-cell leukemia Burkitt-type, in remission</i>
<i>C91.Z1</i>	<i>Other lymphoid leukemia, in remission</i>
<i>C92.01</i>	<i>Acute myeloblastic leukemia, in remission</i>
<i>C92.11</i>	<i>Chronic myeloid leukemia, BCR/ABL-positive, in remission</i>
<i>C92.21</i>	<i>Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission</i>
<i>C92.31</i>	<i>Myeloid sarcoma, in remission</i>
<i>C92.41</i>	<i>Acute promyelocytic leukemia, in remission</i>
<i>C92.51</i>	<i>Acute myelomonocytic leukemia, in remission</i>
<i>C92.61</i>	<i>Acute myeloid leukemia with 11q23-abnormality in remission</i>
<i>C92.91</i>	<i>Myeloid leukemia, unspecified in remission</i>
<i>C92.A1</i>	<i>Acute myeloid leukemia with multilineage dysplasia, in remission</i>
<i>C92.Z1</i>	<i>Other myeloid leukemia, in remission</i>
<i>C93.01</i>	<i>Acute monoblastic/monocytic leukemia, in remission</i>

<i>C93.11</i>	<i>Chronic myelomonocytic leukemia, in remission</i>
<i>C93.31</i>	<i>Juvenile myelomonocytic leukemia, in remission</i>
<i>C93.91</i>	<i>Monocytic leukemia, unspecified in remission</i>
<i>C93.Z1</i>	<i>Other monocytic leukemia, in remission</i>
<i>C94.01</i>	<i>Acute erythroid leukemia, in remission</i>
<i>C94.21</i>	<i>Acute megakaryoblastic leukemia, in remission</i>
<i>C94.31</i>	<i>Mast cell leukemia, in remission</i>
<i>C94.81</i>	<i>Other specified leukemias, in remission</i>
<i>C95.01</i>	<i>Acute leukemia of unspecified cell type, in remission</i>
<i>C95.11</i>	<i>Chronic leukemia of unspecified cell type, in remission</i>
<i>C95.91</i>	<i>Leukemia, unspecified, in remission</i>
<i>D45</i>	<i>Polycythemia vera</i>

- ii. *For the treatment of aplastic anemia (ICD-9-CM codes 284.0 through 284.9; see table below for ICD-10-CM codes)*

<i>ICD-10</i>	<i>Description</i>
<i>D60.0</i>	<i>Chronic acquired pure red cell aplasia</i>
<i>D60.1</i>	<i>Transient acquired pure red cell aplasia</i>
<i>D60.8</i>	<i>Other acquired pure red cell aplasias</i>
<i>D60.9</i>	<i>Acquired pure red cell aplasia, unspecified</i>
<i>D61.01</i>	<i>Constitutional (pure) red blood cell aplasia</i>
<i>D61.09</i>	<i>Other constitutional aplastic anemia</i>
<i>D61.1</i>	<i>Drug-induced aplastic anemia</i>
<i>D61.2</i>	<i>Aplastic anemia due to other external agents</i>
<i>D61.3</i>	<i>Idiopathic aplastic anemia</i>
<i>D61.810</i>	<i>Antineoplastic chemotherapy induced pancytopenia</i>
<i>D61.811</i>	<i>Other drug-induced pancytopenia</i>
<i>D61.818</i>	<i>Other pancytopenia</i>
<i>D61.82</i>	<i>Myelophthisis</i>
<i>D61.89</i>	<i>Other specified aplastic anemias and other bone marrow failure syndromes</i>
<i>D61.9</i>	<i>Aplastic anemia, unspecified</i>

b. *Effective for services performed on or after June 3, 1985:*

- i. *For the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2; ICD-10-CM codes D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, and D81.9).*

- ii. *For the treatment of Wiskott-Aldrich syndrome (ICD-9-CM code 279.12; ICD-10-CM code D82.0)*

c. *Effective for services performed on or after August 4, 2010:*

For the treatment of Myelodysplastic Syndromes (MDS) (ICD-9-CM codes 238.72, 238.73, 238.74, 238.75 and ICD-10-CM codes D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.Z) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.

d. *Effective for services performed on or after January 27, 2016:*

- i. *Allogeneic HSCT for multiple myeloma (ICD-10-CM codes C90.00, C90.01, and C90.02) 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. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.*
- ii. *Allogeneic HSCT for myelofibrosis (MF) (ICD-10-CM codes C94.40, C94.41, C94.42, D47.4, and D75.81) 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. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.*
- iii. *Allogeneic HSCT for sickle cell disease (SCD) (ICD-10-CM codes D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, and D57.819) is covered by Medicare only for beneficiaries with severe, symptomatic SCD who participate in an approved prospective clinical study. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.*

