American Society *of* Interventional Pain Physicians®
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Clinical Knowledge
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RE: Comment on Evicore interventional pain management guidelines

Dear Ms Petersen:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 51 state societies of interventional pain physicians, we would like to thank Evicore for requesting us to provide input in the development of pain management guidelines.

We would like to provide some background on interventional pain as a specialty and ASIPP as follows.

ASIPP is a not-for-profit professional organization founded in 1998, now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

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 sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (1).

Interventional pain management techniques are 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 (2).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (3).

Our comments are specific to the various procedures you requested commentary on.

Our comments are based on appropriate evidence synthesis without bias or conflicts of interest to provide appropriate care, reduce utilization and healthcare costs, and control the current opioid epidemic. As you are well aware, the opioid epidemic continues to escalate. Despite the evidence that this opioid epidemic is

based on illicit fentanyl and heroin, it is also imperative to accept that the gateway drugs have been prescription opioids since 2010, replacing traditional marijuana. Despite the reducing prevalence of opioid prescriptions, opioid deaths continue to increase (Figs. 1-3) (4-6). While Congress and the Administration are looking into various aspects of the opioid epidemic, a multitude of organizations, including the National Academies of Sciences, Engineering and Medicine (7) and 32 states attorney generals have recommended the utilization of nonopioid techniques including interventional techniques. A recent analysis of utilization of various techniques, showed that there has been significant reduction in epidural injections and lumbar facet joint nerve blocks while there was minimal increase in transforaminal epidural injections and a significant increase in radiofrequency neurotomy (Figs. 4 and 5). Further, significant decreases are seen for adhesiolysis as shown in Fig. 6 (9). These factors must be taken into consideration in guideline development and policymaking, not only to control the opioid epidemic, but also to provide appropriate patient care and to increase their ability to receive access to this care. This leads to the development of guidelines which cover all procedures based on real evidence rather than biased or inappropriately performed evidence synthesis (8-10).

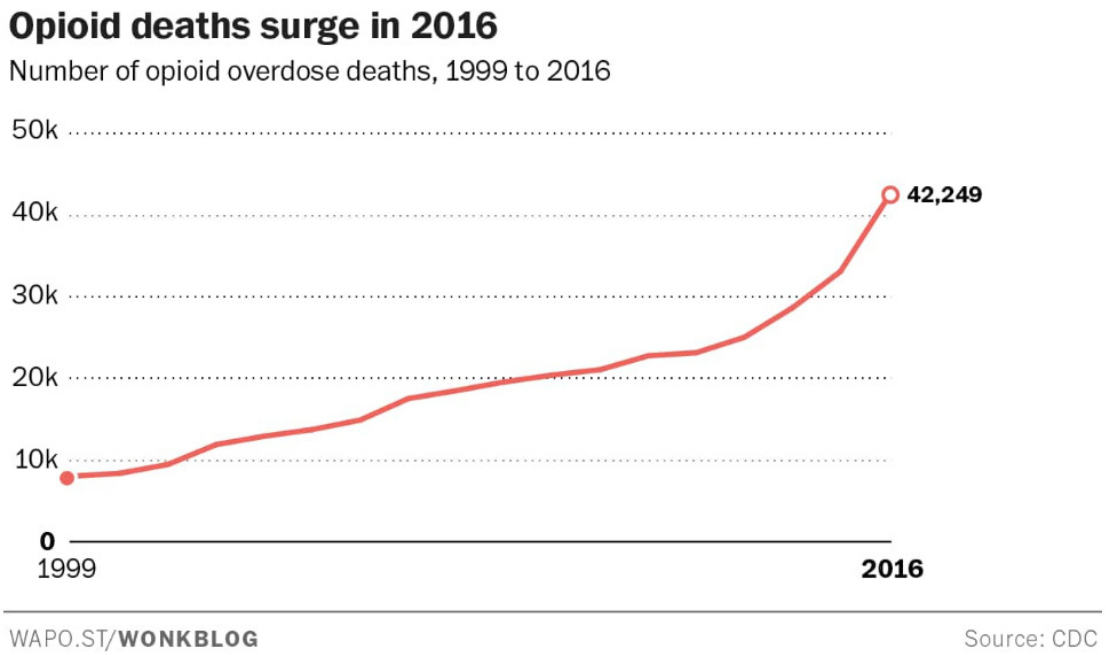

Fig. 1. *Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.*

Source: Ingraham C. CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase.' *The Washington Post*, December 21, 2017. https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b (4)

