Medicare Medical Policy

Stem Cell Transplantation

MEDICARE MEDICAL POLICY NUMBER: 283

Effective Date: 3/1/2025

Last Review Date: 2/2025

Next Annual Review: 2/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
NOTES: The Medicare National Coverage Determination (NCD) for Stem Cell Transplantation (Formerly 110.8.1) (110.23) provides coverage criteria for stem cell transplants for many indications. Under this NCD, there are two primary techniques for hematopoietic stem cell transplants: • Autologous (AuSCT): Restores stem cells using the **patient's own** cells. • Allogeneic (HSCT or allo-HSCT): A **healthy donor's** stem cell or bone marrow is used. Review the NCD to identify covered and non-covered indications for stem cell transplantation. The following rows list the indications called out within the NCD as either covered or non-covered. ***Attention should be paid to the technique used (AuSCT vs. HSCT), as some indications may be considered medically necessary under one technique, but not the other.***	
ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT; Allo-HSCT)	
Aplastic Anemia	NCD (110.23) (Section B.I.a)
Leukemia and Leukemia in Remission	NCD (110.23) (Section B.I.a) **Note:** These include, but may not be limited to, chronic lymphocytic leukemia (CLL), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia [ALL], acute myeloid leukemia (AML).
Multiple Myeloma (MM)	• **Between 5/24/1996 to 1/26/2016:** NCD (110.23) (Section C.I) • **On and after 1/26/2016:** NCD (110.23) (Section B.I.d) **Note:** For Medicare-approved studies, see the Medicare web page for Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma.
Myelodysplastic Syndromes (MDS)	• NCD (110.23) (Section B.I.c) **Notes:** • MDS is defined by the NCD as “a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells."

	• **For services prior to March 6, 2024:** Prior to March 6, 2024, Medicare only allowed coverage of stem cell transplantation for MDS under the Coverage with Evidence Development (CED) provision and services needed to be rendered in the context of a Medicare-approved, prospective clinical study. For Medicare-approved studies, see the Medicare web page for Allogeneic Hematopoietic Stem Cell Transplant for MDS. • **For services on/after March 6, 2024:** CMS removed the CED requirement for allogenic HSCT for this indication. Apply NCD as noted above.
Myelofibrosis (MF)	NCD (110.23) (Section B.I.e) **Note:** For Medicare-approved studies, see the Medicare web page for Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis.
Primary Refractory or Relapsed B- and T-cell Lymphomas	LCD: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (L39398)
Severe Combined Immunodeficiency Disease (SCID) (i.e., Autoimmune Disease)	NCD (110.23) (Section B.I.b)
Sickle Cell Disease (SCD) (severe and symptomatic)	NCD (110.23) (Section B.I.f) **Note:** For Medicare-approved studies, see the Medicare web page for Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease.
Wiscott-Aldrich Syndrome	NCD (110.23) (Section B.I.b)
AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (AuSCT)	
*Acute Leukemia **in** Remission*	NCD (110.23) (Section B.II.a.1)
Advanced Hodgkin's Disease	NCD (110.23) (Section B.II.a.4)
Multiple Myeloma (MM)	NCD (110.23) (Section B.II.b)
Primary Amyloid Light Chain (AL) Amyloidosis	NCD (110.23) (Section B.II.c) **Note:** This is for high dose melphalan (HDM) together with AuSCT.
Recurrent or Refractory Neuroblastoma	NCD (110.23) (Section B.II.a.3)
Resistant Non-Hodgkin's Lymphomas	NCD (110.23) (Section B.II.a.2) **Note:** Includes those presenting with poor prognostic features following an initial response.
*Acute Leukemia **Not** in Remission*	NCD (110.23) (Section C.II.a)
Chronic Granulocytic Leukemia	NCD (110.23) (Section C.II.b)