II. Autologous Stem Cell Transplantation (AuSCT)

HCPCS Code 38241

ICD-9-CM Procedure Codes 41.01, 41.04, 41.07, and 41.09;

ICD-10-PCS Procedure Codes 30230AZ, 30230G0, 30230Y0, 30233G0, 30233Y0, 30240G0, 30240Y0, 30243G0, 30243Y0, 30250G0, 30250Y0, 30253G0, 30253Y0, 30260G0, 30260Y0, 30263G0, and 30263Y0

a. Effective for services performed on or after April 28, 1989:

Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched (ICD-9-CM codes 204.01, 205.01, 206.01, 207.01, 208.01; ICD-10-CM diagnosis codes C91.01, C92.01, C92.41, C92.51, C92.61, C92.A1, C93.01, C94.01, C94.21, C94.41, C95.01);

Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response (ICD-9-CM codes 200.00 - 200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88 or 202.90-202.98; ICD-10-CM diagnosis codes C82.00-C85.29, C85.80-C86.6, C96.4, and C96.Z-C96.9);

Recurrent or refractory neuroblastoma (see ICD-9-CM codes Neoplasm by site, malignant for the appropriate diagnosis code; if ICD-10-CM is applicable the following ranges are reported: C00 - C96, and D00 - D09 Resistant non-Hodgkin's lymphomas); or,

Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor (ICD-9-CM codes 201.00 - 201.98; ICD-10-CM codes C81.00 - C81.99).

b. Effective for services performed on or after October 1, 2000:

Single AuSCT is only covered for Durie-Salmon Stage II or III multiple myeloma patients (ICD-9-CM codes 203.00 or 238.6; ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9) 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 (ICD-9-CM code 277.3 or 277.39) who meet the following criteria:

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

<i>ICD-9-CM code</i>	<i>Description</i>	<i>ICD-10-CM code</i>	<i>Description</i>
<i>277.30</i>	<i>Amyloidosis, unspecified</i>	<i>E85.9</i>	<i>Amyloidosis, unspecified</i>
<i>277.39</i>	<i>Other amyloidosis</i>	<i>E85.8</i>	<i>Other amyloidosis</i>
		<i>E85.4</i>	<i>Organ-limited amyloidosis</i>

As the ICD-9-CM codes 277.3, and 277.39 for amyloidosis do not differentiate between primary and non-primary, A/B MACs (B) should perform prepay reviews on all claims with a diagnosis of ICD-9-CM code 277.3 to determine whether payment is appropriate.

If ICD-10-CM is applicable, as the applicable ICD-10 CM codes E85.4, E85.8, and E85.9 for amyloidosis do not differentiate between primary and non-primary, A/B MACs (B) should perform prepay reviews on all claims with a diagnosis of ICD-10-CM code E85.4, E85.8, and E85.9 to determine whether payment is appropriate.

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 27, 2016, allogeneic HSCT is not covered as treatment for multiple myeloma (if ICD-9-CM is applicable, ICD-9-CM code 203.00 and 203.01; or if ICD-10-CM is applicable, ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9).

II. Autologous Stem Cell Transplantation (AuSCT)

AuSCT is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare for the following conditions:

- a) Acute leukemia not in remission (if ICD-9-CM is applicable, ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00; or if ICD-10-CM is applicable, ICD-10-CM codes C91.00, C92.00, C93.00, C94.00, and C95.00)*

- b) *Chronic granulocytic leukemia (if ICD-9-CM is applicable, ICD-9-CM codes 205.10 and 205.11; or if ICD-10-CM is applicable, ICD-10-CM codes C92.10 and C92.11);*
- c) *Solid tumors (other than neuroblastoma) (if ICD-9-CM is applicable, ICD-9-CM codes 140.0 through 199.1; or if ICD-10-CM is applicable, ICD-10-CM codes C00.0 – C80.2 and D00.0 – D09.9);*
- d) *Up to October 1, 2000, multiple myeloma (if ICD-9-CM is applicable, ICD-9-CM code 203.00 and 203.01; or if ICD-10-CM is applicable, ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9);*
- e) *Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma (if ICD-9-CM is applicable, ICD-9-CM code 203.00 and 203.01; or if ICD-10-CM is applicable, ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9);*
- f) *Effective October 1, 2000, non-primary AL amyloidosis (see table below for applicable ICD codes); and,*
- g) *Effective October 1, 2000, through March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older (see table below for applicable ICD codes).*

