February 10, 2023

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Re: LCD Reconsideration Request - Facet Joint Interventions for Pain Management (L38765)

Dear Medicare Director:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 49 state societies, we are requesting the following changes since almost all insurers are moving on adapting CMS guidelines in many disorders, mainly so for facet joint interventions and epidural interventions. All the other insurers are following the same philosophy causing significant issues related to the access.

Please consider the suggested recommendations as follows:

Coverage Guidance
B. Therapeutic Facet Joint Procedures (IA or MBB)

Therapeutic facet joint procedures **(intraarticular injections or medial branch blocks)** are considered medically reasonable and necessary for patients who meet **ALL** the following criteria:

a. The patient has had two (2) medically reasonable and necessary diagnostic facet joint procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); **AND**

b. Subsequent therapeutic facet joint procedures at the same anatomic site results in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure **or** at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale; **AND**

c. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device)

History
We believe that medial branch language was removed from the therapeutic facet joint procedures section without appropriate consideration based on some comments received by organizations which are opposed to therapeutic facet joint interventions, except for radiofrequency neurotomy. However, it is ironic that they have not even reviewed the appropriate literature and quote definitely they are not therapeutic procedures and do not provide extended pain relief. The evidence shown is in contradiction to personal opinion. The value of the literature by SIS formerly ISIS was refuted by Carragee et al (1).

In LCD reconsideration, the authors have provided extensive information. It is a common practice that a large proportion of patients are on opioids, along with interventional techniques, unless these are performed in acute physiatry practice and they eventually end up again in pain clinics or with other physicians receiving opioids. In addition, if the procedures are performed in military service, only a small proportion may be on opioids. Thus, these studies and opinions are not clinically applicable. Even after using GRADE evidence, facet joint nerve blocks do withstand the analysis and the grading provided by Best Practices guidance derived from AHRQ.

Yet, facet joint nerve blocks or medial branch blocks and L5 dorsal ramus blocks have not been covered for therapeutic purposes. As you know, intraarticular injections are technically difficult and also require steroids with complications related to the technical component of the procedure and steroids. Further, it may require deeper sedation levels. In contrast, medial branch blocks are easily performed, more patients are comfortable, and may not require much sedation. Consequently, by removing this option, access will be affected significantly and negatively.

It is important to consider that since all insurers are adapting CMS guidelines provided in the form of LCDs, it becomes an access issue to all, not just the ones covered by fee-for-service Medicare.

The criticism of evidence is based on systematic bias by some authors. It is an inherent tendency of a process to support particular outcome. Bias has been shown in selecting the studies for literature review and in interpretation of the results. Some of the comments are based on without reviewing the literature and others are based on academic superiority. In any case, overall evidence described in LCD continues to be superior for therapeutic facet joint nerve blocks compared to therapeutic intraarticular injections. At this time, we are not requesting to remove therapeutic intraarticular injections, they have a role. However, we would like you to reinstate the language covering medial branch blocks and remove the confusion.

As a reference, the retired LCDs, which were effective prior to May 2021, provided a similar but separate description:

LCD L35936 from NGS, but similar to all other jurisdictions except CGS, described therapeutic injections as follows:

Therapeutic Injections:

- Either intraarticular injections or medial branch blocks may provide temporary or long-lasting or permanent relief of facet-mediated pain. Injections may be repeated if the first injection results in significant pain relief (>50%) for at least 3 months. (See Limitations section for total number of injections that may be performed in one year.)
- Recurrent pain at the site of previously treated facet joint may be treated without additional diagnostic blocks if >50% pain relief from the previous block(s) lasted at least 3 months.

CGS Administrators LCD L34832 described therapeutic facet joint nerve blocks in the following way:

Therapeutic Intraarticular (IA) Facet Injections:

- Emerging evidence suggests that benefit from palliative care with IA injections may accrue in some patients and is potentially Medicare reimbursable. There is additional limited evidence that facet joint cyst rupture might be effective in a limited number of patients and is potentially Medicare reimbursable.

