

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	PROLOTHERAPY
Policy Number	8.01.10
Category	Technology Assessment
Effective Date	10/18/01
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Product Disclaimer	<ul style="list-style-type: none"> • 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

Based on our criteria and assessment of the peer-reviewed literature, prolotherapy has not been medically proven to be effective and is considered **investigational** as a treatment of musculoskeletal pain and/or instability (e.g., laxity, weakness).

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Prolotherapy describes a procedure for healing and strengthening lax ligaments by injecting proliferating agents/sclerosing solutions directly into torn or stretched ligaments. “Proliferatives” act 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, combinations of dextrose, glycerine phenol, Sarapin or dextrose alone. Polidocanol and sodium morrhuate, vascular sclerosants, have also been utilized to sclerose 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. Prolotherapy may also be referred to proliferant injection, joint sclerotherapy, regenerative injection therapy, or nonsurgical tendon, ligament and joint reconstruction.

RATIONALE

Although individual ingredients such as dextrose and lidocaine are approved for injection by the 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.

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Scientific data demonstrating the effectiveness of prolotherapy for the treatment of joint and ligament instability is limited and interpretation complicated by variations in treatment protocols, the use of concomitant treatments, and lack of a non-injection control group. As with any therapy for pain, a placebo effect is anticipated and 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. In the two clinical trials referenced (both by Reeves), it is not known whether the incremental improvement in the non-pain-related outcomes of the prolotherapy group compared to the control group is clinically significant. The clinical significance of an isolated finding of improved flexion without a corresponding significant improvement in pain is uncertain. Additional studies with larger control and experimental groups must be conducted to evaluate the efficacy of prolotherapy for joint or ligament instability. There is inadequate evidence of the effectiveness of Sarapin for pain.

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 updates.

CPT Codes

Code	Description
No specific code(s)	

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HCPCS Codes

Code	Description
M0076 (E/I)	Prolotherapy

ICD10 Codes

Code	Description
M51.14-M51.17	Intervertebral disc disorders with radiculopathy (code range)
M54.14-M54.17	Radiculopathy (code range)
M545	Low back pain

REFERENCES

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*Key Article

KEY WORDS

Proliferating agent, Prolotherapy, Sarapin, Sclerosing

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for prolotherapy. 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&>.