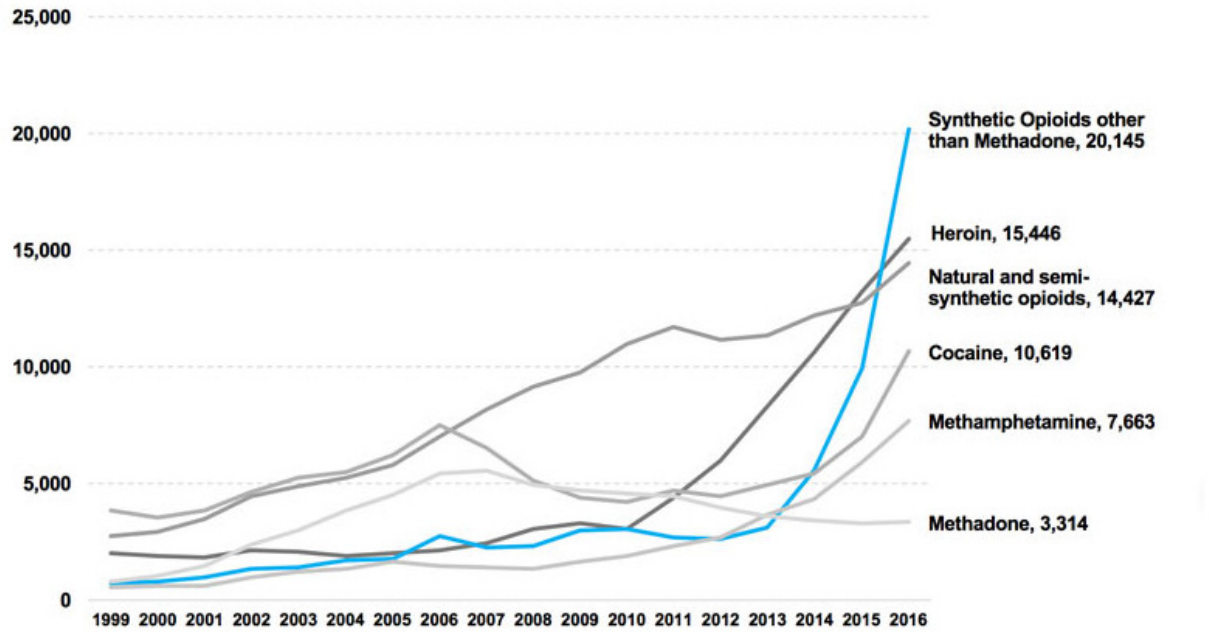

Fig. 2. *Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.*

Source: Singer JA. Stop calling it an opioid crisis – it's a heroin and fentanyl crisis. *Cato Institute*, January 9, 2018. https://www.cato.org/blog/stop-calling-it-opioid-crisis-its-heroin-fentanyl-crisis (5).

