



Clinical Review Criteria Prolotherapy & Sclerotherapy

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Criteria

For Medicare Members

| Source | Policy |
|--|---|
| CMS Coverage Manuals | None |
| National Coverage Determinations (NCD) | Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7) <i>This service is not covered per Medicare criteria.</i> |
| Local Coverage Determinations (LCD) | None |
| Local Coverage Article | None |

For Non-Medicare Members

| Service | Policy |
|--|--|
| Prolotherapy/Sclerotherapy for ANY indication | There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. |

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Back pain is the most prevalent musculoskeletal condition encountered in primary care and is estimated to affect 65-80% of people during their life. The majority of back pain is benign, self-limiting and requires symptomatic therapy only. Back pain is often related to muscular, tendon or ligament strain or injury. Common treatments include physical therapy, steroidal and nonsteroidal anti-inflammatory drugs and chiropractic manipulation. One proposed treatment for chronic low back pain, which is resistant to other treatments, is the injection of sclerosing compounds into back tissue to produce scarring and potentially stabilize soft tissue in the area of the injury.

Prolotherapy, also called sclerotherapy and proliferative injection therapy, has been used as a treatment for chronic low-back pain since the 1950s (Dechow). Sclerosing agents are injected into the fibro-osseous junctions of the lower back. The rationale for using prolotherapy is that the injection of irritant solutions into a pain site will initiate local inflammation. The inflammation then begins a cascade of wound healing which results in the deposition of new collagen and stronger ligaments (Banks).

Medical Technology Assessment Committee (MTAC)

Prolotherapy/Sclerotherapy for Low Back Pain

06/09/1999: MTAC REVIEW

Evidence Conclusion: The published evidence consists of two randomized trials, one showing a 1.5-point improvement (7.5-point visual analogue scale) in pain and a 4.9 point improvement (33 item scale) in disability between the proliferant and placebo groups at 6 months. The experimental regimen also included injectable steroids, forceful spinal manipulation and different anesthetic volumes, therefore differences between experimental and placebo groups cannot be attributed only to proliferant. The second trial reports a less than 1-point difference in pain and disability scores between proliferant and placebo at 6 months. Overall, there is weak evidence that an intensive intervention (including proliferant) produces a statistically and clinically significant improvement in pain and disability. When proliferant and placebo are directly compared, there is weak evidence that proliferant provides no additional benefit compared to placebo.

Articles: Ongley, MJ, et al, A New Approach to the Treatment of Chronic Low Back Pain, 1987, *Lancet*, ii: 143-148. See [Evidence Table](#). Klein, RG, et al, A Randomized Double-Blind Trial of Dextrose-Glycerine-Phenol Injections for Chronic Low Back Pain, *Journal of Spinal Disorders*, 1993, 6:23-33 See [Evidence Table](#).

The use of prolo/sclerotherapy in the treatment of low back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/10/2002: MTAC REVIEW

Prolotherapy/Sclerotherapy for Low Back Pain

Evidence Conclusion: One new RCT was identified on prolotherapy/sclerotherapy for low back pain (Dechow). This was a valid RCT that compared three, once-weekly injections with sclerosing agents to placebo injections. The authors did not find statistically significant differences in pain, disability or spinal flexion between groups. There was clearly no effect of the intervention on disability, but it is possible that there could be smaller, yet clinically significant differences in pain or spinal flexion that this study was unable to detect.

Prolotherapy/sclerotherapy was previously reviewed by MTAC in April 1999. In the first MTAC review, two RCTs were critically appraised. Both were limited in that the treatment group received multiple interventions so the effectiveness of prolotherapy itself could not be determined. In summary, there is insufficient evidence that prolotherapy/sclerotherapy as a stand-alone intervention is effective for reducing low back pain. The results of one RCT powered to detect a 50% reduction in pain levels between groups suggest that it may be an ineffective intervention.

Articles: The search yielded six articles. There were two empirical studies, one of which was included in the initial MTAC review in 1999. The other study, an RCT, was evaluated. No additional empirical studies were identified from the appeal materials. The following article was critically appraised: Dechow E, Davies RK, Carr AJ, Thompson PW. A randomized, double-blind, placebo-controlled trial of sclerosing injections in patients with chronic low back pain. *Rheumatology* 1999; 38:1255-59. See [Evidence Table](#).

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Applicable Codes

Considered Not Medically Necessary:

| CPT® or HCPC Codes | Description |
|--------------------|--------------|
| M0076 | Prolotherapy |

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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| Date Created | Date Reviewed | Date Last Revised |
|--------------|--|-------------------|
| 04/1999 | 04/05/2011 ^{MDCRPC} , 02/07/2012 ^{MDCRPC} , 12/04/2012 ^{MDCRPC} , 12/01/2013 ^{MPC} , 08/05/2014 ^{MPC} , 06/02/2015 ^{MPC} , 04/05/2016 ^{MPC} , 02/07/2017 ^{MPC} , 12/05/2017 ^{MPC} , 11/06/2018 ^{MPC} , 11/05/2019 ^{MPC} , 11/03/2020 ^{MPC} , 11/02/2021 ^{MPC} , 11/01/2022 ^{MPC} , 11/07/2023 ^{MPC} , 08/06/2024 ^{MPC} | 04/05/2011 |

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

| Revision History | Description |
|------------------|-------------|
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