MEDICAL POLICY

Capital BLUE

POLICY TITLE	PROLOTHERAPY
POLICY NUMBER	MP-2.061

Original Issue Date (Created):	**8/23/2002**
Most Recent Review Date (Revised):	**12/4/2018**
Effective Date:	**2/1/2019**

I. POLICY

Prolotherapy is considered **investigational** as a treatment of musculoskeletal pain, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP-4.039 Orthopedic Applications of Platelet Rich Plasma.
MP-5.048 Diagnosis and Treatment of Sacroiliac Joint Pain

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-2.01.26, Prolotherapy. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Prolotherapy describes a procedure intended for healing and strengthening ligaments and tendons by injecting an agent that induces inflammation and stimulates endogenous repair mechanisms. Prolotherapy may also be referred to as proliferant injection, prolo, joint sclerotherapy, regenerative injection therapy, growth factor stimulation injection, or nonsurgical tendon, ligament, and joint reconstruction.

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The goal of prolotherapy is to promote tissue repair or growth by prompting release of growth factors, such as cytokines, or 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, glycerine, 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. Treatment of musculoskeletal pain conditions (e.g., tendinopathies) with PRP is discussed in MP-4.039 Orthopedic Applications of Platelet Rich Plasma.

Regulatory status

The U.S. Food and Drug Administration has approved sclerosing agents for use in treating spider/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.

IV. RATIONALE

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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.

V. DEFINITIONS

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CYTOKINES refer to one or more than one hundred (100) distinct proteins produced primarily by white blood cells. They provide signals to regulate immunological aspects of cell growth and function during both inflammation and specific immune response.

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

HCPCS Code	Description
M0076	Prolotherapy

IX. REFERENCES

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2. *Dagenais S, Mayer J, Haldeman S, et al. Evidence-informed management of chronic low back pain with prolotherapy. Spine J. Jan-Feb 2008;8(1):203-212. PMID 18164468*

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3. *Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). May 1 2009;34(10):1078-1093. PMID 19363456*
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Other

Taber's Cyclopedic Medical Dictionary, 20th edition.

X. POLICY HISTORY

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MP 2.061	**CAC 10/28/03**
	CAC 7/26/05
	CAC 7/25/06
	CAC 7/31/07
	CAC 7/29/08
	CAC 7/28/09 Consensus Review
	CAC 9/20/10 Adopt BCBSA.
	CAC 10/25/11 Consensus Review. FEP variation changed to refer to FEP policy manual

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	CAC 1/29/13 Consensus review. References updated; no changes to policy statement. Codes reviewed 11/27/12
	CAC 1/28/14 Consensus review. References updated; no changes to policy statement. Rationale added.
	CAC 1/27/15 Consensus. References and rationale updated. No change to policy statements.
	CAC 1/26/16 Consensus. References and rationale updated. No change to policy statements. Coding reviewed.
	Administrative Update 11/10/16 Variation reformatting
	CAC 1/31/17 Consensus review. No change to the policy statement. References reviewed. Coding reviewed.
	12/12/17 Consensus review. No change to the policy statement. Rationale and references updated.
	12/4/18 Consensus. No change to policy statements. References updated. Rationale condensed.

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