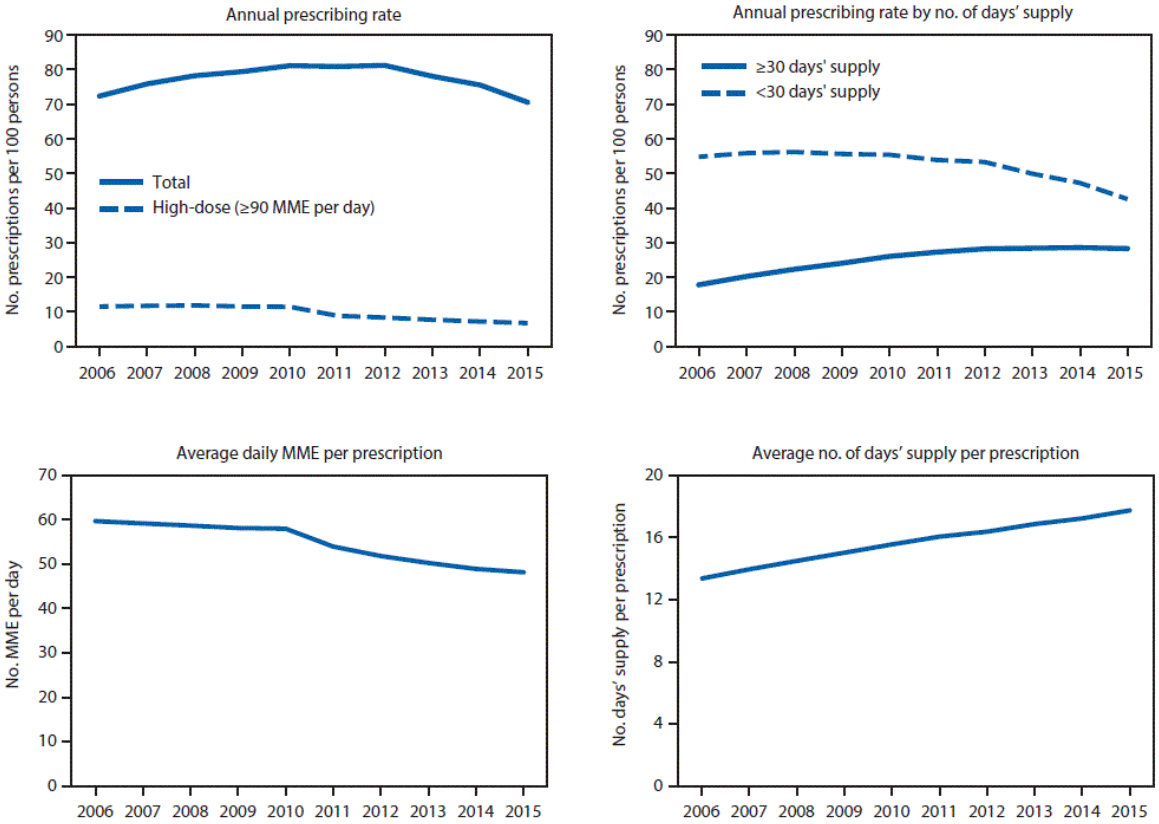

Fig. 3. *Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.*

Source: Guy Jr GP, et al. Vital Signs: Changes in opioid prescribing in the United States, 2006-2015. *MMWR Morb Mortal Wkly Rep* 2017; 66:697-704 (6).

