

Medicare Medical Policy

Stem Cell Therapy for Orthopedic Applications

MEDICARE MEDICAL POLICY NUMBER: 372

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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”).

PRODUCT AND BENEFIT APPLICATION

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
<i>Stem Cells Combined with Platelet-Rich Plasma (PRP) for Orthopedic Applications</i>	For stem cells combined with PRP for orthopedic conditions, see the separate Medicare medical policy for <i>Platelet-Rich Plasma (PRP) for Orthopedic Indications, Wound Care and Other Miscellaneous Conditions (Medicare Only)</i> (See Cross References)
<i>Amniotic Membrane, Amniotic Fluid or Other Placental-Derived Product Injections and/or Applications for Orthopedic Applications</i>	Local Coverage Determination (LCD): Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (L39118) NOTE: For the purposes of this LCD, the terms amniotic and placental-derived products are used to mean ANY product derived from ANY combination of amniotic membrane, chorion, placenta, Wharton’s jelly, umbilical cord, amniotic fluid, and/or umbilical cord blood.

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 therapy products for orthopedic conditions in a coverage manual.
- **National Coverage Determination (NCD):** The Medicare NCD for *Stem Cell Transplantation (Formerly 110.8.1)*, [[110.23](#)] has published guidance for stem cell transplantation, this NCD does **not** address orthopedic applications of stem cell therapy. The NCD states any use of stem cell transplantation not otherwise 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):** As of the most recent policy review, no MAC has an LCD for the use of stem cell therapy for orthopedic conditions.

- 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)].*

Stem Cell Therapy Products Derived from Any Other Tissue or Source When Used for Orthopedic Applications

Mesenchymal Stem Cell Therapy (e.g., Regenexx, Stravix®)

Allograft Bone Products Containing Viable Stem Cells, (e.g., demineralized bone matrix (DBM) with stem cells [e.g., BIO4®, OSTEOCEL® Plus, OSTEOCEL® Pro, OsteoVive™_ =) Trinity Evolution®, Trinity ELITE®, VIA® Form, VIA® Graft, ViviGen®])

Company medical policy for [Stem Cell Therapy for Orthopedic Applications](#)

- I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

NOTE: In accordance with CMS rules, if a stem cell therapy service is determined to be “not medically necessary,” the non-coverage position extends to **all** services related to the non-covered procedure, including the harvesting of stem cell material. *(Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare)*

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 Transplantation](#), MP283
- [Platelet-Rich Plasma \(PRP\) for Orthopedic Indications, Wound Care and Other Miscellaneous Conditions](#), MP224
- [Prolotherapy](#), MP334

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, current standards of care, 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.

No coverage guidance is published by Medicare for stem cell therapy for the treatment of orthopedic or musculoskeletal indications. While the Centers for Medicare & Medicaid Services (CMS) has published guidance for stem cell transplantation (see the National Coverage Determination (NCD) for *Stem Cell Transplantation (Formerly 110.8.1)*, [\[110.23\]](#)), this NCD does not address orthopedic applications of stem cell therapy. The NCD states any use of stem cell transplantation not otherwise addressed by the NCD are at local MAC discretion. The local MAC for the Company service area – Noridian – has published guidance on amniotic and placental-derived products, but they do not have published guidance on stem cell therapies for orthopedic applications.

Since there are not fully established coverage criteria for stem cell therapy for the treatment of orthopedic or musculoskeletal conditions available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. 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

There are a limited number of specific codes available for use for orthopedic applications of stem cell therapy. When a specific CPT or HCPCS code is not available, the appropriate CPT code for reporting this procedure would be the code for an unlisted procedure of the body area on which the procedure is performed. The unlisted codes listed below may not be all-inclusive.

The additional codes listed on this policy are not appropriate when billed for stem cell therapies for orthopedic applications and are considered not medically necessary per the policy criteria.

CODES*		
CPT	0565T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation
	0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral
	0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
	0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
	0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
	0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
	0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
	0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
	0814T	Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral
	20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision
	20999	Unlisted procedure, musculoskeletal system, general
	29999	Unlisted procedure, arthroscopy

	38205	Blood derived hematopoietic progenitor cell harvesting for transplantation, per collection allogeneic
	38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
	38230	Bone marrow harvesting for transplantation; allogeneic
	38232	Bone marrow harvesting for transplantation; autologous
	38241	Hematopoietic progenitor cell (HPC); autologous transplantation
HCPCS	Q4206	Fluid flow or fluid GF, 1 cc

***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

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy
12/2023	Interim update, add LCD L39118 for amniotic derived products used for non-wound orthopedic conditions
1/2024	Q1 2024 code updates
3/2024	Annual review, no changes to criteria but language revision due to prior Company policy change from “Investigational” to “not medically necessary”, add codes for injection of allogeneic cellular product for intervertebral disc use
1/2025	Annual review, no change to criteria