MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Prolotherapy**
Policy Number	**8.01.10**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 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**
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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)	

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HCPCS Codes

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

ICD10 Codes

Code	Description
	Numerous

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*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.