

FEP 2.01.26 Prolotherapy

Effective Date: April 15, 2018

Related Policies:

2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors as a Primary Treatment of Wound Healing and Other Miscellaneous Conditions
6.01.23 Sacroiliac Joint Arthrography and Injection

Prolotherapy

Description

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.

FDA 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.

POLICY STATEMENT

Prolotherapy is considered **investigational** as a treatment of musculoskeletal pain.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

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. 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.

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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.²² 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 Coverage Issues Manual #35-13 states that prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents are not covered, noting that the medical effectiveness of these therapies has not been verified by scientifically controlled studies. In 1999, on request for reconsideration of coverage of prolotherapy for treatment for chronic low back pain, Medicare retained its noncoverage decision for prolotherapy, citing a lack of scientific evidence on which to base a decision.²³

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POLICY HISTORY

| Date | Action | Description |
|----------------|-----------------------|--|
| September 2011 | New Policy | |
| December 2012 | Update Policy | Updated rationale and references, no change in policy statement. |
| December 2013 | Update Policy | Policy updated with literature review; references 11 and 16 added; reference 20 updated; policy statement unchanged. |
| December 2014 | Update Policy | Policy updated with literature review adding reference 20. No change to policy statement. |
| December 2015 | Update Policy | Policy updated with literature review through June 30, 2015; references 12 and 15 added; policy statement unchanged. |
| March 2017 | Administrative Review | Policy reviewed with no changes. |
| March 2018 | Update Policy | Policy updated with literature review through September 14, 2017; reference 22 added. Policy statement unchanged. |

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