MEDICAL POLICY

Excellus
An independent licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY DETAILS	
Medical Policy Title	**Prolotherapy**
Policy Number	**8.01.10**
Category	**Technology Assessment**
Original Effective Date	**09/16/99**
Committee Approval Date	**05/01/00, 09/19/01, 07/18/02, 09/18/03, 06/17/04, 03/17/05, 03/16/06, 03/15/07, 02/21/08, 01/15/09, 10/29/09, 10/28/10, 09/15/11**
Current Effective Date	**12/19/24**
Archived Date	**09/20/12**
Archive Review Date	**09/19/13, 09/18/14, 09/17/15, 09/15/16, 09/21/17, 06/21/18, 12/20/18, 12/19/19, 12/17/20, 12/16/21, 12/22/22, 12/21/23, 12/19/24**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, prolotherapy has not been medically proven to be effective and, therefore, is considered **investigational** as a treatment of musculoskeletal pain and/or instability (e.g., laxity, weakness).

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Prolotherapy, is used to treat joint and muscle pain. Prolotherapy is sometimes referred to as proliferation therapy; joint sclerotherapy; regenerative injection therapy; or nonsurgical tendon, ligament and joint reconstruction, Prolotherapy is a procedure for healing and strengthening lax ligaments by injecting proliferating agents/sclerosing solutions directly into torn or stretched ligaments. Proliferative therapy acts to promote tissue repair or growth by prompting release of growth factors, such as cytokines, or increasing the effectiveness of existing circulating growth factors. Agents used with prolotherapy have included zinc sulfate; psyllium seed oil; dextrose, and combinations of dextrose, glycerin phenol, and sarapin. In the last several years newer formulas include platelet rich plasma and autologous adult stem cell. Polidocanol and sodium morrhuate, which are vascular scleroscants, have also been utilized to sclerosed areas of high intratendinous blood flow associated with tendinopathies. Prolotherapy has been investigated as a treatment of various etiologies of pain, including arthritis, degenerative disc disease, fibromyalgia, tendonitis, and plantar fasciitis. Prolotherapy may involve a single injection or a series of injections, often diluted with a local anesthetic.

RATIONALE

Although individual ingredients such as dextrose and lidocaine are approved for injection by the U.S. Food and Drug Administration (FDA), they are not approved for prolotherapy. Drug solutions injected during prolotherapy are typically prepared by compound pharmacies or individual practitioners and, therefore, are not subject to regulation by the FDA.

Scientific data demonstrating the effectiveness of prolotherapy for the treatment of chronic back pain and joint and ligament instability are limited, and interpretation is complicated by variations in treatment protocols, the use of concomitant treatments, and the lack of a non-injection control group. As with any therapy for pain, a placebo effect is anticipated; therefore, randomized, placebo-controlled trials are necessary to investigate the extent of the placebo effect and to determine whether any improvement with prolotherapy exceeds that associated with a placebo. Yelland et al. (2004) reported on a partially blinded randomized, controlled trial of prolotherapy injections, saline injections, and exercises for chronic low back pain in 110 subjects. While decreases in pain and disability were found in all study groups, there were no significant differences between treatment groups at 12 and 24 months. The effects of prolotherapy did not significantly exceed placebo effects.

Kim et al. (2010), compared intra-articular prolotherapy with intra-articular corticosteroid injection for sacroiliac pain. The randomized double-blind study included 48 patients with sacroiliac joint pain lasting more than three months, confirmed by a greater than 50% improvement in response to local anesthetic block. The injections were performed on a biweekly schedule (maximum of three injections) under fluoroscopic guidance with confirmation of the intra-articular location with an arthrogram. Pain and disability scores were assessed at baseline, two weeks, and monthly after completion of treatment. At 15 months after treatment, 58.7% of patients in the prolotherapy group reported relief greater than 50% in comparison with 10.2% of the steroid group. Key differences between this and other studies on prolotherapy were the selection of patients using a diagnostic sacroiliac joint block and the use of an arthrogram to confirm the location of the injection. Additional trials are needed to confirm the safety and efficacy of this procedure.

There is inadequate evidence of the effectiveness of sarapin for pain.

Heber et al (2024), compared the effectiveness of platelet rich plasma (PRP) injections to other conservative treatment modalities for the management of plantar fasciitis. A systematic review and a meta-analysis were conducted comparing PRP to other treatment modalities. There were 21 randomized control trials (RCT) and a total of 1356 patients included. Reported outcomes included visual analog scale (VAS) pain scores, plantar fascia thickness (PFT), American Orthopaedic Foot and Ankle Society (AOFAS) scores, and total Foot Function Index (FFI). PRP demonstrated significantly greater improvements in VAS pain scores compared to extracorporeal shock wave therapy (ESWT), corticosteroid injections (CSI), and placebo . Researchers found that PRP demonstrated significantly greater improvements in AOFAS scores over CSI and placebo but there were no significant differences among PRP, ESWT, CSI, dextrose prolotherapy (DPT), and meridian trigger points (MTP) in enhancing foot functionality. This study contained a high degree of heterogeneity among the included studies, and the method of PRP preparation varied significantly. The meta-analysis found no superiority of PRP over other treatments in measures such as VAS pain, PFT, and FFI which raises questions about the generalizability of the findings. PRP as a treatment option for a variety of musculoskeletal conditions warrants further evaluation and a more standardized approach to PRP preparation and outcome management.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy update.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
No specific code(s)	

HCPCS Codes

Code	Description
M0076 **(E/I)**	Prolotherapy

ICD10 Codes

Code	Description
	Numerous

REFERENCES

Akcay S, et al. Dextrose prolotherapy versus normal saline injection for the treatment of lateral epicondylopathy: a randomized controlled trial. J Altern Complement Med 2020 Sep 28.