Therapeutic Facet Joint Nerve Blocks:

- When dual MBBs provide greater than 80% relief of the primary or index pain consistent with the expected physiological effects of the agents utilized index pain with ability to perform previously painful movements, followed by at least 50% improvement for 6 weeks with pain and function, therapeutic facet joint nerve blocks may be considered.
- Repeat therapeutic facet joint nerve block procedures involving the same joint or the same region will only be considered medically necessary if the patient experienced

greater than 50% improvement of pain and improvement in patient specific ADLs documents for at least 2½ to 3 months.

- Repeat therapeutic medial branch blocks to treat recurrent facet joint pain in patient who has failed other conservative measures may be covered without repeating MBB injections if the patient has experienced expected or prolonged relief of pain with improvement in function (2½ to 3 months) in the past following therapeutic facet joint injections.

Evidence Assessment:
Therapeutic facet joint nerve blocks are one of the well-studied procedures in the Medicare population in the United States. As shown in comprehensive evidence-based guidelines for facet joint interventions from ASIPP (2), there is Level II evidence with moderate strength of recommendation for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials, with long-term improvement (3-5).

Similar to the lumbar spine, there is Level II evidence with moderate strength of recommendation for cervical therapeutic facet joint nerve blocks with inclusion of one relevant randomized controlled trial and 3 observational studies, with long-term improvement (6-9).

In the thoracic spine also, the evidence is Level II with moderate strength of recommendation for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials and 3 observational studies (10-14).

To emphasize, the majority of these studies were performed in the United States and included a large proportion of Medicare patients. The evidence has improved since the previous publication of LCD, at which time there were fewer of these studies.

The guidelines and systematic reviews have assessed the quality of these studies and trials and have arrived at the conclusion that these studies are of moderate to high quality, and showed Level II evidence, with moderate strength of recommendation.

Recently, 3 important studies have been published demonstrating the therapeutic utility of facet joint nerve blocks with long-term improvement.

van Eerd et al (15) in a randomized trial assessed the efficacy and long-term effect of radiofrequency denervation in patients with clinically diagnosed cervical facet joint pain. They compared radiofrequency denervation plus an injection of bupivacaine with the injection of bupivacaine alone, with a sham radiofrequency neurotomy treatment in 76 patients. Another interesting aspect of the study is that they produced a single lesion with a 5 cm needle with a 5 mm active tip. The primary outcome was measured at 6 months and consisted of pain intensity, self-reported treatment effect, improvement in the Neck Pain Disability Index, and the use of pain medication. The results were positive in the intervention group showing 55.6% with greater than 30% pain decrease versus 51.3% in the control group with no significant difference. The Neck Disability Index was 15 ± 8.7% in the intervention group compared with 16.5 ± 7.2 in the local anesthetic group. However, the median time to end of the treatment success for patients in the radiofrequency group was 42 months compared to 12 months in the bupivacaine group which was a significant difference. This study illustrates the importance of local anesthetic alone blockade with significant improvement noted at 3 months, 6 months, and up to one-year. Further, the study has not included diagnostic blocks explaining lower levels of success. In contrast to a multitude of other studies, they used a single lesion, which is similar to clinical practice.

Among the observational studies, Manchikanti et al (16,17) assessed the comparative effectiveness of clinical outcomes and cost utility of therapeutic facet joint nerve blocks with radiofrequency neurotomy in the cervical and lumbar spine.

In the cervical study (16), the main outcome was numeric rating scale (NRS), where significant improvement was defined as 50% or greater improvement in pain relief. In this study, 132 patients receiving cervical medial branch blocks and 163 patients with cervical radiofrequency neurotomy were included. One hundred seven patients in the cervical medial branch group and 105 patients in the radiofrequency group completed one-year follow-up.

