

## Stem Cell and Bone Marrow Transplants

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### IMPORTANT REMINDER

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

### DESCRIPTION

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) uses a portion of a healthy donor's stem cell or bone marrow for intravenous infusion. 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. (NCD 110.23)

## MEDICARE ADVANTAGE POLICY CRITERIA

Indication:	Criteria
<i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
<b>ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT)</b>	
<i>If the request is for HSCT, and if the indication is not in the following list, check the "All Others" list below. Also, additional coverage guidance is found in the "Policy Guidelines" section below.</i>	
Leukemia  <b>Examples:</b> <ul style="list-style-type: none"> <li>Chronic Lymphocytic Leukemia (CLL)</li> <li>Chronic Myelogenous Leukemia (CML)</li> <li>Acute Lymphoblastic Leukemia (ALL)</li> <li>Acute Myeloid Leukemia (AML)</li> </ul>	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section B.I.a.</i> )
Leukemia in remission  <b>Examples:</b> <ul style="list-style-type: none"> <li>Same as above</li> </ul>	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section B.I.a.</i> )
Aplastic anemia	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section B.I.a.</i> )
Severe combined immunodeficiency disease (SCID) (Also known as Autoimmune disease)	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section B.I.b.</i> )
Wiscott-Aldrich syndrome	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section B.I.b.</i> )
Myelodysplastic Syndromes (MDS)  <b>NCD Definition:</b> "MDS refers to a group of diverse blood disorders in which the	<b>National Coverage Determinations (NCD)</b>  Stem Cell Transplantation Formerly 110.8.1

<b>Indication:</b> <i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	<b>Criteria</b> For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
<i>bone marrow does not produce enough healthy, functioning blood cells."</i>	(NCD 110.23) <i>(Section B.I.c.)</i> *To find Medicare-approved studies, see the Medicare web page for <a href="#">Allogeneic Hematopoietic Stem Cell Transplant for MDS</a>
Multiple myeloma (MM) (on and after 1/26/2016)	<div data-bbox="816 537 1438 573" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.I.d.)</i> *To find Medicare-approved studies, see the Medicare web page for <a href="#">Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma</a>
Myelofibrosis (MF)	<div data-bbox="816 909 1438 945" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.I.e.)</i> *To find Medicare-approved studies, see the Medicare web page for <a href="#">Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis</a>
Severe, symptomatic sickle cell disease (SCD)	<div data-bbox="816 1281 1438 1316" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.I.f.)</i> *To find Medicare-approved studies, see the Medicare web page for <a href="#">Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease</a>
Primary Refractory or Relapsed Hodgkin's Lymphoma	<div data-bbox="800 1652 1455 1766" style="background-color: #d3d3d3; padding: 2px;"> <b>Noridian Healthcare Solutions (Noridian)</b>  <b>Local Coverage Determinations (LCDs) and Articles</b> </div> <div data-bbox="800 1776 1455 1837" style="background-color: #d3d3d3; padding: 2px;"> <i>For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a></i> </div> Allogeneic Hematopoietic Cell Transplantation

Indication:	Criteria
<i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
	<p>for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin LCD (L39398)</p> <p>Billing and Coding: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory of Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin Article (A59177)</p>
Primary Refractory or Relapsed Non-Hodgkin's Lymphoma with B-cell or T-cell Origin	<div data-bbox="800 703 1458 898"> <p><b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles</b></p> <p><i>For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a></i></p> </div> <p>Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin LCD (L39398)</p> <p>Billing and Coding: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory of Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin Article (A59177)</p>
<b>AUTOLOGOUS STEM CELL TRANSPLANTATION (AuSCT)</b>	
<i>If the request is for AuSCT, and if the indication is not in the following list, check the "All Others" list below. Also, additional coverage guidance is found in the "Policy Guidelines" section below.</i>	
Acute leukemia in remission	<div data-bbox="800 1486 1458 1522"> <p><b>National Coverage Determinations (NCD)</b></p> </div> <p>Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) (<i>Section B.II.a.1.</i>)</p>
Non-Hodgkin's lymphomas	<div data-bbox="800 1665 1458 1701"> <p><b>National Coverage Determinations (NCD)</b></p> </div> <p>Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) (<i>Section B.II.a.2.</i>)</p>
Neuroblastoma	<div data-bbox="800 1843 1458 1879"> <p><b>National Coverage Determinations (NCD)</b></p> </div>