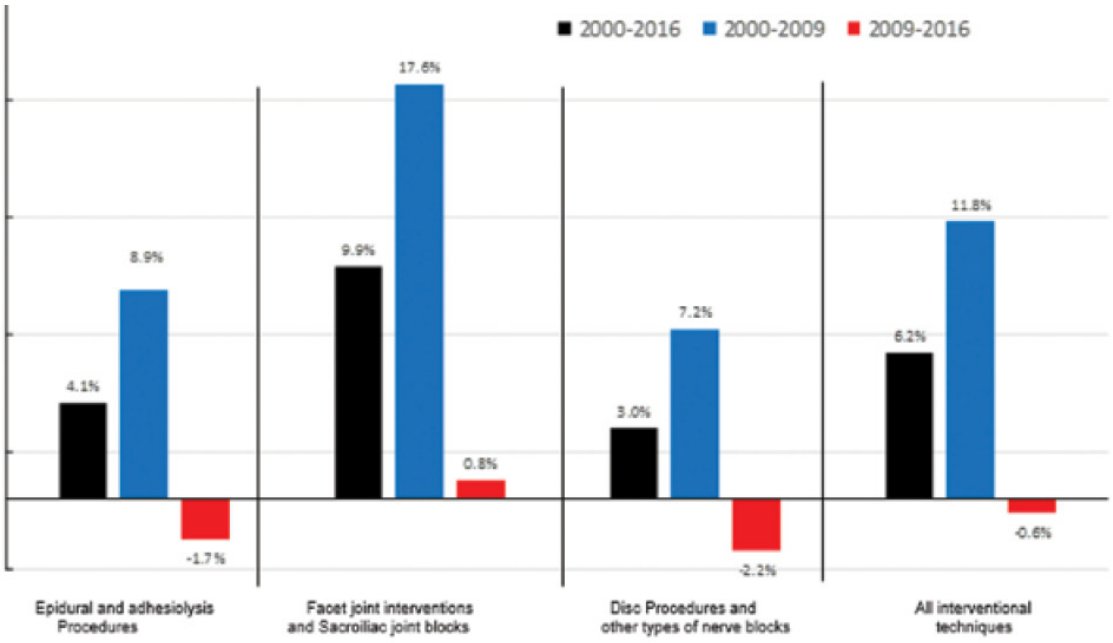

Fig 4. *Comparative analysis of epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.*

