Prolotherapy

Policy # 00106
Original Effective Date: 10/21/2002
Current Effective Date: 07/11/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers prolotherapy as a treatment of musculoskeletal pain to be **investigational.***

Background/Overview

The goal of prolotherapy is to promote tissue repair or growth by prompting release of growth factors, such as cytokines, or by increasing the effectiveness of existing circulating growth factors. The mechanism of action is not well-understood but may involve local irritation and/or cell lysis. Agents used with prolotherapy have included zinc sulfate, psyllium seed oil, combinations of dextrose; glycerin; and phenol, or dextrose alone, often combined with a local anesthetic. Polidocanol and sodium morrhuate, vascular sclerosants, have also been used to sclerose areas of high intratendinous blood flow associated with tendinopathies. Prolotherapy typically involves multiple injections per session conducted over a series of treatment sessions.

A similar approach involves the injection of autologous platelet-rich plasma (PRP), which contains a high concentration of platelet-derived growth factors.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Sclerosing agents have been approved by the U.S. FDA 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.

Centers for Medicare and Medicaid Services (CMS)
The Coverage Issues Manual #35-13 states that prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents are not covered, noting that the medical effectiveness of these therapies has not been verified by scientifically controlled studies. In 1999, on request for reconsideration of coverage of prolotherapy for treatment for chronic low back pain, Medicare retained its decision for noncoverage of prolotherapy again, citing a lack of scientific evidence on which to base a decision.

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Rationale/Source

Prolotherapy has been investigated as a treatment of various etiologies of musculoskeletal pain, including arthritis, degenerative disc disease, fibromyalgia, tendinitis, and plantar fasciitis. As with any therapy for pain, a placebo effect is anticipated, and thus 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. When this evidence review was created in 1997, there was extensive literature on prolotherapy; however, a literature search revealed only 4 randomized placebo-controlled trials. The literature has since been updated periodically with searches of the MEDLINE database. The most recent literature update was performed through June 30, 2015. Following is a description of key studies to date, focusing on randomized controlled trials (RCTs) and systematic reviews.

PROLOTHERAPY

Chronic Neck and Back Pain

In 2004, a Cochrane review concluded that prolotherapy injections have not been proven to be more effective than placebo injections. Two 2005 reviews also noted that there was limited high-quality data to support prolotherapy and that the great variation in injection and treatment protocols limited interpretation of the data. An updated 2007 Cochrane review on prolotherapy for chronic low back pain concluded that "When used alone, prolotherapy is not an effective treatment for chronic low back pain." The authors also concluded that, although confounded by cointerventions and heterogeneity of studies, "When combined with spinal manipulation, exercise, and other interventions, prolotherapy may improve chronic low-back pain and disability." A 2008 systematic review (of the same 5 studies included in the Cochrane review and by one of the same authors) concluded that despite its use for more than 50 years, there is no evidence of efficacy for prolotherapy injections alone for chronic low back pain. The same evidence was evaluated in a 2009 systematic review conducted for the American Pain Society. The authors of this review concluded that prolotherapy was ineffective when used alone for chronic low back pain.

Three randomized trials were identified that focused on the use of injections of dextrose, glycerin, and phenol as a treatment of low back pain. In 1987, Ongley et al reported on a trial of 81 patients with low back pain who were randomly assigned to receive spinal manipulation plus prolotherapy compared with a control group that received less forceful spinal manipulation, less local anesthesia, and placebo injections of saline. Although improved responses were reported for the treatment group, it is not possible to evaluate the contribution of prolotherapy compared with the impact of the different types of spinal manipulation.

In 1993, Klein et al reported on a trial that randomly assigned 79 patients with low back pain to receive a series of 6 weekly injections using either saline or a proliferant solution of dextrose, glycerin, and phenol. Thirty of the 39 patients assigned to the proliferant group achieved a 50% or greater diminution in pain compared with 21 of the 40 in the placebo group. While the incremental benefit of the treatment group was statistically significant (p=0.04), blinding of the treatment groups was not maintained, because those assigned to the proliferant group experienced a clinically recognizable local inflammatory response.