Apaydin H, et al. Injection therapy in patients with lateral epicondylalgia: hyaluronic acid or dextrose prolotherapy? a single-blind, randomized clinical trial. J Altern Complement Med 2020 Sep 15.

Arias-Vazquez PI, et al. Prolotherapy for knee osteoarthritis using hypertonic dextrose vs other interventional treatments: systematic review of clinical trials. Adv Rheumatol 2019 Aug 19;59(1):39.

Bayat M, et al. Is dextrose prolotherapy superior to corticosteroid injection in patients with chronic lateral epicondylitis?: a randomized clinical trial. Orthop Res Rev 2019 Nov 5;11:167-175.

Chung MW, et al. Effects of dextrose prolotherapy on tendinopathy, fasciopathy, and ligament injuries, fact or myth?: a systematic review and meta-analysis. Medicine (Baltimore) 2020 Nov 13;99(46):e23201.

*Dagenais S, et al. Intraligamentous injection of sclerosing solutions (prolotherapy) for spinal pain: a critical review of the literature. Spine J 2005;5:310-28.

*Dagenais S, et al. Prolotherapy injections for chronic low-back pain. Cochrane Database Syst Rev 2007 Apr 18;(2):CD004059.

Dubin J, et al. Staff of the American Academy of Orthopaedic Surgeons on Behalf of the Platelet-Rich Plasma (PRP) for Knee Osteoarthritis Technology Overview Workgroup and Contributors. American Academy of Orthopaedic Surgeons Technology Overview Summary: Platelet-rich plasma (prp) for knee osteoarthritis. J Am Acad Orthop Surg 2024 Apr 1;32(7):296-301.

Herber A, et al Platelet rich plasma therapy versus other modalities for treatment of plantar fasciitis: A systematic review and meta-analysis. Foot Ankle Surg 2024 Jun;30(4):285-293.

*Kim SR, et al. Critical review of prolotherapy for osteoarthritis, low back pain, and other musculoskeletal conditions: a physiatric perspective. Am J Phys Med Rehabil 2004;83:379-89.

*Kim WM, et al. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med 2010 Dec;16(12):1285-90.

Louw WF, et al. Treatment of temporomandibular dysfunction with hypertonic dextrose injection (prolotherapy): a randomized controlled trial with long-term partial crossover. Mayo Clin Proc 2019 May;94(5):820-832.

Mansiz-Kaplan B, et al. Effect of dextrose prolotherapy on pain intensity, disability, and plantar fascia thickness in unilateral plantar fasciitis: a randomized, controlled, double-blind study. Am J Phys Med Rehabil 2020 Apr;99(4):318-324.

Morath O, et al. Sclerotherapy and prolotherapy for chronic patellar tendinopathies - a promising therapy with limited available evidence, a systematic review. J Exp Orthop 2020 Nov 9;7(1):89.

Öztürk MU, et al. A comparative analysis of prolotherapy efficacy in patients with knee osteoarthritis across varied dextrose concentrations. Clin Rheumatol 2023 Dec;42(12):3321-3331.

*Reeves KD, et al. Long-term effects of dextrose prolotherapy for anterior cruciate ligament laxity. Altern Therap 2003 May/Jun;9(3):58-62.

*Robago D, et al. A systematic review of prolotherapy for chronic musculoskeletal pain. Clin J Sport Med 2005;15(5):E376-7.

Sert AT, et al. The effects of dextrose prolotherapy in symptomatic knee osteoarthritis: a randomized controlled study. J Altern Complement Med 2020 May;26(5):409-417.

The American Osteopathic Association of Prolotherapy Regenerative Medicine. What is Prolotherapy?[https://prolotherapycollege.org/what-is-prolotherapy/] accessed 11/07/24.

Waluyo Y, et al. Efficacy of prolotherapy for osteoarthritis: A systematic review. J Rehabil Med 2023 Feb 27;55.

*Yelland MJ, et al. Prolotherapy injections, saline injections, and exercises for chronic low-back pain: a randomized trial. Spine 2004;29(1):9-16.

Yelland M, et al. Prolotherapy injections and physiotherapy used singly and in combination for lateral epicondylalgia: a single-blinded randomised clinical trial. BMC Musculoskelet Disord 2019 Nov 3;20(1):509.

*Key Article

KEY WORDS

Proliferating agent, prolotherapy, sarapin, sclerosing

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) 150.7 for prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&. accessed 11/07/24.