

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 12781</b>	<b>Date: August 21, 2024</b>
	<b>Change Request 13604</b>

**Transmittal 12627 issued May 09, 2024, is being rescinded and replaced by Transmittal 12781, dated August 21, 2024, to update business requirements 13604-04.2, and in 13604-04. 3 to add two procedure codes and revise the references to the remarks language. Business requirements BR 13604-04.3.1 and 13604-04.4 have been removed. The corresponding changes have been made to the Claims Processing Manual (pub. 100-04) IOM and the ICD-10 spreadsheet for pub. 100-04 has also been updated and replaced. Revisions have been also updated in the companion manual Publication 100-03. All other information remains the same.**

**SUBJECT: Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors that CMS is expanding Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with MDS who meet specific criteria.

**EFFECTIVE DATE: March 6, 2024**

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

**IMPLEMENTATION DATE: October 7, 2024**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	3/90/3/1-Allogeneic for 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: 12781	Date: August 21, 2024	Change Request: 13604
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**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors that CMS is expanding Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with MDS who meet specific criteria.

## **II. GENERAL INFORMATION**

**A. Background:** The purpose of this Change Request (CR) is to inform contractors that CMS is expanding Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with MDS who meet specific criteria.

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.

Myelodysplastic Syndromes (MDS) are a heterogeneous group of hematologic disorders characterized by (1) cytopenia (decreased number of red blood cells, white blood cells and platelets) due to bone marrow failure and (2) the potential development of acute myeloid leukemia (AML). The bone marrow does not produce enough healthy, functioning blood cells. For treatment purposes, patients with MDS are often stratified into risk groups based on the potential development of AML, which varies widely across MDS subtypes.

**B. Policy:** On March 6, 2024, CMS issued a final decision under National Coverage Determination (NCD) 110.23 to expand Medicare coverage for allogeneic hematopoietic stem cell transplant using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with MDS who have prognostic risk scores of:

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

For these patients, the evidence demonstrates that the treatment is reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (the Act).

In addition, coverage of all other indications for stem cell transplantation not otherwise specified will be made by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act.

Refer to Publication (Pub) 100-03, NCD Manual, chapter 1, section 110.23, for information regarding this NCD and Pub. 100-04, Claims Processing Manual (CPM), chapter 3, section 90.3.1 for further billing instructions.

### III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13604 - 04.1	<p>Effective for claims with dates of service on and after March 6, 2024, contractors shall be aware that Medicare is expanding coverage for allogeneic (HSCT) using bone marrow, peripheral blood or umbilical cord blood stem cell products for Medicare patients with MDS who have prognostic risk scores of:</p> <ul style="list-style-type: none"> <li>• <math>\geq 1.5</math> (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or</li> <li>• <math>\geq 4.5</math> (high or very high) using the International Prognostic Scoring System - Revised (IPSS-R), or</li> <li>• <math>\geq 0.5</math> (high or very high) using the Molecular International Prognostic Scoring System (IPSS-M).</li> </ul> <p>In addition, coverage of all other indications for stem cell transplantation not otherwise specified will be made by local MACs under section 1862(a)(1)(A) of the Act. Please see Pub. 100-03, chapter 1, section 110.23, of the NCD Manual, and Pub. 100-04,</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	chapter 3, section 90.3.1, of the CPM, for further instructions.									
13604 - 04.2	Contractors shall end-date the ICD-10 Diagnosis Codes and ICD-10-PCS Codes effective March 5, 2024, that are included in existing edits for allogeneic (HSCT) for (MDS) in the context of a Medicare-approved clinical study under a Coverage with Evidence Development (CED).  Note: CED should remain for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease.	X	X			X	X			
13604 - 04.3	Effective for claims with dates of service on and after March 6, 2024, contractors shall allow payment for HSCT for MDS under NCD 110.23, when the professional claim for HCPCS code 38240 or institutional claim (TOB 11 X only) for ICD-10-PCS 30233X2, 30233X3, 30243X2, 30243X3, XW133C8, or XW143C8 included:  <ul style="list-style-type: none"> <li>• Modifier KX to indicate that they have a qualifying prognostic risk score in their medical record (professional claims only)</li> <li>• For institutional claims, (TOB 11 X only) providers report the CR13604 in Loop 2300 Billing Note NTE02, or in the remark field locator (FL)80 on Line 1, position 1, on DDE or paper claims to indicate that they have qualifying prognostic</li> </ul>					X	X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>risk score in their medical record; and</p> <ul style="list-style-type: none"> <li>• <ul style="list-style-type: none"> <li>○ Intermediate-2 or high (IPSS), or,</li> <li>○ high or very high (IPSS-R), or,</li> <li>○ high or very high (IPSS-M), and,</li> </ul> </li> <li>• One of the following ICD-10-CM Diagnosis Codes:</li> </ul> <p>D46.A D46.B D46.C</p> <p>D46.Z</p> <p>D46.0</p> <p>D46.1</p> <p>D46.4 D46.9 D46.20 D46.21 D46.22</p> <p>Please note the existing PCS codes from CRs 9861 and 13507 related to Allogeneic also apply to claims after 3/6/24. (30233G2, 30233G3, 30233U2, 30233U3, 30233Y2, 30233Y3, 30243G2, 30243G3, 30243U2, 30243U3, 30243Y2, 30243Y3.)</p>									
13604 - 04.3.1	This business requirement has been deleted	X								
13604 - 04.3.2	Contractors shall deny claims for HSCT for MDS if not submitted as per BR 13604-04.3	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13604 - 04.3.3	<p>Contractors shall use the following messages, as appropriate, when denying claims for HSCT for MDS that do not meet billing requirements as per 13604-04.3:</p> <p>MSN 9.4 - This item or service was denied because information required to make payment was incorrect.</p> <p>Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta.</p> <p>CARC 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)</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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code: CO</p>	X	X							
13604 - 04.4	This business requirement has been deleted.	X								
13604 - 04.4.1	Effective for claims with dates of service on and after March 6, 2024, contractors shall deny claims for HSCT for MDS according to NCD 110.23, if					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	submitted with a Type of Bill (TOB) other than TOB 11X.									
13604 - 04.4.2	<p>Contractors shall use the following messages when denying claims with a TOB other than TOB 11X:</p> <p>MSN 9.4 - This item or service was denied because information required to make payment was incorrect.</p> <p>Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta.</p> <p>CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC MA30 - Missing/incomplete/invalid type of bill.</p> <p>Group Code: CO</p>	X								
13604 - 04.5	For claims with dates of service prior to the October 6, 2024 implementation date of this CR, contractors shall perform necessary adjustments only when affected claims are brought to their attention.	X	X							

**IV. PROVIDER EDUCATION TABLE**



Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13604 - 04.6	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.	X	X			

**V. 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**

**VI. CONTACTS**

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

**VII. FUNDING**

**Section A: For Medicare Administrative Contractors (MACs):**

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**ATTACHMENTS: 1**