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

Stem Cell and Bone Marrow Transplants

Published: 02/01/2024

Next Review: 08/2024

Last Review: 01/2024 ***Medicare Link(s) Revised:*** *02/01/2024*

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 may 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: ***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**	**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)*	
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)* *To find Medicare-approved studies, see the Medicare web page for *Allogeneic*	

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	Hematopoietic Stem Cell Transplant for MDS	
Multiple myeloma (MM) (on and after 1/26/2016)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.d)* *To find Medicare-approved studies, see the Medicare web page for *Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma*	
Myelofibrosis (MF)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.e)* *To find Medicare-approved studies, see the Medicare web page for *Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis*	
Severe, symptomatic sickle cell disease (SCD)	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.I.f)* *To find Medicare-approved studies, see the Medicare web page for *Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease*	
Primary Refractory or Relapsed Hodgkin's Lymphoma	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)	

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	Medical Policy Manual
	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)	
Primary Refractory or Relapsed Non-Hodgkin's Lymphoma with B-cell or T-cell Origin	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) 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)	
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)*	

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**	**Medical Policy Manual**
Advanced Hodgkin's disease	Stem Cell Transplantation Formerly 110.8.1 (110.23) *(Section B.II.a.4)*	
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, LCD, or Article		
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*	Hematopoietic Cell Transplantation Policies, Transplant Index Page, *(Select*
Astrocytomas (HSCT or AuSCT)		
Gliomas (HSCT or AuSCT)		

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**	**Medical Policy Manual**
Solid Tumors (HSCT only)	*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.*	*the applicable transplant policy within this index)* *(See "Note" below)*
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)		
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*		

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	Medical Policy Manual
[seminomas or nonseminomatous tumors] and ovarian and extragonadal germ-cell tumors [e.g., retroperitoneal or mediastinal tumors]		
Hodgkin Lymphoma (tandem HCT only)		
Non-Hodgkin Lymphoma (tandem HCT only)		
POEMS syndrome *(HSCT or AuSCT)* *(Also known as osteosclerotic myeloma, Crow-Fukase syndrome, or Takasuki syndrome)*		
Small Lymphocytic Lymphoma		
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).

See "Policy Guidelines"

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. 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 *(Not valid for Medicare purposes)*
	38208	; thawing of previously frozen harvest, without washing, per donor *(Not valid for Medicare purposes)*
	38209	; thawing of previously frozen harvest with washing, per donor *(Not valid for Medicare purposes)*
	38210	; specific cell depletion with harvest, T cell depletion *(Not valid for Medicare purposes)*
	38211	; tumor cell depletion *(Not valid for Medicare purposes)*
	38212	; red blood cell removal *(Not valid for Medicare purposes)*
	38213	; platelet depletion *(Not valid for Medicare purposes)*
	38214	; plasma (volume) depletion *(Not valid for Medicare purposes)*
	38215	; cell concentration in plasma, mononuclear, or buffy coat layer *(Not valid for Medicare purposes)*
	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	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 *(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

Codes	Number	Description
		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.*