

## **Prolotherapy**

Dates Reviewed: 05/2011, 04/2012, 02/2013, 02/2014, 08/2015, 12/2017, 11/2018, 11/2019, 11/2020

**Developed By:** Medical Necessity Criteria Committee

## I. Description

Prolotherapy is a technique utilizing the injection of a sclerosing agent into the joints, muscles, tendons, or ligaments for the purpose of inducing an inflammatory response. Prolotherapy may also be referred to as proliferant injection or proliferation therapy, prolo, joint sclerotherapy, growth factor stimulation injection, nonsurgical tendon, ligament, and joint reconstruction, intra-articular regenerative injection therapy. Common prolotherapy agents used are zinc sulfate, dextrose, glucose, glycerin, fibrin glue, phenol, sodium morrhuate, or platelet-rich plasma. Typically, prolotherapy involves multiple sessions with each session requiring multiple injections.

Extensive prolotherapy literature exists. Evidence in the peer-reviewed literature evaluating prolotherapy consists of case series and systematic reviews with few randomized controlled clinical trials. Peer review literature does not substantiate the value of this therapy. Cochrane review of 2004 concluded that prolotherapy injections have not been proven to be more effective than placebo injections. American College of Occupational and Environmental Medicine guideline of 2007 does not recommend prolotherapy injections for acute, subacute, chronic low back pain or radicular pain syndrome.

#### II. Criteria: CWOI HCS-0055

A. Prolotherapy is considered investigational for all indications and is NOT covered by Moda Health.

#### III. Information Submitted with the Prior Authorization Request:

1. None. Prolotherapy is considered investigational.

#### IV. CPT or HCPC codes NOT covered:

Codes	Description
M0076	Prolotherapy

#### V. Annual Review History

Review Date	Revisions	Effective Date
02/2013	Annual Review: Added table with review date, revisions, and effective	03/1/2013
	date.	
02/2014	Annual Review: No change	02/25/2014
08/2015	Annual Review: Added Medicare criteria, ICD-10 codes	08/26/2016
12/2017	Annual Review: Removed criteria for Platelet Rich Plasma injections and	12/06/2017
	will refer to MCG A-0630	
11/2018	Annual Review: No change	11/28/2018
11/2019	Annual Review: No changes	12/5/2019
11/2020	Annual Review: No changes	12/1/2020

#### VI. References

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- 2. American Association of Orthopaedic Medicine. Position Statement. Information on Injection Treatments. Accessed November 19, 2010. Available at URL address: http://www.aaomed.org/Information-Injection-Treatments.php
- 3. Centers for Medicare & Medicaid Services (CMS). Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents. Coverage Issues Manual. 35-13. Accessed December 5, 2017 at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&DocID=150.7&ncd\_id=150.7&ncd\_version=1&basket=ncd\*3 a%24150.7\*3a%241\*3a%24Prolotherapy%7c%7c+Joint+Sclerotherapy%7c%7c+and+Ligamento us+Injections+with+Sclerosing+Agents&bc=gAAAABAAAAA&
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- 12. Manchikanti L, Manchikanti KN, Manchukonda R, et al. Evaluation of lumbar facet joint nerve blocks in the management of chronic low back pain: Preliminary report of a randomized, double-blind controlled trial: clinical trial NCT00355914. Pain Physician. 2007;10(3):425-440.
- 13. Rabago D, Best TM, Beamsley M, Patterson J. A systematic review of prolotherapy for chronic musculoskeletal pain. Clin J Sport Med. 2005;15(5):376-380
- 14. Rabago D, Best TM, Zgierska AE, et al. A systematic review of four injection therapies for lateral epicondylosis: Prolotherapy, polidocanol, whole blood and platelet-rich plasma. Br J Sports Med. 2009;43(7):471-481.
- 15. Robago D, Slattengren A, Zgierska A. Prolotherapy in primary care practice. Prim Care. 2010 Mar;37(1):65-80.
- 16. Scarpone M, Rabago DP, Zgierska A, et al. The efficacy of prolotherapy for lateral epicondylosis: A pilot study. Clin J Sport Med. 2008;18(3):248-254.
- 17. Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3); Effective 8/2/2012; Implementation date 7/1/2013
- 18. Physician advisors.

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):			
National Coverage Determination (NCD) Prolotherapy, Joint Sclerotherapy and Ligamentous Injections with Sclerosing Agents (150.7)				
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&DocID=150.7&kq=true&bc=gAAAABAAAAAAAAA3d%3d&				

# NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC		