Decision Memo for Prolotherapy for Chronic Low Back Pain (CAG-00045N)

Decision Summary

Retaining Medicare's Current Coverage Policy

Dr. Abraham submitted a number of additional materials to support his request. The materials included some articles describing the technique and increased awareness of prolotherapy, as well as some listings of conferences and member organizations in which prolotherapy is taught and practiced. While this information supports Dr. Abraham's contention that prolotherapy has many disciples, it does not provide HCFA with any scientific evidence on which to base a coverage decision, nor does it prove that treating low back pain with prolotherapy has evolved into the prevailing standard of care.

Some of the materials Dr. Abraham provided noted that further studies on the benefits of prolotherapy are now being conducted. Should these additional studies be developed with larger sample sizes and should the results be based on objective measures that can clearly attribute the claimed benefits to the therapy under investigation, HCFA would be happy to reconsider the issue.

Back to Top

Decision Memo

TO: File: Prolotherapy for Low Back Pain
CAG-00045N

FROM:

Grant P. Bagley, MD, JD
Director, Coverage and Analysis Group

Erica Bisguier, JD, MPH
Health Insurance Specialist, Coverage and Analysis Group

Dorothy Honemann, MHS
Health Insurance Specialist, Coverage and Analysis Group

RE: National Non-Coverage Decision
DATE: September 27, 1999

This memo serves four purposes: (1) describes and provides the history of prolotherapy as a treatment for low back pain; (2) outlines Medicare's past and current coverage policy; (3) analyzes the relevant scientific data, including the material submitted by the requestor; and (4) delineates the reason for retaining Medicare's current non-coverage decision policy.

Description and Background of Prolotherapy

The term "prolotherapy" is a derivation of "proliferative injection therapy" and is also known as sclerotherapy. The practice of prolotherapy is used by doctors of osteopathy and other physicians to treat a number of different types of chronic pain. Prolotherapy consists of a series of intraligamentous and intratendinous injections of solutions in trigger points near the pained area to induce the proliferation of new cells.

Proponents of this treatment suggest that looseness in the supporting ligaments and tendons around the joints causes the pain, inducing the muscles to contract against the ligament and irritate the nerve endings. The physicians using this treatment method for low back pain believe the ligament laxity to be concentrated in the sacroiliac joint. During a physical examination a physician will identify trigger points generally in the muscles overlying the sacroiliac joint. The physician then may inject proliferant substances into the supporting ligament and tendon tissue.

The practice of sclerotherapy or prolotherapy to produce dense fibrous tissue in an effort to strengthen the attachment of ligaments and tendons is not new. Forms of this therapy apparently date back to Hippocrates, however, prolotherapy recently found favor with osteopaths following the teachings of George Hackett, MD, who in 1939 began using a local injectable irritant to initiate the healing process. It was Dr. Hackett who coined the term "prolotherapy" because sclerotherapy implied scar formation, which, according to Dr. Hackett, did not occur with prolotherapy. Nevertheless, both processes use trigger point injections to form new cells in an effort to support weakened muscles. Although the method has been in use for some time, to date there is no strong clinical evidence to support the efficacy of the treatment.

Prolotherapy injections are intended to mimic the natural healing process by causing an influx of fibroblasts that synthesize collagen at the injection site, leading to the formation of new ligament and tendon tissue. The newly produced collagen is intended to support the injured or loosened ligaments, creating a more stable and strong muscle base, in the process, alleviating pain.

There are three classes of proliferant solutions used to initiate inflammation: chemical irritants (e.g. phenol), osmotic shock agents (e.g. hypertonic dextrose and glycerin), and chemotactic agents (e.g. morrhuate sodium, a fatty acid derivative of cod liver oil). The two studies supplied by the requestor used a dextrose-glycerine-phenol solution.

Treatment of Chronic Low Back Pain

Back pain is a common complaint, often without a clear injury or identifiable cause. Once injured, a patient may experience pain intermittently for an indefinite time. Most back pain is caused by musculoligamentous strain, degenerative disc disease, or facet arthritis. Conventional medical opinion consists of symptomatic treatment for back pain after analysis of clinical presentations and a differential diagnosis are completed. The treating physician must identify the root cause of pain and rule out other potential conditions, such as severe osteoporosis, metastatic carcinoma, myeloma, and infection, by taking a complete history and physical examination.

