

**Comments and Responses Regarding Draft Local Coverage  
Determination:  
Pain Management**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Pain Management LCD. The official notice period for the final LCD begins on November 01, 2014, and the final determination will become effective on December 16, 2014.

**Comment:** Physician assistants (PAs) and certified registered nurse anesthetists (CRNAs) were concerned that the “Provider Qualifications” might exclude the ability of non-physician practitioners (NPPs) to be reimbursed for spine interventional pain management procedures. Physicians noted that the statements about credentialing did not include ambulatory surgical center (ASC) participation.

**Response:** NGS anticipates non-physician practitioners (NPPs) will practice within their state scopes of practice and abide by Medicare regulations and policies. Although the language described typical physician training, we would see “a post-graduate training course accredited by an established national accrediting body or accredited professional training program” applicable to NPPs. We agree that ASCs should be included in remarks about credentialing. The final language is as follows:

Patient safety and quality of care mandate that healthcare professionals who perform spinal pain management procedures are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. (At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical

performance of the procedure and utilization of the required associated imaging modalities). A practitioner who works in a hospital or ASC facility at any time should be credentialed by the facility for any procedure also performed in an office setting.

**Comment:** Physical therapists asked that the training requirements not be applicable to those performing trigger point, tendon sheaths, ligaments, ganglion cyst and carpal and tarsal tunnel injections.

**Response:** Although we would expect all practitioners to be trained for and competent in procedures performed, the requirement was present for those performing interventional spine procedures. Therefore, the word “spinal” has been added before “pain management” for clarification.

**Comment:** Physical therapists requested we add dry needling as a covered service for trigger points. Acknowledging acupuncture is a non-covered service in Medicare, they wrote that dry needling was different and based on Western medical concepts.

**Response:** Included in submitted materials was a very comprehensive document, “Physical Therapists & The Performance of Dry Needling” produced by the American Physical Therapy Association. Appendix D - Research included the results of two review articles, a Cochrane review, a clinical review, an evidence summary, and a systematic review and meta-analysis. The first review article addressed the effectiveness of dry needling and injections of myofascial trigger points (MTrPs) associated with plantar heel pain. Conclusions were that there was limited evidence for the effectiveness of dry needling and/or injections of plantar heel pain MTrPs, but the studies were heterogeneous and of poor quality. More research was recommended. The second review concluded that there was no evidence that needling therapies have efficacy beyond placebo. The Cochrane review concluded that acupuncture was more effective for pain relief and functional improvement for patients with back pain in the short term than no treatment or sham treatment but that the studies were of low methodologic quality and more trials of higher quality were needed. The other three studies also recommended additional studies were needed.

Kietrys et al. (2013) performed a meta-analysis in the effectiveness of dry needling on upper - quarter myofascial pain. Twelve (12) randomized controlled trials were included. Looking at immediate and four-week results, they recommended dry needling for immediate relief and cautiously recommended it for reduction of pain at four weeks. However, they acknowledged that there were a limited number of studies thus far and methodological flaws and high heterogeneity could affect the results of the meta-analyses. A letter from another provider supporting dry needling was also received listing multiple references.

Given the information currently available, dry needling will not be added as a covered service for treatment of trigger points. A non-coverage statement has been added to the LCD.

**Comment:** A question was received asking if a modifier could be used if two different ligaments were injected in two separate locations on the same day (e.g., elbow and ankle).

**Response:** Anatomic modifiers (-LT, -RT), the bilateral modifier (-50), or modifier -59 may be submitted when it is medically necessary to inject different anatomic structures in the same session. Effective January 1, 2015, modifier -XS (Separate structure) may be submitted in lieu of modifier -59. Modifier -50 may not be used for ambulatory surgery center claims.

**Comment:** A question was asked about the use of G0260.

**Response:** G0260 is used when the SI joint injection is performed in a location paid by OPPS methodology, e.g., out-patient hospital facility.

**Comment:** We were asked to expand the use of intrathecal injections to include non-cancer pain and also to include additional drugs, e.g., morphine (J2275), fentanyl (J3010), clonidine (J0735) and ziconotide (J2278).

**Response:** We decided to remove intrathecal injections from the local coverage determination. We would anticipate appropriate and medically necessary use without an LCD.

**Comment:** One commenter stated that double-comparative blocks are “not the norm” for sacroiliac (SI) joint injections.

**Response:** We are aware that some practitioners do not use controlled blocks for diagnostic SI joint injections. However, we were not presented with information to support the lack of controlled blocks being necessary to limit false positive results. Therefore, the requirement for double-comparative blocks for diagnosis remains in the LCD.

**Comment:** Two commenters objected to the detailed descriptions of amount of injectate, etc. They also asked that the percentage of relief required soon after the injection be lowered from 80% to 50%.

