

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



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Related Change Request (CR) #: CR 9620

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Effective Date: January 27, 2016

Related CR Transmittal #: R193NCD and R3556CP

Implementation Date: October 3, 2016

Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease, and Myelodysplastic Syndromes

Note: This article was revised on September 26, 2016, to correct the language regarding the submission of professional claims on page 4 of the article. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians and providers submitting stem cell transplantation claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9620, from which this article was developed, notifies providers that effective for claims with dates of service on and after January 27, 2016, for the use of allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for treatment of Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease is covered by Medicare, but only if provided in the context of a Medicare-approved clinical study meeting specific criteria under the Coverage with Evidence Development (CED) paradigm.

CR9620 also clarifies the ICD-9 and ICD-10 diagnosis codes for allogeneic HSCT for treatment of Myelodysplastic Syndromes (MDS) in the context of a Medicare-approved, prospective clinical study under CED. Specifically, for dates of service on or after August 4, 2010, through September 30, 2015, the ICD-9-CM diagnosis codes are 238.72, 238.73, 238.74, or 238.75 AND clinical trial ICD-9-CM diagnosis code V70.7. For dates of service on or after October 1, 2015, the ICD-10-CM diagnosis codes are D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, or D46.Z AND clinical trial

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ICD-10-CM diagnosis code Z00.6. Make sure your billing staff is aware of these determinations.

Background

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, the Centers for Medicare & Medicaid Services (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 CED. CR 7137 (see the article, MM7137 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7137.pdf>) provides specific ICD-9 related coding and claims processing requirements regarding this particular coverage decision, and CRs 8197 and 8691 (see MM8197 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8197.pdf> and MM8691 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8691.pdf>) 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.

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 Section 1862(a)(1)(E) of the Social Security Act (the Act) for allogeneic HSCT for the following indications:

- Multiple Myeloma
- Myelofibrosis
- Sickle Cell Disease

Refer to the following Medicare manual sections for more information regarding this NCD and further billing instructions specific to this NCD and the business requirements specific to CR9620:

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- Chapter 1, Section 110.23, of the “Medicare NCD Manual,” which is attached to the CR9620 NCD transmittal at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R191NCD.pdf>
- Chapter 1, Section 310.1, of the “Medicare NCD Manual,” available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf, and
- Chapter 32, Sections 69 and 90, of the “Medicare Claims Processing Manual,” available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>.

Please note, Chapter 1, Section 110.8.1 has been removed from the "NCD Manual" and incorporated into Chapter 1, Section 110.23.

In addition to the diagnosis codes detailed at the beginning of this article, providers need to be aware of the other billing requirements, as follows:

Inpatient Claims

For claims submitted on type of bill 11X for discharges on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An ICD-10-PCS procedure code of 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, or 30263Y1 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND
- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
 - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
 - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
 - 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

Outpatient Claims

For claims submitted on type of bill 13X or 85X for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND

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- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
 - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
 - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
 - 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

Method II Critical Access Hospital (CAH) Claims

For claims submitted on type of bill 85X with Revenue Codes 96X, 97X, or 98X for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND
- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
 - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
 - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
 - 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

Professional Claims

For professional claims submitted for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- The Q0 modifier AND
- A Place of Service Code of 19, 21, or 22 along with the appropriate ICD-10-CM diagnosis code of:
 - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
 - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR

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- 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

For all of the above claims types submitted without the requisite coding, MACs will deny the claims using the following messages:

- Claim Adjustment Reason Code (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.
- Remittance Advice Remarks Code (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 an Advance Beneficiary Notice (ABN)/Hospital Notice on Non-Coverage (HINN), otherwise Contractual Obligation (CO)

For claims with dates of service prior to the implementation date of CR9620, MACs shall perform necessary adjustments only when the provider brings such claims to the attention of their MAC.

Additional Information

The official instruction, CR9620, consists of two transmittals. The first updates the “Medicare Claims Processing Manual” at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3556CP.pdf>. The second transmittal updates the “Medicare NCD Manual” at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R193NCD.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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Document History

Date of Change	Description
September 26, 2016,	The article was revised to correct the language on page 4 regarding professional claims.
July 5, 2016	The article was revised due to an updated Change Request (CR). That CR revised Shared System Maintainer (SSM) responsibility. The transmittal number, CR release date and link to the transmittal also changed.
May 9, 2016	Initial article release

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