In 2004, Yelland et al reported on a partially blinded RCT on prolotherapy injections, saline injections, and exercises for chronic low back pain in 110 subjects. While decreases in pain and disability were noted in all study groups, there were no significant differences between treatment groups at 12 and 24 months. Therefore, the effects of prolotherapy did not significantly exceed placebo effects.

Dagenais et al also conducted a survey of practitioners of prolotherapy for back and neck pain. Completed surveys (n=171, 50% response rate) revealed that practitioners had a median of 10 years of experience, with a median 2000 treatments in 500 patients. About 500 adverse events (25% of treatments) were reported; 69 (14% of patients) required hospitalization. Adverse events included spinal disc injury, hemorrhage, infection, nerve damage, pneumothorax, spinal headache, spinal cord insult, and systemic reactions. The efficacy of prolotherapy for chronic neck and back pain has not been demonstrated.

Other Musculoskeletal Pain
Reeves and Hassanein (2003) reported on a study of dextrose prolotherapy for anterior cruciate ligament laxity. Of 16 evaluable patients, statistically significant improvements were found at 6, 12, and 36 months in anterior cruciate ligament laxity, pain, swelling, and knee range of motion. However, this was a small, nonrandomized trial and, as previously noted, without placebo control, the extent that improvements with prolotherapy exceed those associated with a placebo cannot be determined.

A 2010 publication by Kim et al compared intra-articular prolotherapy with intra-articular corticosteroid injection for sacroiliac pain. The double-blind, randomized study included 48 patients with sacroiliac joint pain lasting 3 months or more, confirmed by 50% or more improvement in response to local anesthetic block. The injections were performed on a biweekly schedule (maximum of 3 injections) under fluoroscopic guidance with confirmation of the intra-articular location with an arthrogram. Pain and disability scores were assessed at baseline, 2 weeks, and monthly after completion of treatment. At 2 weeks after treatment, all patients met the primary outcome measure of 50% or more reduction in pain scores, and there was no significant difference between the groups. The numeric rating scale for pain was reduced from 6.3 to 1.4 in the prolotherapy group and from 6.7 to 1.9 in the steroid group. The Oswestry Disability Index score decreased from 33.9 to 11.1 in the prolotherapy group and from 35.7 to 15.5 in the steroid group. Kaplan-Meier survival analysis showed a significantly greater percentage of patients with sustained relief following prolotherapy. At 6 months after treatment, 63.6% of patients in the prolotherapy group reported 50% or more improvement from baseline compared with 27.2% of the steroid group. At 15 months after treatment, 58.7% of patients in the prolotherapy group reported 50% or more relief compared 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.

Osteoarthritis
Rabago et al reported an RCT of prolotherapy for knee osteoarthritis in 2013. This trial was supported by the National Center for Complementary and Alternative Medicine. Ninety patients were randomized to blinded injections (3-5 treatments with dextrose prolotherapy or saline) or at-home exercise. All 3 groups

showed improvements on the composite Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), with significantly greater improvement in the prolotherapy group (15.3 points) than in the saline and exercise groups (7.6 and 8.2 points, respectively). At 52 weeks, 50% of prolotherapy patients achieved the minimum clinically important difference of a 12-point change in WOMAC score, compared with 30% of saline-treated patients and 24% of exercise participants. Knee pain scores also improved more in the prolotherapy group. In 2015, Rabago et al reported 2.5-year telephone follow-up from prolotherapy-treated patients in their randomized trial and from 2 uncontrolled open-label studies. The 3 prolotherapy groups were comparable, having undergone similar treatment courses and showing similar improvements in WOMAC score at 52 weeks (15.3, 12.4, 15.9 points, respectively). At a mean 2.5-year follow-up (range, 1.5-3.5 years), the 65 patients who agreed to participate in this follow-up study had a mean 20.9-point improvement in the WOMAC score. There is a risk of bias due to the open-label design and the relatively high proportion (10%) of prolotherapy-treated patients who declined to participate in the telephone interview.