<b>Indication:</b> <i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	<b>Criteria</b> For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
	Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.II.a.3.)</i>
Advanced Hodgkin's disease	<div data-bbox="789 426 1453 478" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.II.a.4.)</i>
Multiple myeloma (MM)	<div data-bbox="789 615 1453 667" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.II.b.)</i>
Primary amyloid light chain (AL) amyloidosis	<div data-bbox="789 804 1453 856" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section B.II.c.)</i>
Acute leukemia not in remission	<div data-bbox="789 993 1453 1045" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section C.II.a.)</i>
Chronic granulocytic leukemia	<div data-bbox="789 1182 1453 1234" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section C.II.b.)</i>
Solid tumors (other than neuroblastoma)	<div data-bbox="789 1371 1453 1423" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section C.II.c.)</i>
Multiple myeloma (prior to 10/1/2000)	<div data-bbox="789 1560 1453 1612" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section C.II.d.)</i>
Tandem transplantation for multiple myeloma	<div data-bbox="789 1749 1453 1801" style="background-color: #d3d3d3; padding: 2px;"><b>National Coverage Determinations (NCD)</b></div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) <i>(Section C.II.e.)</i>

<b>Indication:</b> <i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	<b>Criteria</b> For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
Non-primary AL amyloidosis	<div data-bbox="816 333 1438 369" data-label="Section-Header"> <b>National Coverage Determinations (NCD)</b> </div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section C.II.f.</i> )
Primary AL amyloidosis (between 10/1/2000 to 3/14/2015)	<div data-bbox="816 522 1438 558" data-label="Section-Header"> <b>National Coverage Determinations (NCD)</b> </div> Stem Cell Transplantation Formerly 110.8.1 (NCD 110.23) ( <i>Section C.II.g.</i> )
<b>ALL OTHER INDICATIONS NOT ADDRESSED BY NCD, LCD, or Article</b>	
Waldenström Macroglobulinemia (HSCT or AuSCT)	<div data-bbox="816 753 1438 789" data-label="Section-Header"> <b>National Coverage Determinations (NCD)</b> </div> <p>According to NCD 110.23, stem cell transplantation for indications not otherwise noted within the NCD as nationally covered or non-covered remain at Medicare Administrative Contractor discretion. Medicare coverage guidance is not available in the health plan's service area for stem cell transplantation for various carcinomas and conditions. Therefore, the health plan's medical policy is applicable for conditions not otherwise specified in the NCD.</p> <div data-bbox="956 1152 1297 1188" data-label="Section-Header"> <b>Medical Policy Manual</b> </div> Hematopoietic Cell Transplantation Policies, <a href="#">Transplant Index Page</a> , (Select the applicable transplant policy within the search) ( <i>See "Note" below</i> )
Astrocytomas (HSCT or AuSCT)	
Gliomas (HSCT or AuSCT)	
Solid Tumors (HSCT only)	
Central Nervous System (CNS) Embryonal Tumors and Ependymoma	
<p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• Medulloblastoma</li> <li>• Medulloepithelioma</li> <li>• Supratentorial PNETs [pineoblastoma, cerebral neuroblastoma, ganglioneuroblastoma]</li> <li>• Ependymblastoma</li> <li>• Atypical teratoid/rhabdoid tumor [AT/RT]</li> </ul> <p>For <b><u>any</u></b> type of neuroblastoma, this section would apply to HSCT ONLY. All other types of CNS tumors and ependymoma, this section would apply to both HSCT and AuSCT</p>	
Chronic Lymphocytic Leukemia (CLL) (AuHCT and tandem HCT only)	
Chronic Myelogenous Leukemia (CML)	

