CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12868	**Date: October 7, 2024**
	Change Request 13604

Transmittal 12813 issued August 28, 2024, is being rescinded and replaced by Transmittal 12868, dated October 7, 2024, to revise line 8 of the attached spreadsheet to align with billing guidance in Claims Processing Manual (CPM), and revise Pub 100-04 BR 04.3.3 and CPM to add Group Code PR to messaging. This correction does not make any revisions to Pub. 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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: 12868	Date: October 7, 2024	Change Request: 13604

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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:

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

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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13604 - 04.1	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: • ≥ 1.5 (Intermediate-2 or high) using the International Prognostic Scoring System (IPSS), or • ≥ 4.5 (high or very high) using the International Prognostic Scoring System - Revised (IPSS-R), or • ≥ 0.5 (high or very high) using the Molecular International Prognostic Scoring System (IPSS-M). 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,	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	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: • Modifier KX to indicate that they have a qualifying prognostic risk score in their medical record (professional claims only) • 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					X	X			

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	risk score in their medical record; and • o Intermediate-2 or high (IPSS), or, o high or very high (IPSS-R), or, o high or very high (IPSS-M), and, • One of the following ICD-10-CM Diagnosis Codes: D46.A D46.B D46.C D46.Z D46.0 D46.1 D46.4 D46.9 D46.20 D46.21 D46.22 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.)									
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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13604 - 04.3.3	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: MSN 9.4 - This item or service was denied because information required to make payment was incorrect. Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta. 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.) 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 www.cms.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: CO or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item.)	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
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 submitted with a Type of Bill (TOB) other than TOB 11X.					X				
13604 - 04.4.2	Contractors shall use the following messages when denying claims with a TOB other than TOB 11X: MSN 9.4 - This item or service was denied because information required to make payment was incorrect. Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta. 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. RARC MA30 - Missing/incomplete/invalid type of bill. Group Code: CO	X								
13604 - 04.5	For claims with dates of service prior to the October 6, 2024 implementation date of this CR,	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	contractors shall perform necessary adjustments only when affected claims are brought to their attention.									

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):
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: 1

Medicare Claims Processing Manual

Chapter 3 - Inpatient Hospital Billing

(Rev. 12868; Issued: 10-07-24)

90.3.1 - Allogeneic for Stem Cell Transplantation

(Rev. 12868; Issued:10-07-24 Effective:03-06-24; Implementation: 10-07-24)

A. Definition of Acquisition Charges for Allogeneic Stem Cell Transplants

1. Effective for Cost Reporting Periods Beginning Prior to October 1, 2020

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. Effective for Cost Reporting Periods Beginning on or After October 1, 2020

Allogeneic hematopoietic stem cell acquisition costs are as follows:

- Registry fees from a national donor registry described in 42 U.S.C. 274k, 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 the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services), and transportation costs of stem cells if the recipient hospital incurred or paid such costs.

- Post-operative/post-procedure evaluation of donor.

- Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

Effective for cost reporting periods beginning on or after October 1, 2020, a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual during such a period, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis.

Payment for allogeneic hematopoietic stem cell acquisition services continues to be included in the OPPS APC payment when the transplant occurs in the outpatient setting.

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).

B. 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, allogeneic bone marrow/stem cell acquisition charges shall be billed using revenue code 0815. Revenue code 0815 (Allogeneic Stem Cell Acquisition/Donor Services) charges should include all services required to acquire stem cells from a donor, as defined above. Effective for discharges occurring on or after October 1, 2021, such charges are not considered for the IPPS outlier calculation when billed for an allogeneic stem cell transplant.

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 in collecting allogeneic hematopoietic stem cells including all invoices or statements for purchased services for all donors and their service charges. Records must be for the person receiving the service (donor or recipient). Beginning October 1, 2020, for all donor sources, the hospital must identify the prospective recipient and include the recipient's Medicare beneficiary identification number. 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. The hospital shows charges for acquiring allogeneic hematopoietic stem cells for transplant in revenue code 0815.

C. Coverage Expansion for Allogeneic Stem Cell Services Effective March 6, 2024

On March 6, 2024, CMS issued a final decision to expand Medicare coverage for allogeneic hematopoietic stem cell transplant (HSCT) using bone marrow, peripheral blood, or umbilical cord blood stem cell products for Medicare patients with myelodysplastic (MDS) syndromes who have prognostic risk scores of:

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

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 under section 1862(a)(1)(A) of the Act.

C. Billing for Allogeneic Stem Cell Services on or after March 6, 2024

1. Effective for claims with dates of service on and after March 6, 2024

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:

- *Modifier KX to indicate that they have a qualifying prognostic risk score in their medical record (professional claims only);*

- *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 risk score in their medical record; and*

    - *Intermediate-2 or high (IPSS), or,*
    - *high or very high (IPSS-R), or,*
    - *high or very high (IPSS-M), and,*

- *One of the following ICD-10-CM Diagnosis Codes:*

D46.A
D46.B
D46.C
D46.Z
D46.0
D46.1
D46.4
D46.9
D46.20

D46.21
D46.22

Please note the existing PCS codes related to Allogeneic also apply to claims after March 6, 2024. (30233G2, 30233G3, 30233U2, 30233U3, 30233Y2, 30233Y3, 30243G2, 30243G3, 30243U2, 30243U3, 30243Y2, 30243Y3.)

2. Messaging Effective March 6, 2024

Contractors shall use the following messages, as appropriate, when denying claims without required diagnostic or procedure coding:

MSN 9.4 - This item or service was denied because information required to make payment was incorrect.

Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta.
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.)

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 www.cms.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: CO

Contractors shall use the following messages, as appropriate, when denying claims for HSCT for MDS, if submitted with a TOB other than TOB 11X:

Contractors shall use the following messages when denying claims with a TOB other than TOB 11X:

MSN 9.4 - This item or service was denied because information required to make payment was incorrect.

Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta.

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.

RARC MA30 - Missing/incomplete/invalid type of bill.

Group Code: CO or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item.)