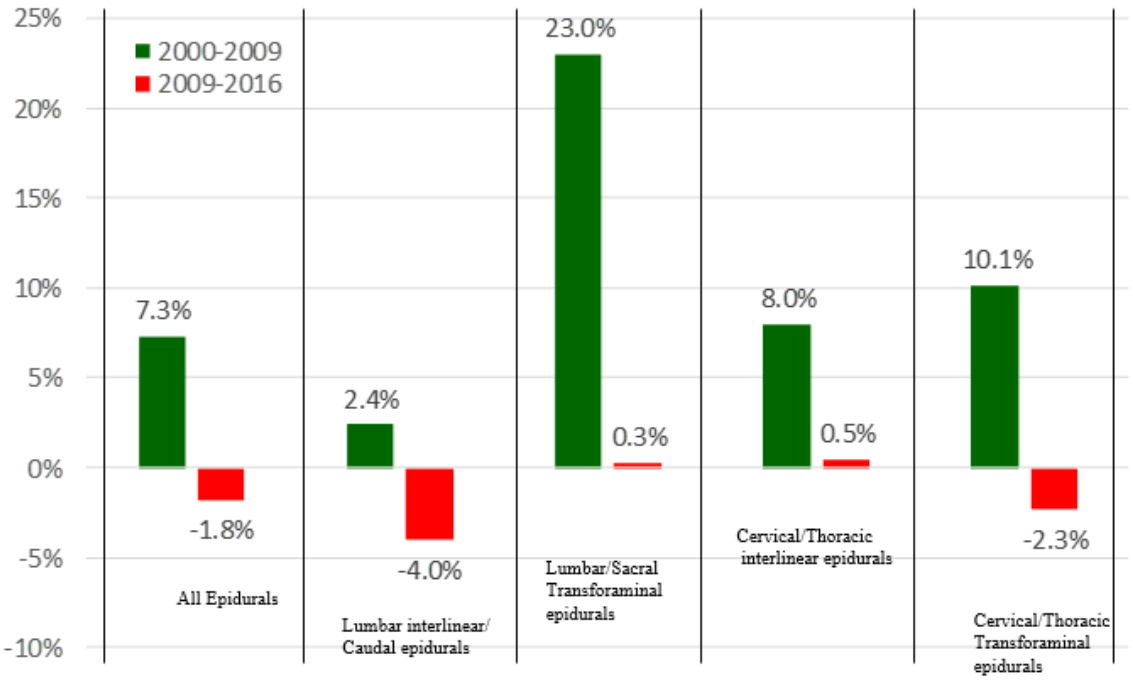

Fig 5. *Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.*

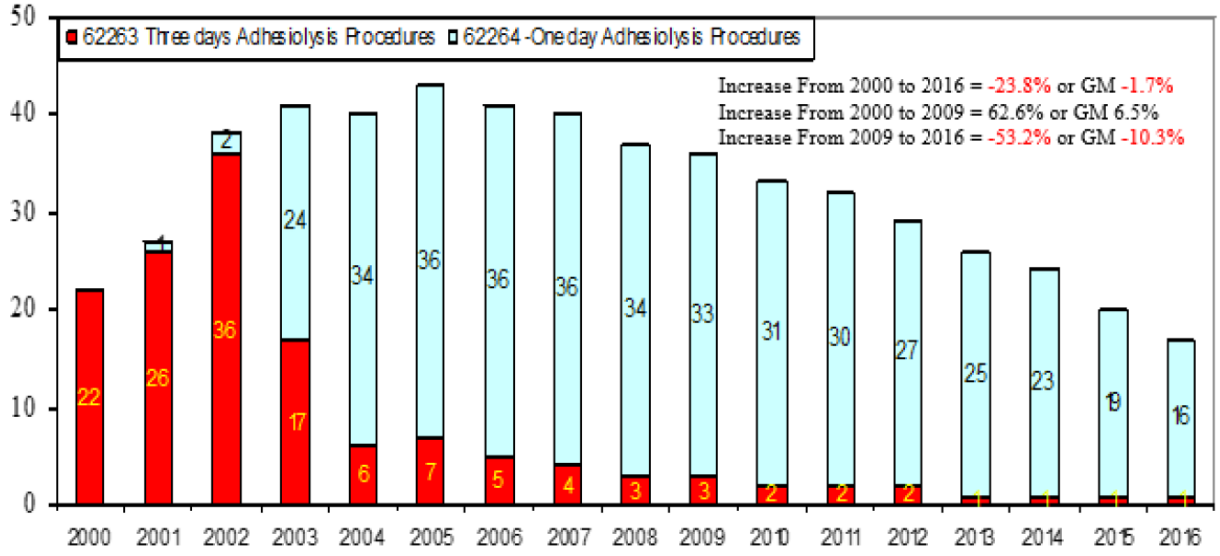

Fig 6. *Frequency of utilization of 3-day and 1-day adhesiolysis procedures from 2000 to 2016, in Medicare recipients.*

Source: Manchikanti L, Pampati V, Benyamin RM, Hirsch JA. Declining utilization of percutaneous epidural adhesiolysis in Medicare population: Evidence-based or over-regulated? *IPM Reports* 2018; 2:9-18 (9).

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Our comments are related to, as per your request, for various procedures.

CMM-201 FACET JOINT INJECTIONS/MEDIAL BRANCH BLOCKS

CMM-201.1: Definitions

The guidelines appropriately define facet joint injections/medial branch blocks.

CMM-201.2: General Guidelines

The description here allows for neck pain or low back pain in the absence of an untreated radiculopathy. This seems to exclude thoracic diagnostic facet joint nerve blocks. It is only appropriate to include thoracic facet joint nerve blocks based on the CPT coding process, as well as the available literature. As you are aware, CPT codes are the same for facet joint nerve blocks or intraarticular injections (CPT 64490-64495).

Thoracic diagnostic facet joint nerve blocks have been evaluated in 3 appropriately performed prevalence studies with dual diagnostic blocks (1-3). Consequently, it is requested that diagnostic facet joint nerve blocks be allowed. Further, appropriately performed systematic reviews with best evidence synthesis have shown moderate or Level II evidence (4,5). Consequently, it is requested that thoracic facet joint nerve blocks be allowed and clearly described to avoid confusion and further refusals of care.

