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Medicare Advantage Policy Manual **Policy ID:** M-TRA45

Stem Cell / 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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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: ***Listed by type of transplant (HSCT or AuSCT) and then by indication***	**CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)***	**Medical Policy Manual**
ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) ***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.***		
Leukemia ***Examples:*** • *Chronic Lymphocytic Leukemia (CLL)* • *Chronic Myelogenous Leukemia (CML)* • *Acute Lymphoblastic Leukemia (ALL)* • *Acute Myeloid Leukemia (AML)*	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.a)*	
Leukemia in remission ***Examples:*** • *Same as above*	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.a)*	
Aplastic anemia	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.a)*	
Severe combined immunodeficiency disease (SCID) (Also known as Autoimmune disease)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.b)*	
Wiscott-Aldrich syndrome	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.b)*	

Indication: *Listed by type of transplant (HSCT or AuSCT) and then by indication*	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)*	Medical Policy Manual
Myelodysplastic Syndromes (MDS) ***NCD Definition:*** *"MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells."*	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.c)*	
Multiple myeloma (MM) (on and after 1/26/2016)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.d)*	
Myelofibrosis (MF)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.e)*	
Severe, symptomatic sickle cell disease (SCD)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.f)*	
Multiple myeloma (MM) (between 5/24/1996 to 1/26/2016)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.I)*	
AUTOLOGOUS STEM CELL TRANSPLANTATION (AuSCT) ***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.***		
Acute leukemia in remission	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.a.1)*	
Non-Hodgkin's lymphomas	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.a.2)*	
Neuroblastoma	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.a.3)*	
Advanced Hodgkin's disease	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.a.4)*	

Indication: ***Listed by type of transplant (HSCT or AuSCT) and then by indication***	**CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)***	**Medical Policy Manual**
Multiple myeloma (MM)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.b)*	
Primary amyloid light chain (AL) amyloidosis	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.c)*	
Acute leukemia not in remission	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.a)*	
Chronic granulocytic leukemia	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.b)*	
Solid tumors (other than neuroblastoma)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.c)*	
Multiple myeloma (prior to 10/1/2000)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.d)*	
Tandem transplantation for multiple myeloma	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.e)*	
Non-primary AL amyloidosis	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.f)*	
Primary AL amyloidosis (between 10/1/2000 to 3/14/2015)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section C.II.g)*	
ALL OTHER INDICATIONS NOT ADDRESSED BY NCD		
Waldenström Macroglobulinemia (HSCT or AuSCT)	*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*	Hematopoietic Cell Transplantation Index, Transplant, Policy No. 45 *(Select the applicable transplant policy within this index)* *(See "Note" below)*
Astrocytomas (HSCT or AuSCT)		
Gliomas (HSCT or AuSCT)		
Breast cancer (HSCT only)		

Indication: *Listed by type of transplant (HSCT or AuSCT) and then by indication*	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)*	Medical Policy Manual
Solid Tumors (HSCT only)	*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.*	
Central Nervous System (CNS) Embryonal Tumors and Ependymoma ***Examples:*** • Medulloblastoma • Medulloepithelioma • Supratentorial PNETs [pineoblastoma, cerebral neuroblastoma, ganglioneuroblastoma] • Ependymoblastoma • Atypical teratoid/rhabdoid tumor [AT/RT]) *For **any** 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*		
Chronic Lymphocytic Leukemia (CLL) (AuHCT and tandem HCT only)		
Chronic Myelogenous Leukemia (CML) (AuHCT and tandem HCT only)		
Donor Lymphocyte Infusion (DLI)		

Indication: ***Listed by type of transplant (HSCT or AuSCT) and then by indication***	**CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)***	**Medical Policy Manual**
Epithelial Ovarian Cancer *For cystic only. If for solid, see separate "solid tumor" listing) (HSCT or AuSCT)*		
Genetic Diseases, acquired anemias (includes sickle cell disease, or SCD) *(Not by the NCD)*		
Germ Cell Tumors *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]*		
Hodgkin Lymphoma (HSCT and tandem HCT only)		
Non-Hodgkin Lymphoma (HSCT and tandem HCT only)		
POEMS syndrome *(HSCT or AuSCT)* *(Also known as osteosclerotic myeloma, Crow-Fukase syndrome, or Takasuki syndrome)*		

Indication: *Listed by type of transplant (HSCT or AuSCT) and then by indication*	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Local Coverage Determinations (LCD) and Articles (LCA)*	Medical Policy Manual
Small Lymphocytic Lymphoma and Myeloproliferative Neoplasms (MPN) *(Not addressed by the NCD)*		

NOTE: 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. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 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 ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

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

Immunological Cellular Therapies and Gene Therapies, Medicine, Policy No. M-42

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

REFERENCES

1. Services, §90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS), B. Adjudication Requirements
2. Medicare Coverage With Evidence Development Webpage - Allogeneic Hematopoietic Stem Cell Transplant for MDS

CODING

NOTE: HCPCS codes S2140, S2142, and S2150 are 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
	38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogeneic
	38206	; autologous
	38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
	38208	; thawing of previously frozen harvest, without washing, per donor
	38209	; thawing of previously frozen harvest with washing, per donor
	38210	; specific cell depletion with harvest, T cell depletion
	38211	; tumor cell depletion
	38212	; red blood cell removal
	38213	; platelet depletion
	38214	; plasma (volume) depletion
	38215	; cell concentration in plasma, mononuclear, or buffy coat layer
	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
HCPCS	J9000–J9999	Chemotherapy drugs code range
	Q0083–Q0085	Chemotherapy administration code range
	S2140	Cord blood harvesting for transplantation; allogeneic *(Not valid for Medicare purposes)*
	S2142	Cord blood derived stem-cell transplantation, allogeneic *(Not valid for Medicare purposes)*
	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)*

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*