FEP Medical Policy Manual

FEP 2.01.26 Prolotherapy

Effective Policy Date: April 1, 2022

Original Policy Date: September 2011

Related Policies:

None

Prolotherapy

Description

Prolotherapy describes a procedure intended for healing and strengthening ligaments and tendons by injecting an agent that induces inflammation and stimulates endogenous repair mechanisms. Prolotherapy may also be referred to as proliferant injection, prolo, joint sclerotherapy, regenerative injection therapy, growth factor stimulation injection, or nonsurgical tendon, ligament, and joint reconstruction.

OBJECTIVE

The objective of this evidence review is to determine whether the use of prolotherapy improves the net health outcome in individuals who suffer from musculoskeletal pain, osteoarthritic pain, or tendinopathies of the upper or lower limbs.

POLICY STATEMENT

Prolotherapy is considered **investigational** as a treatment of musculoskeletal pain.

POLICY GUIDELINES

Coding

HCPCS code M0076 code specifically describes prolotherapy. However, providers maybe using nonspecific CPT codes.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Sclerosing agents have been approved by the U.S. Food and Drug Administration for use in treating spider and varicose veins. These sclerosing agents include Asclera (polidocanol), Varithena (an injectable polidocanol foam), Sotradecol (sodium tetradecyl sulfate), Ethamolin (ethanolamine oleate), and Scleromate (sodium morrhuate). These agents are not currently approved as joint and ligamentous sclerosing agents.

RATIONALE

Summary of Evidence

For individuals who have musculoskeletal pain (eg, chronic neck, back pain), osteoarthritic pain, or tendinopathies of the upper or lower limbs who receive prolotherapy, the evidence includes small randomized trials with inconsistent results. Relevant outcomes are symptoms, functional outcomes, and quality of life. The strongest evidence evaluates the use of prolotherapy for the treatment of osteoarthritis, but the clinical significance of the therapeutic results is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Orthopedic Medicine

As of September 2020, the American Association of Orthopedic Medicine (AAOM) currently has a recommendation posted online for the use of prolotherapy for back pain, with an unknown original publication date.[27.] The AAOM has indicated that "....prolotherapy should be considered a valid treatment option in a selected group of chronic low back pain patients."

American College of Rheumatology/Arthritis Foundation

The 2019 American College of Rheumatology/Arthritis Foundation guideline for osteoarthritis of the hand, hip, and knee conditionally recommends against the use of prolotherapy in patients with knee and/or hip osteoarthritis, given limited number of trials involving small sample sizes showing limited effect.[28.] The guideline does not make any recommendation regarding hand osteoarthritis, given lack of trials.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid currently do not cover prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents.[29.]

REFERENCES

1. Dagenais S, Yelland MJ, Del Mar C, et al. Prolotherapy injections for chronic low-back pain. Cochrane Database Syst Rev. Apr 18 2007; (2): CD004059. PMID 17443537
2. Dagenais S, Mayer J, Haldeman S, et al. Evidence-informed management of chronic low back pain with prolotherapy. Spine J. Jan-Feb 2008; 8(1): 203-12. PMID 18164468
3. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). May 01 2009; 34(10): 1078-93. PMID 19363456
4. Yelland MJ, Glasziou PP, Bogduk N, et al. Prolotherapy injections, saline injections, and exercises for chronic low-back pain: a randomized trial. Spine (Phila Pa 1976). Jan 01 2004; 29(1): 9-16; discussion 16. PMID 14699269
5. Klein RG, Eek BC, DeLong WB, et al. A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic, low back pain. J Spinal Disord. Feb 1993; 6(1): 23-33. PMID 8439713
6. Ongley MJ, Klein RG, Dorman TA, et al. A new approach to the treatment of chronic low back pain. Lancet. Jul 18 1987; 2(8551): 143-6. PMID 2439856
7. Kim WM, Lee HG, Jeong CW, et al. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med. Dec 2010; 16(12): 1285-90. PMID 21138388
8. Reeves KD, Hassanein KM. Long-term effects of dextrose prolotherapy for anterior cruciate ligament laxity. Altern Ther Health Med. May-Jun 2003; 9(3): 58-62. PMID 12776476
9. Wee TC, Neo EJR, Tan YL. Dextrose prolotherapy in knee osteoarthritis: A systematic review and meta-analysis. J Clin Orthop Trauma. Aug 2021; 19: 108-117. PMID 34046305
10. Sert AT, Sen EI, Esmaeilzadeh S, et al. The Effects of Dextrose Prolotherapy in Symptomatic Knee Osteoarthritis: A Randomized Controlled Study. J Altern Complement Med. May 2020; 26(5): 409-417. PMID 32223554
11. Rabago D, Patterson JJ, Mundt M, et al. Dextrose prolotherapy for knee osteoarthritis: a randomized controlled trial. Ann Fam Med. May-Jun 2013; 11(3): 229-37. PMID 23690322