Solid Tumors (Other Than Neuroblastoma)	NCD (110.23) (Section C.II.c)
*Multiple Myeloma (**Prior to** October 1, 2000)*	NCD (110.23) (Section C.II.d)
Tandem Transplantation (Multiple Rounds of AuSCT) for Multiple Myeloma	NCD (110.23) (Section C.II.e)
*Non Primary AL Amyloidosis (**As of** October 1, 2000)*	NCD (110.23) (Section C.II.f)
*Primary AL Amyloidosis for Individuals >64 Years (**Between** October 1, 2000 and March 14, 2005)*	NCD (110.23) (Section C.II.g)
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see* Policy Guidelines *below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for stem cell transplant services in a coverage manual. • **National Coverage Determination (NCD):** Primary coverage of stem cell transplants is addressed by the NCD 110.23. According to this NCD, coverage of stem cell transplants for indications **not** addressed by the NCD are at local Medicare Administrative Contractor (MAC) discretion. This NCD is considered "not fully established" under CFR § 422.101(6)(i)(B) as it provides explicit flexibility for coverage decisions beyond the NCD. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** With the exception of the Noridian LCD for *Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin* noted in the list above, as of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for stem cell transplants for other indications. • Therefore, in the absence of **fully established** Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies provide flexibility for coverage decisions beyond the NCD and LCD. • ***NOTE:** The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Any indication not otherwise noted as covered or not covered within the NCD or LCD	Company medical policy for Stem Cell Transplantation I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "not medically necessary" by the Company policy. See *Policy Guidelines below.*

	Examples Include (may not be all-inclusive): • *Donor Lymphocyte Infusion (DLI)* • *Genetic Diseases, acquired anemias (includes sickle cell disease, or SCD)*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Stem Cell Therapy for Orthopedic Applications, MP36

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for the use of stem cell transplantation for all indications available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied for any indication not addressed in an NCD or LCD. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- LCA: Billing and Coding: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (A59177)

The *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[3], indicates CPT code 38204 has been assigned a Status Indicator of "B." This is defined as a "Bundled code." This code denies as a bundled service, as indicated in the Company Coding Policy *(Bundled or Adjunct Services,* CP13*)*.

In addition, the NPFSRVF indicates CPT codes 38207-38215 have been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." Providers may need to use alternate available CPT or HCPCS codes to report for the service if the code is not accepted by the Plan.

CODES*		
CPT	0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest
	0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest
	0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if

		performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy
	38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition *(CMS-assigned Status "B" code – See above billing guidelines)*
	38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
	38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
	38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage *(CMS-assigned Status "I" code – See above billing guidelines)*
	38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor *(CMS-assigned Status "I" code – See above billing guidelines)*
	38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor *(CMS-assigned Status "I" code – See above billing guidelines)*
	38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion *(CMS-assigned Status "I" code – See above billing guidelines)*
	38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion *(CMS-assigned Status "I" code – See above billing guidelines)*
	38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal *(CMS-assigned Status "I" code – See above billing guidelines)*
	38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion *(CMS-assigned Status "I" code – See above billing guidelines)*
	38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion *(CMS-assigned Status "I" code – See above billing guidelines)*
	38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer *(CMS-assigned Status "I" code – See above billing guidelines)*
	38230	Bone marrow harvesting for transplantation; allogeneic
	38232	Bone marrow harvesting for transplantation; autologous
	38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
	38241	Hematopoietic progenitor cell (HPC); autologous transplantation
	38242	Allogeneic lymphocyte infusions
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**

- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Federal Register / Vol. 78, No. 152 / Wednesday, August 7, 2013 / Notices; https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf. Accessed: 03/11/2024.
2. Medicare Claims Processing Manual, Chapter 3 - Inpatient Hospital Billing, §90.3 - Stem Cell Transplantation; Last Updated: 11/2021; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf
3. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2022	Annual review (converted to new format 2/2023)
3/2023	Annual review; added new Noridian LCD
4/2024	Interim update; update allogenic HSCT for MDS criteria
5/2024	Annual review, no change to criteria but language revision due to Company policy change from "investigational" to "not medically necessary"; update codes to align with prior authorization list
3/2025	Annual review; update criteria for stem cell transplants for MDS to replace the CMS Final Decision memo with the updated NCD