Depending on the severity and nature of the back injury, the physician employing conventional treatments may order bed rest or warm baths. Some recently conducted studies suggest that remaining active, rather than rest, can have a more palliative effect on the patient with back pain. This swing in treatment ideology has physicians recommending mild daily exercise such as brisk walking or swimming. These treatments may be used in conjunction with a mild analgesic and anti-inflammatory agents. Chronic or disabling low back pain that persists after 4 to 6 weeks of comprehensive conservative therapy may be treated with surgery if the cause is lumbar disc herniation and the patient has lost control of the bowel or bladder.

Further, the conservative physician may suspect that unaddressed psychopathology and social factors such as depression underlie the patient's pain. The physician must examine whether the patient fails to improve with conventional therapy because of these psychosocial issues. Debilitating pain can attack a patient's feeling of self-worth and self-reliance, generating a pattern of depression that self-perpetuates.

History of Medicare's Prolotherapy Coverage Policy

The Coverage Issues Manual (CIM) '35-13, "Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents - Not Covered," states that the medical effectiveness of these therapies has not been verified by scientifically controlled studies, and therefore, cannot be covered by the Social Security Act, '1862(a)(1), as a "reasonable and necessary" treatment. This policy of non-coverage along with an erroneous Administrative Law Judge (ALJ) opinion issued in favor of Irwin Abraham, MD, in December 1997, on behalf of a Medicare beneficiary, prompted Dr. Abraham to request a national coverage decision reversing the current policy of non-coverage.

Prolotherapy was last examined for coverage by the Health Care Financing Administration (HCFA) in September 1992. The request had been generated by a beneficiary claiming a benefit from the prolotherapy treatments she had been receiving. HCFA received a number of anecdotal accounts of significant benefit derived from prolotherapy treatments, but when a literature search was conducted it failed to produce any scientifically sound studies on which to base a coverage decision.

The ALJ decision in favor of Dr. Abraham was based on Dr. Abraham's ability to successfully bill HCFA under the CPT code 20550, "Injection, tendon sheath, ligament, trigger points or ganglion cyst" in the past. However, after the carrier identified the treatment of Dr. Abraham's patient as prolotherapy, the carrier denied further payment. The ALJ reasoned that because the treatment had been paid for in the past, the carrier was estopped from further payment for the same procedure on the same patient who claims a benefit from the treatment. The ALJ further reasoned that payment for this treatment in the past and the teaching of this method in some medical schools is sufficient evidence that HCFA had modified its policy regarding prolotherapy. Unfortunately, the ALJ did not address the possibility that the carrier had mistakenly paid for the treatment before recognizing it as the non-covered prolotherapy. Furthermore, because the carrier failed to submit evidence that prolotherapy was indeed experimental and investigational, the ALJ determined that without advance notice to the beneficiary that the procedure was non-covered, Medicare would cover the treatment as reasonable and necessary.

HCFA conducted a new electronic literature search using MEDLINE and Ovid. The results only provided editorial articles devoid of any new scientific research. Also, HCFA staff searched the internet and contacted the American Association of Osteopaths for a complete list of current scientific evidence on the efficacy of prolotherapy. None of these efforts produced significant evidence to support the coverage request.

Analysis of Scientific Evidence

In light of the aforementioned ALJ decision, Dr. Abraham's confusion regarding the policy here is just; however, an ALJ decision is neither binding nor precedent setting on HCFA's national coverage NCDs. Dr. Abraham supplied HCFA with five articles, two of which are clinical trials that support his request for coverage of prolotherapy. Neither of these articles contain sufficient evidence to persuade HCFA to alter the policy now in place.

The Ongley et al. article: "A New approach to the Treatment of Chronic Low Back Pain," published in **The Lancet**, July 1987, studied 81 patients with chronic low back pain with an average duration of ten years in a double-blinded study to compare prolotherapy injections with a non-proliferant injectable course of therapy. Forty of the 81 patients received a regimen of forceful spinal manipulation and injections of a dextrose-glycerine-phenol solution. The 41 patients in the placebo group received less extensive initial local anesthesia (<10 ml 0.5% lignocaine compared with infiltration of 60 ml 0.5% lignocaine in treatment group), a non-forceful manipulation and saline as a substitute for the proliferant used in the experimental group. Also, the experimental group on the first day received a regimen including infiltration of triamcinolone (an anti-inflammatory) into the gluteus medius origin, whereas the placebo group only received lignocaine into the gluteus medius origin. The program included exercises in both groups to encourage the synthesis of the new cells with existing connective tissue. While the authors concluded that "the experimental regimen is a safe and effective treatment for chronic low back pain that has not responded to other conservative forms of treatment," they write earlier in the body of the results section of the paper that "(i)ndependent evaluation of physical signs revealed no significant differences between the groups after treatment."