The results reported average relief duration of each procedure for cervical medial branch blocks was 13 to 14 weeks, whereas for radiofrequency neurotomy, it was 20 to 25 weeks. Cervical medial branch blocks were repeated if needed after 3 months, whereas radiofrequency neurotomy was repeated after 6 months. Consequently, the maximum number of procedures in the medial branch blocks was 4 per year, whereas radiofrequency neurotomy group were 2 per year. The results showed significant improvement reported in 100%, 94%, and 81% of the patients in the medial branch blocks group compared to 100%, 69%, and 64% in the radiofrequency neurotomy group at 3, 6, and 12-month follow-up, with significant differences noted at 6 and 12 months.

Manchikanti et al (17) also studied the comparative effectiveness of facet joint nerve blocks and radiofrequency neurotomy in the lumbar spine. The main outcome measure was pain relief measured by the Numeric Rating Scale (NRS) evaluated at 3, 6, and 12 months. Significant improvement was defined as at least 50% improvement in pain relief. A total of 326 patients met the inclusion criteria with 99 patients receiving lumbar facet joint nerve blocks (lumbar medial branch blocks with L5 dorsal ramus block) and 227 receiving lumbar radiofrequency neurotomy. Forty-eight patients in the facet joint nerve block group and 148 patients in the radiofrequency group completed one-year follow-up.

The results reported average relief duration of each procedure for lumbar medial branch blocks was 13 weeks, whereas for radiofrequency neurotomy, it was 21 to 25 weeks. Lumbar medial branch blocks were repeated if needed after 3 months, whereas radiofrequency neurotomy was repeated after 6 months. Consequently, the maximum number of procedures in the medial branch blocks was 4 per year, whereas radiofrequency neurotomy group were 2 per year. Patients experienced significant improvement in both groups from baseline to 12 months with significant pain relief ($\geq$ 50%). Significant pain relief was recorded in 100%, 99%, and 79% of the patients in the facet joint nerve block group, whereas it was 100%, 74%, and 65% in the radiofrequency neurotomy group at the 3, 6, and 12 month follow-up, with a significant difference at 6 months.

Manchikanti et al (16,17) also performed a cost utility analysis for cervical facet joint nerve blocks compared to cervical radiofrequency neurotomy and lumbar facet joint nerve blocks compared to lumbar facet joint nerve radiofrequency neurotomy. Quality adjusted life year (QALY) for cervical medial branch blocks was shown as $4,994 for cervical medial branch blocks compared to $5,364 for cervical radiofrequency neurotomy. Similarly, for lumbar facet joint nerve blocks for average cost for QALY was $4,664 whereas for lumbar radiofrequency neurotomy, cost of QALY was $5,446. Overall, the costs appear to be somewhat less for medial branch or facet joint nerve blocks compared to radiofrequency neurotomy. These costs are similar to published data on many interventional procedures, including spinal cord stimulation, surgical intervention on one end of the spectrum and physical therapy at the other end of the spectrum (Fig. 1).

More importantly, withdrawal rates from the treatment were higher both in cervical and lumbar radiofrequency groups compared to facet joint nerve blocks groups. These studies showed 5% in

the cervical facet joint nerve block group and 12% in the lumbar facet joint nerve block group compared to 33% in the cervical facet joint nerve radiofrequency group and 35% in the lumbar facet joint nerve radiofrequency group being converted to various other treatment groups either due to side effects or inadequate relief.

More recent evidence published after publication of LCD and 2020 ASIPP guidelines includes the following:

In the systematic review by Baroncini et al (30) conducted according to the PRISMA statement concluded that injections of chronic low back pain deriving from facet joints arthritis are encouraging especially when considering medial branch blocks. In this systematic review, the authors considered all the randomized clinical trials of injection treatments for chronic low back pain. The outcomes assessment included Oswestry Disability Index (ODI) and the Numeric Rating Scale (NRS). They reviewed data from 587 patients with a mean follow-up of 12.4 ± 10.5 months. The methodologic quality assessment showed very low selection bias, detection bias, attrition and reporting bias.

