



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0006

Subject **Prolotherapy**

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Prolotherapy is specifically excluded under some benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

CIGNA does not cover prolotherapy for any indication because it is considered experimental, investigational or unproven.

General Background

Prolotherapy is a procedure that consists of injecting sclerosing solutions into the joints, muscles, ligaments, or tendons in an attempt to increase joint stability. The proliferation of fibrous tissue caused by the body's natural inflammatory response to the injected drug is believed to increase joint stability. Prolotherapy may also be referred to as regenerative injection therapy; growth factor stimulation injection; nonsurgical tendon, ligament and joint reconstruction; proliferant injection; prolo; and joint sclerotherapy (Dagenais, et al. 2008).

The diagnosis and treatment of joint or ligament instability is individualized and often complex. For acute or chronic conditions in which the ligaments or tendons are strained or torn, therapists commonly combine modalities that promote flexibility and resolve inflammation while maintaining stability and maximum function. Conservative treatment options may include rest, the use of mild analgesics and anti-inflammatory drugs, compression and/or mild exercise. Chronic or disabling pain may be treated with physical therapy, cortisone injections or surgery.

Injecting proliferative/sclerosing agents is thought to cause an influx of fibroblasts to the affected site, thereby causing the growth of fibrous new ligament or tendon tissue. Sclerosing agents act as inflammatory agents that cause minor injury to the ligament and initiate the first step in the wound healing process, leading to new collagen formation. Proponents suggest this may lead to increased ligament strength for back support. Sclerosing agents include chemical irritants, osmotic shock agents, and chemotactic agents. Among the agents that are commonly used are zinc sulfate; psyllium seed oil; hypertonic glucose; combinations of dextrose, glycerine phenol, and Sarapin[®]; or dextrose alone.

Prolotherapy techniques vary depending on the type of solution used, the frequency and volume of injections and use of other cointerventions (Dagenais, et al. 2008). Prolotherapy may involve a single injection or a series of injections, often diluted with a local anesthetic. Prior to injection, the physician attempts to identify pain trigger points during a physical examination. The sclerosant is injected next to the injury site at the interface between the bone and tendon, ligament or fascia. For patients with lower back pain, the physician generally injects the muscles overlying the sacroiliac joint.

Prolotherapy has been investigated as a treatment for various etiologies of pain, including arthritis, degenerative disc disease, fibromyalgia, tendonitis, plantar fasciitis, and soft tissue injuries.

Literature Review

There is lack of scientific data to support the efficacy of prolotherapy as a treatment for joint or ligament instability. Evidence in the peer-reviewed scientific literature evaluating prolotherapy injections consists of case series and systematic reviews with few randomized controlled clinical trials (Dagenais, et al., 2008; Hooper, et al., 2007; Dagenais, et al., 2007; Dagenais, et al., 2006; Robago, et al., 2005; Topol, et al., 2005; Kim, et al., 2004; Yelland, et al., 2004). Much of the published data indicate prolotherapy injections have not been proven to be as effective as or more effective than placebo injections. Although the results of some studies in the medical literature evaluating prolotherapy support improvement in pain (Reeves and Hassanein, 2000a; Yelland, et al., 2004; Topol, et al., 2005; Wilkinson, 2005; Hooper, et al, 2007; Khan, et al., 2008; Scarpone, et al., 2008; Cusi, et al., 2010) treatment was often combined with other modalities (e.g., exercise, spinal manipulation) and various pharmaceutical solutions were utilized. Consequently, heterogeneity among clinical trials does not allow generalization across studies. Heterogeneity among studies, small populations, short-term outcomes, lack of control groups and the use of co-interventions leads to weak or inconsistent conclusions regarding improvement in net health outcomes as a direct result from prolotherapy injections.

The California Technology Assessment Forum reviewed the scientific evidence for the use of prolotherapy for the treatment of chronic low back pain (Feldman, 2004) and reported that one early study was able to demonstrate conclusively that prolotherapy was significantly superior to placebo for treatment of chronic low back pain. Subsequent research however has not been able to replicate this finding. The author stated it is, therefore, not possible to conclude from the published literature that prolotherapy is superior to placebo injection for the treatment of chronic low back pain or is as beneficial as alternative treatments.

The American Pain Society published guidelines for low back pain (Chou, et al, 2009). Based on their review of the available evidence prolotherapy was not recommended for patients with persistent nonradicular low back pain because it was found to be no more effective than sham therapies.

Summary

Evidence in the peer-reviewed scientific literature evaluating prolotherapy injections consists of case series and systematic reviews with few randomized controlled clinical trials and is considered insufficient to support safety, efficacy and improvement in clinical outcomes as a result of this therapy.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/ Investigational/Unproven and Not Covered when used to report prolotherapy services:

| CPT®* Codes | Description |
|------------------------------|---|
| 20550 | Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia") |
| 20551 | Injection(s); single tendon origin/insertion |

| HCPCS Codes | Description |
|------------------------------|--------------------|
| M0076 | Prolotherapy |

| ICD-9-CM Diagnosis Codes | Description |
|---|--------------------|
| | All codes |

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

| <u>Pre-Merger Organizations</u> | <u>Last Review Date</u> | <u>Policy Number</u> | <u>Title</u> |
|-------------------------------------|-----------------------------|--------------------------|--------------|
| CIGNA HealthCare | 12/15/2007 | 0006 | Prolotherapy |

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