# *Medicare Medical Policy*

# Stem Cell Therapy for Orthopedic Applications

**MEDICARE MEDICAL POLICY NUMBER:** 372

**Effective Date:** 1/1/2024

**Last Review Date:** 11/2023

**Next Annual Review:** 12/2023



**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 |
|---|---|
| *Stem Cells Combined with Platelet-Rich Plasma (PRP) for Orthopedic Applications* | For stem cells combined with PRP for orthopedic conditions, see the separate Medicare medical policy for *Platelet-Rich Plasma (PRP) for Orthopedic Indications, Wound Care and Other Miscellaneous Conditions (Medicare Only) (See Cross References)* |
| *Amniotic Membrane, Amniotic Fluid or Other Placental-Derived Product Injections and/or Applications for Orthopedic Applications* | Local Coverage Determination (LCD): Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (L39118)<br><br>**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. |
| *Stem Cell Therapy Products Derived from Any Other Tissue or Source When Used for Orthopedic Applications*<br><br>*Mesenchymal Stem Cell Therapy (e.g., Regenexx, Stravix®)*<br><br>*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<br><br>I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.* |

**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**

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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 S*tem 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 Medicare Administrative Contractor (MAC) discretion, but the local MAC for the Company service area – Noridian – does not have published guidance on stem cell therapies for orthopedic applications either. Therefore, the Company policy criteria will be applied.

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

## 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 |
| | 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 |