

Prolotherapy

Policy # 00106

Original Effective Date: 10/21/2002

Current Effective Date: 08/01/2026

Retired Date: 08/14/2023

Returned to Active Status: 08/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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. Food and Drug Administration for use in treating spider veins, varicose veins, or esophageal varices. These sclerosing agents include Asclera^{®†} (polidocanol), Varithena^{®†} (an injectable polidocanol foam), Sotradecol^{®†} (sodium tetradecyl

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sulfate), and Ethamolin^{®†} (ethanolamine oleate). These agents are not currently approved as joint and ligamentous sclerosing agents.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence

For individuals who have musculoskeletal pain (eg, chronic neck or 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 that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Foot and Ankle Surgeons

A 2017 guideline from the American College of Foot and Ankle Surgeons on acquired infracalcaneal heel pain states that evidence regarding the efficacy and safety of prolotherapy for treatment of plantar fasciitis is uncertain, which makes its use neither appropriate nor inappropriate. The same statement is made for platelet-rich plasma, amniotic tissue, botulinum toxin, and needling.

American College of Rheumatology/Arthritis Foundation

The 2019 American College of Rheumatology/Arthritis Foundation guideline for osteoarthritis of the hand, hip, and knee conditionally recommends against the use of prolotherapy in patients with

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knee and/or hip osteoarthritis, given limited number of trials involving small sample sizes showing limited effect. The guideline does not make any recommendation regarding hand osteoarthritis, given lack of trials.

North American Spine Society

A 2020 guideline on low back pain from the North American Spine Society does not provide a recommendation on prolotherapy but states that sacroiliac ligament prolotherapy deserves further study.

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
<i>Ongoing</i>			
NCT06911359	The Effect of Non-steroidal Anti-inflammatory Drug (NSAID) Use on the Efficacy of Dextrose Prolotherapy in the Treatment of Knee Osteoarthritis: A Randomized Controlled Trial	68	Dec 2025
NCT07102225	Effects of Intra-articular Hypertonic Dextrose and Hyaluronic Acid on Primary Knee Osteoarthritis: A Randomized Control Trial	56	Sept 2026
NCT03411811	Dextrose Prolotherapy in Chronic Ulnar Wrist Pain Resistant to Usual Care: Comparison to a Naive-to-Treatment Cohort Who Receive Usual Care	60	Jan 2023 (unknown status)
NCT05918146	Effects of Hypertonic Dextrose Prolotherapy on Conventional Physical Therapy in Patients With Subdeltoid Bursitis: a Double-blind, Randomized, Placebo-controlled Study	46	Jun 2024 (unknown status)

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<i>Unpublished</i>			
NCT05548738	The Efficacy of Ultrasound and Fluoroscopy Guided Caudal Epidural Prolotherapy Versus Steroids for Chronic Pain Management in Failed Back Surgery Syndrome	80	Jun 2024
NCT05160532	Intraarticular Dextrose Prolotherapy for Symptomatic Knee Osteoarthritis	160	May 2025
NCT05966948	Hypertonic Dextrose Prolotherapy Versus Normal Saline Intra-articular Injection Among Knee Osteoarthritis With Obese Patient	40	Oct 2023
NCT01934868	A Comparison of the Long Term Outcomes of Prolotherapy Versus Interlaminar Epidural Steroid Injections (ESI) for Lumbar Pain Radiating to the Leg	110	Apr 2023
NCT05984121	Which is Outstanding, Local Ozone Injection or Dextrose Prolotherapy Injection in Chronic Plantar Fasciitis?: A Randomised Controlled Study"	60	Mar 2024
NCT04805242	Effects of Dextrose Prolotherapy in Rotator Cuff Disease: A Randomized Controlled Study	60	Nov 2021

NCT: national clinical trial.

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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

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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.
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.
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review.

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07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/01/2021 Medical Policy Committee review.

07/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/07/2022 Medical Policy Committee review.

07/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/06/2023 Medical Policy Committee review

07/12/2023 Medical Policy Implementation Committee approval. Retired policy.

07/02/2026 Medical Policy Committee review

07/08/2026 Medical Policy Implementation Committee review

07/16/2026 Medical Quality Management Committee approval. Policy brought back to active status.

Next Scheduled Review Date: 07/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 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.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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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
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 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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.