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## Office of Inspector General Report: Stem Cell Transplantation

**Note:** We revised this article on March 31, 2020, to update the web links. All other information is unchanged.

### Provider Types Affected

This article is intended for providers billing Medicare Administrative Contractors (MACs) for services related to stem cell transplantation.

### Provider Action Needed

The Office of the Inspector General (OIG) recently completed a review of Medicare claims related to stem cell transplants. This article is intended to address issues of incorrect billing as a result of the [February 2016 OIG report](#) and to clarify coverage of stem cell transplantation. This article does not introduce any new policies. It is intended to clarify the billing for stem cell services.

### Background

The Centers for Medicare & Medicaid Services (CMS) has a coverage policy for stem cell transplantation, and the “Medicare National Coverage Determination (NCD) Manual” ([Publication 100-03, Section 110.23](#)) states that stem cell transplantation is a process in which stem cells are harvested from either a patient’s or donor’s bone marrow or peripheral blood for intravenous infusion.

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## **Types of Stem Cell Transplants that are covered:**

Medicare covers allogeneic and autologous transplants. Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses.

### **1. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)**

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect.

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.

### **2. Autologous Stem Cell Transplantation (AuSCT)**

Autologous stem cell transplantation is a technique for restoring stem cells using the patient's own previously stored cells. Autologous stem cell transplants (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.

In their [February 2016 OIG](#) report, the OIG determined that Medicare paid for many stem cell transplant procedures incorrectly. The main finding was that providers billed these procedures as inpatient when they should have been submitted as outpatient or outpatient with observation services. The key points in the report include:

- According to an independent medical review contractor contracted by OIG for this report, stem cell transplants are routinely performed in the outpatient setting.
- Hospitals may have incorrectly thought that stem cell transplantation was on CMS's list of inpatient-only procedures.

### ***The Two-Midnight Rule***

To assist providers in determining whether inpatient admission is appropriate for payment under Medicare Part A, CMS adopted the Two-Midnight rule for admissions beginning on or after October 1, 2013. This rule established Medicare payment policy regarding the benchmark criteria to use when determining whether an inpatient admission is reasonable and necessary for purposes of payment under Medicare Part A.

In general, the Two-Midnight rule states that:

- Inpatient admissions will generally be payable under Part A if the admitting practitioner expects the patient to require a hospital stay that crosses two midnights and the medical record supports that reasonable expectation.
- Medicare Part A payment is generally not appropriate for hospital stays not expected to span at least two midnights.

The Two-Midnight rule also specifies that all treatment decisions for beneficiaries are based on the medical judgment of physicians and other qualified practitioners. The Two-Midnight

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rule does not prevent the physician or other qualified practitioner from providing any service at any hospital, regardless of the expected duration of the service.

As of CY 2016, for stays for which the physician or other qualified practitioner expects the patient to need less than two midnights of hospital care (and the procedure is not on the inpatient-only list or otherwise listed as a national exception), an inpatient admission may be payable under Medicare Part A on a case-by-case basis based on the judgment of the admitting physician or other qualified practitioner. The documentation in the medical record must support that an inpatient admission is necessary, and is subject to medical review.

## Additional Information

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The OIG report is available at <https://oig.hhs.gov/oas/reports/region9/91402037.pdf>.

The section of the “National Coverage Determinations Manual” that deals with stem cell transplants for treatment of certain conditions is available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part2.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf).

You may want to review the following MLN Matters articles for further information:

- MM9620 - “Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease, and Myelodysplastic Syndromes” is at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9620.pdf>.
- MM6416 - “April 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)” is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6416.pdf>.
- MM4173 - “Stem Cell Transplantation” is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM4173.pdf>.
- MM3797 - “Updated Requirements for Autologous Stem Cell Transplantation (AuSCT) for Amyloidosis” is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3797.pdf>.

There is a fact sheet on the Two-Midnight rule at <https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule-0>.

CMS provides further guidance on the Two-Midnight rule with responses to frequently asked questions at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting\\_110413-v2-CLEAN.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf).

Additional information is in a transcript of an MLN Connects® conference call discussing the Two-Midnight rule, which is available at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2-27-14MidnightRuleTranscript.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

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## DOCUMENT HISTORY

Date of Change	Description
March 31, 2020	We revised this article to update the web links. All other information is unchanged.
June 11, 2019	We revised this article to update the web links. All other information is unchanged.
May 1, 2017	The article was revised to make a number of clarifications and to delete the table that had been in the article.
November 22, 2017	Initial article released.

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