**Protocol**

**Prolotherapy**

(20126)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 07/01/09</th>
<th>Next Review Date: 09/23</th>
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<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 07/07, 03/08, 03/09, 01/10, 01/11, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19, 09/20, 09/21, 09/22</td>
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*This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.*

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

**RELATED PROTOCOLS**

- Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
- Diagnosis and Treatment of Sacroiliac Joint Pain

<table>
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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals:  • With musculoskeletal pain osteoarthritic pain, or tendinopathies of the upper or lower limbs</td>
<td>Interventions of interest are:  • Prolotherapy</td>
<td>Comparators of interest are:  • Observation  • Other conservative therapies</td>
<td>Relevant outcomes include:  • Symptoms  • Functional outcomes  • Quality of life</td>
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**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.

**SUMMARY OF EVIDENCE**

For individuals who have musculoskeletal pain (e.g., 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 that the technology results in an improvement in the net health outcome.
POLICY

Prolotherapy is considered investigational as a treatment of musculoskeletal pain.

BACKGROUND

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. Treatment of musculoskeletal pain conditions (e.g., tendinopathies) with platelet-rich plasma is discussed in the Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions Protocol.

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.

REFERENCEs

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


30. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Facet Joint Interventions for Pain Management (L35936), Revision Effective Date For services performed on or after 02/10/2022.