**Response:** We have revised the LCD not to state specific amounts of injectate. The amount of relief was changed to 75% - 100%. Authors have used 50%, 75%, and 90%. The Interventional Spine Intervention Society (ISIS) *Practice Guidelines for Spinal Diagnostic and Treatment Procedures* states, “It is prudent to consider a response negative if there is  $\leq$ 50% relief, equivocal if there is 51-75% improvement and positive if there is at least 75%

improvement.” Manchikanti et al. (2013) also noted there is good evidence for diagnostic intra-articular sacroiliac joint injections with 75 to 100% pain relief.

**Comment:** It was noted that utilization guidelines for the frequency of SI joint injections was missing and it was requested they be added.

**Response:** The current LCD guidelines for diagnostic and therapeutic interventional spine injections were added.

**Comment:** One commenter noted an alternative approach when the SI joint cannot be accessed is to block the L5 dorsal ramus branch and the S1, S2, and S3 lateral branches. Another noted that a diagnostic injection of the fibrous portion be allowed if the intra-synovial injection only provides temporary relief.

**Response:** Although we received a number of studies of lateral branch radiofrequency ablation, we did not receive information that reviewed lateral branch blocks (LBBs) as diagnostic procedures for SI joint pain. One article (Cohen S et al., 2003) described a pilot study of 18 patients with a positive response to an SI joint injection who were then considered for lateral branch nerve injections and subsequent radiofrequency ablation. Thirteen of the 18 had a positive response ( $\geq 50\%$  decrease in pain) to the LBBs, 9 of whom proceeded to RFA. Five of these nine had a second confirmation of response to a lidocaine joint injection. Eight of the 9 had a  $\geq 50\%$  relief of pain. Dreyfuss et al. (2009) also used LBBs in 15 asymptomatic volunteers to study innervation of the SI joint. He concluded LBBs were physiologically effective at 70% but do not effectively block the intra-articular portion of the SI joint. No papers were submitted reviewing injection of the fibrous portion of the joint for diagnostic purposes. The LCD does note that the amount of injectate should be such that the synovial lining of the joint does not burst and the injectate does not disperse beyond the confines of the target joint.

**Comment:** We were asked whether ultrasound could be used rather than fluoroscopy or computed tomography for image-guidance of SI joint injections.

**Response:** Ultrasound is not considered a satisfactory imaging technique for SI joint injections. The CPT code 27096 and HCPCS code G0260 should not be used if ultrasound is the imaging method.

**Comment:** One commenter noted there were a number of “old” references listed and #17 and #18 should be removed since they do not address the items in this LCD.

**Response:** Since the LCD is being revised rather than starting anew, the older references will be kept and supplemented with newer articles. References #17 and #18 will be removed.

**Comment:** Requests to allow coverage of SI joint radiofrequency neurotomy (SIJ RN) were received.

**Response:** References were listed and a number summarized here.

Muhlner (2009) reviewed SIJRN and noted the evidence for efficacy was limited and suspected that the variable nerve patterns contributed to the difficulty in achieving good results. He also noted the literature showed variability in the methods used to determine the patient's pain was from the SI joint and selection of patients for neurotomy.

Cohen et al. (2008) performed a randomized trial with 28 patients diagnosed with SI joint pain by one injection with  $\geq 75\%$  relief from a six-hour post-block pain diary. The patients were recruited from a pain clinic and had failed conservative therapy and corticosteroid joint injections. Patients were randomized 1:1 to receive true or placebo denervation. Cooled radiofrequency (RF) was used at the S1 – S3 lateral branches and conventional RF at L4 - L5 dorsal rami. The control group had the local anesthetic injections at the sites for denervation but no current. Outcome data were collected by a physician not involved with the lesioning. Patients were seen 1 month later, at 3 and 6 months and then telephone follow-up occurred every 2 months. Patients showing significant relief at 1 month were unblinded three months after treatment. Patients in the control group who did not get relief were offered open label conventional RF. The primary outcome measure was 0 – 20 on a pain scale to reflect pain levels in the prior 10 days. Secondary outcomes were Oswestry disability index scores and opioid and non-opioid drug use. At 1, 3, and 6 months, the treatment group had 60%, 60%, and 57% respectively decrease in pain. The placebo group did not have a significant pain decrease at one month and could not be surveyed later because most chose the crossover treatment path. Oswestry disability indices were also lower in the treatment group. Global perceived effect (GPE) and medication reduction were also significantly better in the treatment group at one month. Five of 14 patients (36%) in the treatment group and 5 of 11 (45%) in the cross-over group did not achieve improvement at three months. Limitations of the study were noted as the decision to target five levels for lesioning, the potential for false-positives using uncontrolled diagnostic blocks, the small numbers of patients, and the test of blinding performed while the local anesthetics were still effective. The authors stated large, multicenter studies with long-term follow-up were needed.

