CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11707	**Date: November 17, 2022**
	Change Request 12979

SUBJECT: Correction to Stem Cell Transplantation Instructions in Chapter 3, Section 90.3

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update stem cell transplantation instructions to restore information that was omitted in error in an earlier transmittal.

EFFECTIVE DATE: December 20, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 20, 2022

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/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: 11707	Date: November 17, 2022	Change Request: 12979

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I. GENERAL INFORMATION

A. Background: Change Request (CR) 12512, issued in December 2021, updated manual instructions in Chapter 3, section 90.3 for stem cell transplantation. CR 12602, issued in May 2022, revised the same section to update procedure codes to be consistent with recent National Coverage Determination updates. In doing so, CR 12602 removed instructions issued in the earlier CR. The current CR reissues section 90.3 to ensure it contains the instructions from both prior updates.

B. Policy: This Change Request contains no new policy. It ensures previously issued manual instructions are accurately reflected in Chapter 3.

II. 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	
12979.1	The contractor shall be aware of the manual updates in Pub 100-04, Chapter 3, Section 90.3.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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): Yvette Rivas, yvette.rivas@cms.hhs.gov , Wil Gehne, wilfried.gehne@cms.hhs.gov

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

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(Rev. 11707; Issued:11-17-22)

90.3 - Stem Cell Transplantation

(Rev. 11707; Issued: 11-17-22; Effective: 12-20-22; Implementation: 12-20-22)

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. *Effective for cost reporting periods beginning on or after October 1, 2020, for subsection (d) hospitals (that is, hospitals paid under the IPPS) furnishing an allogeneic hematopoietic stem cell transplant, such transplant is defined, in accordance with Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94), as the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.*
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 *through September 30, 2010*, these cases were assigned to MS-DRG 009, Bone Marrow Transplant. *Effective October 1, 2010, MS-DRG 009 was deleted and two new separate MS-DRGs were created: MS-DRG 014 (Allogeneic Bone Marrow Transplant) and MS-DRG 015 (Autologous Bone Marrow Transplant). Effective October 1, 2011, Autologous Bone Marrow Transplant was subdivided into two severity levels, deleting MS-DRG 015 and creating two new MS-DRGs: MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC); and MS-DRG 017 (Autologous Bone Marrow Transplant without CC/MCC).*

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 on or before 9/30/2015*; ICD-10-PCS codes 30230G2,30230G3, 30230Y2, 30230Y3, 30233G2, 30233G3, 30233Y2, 30233Y3, 30240G2, 30240G3, 30240Y2, 30240Y3, 30243G2, 30243G3, 30243Y2, and 30243Y3, *as of October 1, 2015*) 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, chapter 32, section 90, for information on coding. *For the latest ICD-10-PCS codes defining MS-DRG 014 for allogeneic stem cell transplants, see the ICD-10-CM/PCS MS-DRG Definitions Manual, available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

  Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. *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.*

  Services to the donor include physician services, hospital care in connection with screening the *donor's* stem cell*s*, and ordinary follow-up care. *For a detailed listing of items comprising allogeneic hematopoietic stem cell acquisition costs, see section 90.3.1.A. of this chapter.*

NOTE: Please note that effective September 30, 2021 PCS codes for Allogeneic SCT 30230G2, 30230G3, 30230Y2, 30230Y3, 30240G2, 30240G3, 30240Y2, 30240Y3 and PCS codes for Autologous SCT 30230C0, 30230G0, 30230Y0, 30240C0, 30240G0, 30240Y0 are end-dated.

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-10-PCS codes 30230C0, 30230G0, 30230Y0, 30233G0, 30233C0, 30233Y0, 30240C0, 30240G0, 30240Y0, 30243C0, 30243G0, and 30243Y0) 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, chapter 32, section 90, for information on coding.

NOTE: Please note that effective September 30, 2021 PCS codes for Allogeneic SCT 30230G2, 30230G3, 30230Y2, 30230Y3, 30240G2, 30240G3, 30240Y2, 30240Y3 and PCS codes for Autologous SCT 30230C0, 30230G0, 30230Y0, 30240C0, 30240G0, 30240Y0 are end-dated.

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, 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 §l862(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, 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.