# **American Society of Interventional Pain Physicians®**

## "The Voice of Interventional Pain Management"

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Re: Comment on Aim Specialty Health. Clinical Appropriateness Guidelines. Musculoskeletal Program: Appropriate Use Criteria: Interventional Pain Management

To Whom it May Concern:

On behalf of American Society of Interventional Pain Physicians (ASIPP), we thank you for publishing the latest guidelines to be effective from 4/9/2023 for Appropriate Use Criteria for Interventional Pain Management. It appears that this version was created on 5/9/2022. We had no opportunity to comment.

As stakeholders of interventional pain management and performing interventional techniques, we would like to comment.

As you are aware, interventional pain management is defined as, "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment" (<a href="http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf">http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf</a>).

Interventional pain management techniques are defined as, "minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain". (https://permanent.fdlp.gov/lps21261/dec2001PainManagement.pdf

In general, the guidelines are very well done. Our comments are related to paravertebral facet joint injection/medial branch nerve block/neurolysis/therapeutic facet joint interventions.

#### **Therapeutic Facet Joint Interventions**

Therapeutic intraarticular facet joint injections and thermal medial branch radiofrequency neurotomy are described. However, therapeutic medial branch blocks are excluded.

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.

Medial branch blocks have been covered throughout the history of LCDs and medical policies. Evidence for medial branch blocks has been evaluated extensively and well published.

Most recent evidence synthesis provided by ASIPP guidelines (1) analyzed the evidence for all facet joint interventions including intraarticular injections, medial branch blocks, and radiofrequency thermoneurolysis. The evidence for therapeutic facet joint interventions has been shown as follows (2-25):

## **Lumbar Spine:**

- The level of evidence is <u>II</u> with <u>moderate</u> strength of recommendation for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials (3,4,11), with long-term improvement.
- The evidence is <u>IV</u> with <u>weak</u> strength of recommendation for lumbar facet joint intraarticular injections with inclusion of 9 relevant randomized controlled trials (2,9,10,12-17), with majority of them showing lack of effectiveness without the use of local anesthetic.

## **Cervical Spine:**

- The level of evidence is <u>II</u> with <u>moderate</u> strength of recommendation for therapeutic cervical facet joint nerve blocks with inclusion of one relevant randomized controlled trial (7) and 3 observational studies (8,23,24), with long-term improvement.
- The level of evidence is <u>V</u> with <u>weak</u> strength of recommendation for cervical intraarticular facet joint injections with inclusion of 3 relevant randomized controlled trials (21,22,25), the majority showing lack of effectiveness, whereas one study with 6-month follow-up (25), showed lack of long-term improvement.

## **Thoracic Spine:**

- The level of evidence is <u>II</u> with <u>moderate</u> strength of recommendation for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials (5,18) and one observational study (6) with long-term improvement.
- The level of evidence is <u>III</u> with <u>weak to moderate</u> strength of recommendation for thoracic intraarticular facet joint injections with inclusion of one randomized controlled trial with 6 month follow-up (18), with emerging evidence.

More recent evidence after the publication of guidelines includes the following:

In the publication by Manchikanti et al (26), 295 patients met inclusion criteria with 132 patients receiving cervical medial branch blocks and 163 patients with cervical radiofrequency neurotomy. 107 patients in the cervical medial branch group and 105 patients in the radiofrequency group completed one year follow-up.

There was significant improvement in both groups from baseline to 12 months with pain relief and proportion of patients with  $\geq 50\%$  pain relief.

Cost utility analysis showed average cost for quality-adjusted life year (QALY) of \$4,994 for cervical medial branch blocks compared to \$5,364 for cervical radiofrequency neurotomy.

Six of 132 patients (5%) in the cervical medial branch group and 53 of 163 (33%) patients in the cervical radiofrequency neurotomy group were converted to other treatments, either due to side effects (6 patients or 4%) or inadequate relief (47 patients or 29%).

The authors concluded that outcomes of cervical therapeutic medial branch blocks compared with radiofrequency neurotomy demonstrated significantly better outcomes.

In the publication by Manchikanti et al (27), 326 patients met the inclusion criteria with 99 patients receiving lumbar facet joint nerve blocks (lumbar facet joint nerve 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.