Patel et al. (2012) randomized 51 patients 2:1 to lateral branch neurotomy and sham groups. Lateral branch neurotomy (LBN) using cooled RF was administered at the L5 dorsal ramus and the S1 – S3 lateral branches. Patients had double-comparative blocks and  $\geq 75\%$  relief of pain. The physician and technician were not blinded. Unblinding for all occurred at three months and the sham patients were allowed to crossover. Seven (7) treatment patients dropped out 3

months and another two at 6 months. Sixty-four percent (64%) of the patients in the treatment group and 57% in the sham group were able to guess the correct group allocation, but this was considered satisfactory for blinding. At three months, the treatment group had a significantly greater improvement in the NRS pain score, a better SF-36BP at 1 and 3 months, improved SF-36 PF at 3 months and a better ODI at 1 and 3 months. There were no comparisons at 6 and 9 months due to crossovers or dropouts in the sham group. Global perceived effect (GPE) showed significantly different levels at three months. The 9-month GPE was higher (59%) than the 6 month rate which was thought likely due to one patient having a flare-up which then improved and another not achieving secondary outcome requirements at 6 months. The authors did not describe limitations of the study, but it should be noted there was a small number of patients.

Cheng et al. (2013) retrospectively reviewed 88 patients, 30 (34%) of whom had received traditional radiofrequency ablation (t-RFA) and 58 (66%) who received cooled frequency RFA (c-RFA). Patients had had at least a 50% pain relief for < 1 month in response to double-comparative blocks and conservative therapy. Pain relief was grouped as < 50%, 50% - 80%, and > 80%. Patients were evaluated at 1, 3, 6, and 12 months. The primary outcome was the duration of time until the patient reported < 50% pain relief. At three months, 50% to 60% had relief >50% in each group; 40% of the patients had pain relief > 50% in each group at six months; and 30% were able to maintain this level of relief at 9 months. Limitations of the study included its retrospective and observational nature, the relatively small sample size and the lack of functional measurements.

Stelzer et al. (2012) published a case series of 126 patients treated with cooled radiofrequency to the L5 dorsal ramus and S1, S2, and S3 posterior sacral foraminal apertures. Failure of conservative therapy and a  $\geq 50\%$  pain relief to a single SI joint injection. Patients whose relief was longer than the estimated duration of the anesthetic effect were not included. Charts for 105/126 (83%) with an initial pain score and another between 4 and 20 months were reviewed. A >50% decrease in VAS pain scores was used as a measure of success and a two-point decrease in VAS score was another measure assayed. Patients were grouped according to the time to final follow-up: 4 – 6 months (N = 26), 6 – 12 months (N = 45) and > 12 months (N = 34). Significant decreases in VAS scores occurred in each time frame with smaller decreases over time. Quality of life, measured with a questionnaire, was “much improved” or “improved” for the majority in each group. Opioids were stopped in 80%, 31%, and 20% and decreased in 20%, 31%, and 47% reported less use for the respective time periods. Discontinuance of NSAIDs occurred in 74%, 46%, and 45% with less use in 26%, 33%, and 35% for the respective time periods. Limitations of the study were noted as no control group, difficulty in contacting and missing data for some subjects, and the variable periods of follow-up.

Aydin et al. (2012) performed a meta-analysis of RFA for SI joint pain. Five retrospective, four prospective observational, and one randomized placebo controlled study were reviewed. Traditional RFA was used in nine and pulsed in one; the latter was excluded. A 50% improvement in pain post-RFA was the main outcome measure in each. Most patients were followed for 3 and 6 months which were the time frames addressed by the meta-analysis. Half had > 50% pain reduction at 3 months (60.1%) and at 6 months (49.9%). The authors noted that there was inconsistency in diagnostic injection protocols and variation in the RFA techniques, pain assessments, follow-up intervals, and sites for the RFA. They also reviewed the anatomic variability in nerve supply of the SI joint and concluded an accurate anatomical delineation of the joint innervation is needed as well as randomized placebo-controlled or comparative trials are needed to improve outcomes for patients with sacro-iliac joint pain.

Manchikanti et al. (2013) summarized the evidence for radiofrequency neurotomy as fair for cooled and limited for both pulsed and conventional radiofrequency. Hansen et al. (2012) reached similar conclusions. There were no requests for coverage of pulsed RF received in the comments on the draft LCD.

Ho et al. (2013) performed a chart review of 20 consecutive patients who had received cooled RFA during a prior two year period. Conservative therapy had failed, one diagnostic block had been performed and five had previously received traditional RFA. Short-term pain relief was present at one and three months and continued at one and three years for the group. One patient who had been on oral morphine required long-term opioid therapy. Another required an intrathecal pump. GPE for patient satisfaction was positive for 16 patients. The authors acknowledged that although the length of follow-up was longer than usually described, there were no controls, no sham treatments, and no comparative treatments.

The evidence is considered to be insufficient to support improved patient outcomes for radiofrequency neurotomy for low back pain thought to be due to sacro-iliac joint disease. Therefore, radiofrequency neurotomy for the SI joint/nerves will not be added to the LCD as a covered service. The following has been added to the LCD.

**SACROILIAC JOINT/NERVE RADIOFREQUENCY ABLATION:**

Radiofrequency ablation used for sacro-iliac joint pain is considered not medically necessary/investigational whether performed using traditional, cooled, or pulsed radiofrequency.

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