Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Subchondroplasty

Description/Background

The Subchondroplasty® (SCP) Procedure is a minimally-invasive fluoroscopically-assisted procedure that targets and fills subchondral bone defects associated with chronic bone marrow lesions frequently associated with osteoarthritis, primarily of the knee and ankle.

A substance called AccuFill (a calcium phosphate mineral compound) is injected arthroscopically into the subchondral defect – it hardens quickly once injected and mimics the strength of normal cancellous bone, and is replaced with new bone during the healing process. It is designed to treat subchondral defects associated with chronic bone marrow edema.

Regulatory Status

SCP injections are a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. AccuFill Bone Substitute Material (Zimmer Knee Creations) received FDA 510(k) Premarket Notification clearance (K190814) on October 10, 2019.

Medical Policy Statement

The Subchondroplasty® (SCP®) Procedure is considered experimental/investigational. Evidence based conclusions regarding safety, efficacy, and the impact on net health outcomes has yet to be determined.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

27899 29999 L8699 0707T

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Subchondral injection of calcium phosphate bone substitute, into the area of subchondral bone edema, as part of treatment for osteochondritis dissecans of the knee, and other joints has been reported in the literature (Levy, Cousins, 2020; Bonadio, et al., 2017; Cohen, Sharkey, 2016; Abrams, et al., 2013). Conservative treatment of osteoarthritis-related bone marrow lesions generally includes pain control, reduction in weight bearing, activity modification, and appropriate nutrition including additional calcium and vitamin D during treatment if appropriate. The Subchondroplasty® (SCP®) procedure (Zimmer Holdings, Inc.; Warsaw, IN), aimed at treating such defects, is a minimally invasive surgery designed to access and treat bone defects associated with chronic bone marrow lesions by filling them with a biomimetic bone substitute material.

Nairn et al. (2021) published the results of a systematic review evaluating safety and early results of Subchondroplasty® for the treatment of bone marrow lesions. The authors review included 17 studies; all studies were graded as level 4 evidence except one which was graded level 3. The review included 756 subjects in total, 13 studies investigated use for the knee and four evaluated use for foot and ankle joint pain related to a bone marrow lesion. Mean pain scores using VAS improved postoperatively (7.8 +/- 0.6 to 3.4 +/- 0.7), functional scores improved when reported (IKDC 31.7 ± 1.9-54.0 ± 4.2 and KOOS 38.1 ± 0.6-70.0 ± 4.1) and there were high levels of patient satisfaction postoperatively. Complications occurred in seven cases, most seriously osteomyelitis and avascular necrosis. In addition, the authors reported that the rate at which subjects converted to arthroplasty ranged from 12.5 to 30% with follow-up ranging from 10 months to seven years. In the author's opinion, low quality studies supported a reduction of pain, improved function, high patient satisfaction and a subsequent delay in more invasive procedures. However additional high quality studies with long term follow-up are required to determine any impact to clinical practice recommendations.

SUMMARY OF EVIDENCE

Evidence in the peer reviewed scientific literature evaluating injection of a calcium phosphate bone substitute into the area of subchondral bone edema, or of the Subchondroplasty® procedure, in the treatment of chronic bone marrow lesions / bone marrow edema is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Clinical trials that might influence this review are listed in Table 1.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03921489	Subchondroplasty for Treatment of Bone Marrow Edema in the Foot and Ankle	20	Jun 2024
NCT06027697	Prospective Evaluation of Subchondroplasty in Advanced Knee Osteoarthritis.	55	Sept 2028
Unpublished			
NCT03430219	Subchondroplasty Procedure in Patients With Bone Marrow Lesions	93	Mar 2023
NCT03112200	Subchondroplasty® Knee RCT (PRESERVE Knee)	134	Mar 2023

NCT: national clinical trial

Government Regulations

National:

No National Coverage Decision on this procedure.

Local:

No Local Coverage Decision on this procedure.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Abrams GD, Alentorn-Geli E, Harris JD, Cole BJ. Treatment of a lateral tibial plateau osteochondritis dissecans lesion with subchondral injection of calcium phosphate. Arthrosc Tech. 2013 Jul 19;2(3):e271- 4
2. Bonadio MB, Giglio PN, Helito CP, Pécora JR, Camanho GL, Demange MK. Subchondroplasty for treating bone marrow lesions in the knee - initial experience. Rev Bras Ortop. 2017 Apr 28;52(3):325- 330.

3. Cohen SB, Sharkey PF. Subchondroplasty for Treating Bone Marrow Lesions. J Knee Surg. 2016 Oct;29(7):555-563.
4. Levy AS, Cousins K. The rational for and efficacy of subchondroplasty in the injured worker. J Orthop. 2020 Mar 27;22:48-52.
5. Nairn LN, Subramaniam M, Ekhtiari S, Axelrod DE, Grant JA, Khan M. Safety and early results of Subchondroplasty® for the treatment of bone marrow lesions in osteoarthritis: a systematic review. Knee Surg Sports Traumatol Arthrosc. 2021 Sep 29.
6. Hayes, Inc. Search and Summary. Accufill Bone Substitute Material (Zimmer) for Ankle Subchondroplasty. Lansdale, PA: Hayes, Inc.; December 10, 2015.
7. Hayes, Inc. Evolving Evidence Review. Subchondral Calcium Phosphate Injections for Knee Bone Marrow Lesions. Lansdale, PA: Hayes, Inc.; Nov 15, 2021, Annual Review Nov 1, 2023.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 20 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/22	12/14/21		Joint policy established
3/1/23	12/20/22		Routine maintenance (ky)
3/1/24	12/19/23		Routine maintenance Vendor: N/A (ky)
3/1/25	12/17/24		Routine maintenance Vendor: N/A (ky)

Next Review Date: 4th Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SUBCHONDROPLASTY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.