

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2062	Date: October 8, 2010
	Change Request 7137

SUBJECT: Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after August 4, 2010, contractors shall be aware that the use of allogeneic HSCT for treatment of MDS 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 110.8.1, of the NCD Manual, for further information.

EFFECTIVE DATE: AUGUST 4, 2010

IMPLEMENTATION DATE: November 10, 2010

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	3/90.3.1/Allogeneic Stem Cell Transplantation
R	32/Table of Contents
N	32/90.6/Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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**

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

Attachment - Business Requirements

Pub. 100-04

Transmittal: 2062

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SUBJECT: Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

EFFECTIVE DATE: AUGUST 4, 2010

IMPLEMENTATION DATE: November 10, 2010

I. GENERAL INFORMATION

A. Background: Myelodysplastic Syndrome (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. On November 10, 2009, the Centers for Medicare & Medicaid Services (CMS) accepted a formal request from several bone marrow and cancer organizations and societies. The requestors asked for national coverage of allogeneic hematopoietic stem cell transplantation (HSCT) for Medicare beneficiaries "who would either be at high risk for progression to leukemia or be at risk for MDS complications that place them at high risk for death or prevent the future possibility of a transplant."

B. Policy: On August 4, 2010, CMS issued a final decision stating that it believes the evidence does not demonstrate that the use of allogeneic HSCT improves health outcomes in Medicare beneficiaries with MDS. Therefore, allogeneic HSCT for MDS is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). However, allogeneic HSCT for MDS is reasonable and necessary under §1862(a)(1)(E) of the Act and therefore covered by Medicare ONLY if provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED).

C. Identifying HSCT for MDS Provided Pursuant to a Medicare-approved Clinical Study under CED:

1. Use of Existing Coding Conventions for Identifying Clinical Trials

Contractors shall use existing clinical trial coding conventions to help identify on a claim that the HSCT for MDS was provided pursuant to a Medicare-approved clinical study under CED, as follows:

a. Inpatient Hospital Claims

- Value Code D4 and 8-digit clinical trial number (when present on the claim) – Refer to Transmittal 310, Change Request 5790, January 18, 2008
- ICD-9 diagnosis code V70.7 - Refer to TR 310, CR 5790, January 18, 2008
- Condition Code 30 - Refer to TR 310, CR 5790, January 18, 2008

b. Professional claims & Outpatient Hospital Claims

- ICD-9 diagnosis code V70.7
- HCPCS modifier Q0
- HCPCS OR ICD-9-CM diagnosis or procedure code (if applicable); for HSCT for MDS, the required diagnosis and procedure coding are specified as noted below.

- 8-digit clinical trial number (when present on the claim)

c. Contractors shall apply the additional coding requirements in the business requirements below.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
7137.04.1	Effective for claims with dates of service on and after August 4, 2010, contractors shall be aware that the use of allogeneic HSCT for treatment of MDS 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 110.8.1, of the NCD Manual, Pub. 100-04, chapter 32, sections 69 and 90.6, and chapter 3, section 90.3.1, of the Claims Processing Manual, for further information.	X		X	X						
7137.04.2	Contractors shall pay inpatient hospital claims (TOB 11X) with discharges on or after August 4, 2010, for HSCT for the treatment of MDS ONLY if they contain all of the following: HSCT-ICD-9-CM procedure codes 41.02, 41.03, 41.05, or 41.08 MDS-ICD-9-CM diagnosis code 238.75 V70.7 CC 30	X		X							
7137.04.2.1	Contractors shall pay outpatient hospital claims (TOBs 13X) with dates of service on or after August 4, 2010, for HSCT for the treatment of MDS ONLY if they contain all of the following: HSCT CPT code 38240 MDS ICD-9-CM diagnosis code 238.75 Clinical Trial ICD-9-CM diagnosis code - V70.7 Clinical Trial Procedure Code Modifier Q0	X		X							
7137.04.2.2	For claims with dates of service on or after August 4, 2010, 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 MDS ONLY if they contain all of the following: HSCT CPT code 38240 MDS ICD-9-CM diagnosis code 238.75 Clinical Trial ICD-9-CM diagnosis code - V70.7	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	Clinical Trial Procedure Code Modifier Q0										
7137.04.3	<p>For claims with dates of service on or after August 4, 2010, contractors shall pay professional claims for HSCT for the treatment of MDS ONLY if they contain all of the following:</p> <p>HSCT CPT code 38240 MDS ICD-9-CM diagnosis code 238.75 Clinical Trial ICD-9-CM diagnosis code - V70.7 Clinical Trial Procedure Code Modifier Q0 POS Code 21 and 22</p>	X			X						
7137.04.4	<p>Contractors shall deny claims for HSCT for the treatment of MDS that do not contain all of the coding included in BRs 7137.04.2, 7137.04.2.1, 7137.04.2.2, and 7137.04.3 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 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 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>	X		X	X						
7137.04.5	For claims with dates of service between August 4, 2010, and the implementation date of this CR, contractors shall perform necessary adjustments only when affected claims are brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
7137.04.6	<p>A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your 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.</p>	X		X	X						