The Ongley study fails to support the coverage of prolotherapy for a number of reasons. The authors report a subjective improvement in pain amelioration, but they fail to supply any persuasive objective criteria on which to base a coverage decision that must be grounded in scientifically valid evidence. Even the authors acknowledge in their conclusion "(f)uture studies may be needed to analyse [sic] the relative import of each component of the overall procedure." Since the authors chose to provide the participants with manipulation, exercises and anesthesia in addition to the proliferant and saline injections, it is difficult, if not impossible, to isolate the component of the treatment which gave the participants the reported relief.

Establishing a link between the subjective improvement in pain management and a particular regimen is problematical because the participants in the experimental group received a different preparation course with more anesthesia and a forceful manipulation as opposed to the placebo group's faux manipulation. Since the study did not treat the proliferant injections as a single variable, there is no way to positively identify prolotherapy as the cause of the pain relief rather than the forceful manipulation. Also, because Medicare currently covers forceful manipulation and massage therapy by a qualified provider, HCFA would need evidence that the addition of another variable, such as prolotherapy, to a patient's course of treatment would provide greater benefit than that which is currently covered. Furthermore, even if the results concluded that the benefit in pain reduction could be positively attributed to prolotherapy, the sample size of 81 patients is really an insufficient number on which to base a positive national coverage decision.

The more recent study submitted by Dr. Abraham also falls short of the requisite level of evidence needed for a national coverage decision. The Klein et al. study, "A Randomized Double-Blind Trial of Dextrose-Glycerine-Phenol Injections for Chronic, Low Back Pain" published in 1993, fails in much the same way as the Ongley study before it. Again, the number of participants is small; therefore it would be difficult to use the results in support of a newly crafted national coverage decision.

The Klein study was comprised of 79 patients, 39 of which were placed in the proliferant group. Thirty of 39 patients in the proliferant group achieved a 50% or greater diminution in subjective pain or disability. The control group was not a true placebo because "the patients received four of the five active interventions of the full treatment regimen and demonstrated statistically significant within-group improvements compared to baseline disability and pain scores." Twenty-one of 40 patients in the placebo group reported a 50% or greater diminution in subjective pain and disability scores. A response of more than 50% of patients in the control group reporting improvement suggests that an actual treatment effect rather than a pure placebo response occurred. Even the authors note, "(t)he interventions shared by both treatment groups, including exercises, injection of local anesthetics, repeated needling, and manipulation may all enhance the success of the procedure, but the relative contribution of each intervention requires further study."

The authors identify that further studies are needed to show greater improvement in treating pain with prolotherapy because "the statistical significance was only borderline" when the experimental group was compared to the control group. Also, "objective testing of range of motion, isometric strength, and velocity of movement showed significant improvements in both groups following treatment, but did not favor either" the proliferant or the control group. Further, "the MRI and CT scans showed significant abnormalities in both groups, but these did not correlate with subjective complaints and were not predictive of response to treatment."

A total of 160 patients studied over the past twelve years, with only 79 of the patients receiving the proposed treatment, is not a large enough sample to support a change in the coverage policy. More studies with larger control and experimental groups must be evaluated using regimens designed to isolate variables and correlate them to positive results. Ideally, these studies would consist of improvements in both objective and subjective measurement tools. However, substantial and statistically significant improvements in subjective pain scores could be persuasive if HCFA could attribute the patient benefit to the prolotherapy regimen.

Retaining Medicare's Current Coverage Policy

Dr. Abraham submitted a number of additional materials to support his request. The materials included some articles describing the technique and increased awareness of prolotherapy, as well as some listings of conferences and member organizations in which prolotherapy is taught and practiced. While this information supports Dr. Abraham's contention that prolotherapy has many disciples, it does not provide HCFA with any scientific evidence on which to base a coverage decision, nor does it prove that treating low back pain with prolotherapy has evolved into the prevailing standard of care.

Some of the materials Dr. Abraham provided noted that further studies on the benefits of prolotherapy are now being conducted. Should these additional studies be developed with larger sample sizes and should the results be based on objective measures that can clearly attribute the claimed benefits to the therapy under investigation, HCFA would be happy to reconsider the issue.

Back to Top