



Geisinger Health Plan Policies and Procedure Manual

Policy: MP127

Section: Medical Benefit Policy

Subject: Prolotherapy

Applicable Lines of Business

| | | | |
|-------------------|----------|-------------|----------|
| Commercial | X | CHIP | X |
| Medicare | X | ACA | X |
| Medicaid | X | | |

I. Policy: Prolotherapy

II. Purpose/Objective:

To provide a policy of coverage regarding Prolotherapy

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Prolotherapy is a method of treating musculoskeletal pain. Prolotherapy promotes a localized inflammatory reaction by injecting proliferants into the damaged tendon or ligament to help stimulate the healing process. Prolotherapy is intended to increase joint stability through the proliferation of fibrous tissue caused by the body's natural inflammatory response to the injected drug. Proponents advocate sclerosant injections to promote joint and ligamentous stability in the treatment of low back pain, knee osteoarthritis and other musculoskeletal disorders.

EXCLUSIONS:

The Plan does **NOT** provide coverage for *prolotherapy* because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment:**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Prolotherapy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

M0076 Prolotherapy

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Winifred S. Hayes, Hayes Inc. Online, Sclerotherapy, Joint and Ligamentous Injection. May 2000. Updated 7/9/03; 8/9/04

ECRI, HTAIS Hotline Response, Prolotherapy for Ligament or Tendon Pain. 7/3/02.

Geisinger Clinic TAC Triage Group, Prolotherapy. Dec. 2003.

Reeves KD, Hassanein K, "Randomized, prospective, placebo-controlled double-blind study of dextrose prolotherapy for osteoarthritic thumb and finger joints: evidence of clinical efficacy", *Journal of Alternative and Complimentary Medicine*. 6(4):311-320. Aug. 2000.

Klein RG, Eek BC, DeLong WB, Mooney V, "A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic, low back pain", *Journal of Spinal Disorders*. 6(1):23-33. Feb. 1993.

Yelland MJ, Glaziou PP, Bogduk N, Schluter PJ, McKernon M, "Prolotherapy Injections, Saline Injections, and Exercises for Chronic Low-Back Pain: A Randomized Trial", *Spine* 29(1):9-16. 2004.

Rabago D, Best TM, Beamsley M, Patterson J. A systematic review of prolotherapy for chronic musculoskeletal pain. *Clin J Sport Med*. 2005 Sep;15(5):E376.

Dagenais S, Haldeman S, Wooley JR. Intraligamentous injection of sclerosing solutions (prolotherapy) for spinal pain: a critical review of the literature. *Spine J*. 2005 May-Jun;5(3):310-28.

Dagenais S, Ogunseitan O, Haldeman S, Wooley JR, Newcomb RL. Side effects and adverse events related to intraligamentous injection of sclerosing solutions (prolotherapy) for back and neck pain: a survey of practitioners. *Arch Phys Med Rehabil* 2006 July;87:909-913.

HAYES Alert – Technology Assessment Brief (online) Prolotherapy for orthopedic indications. March 2006; 9(3).

Fullerton BD, Reeves KD. Ultrasonography in regenerative injection (prolotherapy) using dextrose, platelet-rich plasma and other injectants. *Phys Med Rehabil Clin N Am*. 2010 Aug;21(3):585-605.

Yelland MJ, Sweeting KR, Lyftogt JA, Ng SK, Scuffham PA, Evans KAProlotherapy injections and eccentric loading exercises for painful Achilles tendinosis: a randomised trial. *Br J Sports Med*. 2011 Apr;45(5):421-8.

Dagenais S, Mayer J et al. Evidence-informed management of chronic low back pain with prolotherapy. *Spine J* 2008;8(1):203-212.

Scarpone M, Rabago DP, et al. The efficacy of prolotherapy for lateral epicondylitis: a pilot study. *Clin J Sport Med* 2008;18(3):248-254.

American Association of Orthopaedic Medicine (AAOM). Position Statement. Prolotherapy for the Treatment of Back Pain. <http://www.aaomed.org/prolotherapy-back-pain>. Accessed February 2017.

Feldman M. California Technology Assessment Forum (CTAF). Prolotherapy for the treatment of chronic low back pain. 2004. http://icer-review.org/wp-content/uploads/2016/01/564_file_Prolotherapy_for_the_Treatment_of_Chronic_Low_Back_Pain.pdf. Accessed February 2017.

Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7). 1999; under review in 2016. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&DocID=150.7&ncd_id=150.7&ncd_version=1&basket=ncd%253A150%252E7%253A1%253AProlotherapy%257C%257C+Joint+Sclerotherapy%257C%257C+and+Ligamentous+Injections+with+Sclerosing+Agents&bc=gAAAAABAAAAAAA%3d%3d&. Accessed February 2017.