In 2000, Reeves and Hassanein reported on 2 trials that used dextrose for the treatment of osteoarthritis of the knee. The first trial randomized 68 patients with 111 osteoarthritic knees to either 3 bimonthly injections of dextrose or placebo. The patients were evaluated with a visual analog scale (VAS) for pain and swelling, frequency of leg buckling, goniometrically measured flexion, and radiographic measures of joint narrowing. As presented, the data suggested a significant improvement in both the placebo and the treatment groups, but it is difficult to determine the comparative magnitude of improvement between the groups. For example, for the various outcome measures of pain, it appears that there were probably no clinically significant incremental effects of prolotherapy compared with the placebo group. However, for other nonpain outcomes (ie, swelling, buckling, flexion range), prolotherapy might have been associated with a significant incremental improvement. The various outcome measures were combined and assessed using a Hotelling multivariate analysis. With this statistical measurement, prolotherapy demonstrated a statistically superior overall effect (p=0.015) compared with the control group. It should be recognized that the statistical significance of this measure was most likely due to the improvements in the nonpain symptoms (ie, swelling, buckling, flexion range). In summary, it is uncertain whether the incremental improvement in the non-pain-related outcomes of the prolotherapy group compared with the control group is clinically significant.

In a similarly designed 2000 study, the same investigators assessed the effectiveness of prolotherapy as a treatment of osteoarthritic thumb and finger joints. Twenty-seven patients with 150 osteoarthritic joints were randomized to 3 bimonthly injections of either dextrose or water. Patients were evaluated with both VAS for pain and goniometric assessment of joint movement. Because patients had a variable number of joints injected (range, 1-22), the VAS score for every symptomatic joint in each patient was added together for a total and divided by the number of symptomatic joints to provide an average joint pain score for each patient. There were improvements in pain scores in both the placebo and the treatment groups, but the incremental improvement of the treatment group compared with the placebo group was not statistically significant. Regarding flexion, the treatment group reported a statistically significant improvement (p=0.043), while the placebo group reported a greater, statistically significant decrease (p=0.011). Therefore, the

statistically significant difference in flexion between the groups (p=0.003) was primarily related to the decrease in the control group, with a smaller contribution related to the positive response in the treatment group. In summary, the clinical significance of an isolated finding of improved flexion without a corresponding significant improvement in pain is uncertain.

In 2014, Jahangiri et al reported a double-blind, randomized trial that compared prolotherapy with corticosteroid for the treatment of osteoarthritis in the first carpometacarpal joint. Sixty patients were randomized to 3 monthly prolotherapy injections or 2 monthly saline injections plus a corticosteroid injection in the third month. The groups were comparable at baseline, with a VAS score for pain on pressure of 6.7 in the prolotherapy group and 6.4 in the corticosteroid group. At the 6-month follow-up, pain had decreased more (by ≈2 cm on the VAS; VAS final score, <2) in the prolotherapy group compared with the corticosteroid-treated group (p<0.001). Pain on movement and hand function had also improved to a greater extent in the prolotherapy group.

Tendinopathies of the Upper and Lower Limbs

Lateral Epicondylitis

A 2009 systematic review evaluated injection therapies for lateral epicondylitis (tennis elbow); 2 RCTs and a prospective case series on prolotherapy were included. One of the randomized trials was referenced as a report from a 2006 conference on complementary and alternative medicine; no authors are listed in the reference, and the trial does not appear to be available in the peer-reviewed published literature. The second double-blind, randomized placebo-controlled trial (2008) involved 20 patients who had elbow pain for at least 6 months and failure of conservative therapy (rest, physical therapy, nonsteroidal anti-inflammatory drugs, 2 corticosteroid injections) to 3 treatments (over 8 weeks) of prolotherapy or saline injection. There was a significant improvement in pain with prolotherapy injection (5.1 to 0.5 on a Likert scale) compared with saline injection (4.5 to 3.5). Isometric strength also improved (13 to 31 lb vs 10 to 11 lb, respectively), but there was no difference in grip strength between the 2 conditions. The authors indicated that this is the first randomized trial of prolotherapy for tendinopathy and that additional research with a larger study population would be needed.