In reference to therapeutic intraarticular injections or medial branch blocks, the document says that there is a paucity of published scientific evidence supporting the use of therapeutic facet joint injections/medial branch blocks. The document also describes the evidence as anecdotal evidence supporting facet joint injections/medial branch blocks as alternative treatment to radiofrequency ablation/neurotomy for a subset of individuals. The document describes that facet joint injections are only allowed if the initial facet joint injections/medial branch blocks have resulted in a significant pain relief for at least 12 weeks following the facet joint injection/medial branch block and the individual is not a candidate for a radiofrequency joint denervation/ablation procedure. Further, the guideline also permits a repeat facet joint injection may be considered appropriate, although no sooner than 6 months from when the prior diagnostic injection was performed.

Therapeutic medial branch blocks or L5 dorsal ramus blocks have been performed with increasing frequency. Essentially, based on CPT coding, therapeutic medial branch blocks are interchangeable with intraarticular injections. However, there is a wide variation in their effectiveness with medial branch or dorsal ramus blocks showing superior effectiveness. In fact, the evidence for therapeutic medial branch blocks or L5 dorsal ramus blocks is equivalent or often even better than radiofrequency neurotomy as illustrated in multiple systematic reviews, derived from multiple randomized controlled trials (4,6-16).

Based on the comprehensive best evidence synthesis (classified at 5 levels from Level I to Level V) assessment of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain (13),

with inclusion of 21 randomized controlled trials (since this review, a new RCT [12] was published) and 5 observational studies, the following evidence was presented:

- In the lumbar spine, there is Level II evidence for radiofrequency neurotomy and lumbar facet joint nerve blocks, whereas the evidence is Level III for lumbosacral intraarticular injections.
- In the cervical spine, there is Level II evidence for cervical radiofrequency neurotomy and cervical facet joint nerve blocks, and Level IV evidence for cervical intraarticular injections.
- In the thoracic spine, there is Level II evidence for thoracic facet joint nerve blocks and Level IV evidence for radiofrequency neurotomy.

Further, cost utility analysis has been assessed for lumbar and cervical facet joint nerve blocks showing favorable evidence. Based on the similar assessment, the results of cost utility analysis in the cervical spine showed with procedural costs of $2,552 and overall costs of $4,261 per one year improvement in QALY (17).

For the lumbar spine, the results of cost utility analysis showed procedural costs of $2,654.08 and overall costs of $4,432 per one year of QALY (18).

The cost utility analysis was performed from highly regarded surgical literature from Spine Patient Outcomes Research Trial (SPORT) data (19,20). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (19) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (20). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of facet joint injections is estimated to be $4,261 per one year improvement in QALY in cervical spine with facet joint nerve blocks, and $4,432 per one year of QALY in lumbar spine with facet joint nerve blocks with multiplication of the procedural cost by 1.67.

In addition to proven clinical and cost effectiveness:

- Therapeutic facet joint nerve blocks are covered by all Medicare carriers, an overwhelming majority of Medicaid carriers, and multiple commercial insurers.

- Facet joint nerve blocks elicit higher acceptance rate from patients with less fear compared to radiofrequency neurotomy, which seems to elicit more fear and the false notion of burning the nerves as promoted by many.

- It is crucial to consider the role of facet joint pain in lumbar and cervical postsurgery syndrome. Studies have shown significant prevalence of pain of facet joint origin in postsurgery patients (21-24). Further, a significant proportion of patients after post-surgery syndrome with hardware or bone fusion are not candidates for radiofrequency neurotomy; however, they can be treated with facet joint nerve blocks.

- Effectiveness of radiofrequency is not observed in all patients. Consequently, if 80% to 85% of the patients respond to radiofrequency neurotomy after appropriate diagnostic blockade, a 15% to 20% population is without response. Thus, without further treatment,

after failure of radiofrequency neurotomy which is approximately 15% to 20% of the patients, these patients will be left without any further options. However, an overwhelming majority of these patients (after failure of radiofrequency neurotomy), seem to respond to facet joint nerve blocks.