Hung CY, Hsiao MY, Chang KV, et al. Comparative effectiveness of dextrose prolotherapy versus control injections and exercise in the management of osteoarthritis pain: A systematic review and meta-analysis. *J Pain Res*. 2016;9:847-857.

Sit RW, Chung VCh, Reeves KD, et al. Hypertonic dextrose injections (prolotherapy) in the treatment of symptomatic knee osteoarthritis: A systematic review and meta-analysis. *Sci Rep*. 2016;6:25247.

Reeves KD, Sit RW, Rabago DP. Dextrose prolotherapy: A narrative review of basic science, clinical research, and best treatment recommendations. *Phys Med Rehabil Clin N Am*. 2016;27(4):783-823.

Seenauth C, Inouye V, Langland JO. Dextrose prolotherapy for chronic shoulder pain: A case report. *Altern Ther Health Med*. 2018;24(1):56-60

Hassan, F., Trebinjac, S., Murrell, W., & Maffulli, N. The effectiveness of prolotherapy in treating knee osteoarthritis in adults: a systematic review. *British Medical Bulletin*, 2017 Mar 4:1-18.

Ryu K, Ko D, Lim G, Kim E, Lee SH. Ultrasound-Guided Prolotherapy with Polydeoxyribonucleotide for Painful Rotator Cuff Tendinopathy. *Pain Res Manag*. 2018;2018:8286190

Morath O, Kubosch EJ, Taeymans J, et al. The effect of sclerotherapy and prolotherapy on chronic painful Achilles tendinopathy-a systematic review including meta-analysis. *Scand J Med Sci Sports*. 2018 Jan;28(1):4-15

Bayat M, Raeissadat SA, Mortazavian Babaki M, Rahimi-Dehgolan S. Is Dextrose Prolotherapy Superior To Corticosteroid Injection In Patients With Chronic Lateral Epicondylitis?: A Randomized Clinical Trial. *Orthop Res Rev.* 2019;11:167-175.

Akcaay S, Kandemir NG, Kaya T, et al. Dextrose prolotherapy versus normal saline injection for the treatment of lateral epicondylopathy: A randomized controlled trial. *J Altern Complement Med.* 2020;26(12):1159-1168

Catapano M, Zhang K, Mittal N, et al. Effectiveness of dextrose prolotherapy for rotator cuff tendinopathy: A systematic review. *PM R.* 2020;12(3):288-300.

Chung M-W, Hsu C-Y, Chung W-K, Lin Y-N. Effects of dextrose prolotherapy on tendinopathy, fasciopathy, and ligament injuries, fact or myth?: A systematic review and meta-analysis. *Medicine* 2020;99(46):e23201

Cortez VS, Moraes WA, Taba JV, et al. Comparing dextrose prolotherapy with other substances in knee osteoarthritis pain relief: A systematic review. *Clinics (Sao Paulo).* 2022; 77: 100037.

Arias-Vazquez PI, Tovilla-Zarate CA, Castillo-Avila RG, et al. Hypertonic Dextrose Prolotherapy, an Alternative to Intra-Articular Injections With Hyaluronic Acid in the Treatment of Knee Osteoarthritis: Systematic Review and Meta-analysis. *Am J Phys Med Rehabil.* Sep 01 2022; 101(9): 816-825

Zhu M, Rabago D, Chung VC, et al. Effects of Hypertonic Dextrose Injection (Prolotherapy) in Lateral Elbow Tendinosis: A Systematic Review and Meta-analysis. *Arch Phys Med Rehabil.* Feb 28 2022

Fong HPY, Zhu MT, Rabago DP, et al. Effectiveness of Hypertonic Dextrose Injection (Prolotherapy) in Plantar Fasciopathy: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Arch Phys Med Rehabil.* Apr 23 2023

Ahadi T, Cham MB, Mirmoghtadaei M, et al. The effect of dextrose prolotherapy versus placebo/other non-surgical treatments on pain in chronic plantar fasciitis: a systematic review and meta-analysis of clinical trials. *J Foot Ankle Res.* Feb 10 2023; 16(1): 5

Bahgat MM, Abdel-Hamid AM. Is dextrose prolotherapy beneficial in the management of temporomandibular joint internal derangement? A systematic review. *Cranio.* Apr 25 2023: 1-9

Waluyo Y, Artika SR, Insani Nanda Wahyuni AMAK, et al. Efficacy of Prolotherapy for Osteoarthritis: A Systematic Review. *J Rehabil Med.* Feb 27 2023; 55: jrm00372.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/04

Revised:

Reviewed: 1/05, 1/06, 2/07, 2/08, 2/09, 3/10, 3/11, 4/12, 4/13, 4/14, 4/15, 4/16, 4/17, 3/18, 3/19, 3/20, 3/21, 3/22, 3/23, 3/24

CMS UM Oversight Committee Approval: 12/23, 5/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.