

Cohere Medicare Advantage Policy - Subchondroplasty

Clinical Guidelines for Medical Necessity Review

Version: 3.1

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Important Notices

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Policy Information:

Specialty Area: Disorders of the Musculoskeletal System

Policy Name: Cohere Medicare Advantage Policy - Subchondroplasty

Type: $[\underline{X}]$ Adult (18+ yo) | $[\underline{X}]$ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Subchondroplasty

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.

• There are no applicable NCDs and/or LCDs for subchondroplasty.

Description

Subchondroplasty is a novel technique that may reduce pain by treating bone lesions caused by knee osteoarthritis (OA) and insufficiency fractures. The procedure involves injecting bone substitute material into areas requiring structural support in the subchondral bone. 1-3

Medical Necessity Criteria

Indications

Subchondroplasty is considered appropriate if ALL of the following are TRUE:

 There is insufficient evidence of the safety and efficacy of this procedure, and as such, this service is considered not medically necessary.

Non-Indications

Subchondroplasty is not considered appropriate if **ALL** of the following are **TRUE**:

This is not applicable as there are no indications.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

| CPT/HCPCS Code | Code Description |
|----------------|--|
| 0707T | Injection(s), bone-substitute material (e.g., calcium phosphate) into subchondral bone defect (i.e., bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization |

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Refer to the Medical Evidence section for various citations and references to studies conducted to date that are inconsistent, inadequately powered, or otherwise do not allow for solid scientific conclusions. Potential harms and benefits of applying an "unproven and not medically necessary" designation to this procedure might include, but are not limited to, the following:

Potential Harms of applying the clinical criteria included in this policy include, but are not limited to, denying opportunities to improve individual and population health outcomes for individuals with pain secondary to bone lesions caused by knee osteoarthritis (OA) and insufficiency fractures. For example, restricting access to this procedure may increase patient and population reliance upon excessive pain medication, including opioids, diminished functionality contributing to the development of additional medical problems, and loss of economic opportunity.

Potential Benefits include safeguarding patients and populations from unproven technologies, procedures, and medical interventions until safety, efficacy, and expected outcomes of proposed treatment are fully established via peer-reviewed scientific literature. This safeguards patients from failed subchondroplasty procedures, which can lead to pain, inflammation, and the displacement of the materials used, which in turn may require additional surgeries. Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Wood et al. (2023) discussed subschondroplasty to slow or eliminate the need for knee arthroplasty. While effective, the authors note that previous randomized trials lacked control groups that demonstrated successful long-term outcomes. Limitations of the study included transfer bias and the lack of long-term follow-up.⁴

DiMatteo et al. (2024) conducted a small study of 79 patients to measure outcomes at 12-month follow-up of patients with knee OA and recurring BMLs. While the authors note that the procedure is effective for this population, randomized studies are needed to support subchondroplasty. Tran et al. (2022) reported similar results and the need for randomized studies that include a control group and evaluation of long-term clinical.

Di Matteo et al. (2021) performed a systematic review to study the efficacy of intraosseous injections for patients with BMLs and knee osteoarthritis (OA). Twelve studies with 459 patients were included in the review that addressed using three types of injections (calcium phosphate, platelet-rich plasma, and bone marrow concentrate). While injections are minimally invasive and have a low complication rate, the research lacks high-quality evidence to establish support.²

A sufficiently powered longitudinal investigational study initiated in 2021 is underway to assess individual patient and population outcomes, including but not limited to pain medication usage, pain, function, activity levels, and patient satisfaction. The study is critical in evaluating the safety and efficacy of subchondroplasty for the foot and ankle. In addition, investigational studies to date have either been insufficiently powered to draw definitive conclusions or have yielded inconsistent results.⁸

Krebs et al. (2020) conducted a small retrospective chart review to determine the outcomes of knee arthroscopy with adjunctive subchondroplasty. These include improving self-rated visual analog scale (VAS) pain scores, conversion rate to arthroplasty, and overall satisfaction following the procedure. While the procedure demonstrated positive outcomes, additional

research is needed on the limitations of the procedure. The size of the case series was small (12 patients) without a control group; hence, there was no ability to compare it to the intervention group. Postoperative data did not have a standardized collection process (e.g., missed appointments and inability to obtain VAS pain scores at specific follow-up appointments). Finally, magnetic resonance imaging (MRI) was missing for patients, and BML status could not be determined after subchondroplasty.⁹

References

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Clinical Guideline Revision History/Information

| Original Date: May 27, 2024 | | | |
|-----------------------------|------------|--|--|
| Review History | | | |
| Version 2 | 06/12/2024 | 422.101 disclaimer added. | |
| Version 3 | 05/22/2025 | Annual review. | |
| | | No changes to medical necessity criteria or procedure codes. | |
| | | Literature review - Medical Evidence section updated to support non-coverage based on a lack of evidence (Di Matteo et al., 2024; Wood et al., 2023). | |
| Version 3.1 | 07/01/2025 | Added Harms & Benefits section. | |