12. Reeves KD, Hassanein K. Randomized prospective double-blind placebo-controlled study of dextrose prolotherapy for knee osteoarthritis with or without ACL laxity. Altern Ther Health Med. Mar 2000; 6(2): 68-74, 77-80. PMID 10710805
13. Jahangiri A, Moghaddam FR, Najafi S. Hypertonic dextrose versus corticosteroid local injection for the treatment of osteoarthritis in the first carpometacarpal joint: a double-blind randomized clinical trial. J Orthop Sci. Sep 2014; 19(5): 737-43. PMID 25158896
14. Rabago D, Mundt M, Zgierska A, et al. Hypertonic dextrose injection (prolotherapy) for knee osteoarthritis: Long term outcomes. Complement Ther Med. Jun 2015; 23(3): 388-95. PMID 26051574
15. Reeves KD, Hassanein K. Randomized, prospective, placebo-controlled double-blind study of dextrose prolotherapy for osteoarthritic thumb and finger (DIP, PIP, and trapeziometacarpal) joints: evidence of clinical efficacy. J Altern Complement Med. Aug 2000; 6(4): 311-20. PMID 10976977
16. Goh SL, Jaafar Z, Gan YN, et al. Efficacy of prolotherapy in comparison to other therapies for chronic soft tissue injuries: A systematic review and network meta-analysis. PLoS One. 2021; 16(5): e0252204. PMID 34038486
17. Chung MW, Hsu CY, Chung WK, et al. Effects of dextrose prolotherapy on tendinopathy, fasciopathy, and ligament injuries, fact or myth?: A systematic review and meta-analysis. Medicine (Baltimore). Nov 13 2020; 99(46): e23201. PMID 33181700
18. Rabago D, Best TM, Zgierska AE, et al. A systematic review of four injection therapies for lateral epicondylosis: prolotherapy, polidocanol, whole blood and platelet-rich plasma. Br J Sports Med. Jul 2009; 43(7): 471-81. PMID 19028733
19. Scarpone M, Rabago DP, Zgierska A, et al. The efficacy of prolotherapy for lateral epicondylosis: a pilot study. Clin J Sport Med. May 2008; 18(3): 248-54. PMID 18469566
20. Akcay S, Gurel Kandemir N, Kaya T, et al. Dextrose Prolotherapy Versus Normal Saline Injection for the Treatment of Lateral Epicondylopathy: A Randomized Controlled Trial. J Altern Complement Med. Dec 2020; 26(12): 1159-1168. PMID 32990454
21. Apaydin H, Bazancir Z, Altay Z. Injection Therapy in Patients with Lateral Epicondylalgia: Hyaluronic Acid or Dextrose Prolotherapy? A Single-Blind, Randomized Clinical Trial. J Altern Complement Med. Dec 2020; 26(12): 1169-1175. PMID 32931308
22. Bayat M, Raeissadat SA, Mortazavian Babaki M, et al. Is Dextrose Prolotherapy Superior To Corticosteroid Injection In Patients With Chronic Lateral Epicondylitis?: A Randomized Clinical Trial. Orthop Res Rev. 2019; 11: 167-175. PMID 31819675
23. Carayannopoulos A, Borg-Stein J, Sokolof J, et al. Prolotherapy versus corticosteroid injections for the treatment of lateral epicondylosis: a randomized controlled trial. PM R. Aug 2011; 3(8): 706-15. PMID 21871414
24. Yelland MJ, Sweeting KR, Lyftogt JA, et al. Prolotherapy injections and eccentric loading exercises for painful Achilles tendinosis: a randomised trial. Br J Sports Med. Apr 2011; 45(5): 421-8. PMID 19549615
25. Kazempour Mofrad M, Rezasoltani Z, Dadarkhah A, et al. Periarticular Neurofascial Dextrose Prolotherapy Versus Physiotherapy for the Treatment of Chronic Rotator Cuff Tendinopathy: Randomized Clinical Trial. J Clin Rheumatol. Jun 01 2021; 27(4): 136-142. PMID 32975923
26. Bertrand H, Reeves KD, Bennett CJ, et al. Dextrose Prolotherapy Versus Control Injections in Painful Rotator Cuff Tendinopathy. Arch Phys Med Rehabil. Jan 2016; 97(1): 17-25. PMID 26301385
27. American Association of Orthopedic Medicine, Klein RG, Patterson J, et al. Prolotherapy for Back Pain Treatment. n.d.; http://www.aaomed.org/prolotherapy-back-pain. Accessed September 11, 2021.
28. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Rheumatol. Feb 2020; 72(2): 220-233. PMID 31908163
29. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for PROLOTHERAPY, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7). 1999; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&bc=AAAAQAAAAAAA&. Accessed September 11, 2021.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2011	New policy	
December 2012	Replace policy	Updated rationale and references, no change in policy statement.
December 2013	Replace policy	Policy updated with literature review; references 11 and 16 added; reference 20 updated; policy statement unchanged.
December 2014	Replace policy	Policy updated with literature review adding reference 20. No change to policy statement.
December 2015	Replace policy	Policy updated with literature review through June 30, 2015; references 12 and 15 added; policy statement unchanged.
March 2017	Administrative review	Policy reviewed with no changes.

Date	Action	Description
March 2018	Replace policy	Policy updated with literature review through September 14, 2017; reference 22 added. Policy statement unchanged.
March 2019	Replace policy	Policy updated with literature review through September 4, 2018; no references added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through September 6, 2019; no references added. Policy statement unchanged.
March 2021	Replace policy	Policy updated with literature review through October 7, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through September 11, 2021; references added. Policy statement unchanged.