- A significant proportion of obese patients also suffer with facet joint related pain. In these patients, radiofrequency neurotomy may be difficult. In these patients, facet joint nerve blocks can be performed with somewhat of an easier technical challenge providing significant improvement with lower risk (2,3,25).

- In patients with a pacemaker, radiofrequency neurotomy is difficult or associated with some risk, despite development of bipolar radiofrequency which is considered to be safe but not foolproof. In these patients, facet joint nerve blocks will be much safer and easier to perform with patient comfort.

These are multiple and additional benefits of medial branch blocks and it will reduce access to patient care once medial branch blocks are removed from armamentarium of treatment modalities.

We believe that your exclusion of therapeutic medial branch blocks is based on inappropriate interpretation of the evidence, with overall diminution in access and finally contributing to increased disability and health care costs rather than reducing these as you seem to believe it would (26-31).

Consequently, as described above, inappropriate guidelines may be contributing to the opioid epidemic. Thus, it is essential to cover these procedures which are safe and also based on the evidence. As shown in the cost utility analysis, there are similar or less expensive than radiofrequency neurotomy in providing improvement in quality of life years.

The remaining guidance related to facet joint injections/medial branch blocks appears to be appropriate. However, the statement in reference to no more than 3 facet joint levels should be injected during the same session-procedure is not appropriate. It may be modified that the insurer should reimburse no more than 3 facet joint levels. Sometimes patients needs more levels. That doesn't mean that insurers have to reimburse for that, but physicians should have ability to provide appropriate care.

CMM-201.3: Indications
The descriptions are appropriate.

CMM-201.4: Non-Indications
Once again, it may be stated that will be reimbursed only for 3 joint levels.

On another point, the guideline states that on the same day of service when performing other injections such as epidural steroid, sacroiliac in the same region is a non-indication. In the diagnostic phase, multiple injections may be performed. However, the insurer can reimburse only for the facet joint injections or epidural injections, whichever is chosen rather than prohibiting the physician from performing these procedures.

Facet joint injections are performed in post surgery patients at fused posterior spinal motion segment in many patients. While radiofrequency may be associated with additional risk, therapeutic medial branch blocks are highly suitable for this situation as described above.

Finally, the second non-indication in reference to therapeutic facet joint blocks is inappropriate and needs to be eliminated.

The following indication are recommended for therapeutic facet joint injections/medial branch blocks.

Facet joint injections or medial branch blocks are considered medically necessary for any of the following indications:

- For facet joint pain resulting from disease, injury, or surgery when both of the following criteria are met:
    - Failure of at least 3 months of conservative therapy (e.g. exercise, physical methods including physical therapy, chiropractic care, nonsteroidal anti-inflammatory drugs (NSAID's) and/or analgesics).
    - Two positive diagnostic blocks with 80% pain relief.
- A repeat therapeutic facet joint/medial branch block is considered medically necessary when both of the following criteria are met:
    - If there is documented pain relief of at least 50% which has lasted for a minimum of 10 to 13 weeks:
    - The procedures is performed at a minimum of 3 months following the prior therapeutic facet joint procedure, preferably 4 months after the established diagnosis.

This change will not only improve access to patient care, improve quality of patient care, but also will provide cost savings. You are well aware facet joint radiofrequency neurolysis is reimbursed at 200% of facet joint injections. Consequently, with 3 facet joint injections per year, costing 300 units, whereas 2 radiofrequency neurotomies per year will cost 400 units with savings of 100 units.

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CMM-208 RADIOFREQUENCY JOINT ABLATION_DENERVATION

CMM-208.1: Definitions
Definitions of radiofrequency joint denervation/ablation is appropriate.

CMM-208.2: General Guidelines
Once again, as commented in facet joint injections and nerve blocks, the limit of 3 levels may not be appropriate at all times. Reimbursement for only 3 levels is appropriate. Wording must be changed to accommodate various conditions, otherwise patients may be brought more than one time going through appeals process or patients will experience only partial relief of pain.