IV. SUPPORTING INFORMATION

Section a: for any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:
7137.04.2 7137.04.2.1 7137.04.2.2 7137.04.3	Note that the 8-digit clinical trial number may also appear on the claim, at the discretion of the provider (along with Value Code D4 for inpatient claims).

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: Roya Lotfi, Coverage, 410-786-4072, Roya.Lotfi@cms.hhs.gov, Wanda Belle, 410-786-7491, wanda.belle@cms.hhs.gov, Patti Brocato-Simons, Coverage, 410-786- 0261, Patricia.BrocatoSimons@cms.hhs.gov, Institutional Claims Processing: Sarah Shirey-Losso, 410-786-0187, Sarah.Shirey-Losso@cms.hhs.gov, Cami DiGiacomo, 410-786-5888, Cami.DiGiacomo@cms.hhs.gov,

Practitioner Claims Processing: Claudette Sikora, 410-786-5618, Claudette.sikora@cms.hhs.gov, Louisa Rink, 410-786-6359, louisa.rink@cms.hhs.gov.

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

A. For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

Section A: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. For Medicare Administrative Contractors (MACs):

Section B: 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.

90.3.1 - Allogeneic Stem Cell Transplantation

(Rev. 2062, Issued: 10-08-10, Effective: 08-04-10, Implementation: 11-10-10)

A. General

Allogeneic stem cell transplantation (ICD-9-CM Procedure Codes 41.02, 41.03, 41.05, and 41.08, CPT-4 Code 38240) 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 Manual, chapter 1, section 110.8.1, for more information.*

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

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

- For the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91), or aplastic anemia (ICD-9-CM codes 284.0 through 284.9) when it is reasonable and necessary; and

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

- For the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2), and for the treatment of Wiskott-Aldrich syndrome (ICD-9-CM 279.12).

C. Non-Covered Conditions

3. Effective for services performed on or after May 24, 1996:

- Allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.00 and 203.01).

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

The Centers for Medicare & Medicaid Services (CMS) issued an NCD stating that it believes the evidence does not demonstrate that the use of allogeneic hematopoietic stem cell transplantation (HSCT) improves health outcomes in Medicare beneficiaries with Myelodysplastic Syndrome (MDS). Therefore, allogeneic HSCT for MDS is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

However, allogeneic HSCT for MDS is reasonable and necessary under §1862(a)(1)(E) of the Act and therefore covered by Medicare ONLY if provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). These services are covered in

both the inpatient and outpatient hospital setting. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.8.1, for further information about this policy, and Pub. 100-04, MCP Manual, chapter 32, section 90.6, for information on CED.

NOTE: Coverage for conditions other than these specifically designated as covered or non-covered in the *CP or NCD Manuals are left to local Medicare contractor discretion.*

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev. 2062 Issued: 10-08-10)

90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

A. Background

Myelodysplastic Syndrome (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.

On August 4, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) stating that CMS believes that the evidence does not demonstrate that the use of allogeneic hematopoietic stem cell transplantation (HSCT) improves health outcomes in Medicare beneficiaries with MDS. Therefore, allogeneic HSCT for MDS is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). However, allogeneic HSCT for MDS is reasonable and necessary under §1862(a)(1)(E) of the Act and therefore covered by Medicare ONLY if provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). Refer to Pub.100-03, NCD Manual, chapter 1, section 110.8.1, for more information about this policy, and Pub. 100-04, MCP Manual, chapter 3, section 90.3.1, for information on CED.

B. Adjudication Requirements

Payable Conditions. For claims with dates of service on and after August 4, 2010, contractors shall pay for claims for 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, MCP Manual, chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100-04, MCP Manual, chapter 3, section 90.3.3.*
- *Inpatient Hospital Claims: ICD-9-CM procedure codes 41.02, 41.03, 41.05, and 41.08*
- *Outpatient Hospital and Professional Claims: procedure code 38240*
- *ICD-9-CM diagnosis code 238.75*
- *Professional claims only: place of service codes 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.)