In this narrative review by Mazmudar (31), economic value was assessed for facet joint interventions. The authors discussed that even though evidence is noted to be limited, most systematic reviews failed to demonstrate the therapeutic utility of intraarticular facet joint injections in low back pain because of high study heterogeneity. A few good quality studies and systematic reviews describe moderate evidence for the utilization of therapeutic medial branch blocks and radiofrequency neurotomies in alleviating facet joint pain.

In the article by da Rocha (32), patients receiving controlled medial branch blocks, 52% demonstrated >50% improvement in pain after the blockade. All patients underwent a sham injection with sodium chloride, followed by a controlled medial branch block. Fifty-four patients, or 52%, demonstrated > 50% improvement after 3 months. However, lumbar pain returned in 18 individuals after 3 months. This study shows diagnostic procedures themselves may be effective as long as 3 months.

Consequently, therapeutic facet joint nerve blocks are performed only when RF is not a viable option with shared decision making as described for example with presence of a pseudoarthrosis implant as well as additional indications which are described.

Further, as shown in the policy itself, there is extensive literature which is positive for facet joint nerve blocks rather than intraarticular injections. Therapeutic facet joint nerve blocks are often effective for an appropriate duration of treatment and cost utility is also better when compared to radiofrequency neurotomy, and with fewer side effects and greater patient comfort.

Attached, please find full articles.

Overall, we hope that appropriate changes will be made.

If you have any further questions, please feel free to contact us. Thank you again for all your services.

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Re: LCD Reconsideration Request - Facet Joint Interventions for Pain Management (L38765)

Dear Medicare Director:

Thank you for considering our request to include facet joint nerve blocks as therapeutic modality; and we appreciate your promptness. Hopefully this will be presented to the committee as soon as you can. We are hoping that you will expedite the process since it appears that it is an error in following comments.

In addition, we missed providing you with references describing intraarticular injections, the difficulties, and false-negative results, which we are providing below. We will submit further literature as it is available.

As described in our letter, technically facet joint nerve blocks or medial branch blocks are easier to perform and less painful than intraarticular injections. In addition, intraarticular injections have been documented technical failure rate ranging between 29% and 38% for joint, and from 46% to 64% for procedure (1,2). Other issues include false-negative results which may be arising from excessive procedure related pain and discomfort which has been shown to be a cause of false-negative blocks, whereas a less painful procedure is associated with a lower false negative rate, even though this has not been systematically studied (3). One may question that false-negative blocks are only for diagnostic blocks; however, it also indicates lack of appropriate procedure with medicine not reaching the joint space. The technical failure rate for intraarticular injections is higher at L5-S1, which is the most common clinically affected facet joint, along with L4-5 which is the most frequently radiologically degenerated joint and involvement of both joints goes together (4-7). In contrast, lumbar medial branch blocks rarely (less than 2%) miss the targeted nerve (8), even though intravascular uptake, which occurs in between 4% and 19% of injections, may lead to false-negative results. Kaplan et al (9) evaluating the ability of medial branch blocks in a small study to anesthetize facet joints, showed that among the 6 patients in whom intravascular uptake was appreciated, they were still able to perceive pain during capsular distention despite repositioning the needle to avoid intravascular contrast uptake. This may be essentially overcome with appropriate injection practices and also indicates that false negatives may occur from intravascular uptake even with real-time contrast injection; however, these are substantially less than intraarticular injections where the failure rate tends to be 46% to 64% per procedure.

In addition, complications are much more severe in cervical spine followed by thoracic spine, apart from extensive difficulty of entering the facet joint in thoracic spine, the complications of the needle passing through the joint and damaging the spinal cord are very real in the cervical spine, leading to multiple medical liability suits.

Consequently, once again we request that appropriate action be taken soon.

Thank you again for all of your assistance.

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