A small (17 subjects) double-blind, randomized trial compared prolotherapy with corticosteroid injections for chronic lateral epicondylitis was reported in 2011. Each subject received an injection at baseline followed by a second injection at 1 month. VAS for pain, quadruple VAS, and Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) were measured at baseline and at 1, 3, and 6 months. Changes of 2 for in VAS score and 12 for in DASH score were considered clinically significant. Per protocol analysis showed a significant improvement in VAS and DASH at both 3 (2.38 and 19.89) and 6 months (2.63 and 21.76, both respectively) for the prolotherapy group, while the corticosteroid group showed significant improvement for DASH at 3 (13.33) and 6 months (15.56). The study was underpowered to detect a significant difference between the prolotherapy and corticosteroid groups for change in VAS, quadruple VAS, or DASH.

Achilles Tendonitis

Yelland et al (2011) reported a multicenter randomized trial of prolotherapy or exercises for Achilles tendonitis in 43 patients. Inclusion criteria were diagnosis of unilateral or bilateral mid-portion Achilles tendinosis with pain between 2 and 7 cm proximal to the calcaneal attachment in adults older than 18 years with activity-related pain for at least 6 weeks. The sample size was limited by the available resources and slow recruitment rate, resulting in 15 participants in the eccentric loading exercise group, 14 in the prolotherapy group, and 14 in the combined treatment group. Randomization was conducted by a central site and resulted in a lower median duration of pain in the combined treatment group (6 months) than in the exercise alone (21 months) or prolotherapy alone (24 months) groups. An average of 4.4 injections per treatment was directed at tender points in the subcutaneous tissues adjacent to the affected tendon, with 4 to 12 weekly treatments until participants attained pain-free activity or requested to cease treatment. Participants were instructed to perform eccentric loading exercises twice daily in 3 sets of 15 repetitions with the knee straight, and 3 sets of 15 repetitions with the knee bent for 12 weeks, with the load progressively increased by adding weights to a backpack. Clinical reviews were performed at 3, 6, and 12 weeks to check technique and progress. Mean increases in the validated Victorian Institute of Sport Assessment–Achilles (VISA-A) score were 23.7 for exercise alone, 27.5 for prolotherapy alone, and 41.1 for the combined treatment. At 6 weeks and 12 months, these increases were significantly greater for combined treatment (exercise and prolotherapy) than for exercise alone. The predefined minimum clinically important increase of 20 points or more on the VISA-A was obtained by 12 subjects in the combined treatment group and 11 each in the exercise alone and prolotherapy alone groups; the difference was not statistically significant. The percentage of patients achieving full recovery (VISA-A score of ≥90 at 12 months) was 53% for exercise alone, 71% for prolotherapy alone, and 64% for the combined treatment group; but these differences were not significant. Although the authors concluded that prolotherapy may be a cost-effective method to speed recovery in patients with Achilles tendonitis, this trial was limited by the combination of a small number of subjects per group, unequal durations of pain in the treatment groups at baseline, and minimal differences in the number of patients showing recovery (11/14 vs 12/15, respectively). Additional randomized trials are needed to replicate and extend these findings.

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 the effects of the technology on health outcomes.

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09/18/2002	Medical Policy Committee review
10/21/2002	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
07/10/2007	Medical Director review
07/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. Updated Background, Rationale and References. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2011	Medical Policy Committee review
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06/28/2012	Medical Policy Committee review
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01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
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07/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review.
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2019

Coding

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Code Type	Code
CPT	No codes
HCPCS	M0076
ICD-10 Diagnosis	All related diagnoses

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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