Indication:	Criteria
<i>Listed by type of transplant (HSCT or AuSCT) and then by indication</i>	For Medicare Coverage Determinations and Articles, see the <a href="#">Medicare Coverage Database</a>
(AuHCT and tandem HCT only)	
Donor Lymphocyte Infusion (DLI)	
Genetic Diseases, acquired anemias (includes sickle cell disease, or SCD) <i>(Not by the NCD)</i>	
Germ Cell Tumors <i>Germ cells are in egg and sperm cells. Germ cell tumors may include testicular neoplasms [seminomas or nonseminomatous tumors] and ovarian and extragonadal germ-cell tumors [e.g., retroperitoneal or mediastinal tumors]</i>	
Hodgkin Lymphoma (tandem HCT only)	
Non-Hodgkin Lymphoma (tandem HCT only)	
POEMS syndrome <i>(HSCT or AuSCT)</i> <i>(Also known as osteosclerotic myeloma, Crow-Fukase syndrome, or Takasuki syndrome)</i>	
Small Lymphocytic Lymphoma	
Myeloproliferative Neoplasms (MPN) <i>(Not addressed by the NCD)</i>	
<p><b>NOTE:</b> If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (<a href="#">Medicare IOM Pub. No. 100-04, Ch. 23, §30 A</a>). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an <i>objective, evidence-based process, based on authoritative evidence</i>. (<a href="#">Medicare IOM Pub. No. 100-16, Ch. 4, §90.5</a>). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).</p>	



## POLICY GUIDELINES

**Note:** The *Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services*, [§90.2 - HCPCS and Diagnosis Coding – ICD-9-CM Applicable](#) provides a list of medical conditions that may be considered approved conditions for stem cell transplantation.

**Important note:** Stem cell transplantation is only covered when the coverage criteria in the NCD are satisfied. **Inclusion of a medical condition on the list does not imply automatic coverage. All applicable criteria from the cited policy reference must still be met.** (See also [§90.3 - Non-Covered Conditions](#).)

## REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Type of stem cell or bone marrow transplant (autologous stem cell transplantation, or AuSCT, or allogeneic hematopoietic stem cell transplantation, HSCT);
- Indication being treated; and,
- All chart notes and medical records pertinent to the condition and treatment plan, including any past therapies and those outcomes;
- For allogeneic HSCT as a treatment of Myelodysplastic Syndromes (MDS) and multiple myeloma, documentation regarding the Medicare-approved, prospective clinical study, including the National Clinical Trial (NCT) (or study) number.

## CROSS REFERENCES

1. [Coverage with Evidence Development \(CED\) Studies and Registries](#), Medicine, Policy No. M-156

## REFERENCES

1. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, [§90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation \(HSCT\) for Myelodysplastic Syndrome \(MDS\), B. Adjudication Requirements](#)

## CODING

**NOTE:** CPT codes 38207-38215 and HCPCS codes S2140, S2142, and S2150 are all Medicare Status “I” codes, and therefore, are not valid for Medicare or Medicare Advantage use.

Codes	Number	Description
CPT	38204	Management of recipient hematopoietic cell donor search and cell acquisition (Not separately reimbursable)
	38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogeneic
	38206	; autologous



38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage <i>(Not valid for Medicare purposes)</i>
38208	; thawing of previously frozen harvest, without washing, per donor <i>(Not valid for Medicare purposes)</i>
38209	; thawing of previously frozen harvest with washing, per donor <i>(Not valid for Medicare purposes)</i>
38210	; specific cell depletion with harvest, T cell depletion <i>(Not valid for Medicare purposes)</i>
38211	; tumor cell depletion <i>(Not valid for Medicare purposes)</i>
38212	; red blood cell removal <i>(Not valid for Medicare purposes)</i>
38213	; platelet depletion <i>(Not valid for Medicare purposes)</i>
38214	; plasma (volume) depletion <i>(Not valid for Medicare purposes)</i>
38215	; cell concentration in plasma, mononuclear, or buffy coat layer <i>(Not valid for Medicare purposes)</i>
38220	Diagnostic bone marrow; aspiration(s)
38221	Diagnostic bone marrow; biopsy(ies)
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	; autologous transplantation
38242	Allogeneic lymphocyte infusions
<b>HCPCS</b> C9782	Blinded procedure for new york heart association (nyha) class ii or iii heart failure, or canadian cardiovascular society (ccs) class iii or iv chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
S2140	Cord blood harvesting for transplantation; allogeneic <i>(Not valid for Medicare purposes)</i>
S2142	Cord blood derived stem-cell transplantation, allogeneic <i>(Not valid for Medicare purposes)</i>
S2150	Bone marrow or blood-derived peripheral stem-cell harvesting and transplantation, allogeneic or autologous, including pheresis, high-dose chemotherapy, and the number of days of post-transplant care in the global

definition (including drugs; hospitalization; medical surgical, diagnostic and emergency services) *(Not valid for Medicare purposes)*

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