

Corporate Medical Policy

Prolotherapy

File Name: prolotherapy
Origination: 6/2002
Last Review: 4/2023

Description of Procedure or Service

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.

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, glycerin, 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 the BCBSNC policy titled “Growth Factors in Wound Healing”.

Regulatory Status

Sclerosing agents have been approved by the U.S. Food and Drug Administration 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.

Related Policy:

Diagnosis and Treatment of Sacroiliac Joint Pain

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Prolotherapy is considered investigational. BCBSNC does not cover investigational services or procedures.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Prolotherapy is covered

Not applicable.

When Prolotherapy is not covered

Prolotherapy is considered investigational as a treatment of musculoskeletal pain. BCBSNC does not cover investigational services or procedures.

Policy Guidelines

For individuals who have musculoskeletal pain (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 is for the treatment of osteoarthritis, but the clinical significance of the results is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: M0076

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual 2.01.26, Issued 8/15/01

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 02/25/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 4/25/06

Centers for Medicare and Medicaid Services. National Coverage Determination 150.7. Retrieved from

California Technology Assessment Forum (CTAF). Prolotherapy for the treatment of chronic back pain (June 9, 2004). Retrieved from http://www.ctaf.org/sites/default/files/assessments/564_file_Prolotherapy_for_the_Treatment_of_Chronic_Low_Back_Pain.pdf

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American Association of Orthopaedic Medicine. Position Statement. Prolotherapy for the Treatment of Back Pain. Retrieved from <http://orthointegrativesportsmed.com/pdf/aaom-position-statement.pdf>

Dagenais S, Yelland MJ, Del Mar C, Schoene ML. Prolotherapy injections for chronic low-back pain. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD004059. DOI: 10.1002/14651858.CD004059.pub3.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 7/10/08

Veterans Affairs Technical Assessment Program (VATAP). Bibliography: Prolotherapy for musculoskeletal pain. (April 2008). Retrieved from <http://www4.va.gov/vatap/pubs/prolotherapyfinal.pdf>

Best TM, Zgierska AE, Zeisig E, Ryan M Crane D. (July 2009). A systematic review of four injection therapies for lateral epicondylitis: prolotherapy, polidocanol, whole blood and platelet rich plasma. British Journal of Medicine, 43 (7). Retrieved from <http://bjsm.bmj.com/content/43/7/471.long>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/13/09

Specialty Matched Consultant Advisory Panel review 7/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/12/10

Rabago D, Slattengren A, Zgierska A. Prolotherapy in primary care practice. Prim Care. 2010 Mar;37(1):65-80. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831229/?tool=pubmed>

Specialty Matched Consultant Advisory Panel review 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/11/11

National Institute of Health (NIH). Prolotherapy for the Treatment of Plantar Fasciitis. Clinical Trial #NCT01326351. Retrieved from <http://clinicaltrials.gov/ct2/show/NCT01326351?term=nct01326351&rank=1>

Rabago D, Zgierska A, Fortney L, Kijowski R, Mundt M, Ryan M, Grettie J, Patterson JJ. Hypertonic Dextrose Injections (Prolotherapy) for Knee Osteoarthritis: Results of a Single-Arm Uncontrolled Study with 1-Year Follow-Up. The Journal of Alternative and Complementary Medicine. April 2012, 18(4): 408-414. doi:10.1089/acm.2011.0030. Retrieved from <http://online.liebertpub.com/doi/abs/10.1089/acm.2011.0030>

Specialty Matched Consultant Advisory Panel review 7/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/9/12

Specialty Matched Consultant Advisory Panel review 7/2013

Medical Director review 7/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/8/13

Specialty Matched Consultant Advisory Panel review 7/2014

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Medical Director review 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/14/14

Specialty Matched Consultant Advisory Panel review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 8/13/15

Specialty Matched Consultant Advisory Panel 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 11/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 11/8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 11/14/2019

Specialty Matched Consultant Advisory Panel 04/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.26, 11/12/2020

Specialty Matched Consultant Advisory Panel 04/2021

Medical Director review 4/2021

American Association of Orthopedic Medicine, Klein RG, Patterson J, et al. Prolotherapy for Back Pain Treatment. n.d.; <http://www.aomed.org/prolotherapy-back-pain>. Accessed September 11, 2021.

Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Rheumatol*. Feb 2020; 72(2): 220-233. PMID 31908163

Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for PROLOTHERAPY, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7). 1999; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&bc=AAAAQAAAAAAA&>. Accessed September 11, 2021

Specialty Matched Consultant Advisory Panel 04/2022

Medical Director review 4/2022

Specialty Matched Consultant Advisory Panel 04/2023

Medical Director review 4/2023

Policy Implementation/Update Information

6/02 New policy issued.

5/03 Specialty Matched Consultant Advisory Panel review. No change in criteria. Format changes.

6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to policy statement. Benefits Application as well as Billing/Coding sections updated for consistent policy language. MED1341 added as key word. Reference added.

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- 6/18/07 Information added to Description for clarity. Rationale for continued investigational status added to Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review meeting 5/18/07. No changes to policy coverage criteria. (adn)
- 7/6/09 Description section revised. Policy Guidelines section updated. References updated. Specialty Matched Consultant Advisory Panel review meeting 5/21/09. No change to policy statement. (adn)
- 8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Description section updated. References updated. Medical Policy number removed. (mco)
- 8/16/11 Specialty Matched Consultant Advisory Panel review 7/2011. References updated. No changes to policy statement. (mco)
- 9/30/11 References updated. (mco)
- 8/7/12 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 7/2012. References updated. (mco)
- 7/30/13 Specialty Matched Consultant Advisory Panel review 7/2012. Medical Director review 7/2013. References updated. No changes to Policy Statements. (mco)
- 10/1/13 References updated. (mco)
- 8/12/14 Specialty Matched Consultant Advisory Panel review 7/2014. References updated. Medical Director review 7/2014. No changes to Policy Statements. (mco)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. (sk)
- 10/1/15 Reference added. (sk)
- 7/26/16 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)
- 5/26/17 Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (an)
- 6/8/18 Minor changes to Description and Policy Guidelines sections. Reference added. Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy statement. (an)
- 4/30/19 Minor changes to Description section. Reference added. No change to policy statement. Specialty Matched Consultant Advisory Panel review 4/17/2019. (an)
- 4/28/20 References added. No change to policy statement. Specialty Matched Consultant Advisory Panel review 4/15/2020. (eel)
- 5/18/21 References added. Specialty Matched Consultant Advisory Panel review 4/2021. Medical Director review 4/2021. No change to policy statement. (eel)
- 5/3/22 Related policy added. References added. Specialty Matched Consultant Advisory Panel review 4/2022. Medical Director review 4/2022. No change to policy statement. (tt)

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5/2/23 Description updated. References added. Specialty Matched Consultant Advisory Panel review 4/2023. Medical Director review 4/2023. No change to policy statement. (tt)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.