ICD-9-CM codes	Description	ICD-10-CM codes	Description
277.30	<i>Amyloidosis, unspecified</i>	E85.9	<i>Amyloidosis, unspecified</i>
277.31	<i>Familial Mediterranean fever</i>	E85.0	<i>Non-neuropathic hereditary familial amyloidosis</i>
277.39	<i>Other amyloidosis</i>	E85.8	<i>Other amyloidosis</i>
		E85.1	<i>Neuropathic hereditary familial amyloidosis</i>
		E85.2	<i>Hereditary familial amyloidosis, unspecified</i>
		E85.3	<i>Secondary systemic amyloidosis</i>
		E85.4	<i>Organ-limited amyloidosis</i>

As the ICD-9-CM code 277.3 and 277.39 for amyloidosis do not differentiate between primary and non-primary, A/B MACs (B) should perform prepay reviews on all claims with a diagnosis of ICD-9-CM code 277.3 and 277.39 to determine whether payment is appropriate.

If ICD-10-CM is applicable, as the applicable ICD-10 CM codes E85.4, E85.8, and E85.9 for amyloidosis do not differentiate between primary and non-primary, A/B MACs (B) should perform prepay reviews on all claims with a diagnosis of ICD-10-CM code E85.4, E85.8, and E85.9 to determine whether payment is appropriate.

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.

E. Suggested MSN and RA Messages

The contractor shall use an appropriate MSN and RA message such as the following:

MSN - 15.4, The information provided does not support the need for this service or item;

RA - 150, Payment adjusted because the payer deems the information submitted does not support this level of service.

F. Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS), Multiple Myeloma, Myelofibrosis (MF), and for Sickle Cell Disease (SCD)

I. Background

Effective for services performed on or after August 4, 2010, contractors shall pay for claims for allogeneic HSCT for the treatment of Myelodysplastic Syndromes (MDS) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.

Effective for services performed on or after January 27, 2016, contractors shall pay for claims for allogeneic HSCT for the treatment of multiple myeloma, myelofibrosis (MF), and for sickle cell disease (SCD) pursuant to CED, in the context of a Medicare-approved, prospective clinical study.

Refer to Pub.100-03, National Coverage Determinations Manual, Chapter 1, section 110.23, for more information about this policy, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3, for information on inpatient billing of this CED.

II. Adjudication Requirements

Payable Conditions. For claims with dates of service on and after August 4, 2010, contractors shall pay for claims for allogeneic HSCT for MDS when the service was provided pursuant to a Medicare-approved clinical study under CED; these services are paid only in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X).

Contractors shall require the following coding in order to pay for these claims:

- *Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3.1.*
- *If ICD-9-CM is applicable, for Inpatient Hospital Claims: ICD-9-CM procedure codes 41.02, 41.03, 41.05, and 41.08 or,*
- *If ICD-10-CM is applicable, ICD-10-PCS, procedure codes 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, and 30263Y1*
- *If Outpatient Hospital or Professional Claims: HCPCS procedure code 38240*
- *If ICD-9-CM is applicable, ICD-9-CM diagnosis codes 238.72, 238.73, 238.74, 238.75 or,*
- *If ICD-10-CM is applicable, ICD-10-CM codes D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.Z,*
- *Professional claims only: place of service codes 19, 21, or 22.*

Payable Conditions. For claims with dates of service on and after January 27, 2016, contractors shall pay for claims for allogeneic HSCT for multiple myeloma, myelofibrosis (MF), and for sickle cell disease (SCD) when the service was provided pursuant to a Medicare-approved clinical study under CED; these services are paid only in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X).

Contractors shall require the following coding in order to pay for these claims:

- *Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3.1.*
- *ICD-10-PCS codes 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, and 30263Y1*
- *If Outpatient Hospital or Professional Claims: HCPCS procedure code 38240*
- *ICD-10-CM diagnosis codes C90.00, C90.01, C90.02, C94.40, C94.41, C94.42, D47.4, D75.81, D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, and D57.819*
- *Professional claims only: place of service codes 19, 21, or 22.*

Denials. Contractors shall deny claims failing to meet any of the above criteria. In addition, contractors shall apply the following requirements:

- *Providers shall issue a hospital issued notice of non-coverage (HINN) or advance beneficiary notice (ABN) to the beneficiary if the services performed are not provided in accordance with CED.*
- *Contractors shall deny claims that do not meet the criteria for coverage with the following messages:*

CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – Patient Responsibility (PR) if HINN/ABN issued, otherwise Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

MSN 15.20 – The following policies [NCD 110.23] were used when we made this decision. (Las siguientes políticas [NCD 110.23] fueron utilizadas cuando se tomó esta decisión.)