Prolotherapy

Policy # 00106
Original Effective Date: 10/21/2002
Current Effective Date: 08/10/2020

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.

Note: Recombinant and Autologous Platelet Derived Growth Factors for Wound Healing and Other Non Orthopedic Conditions is addressed separately in medical policy 00262.

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 the 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, sodium morrhuate, and 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, 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.

Rationale/Source

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.

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. The 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.

Supplemental Information

Practice Guidelines and Position Statements

American Association of Orthopedic Medicine

The American Association of Orthopedic Medicine currently has a recommendation posted online for the use of prolotherapy for back pain. The Association has indicated that "....prolotherapy should be considered a valid treatment option in a selected group of chronic low back pain patients."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid currently do not cover prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01897259	Comparison of Conservative Methods for the Treatment of Lateral Epicondylitis: A Randomized, Prospective Study	200	Jun 2019
NCT01934868	A Comparison of the Long Term Outcomes of Prolotherapy Versus Interlaminar Epidural Steroid Injections (ESI) for Lumbar Pain Radiating to the Leg	160	Dec 2019
Unpublished			
NCT01617356	Treatment of Temporomandibular Dysfunction With Hypertonic Dextrose Injection: A Randomized Clinical Trial Efficacy	30	Dec 2017 (completed)
NCT01402011	Prolotherapy in the Treatment of Rotator Cuff Tendinopathy, a Randomized Double-blind Placebo-controlled Study	72	Jun 2013 (completed)

NCT: national clinical trial.

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Policy History

Original Effective Date: 10/21/2002
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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.

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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
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/27/2013	Medical Policy Committee review and approval.
07/17/2013	Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.
07/10/2014	Medical Policy Committee review and approval.
07/16/2014	Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.
06/25/2015	Medical Policy Committee review and approval.
07/15/2015	Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.
06/30/2016	Medical Policy Committee review and approval.
07/20/2016	Medical Policy Implementation Committee review and approval. Coverage unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
07/06/2017	Medical Policy Committee review.
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.
07/03/2019	Medical Policy Committee review.

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07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020 Medical Policy Committee review.
07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 07/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes

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HCPCS	M0076
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.