Patients experienced significant improvement in both groups from baseline to 12 months with significant pain relief ( $\geq 50\%$ )

Cost utility analysis showed average costs for quality-adjusted life year (QALY) of \$4,664 for lumbar facet joint nerve blocks and \$5,446 for lumbar radiofrequency neurotomy.

Twelve patients (12%) in the lumbar facet joint nerve block group and 79 patients (35%) in the lumbar radiofrequency group were converted to other treatments, either due to side effects or inadequate relief.

In the randomized controlled trial by van Eerd (28), the authors compared comparative value of local anesthetic blocks with radiofrequency neurotomy in patients with clinically diagnosed cervical facet joint pain showing pain treatment success of 61.1% in both groups, either with local anesthetic alone or local anesthetic and radiofrequency neurotomy with a single lesion at 3 months, 55.6% of the denervation group and 51.3% in the bupivacaine alone group at 6 month follow-up with no significant difference among the groups, once again reinforcing long-term relief of local anesthetic injections.

In the systematic review by Baroncini et al (29) 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  $12.4 \pm 10.5$  months. The methodologic quality assessment showed very low selection bias, detection bias, attrition and reporting bias.

In this narrative review by Mazmudar (30), 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 (31), 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.

Based on this evidence, for all regions of the spine, therapeutic facet joint nerve blocks should be covered with the same indications as therapeutic intraarticular facet joint injections.

## **Exclusion of Thoracic Facet Joint Interventions**

There is emerging evidence showing appropriate diagnosis and management of thoracic facet joint pain.

Diagnosis of thoracic facet joint pain has been established with dual diagnostic blocks with criterion standard of 80%. The evidence in thoracic spine is Level II with moderate strength of recommendation. Based on 3 relevant diagnostic accuracy studies, with controlled comparative local anesthetic blocks, with concordant pain relief, with a criterion standard of 80%, the prevalence rate was shown to be 34% to 48%, whereas false positive rates varied from 42% to 58% (32-34).

The evidence for the rapeutic facet joint interventions is also present (5,6,35).

As shown above, thoracic spine does have moderate evidence with thoracic facet joint nerve blocks, whereas evidence is weak to moderate with Level III for radiofrequency neurotomy and intraarticular facet joint injections.

- The level of evidence is <u>III</u> with <u>weak to moderate</u> strength of recommendation with emerging evidence for thoracic radiofrequency ablation with inclusion of one relevant randomized controlled trial (36) and 3 observational studies (37-39).
- The level of evidence is <u>II</u> with <u>moderate</u> strength of recommendation for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials (5,18) and one observational study (6) with long-term improvement.
- The level of evidence is <u>III</u> with <u>weak to moderate</u> strength of recommendation for thoracic intraarticular facet joint injections with inclusion of one randomized controlled trial with 6 month follow-up (18), with emerging evidence.

In addition to this, since the publication of ASIPP guidelines, the following publications assessed effectiveness of radiofrequency neurotomy with 2 of the 3 studies showing positive results (40-42).

#### **Sacroiliac Joint Injections**

- Therapeutic intraarticular sacroiliac joint injections are performed with the use of corticosteroid with or without the use of anesthetic
- Total injection volume should be limited to 2.0 cc to minimize extravasation of the injectate outside of the sacroiliac joint

Injections are limited with 3 months of relief with a maximum of 3 injections in a 12-month period.

In conformance with Medicare LCD and the available literature, along with your requirement of 3 months of relief, it would be appropriate to allow maximum of 4 injections instead of 3 in a 12-month rolling period, which starts after the diagnostic blocks.

## **Spinal Cord Stimulation**

Under the indications for spinal cord stimulator, we request you please add diabetic neuropathy and other types of peripheral neuropathies.

Thank you for consideration of our request. If you have any questions, please feel free to contact us.

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"The most entrenched conflict of interest in medicine is a disinclination to reverse a previous opinion." *Yudkin JS et al. Lancet 2011* 

"There is no limit to what a man or woman can do, or where he or she can go if he or she doesn't mind who gets the credit." *Ronald Reagan*-modified

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