CMM-208.3: Indications
All of the guidelines are appropriate in this section except for the following:

A repeat radiofrequency joint denervation is allowed with documented pain relief of at least 50%, which has lasted for a minimum of 12 weeks. This should be adjusted to as follows:

> Minimum of 20 weeks, preferably 23 to 26 weeks.
>
> Minimum of 10 to 13 weeks of relief may be applied for therapeutic medial branch blocks or intraarticular injections as we have described above for CMM-201: Facet Joint Injections/Medial Branch Blocks.

CMM-208.4: Non-Indications
In reference to performing radiofrequency neurotomy in a posteriorly fused spinal motion segment, the policy states that it is a non-indication.

While there is evidence that this can be performed safely, it may still face technical difficulties. Consequently, approval of facet joint injection/nerve blocks in these conditions is crucial and facilitates proper management of these patients.

CMM-203 SACROILIAC JOINT INJECTIONS

CMM-203.1: Definitions
Definitions are appropriate.

CMM-203.2: General Guidelines
To standardize all the treatments with interventional techniques, the positive diagnostic response definition may be increased to 80% pain relief for the duration of the local anesthetic.

Further, double diagnostic blocks may be added in the general guidelines.

CMM-203.4: Non-Indications
In this also the 2 diagnostic blocks must be clarified and changed to 80% relief.

CMM-207 EPIDURAL ADHESIOLYSIS

CMM-207.1: Definitions
Definition is appropriate.

CMM-207.2: General Guidelines
These guidelines are inadequate and improper. There is substantial evidence supporting percutaneous adhesiolysis with a single-day and 3-day treatment. Unfortunately, policies not covering epidural adhesiolysis have only increased the costs of health care leading patients to more expensive treatments and opioid therapy leading to the opioid epidemic. There have been multiple randomized controlled trials specifically in post lumbar surgery syndrome and spinal stenosis (1-3) , along with recalcitrant pain with degenerative disc disease (1-8). Overall, significant improvement has been shown in a greater proportion of patients with spinal stenosis, post surgery syndrome, and disc herniation at one and 2-year follow-ups based on pragmatic protocols and administration of the procedures. It should also be considered that these patients have already failed a multitude of interventions including interventional techniques with epidural injection and surgical interventions in many cases.

In addition, cost utility analysis also has been performed, which showed favorable cost utility (9). The cost utility analysis was performed from highly regarded surgical literature of Spine Patient Outcomes Research Trial (SPORT) data (10,11). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (10) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (11). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of percutaneous adhesiolysis is estimated to be $4,425 with multiplication of the procedural cost by 1.67, with significant cost savings overall.

The evidence synthesis utilizing strict criteria of methodologic quality assessment and clinically relevant outcomes shows Level II evidence for percutaneous adhesiolysis after failure of other modalities of treatments.

Based on the above evidence, percutaneous adhesiolysis must be a covered procedure.

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CMM-211 SPINAL CORD STIMULATORS

CMM-211.1: Definitions
Definitions are appropriate.

CMM-211.2: Indications
Indications seem to be extensive including angina and chronic critical limb ischemia which are not the conditions usually treated in the United States with spinal cord stimulation, specifically chronic stable angina pectoris.

CMM-211.3: Replacement
Indications are appropriate.

CMM-211.4: Non-Indications
High frequency spinal cord stimulation as well as low frequency spinal cord stimulation are not considered as experimental. These should be covered procedures. Further, peripheral nerve stimulation may be covered under appropriate circumstances with strict utilization criteria.

The effectiveness of high frequency spinal cord stimulation therapy is supported by one high quality randomized controlled trial (1), one prospective multicenter observational study (2), both with 24-month follow-up, and a high quality systematic review (3). ASIPP is currently updating its interventional pain management guidelines in which HF10 therapy will be included as a recommend treatment option, based on systematic review performed by Grider et al (3). As you know, the Senza SCS system, which delivers HF10 therapy, was approved by the FDA on May 8, 2015, through the PMA process. Subsequent trial by Kapural et al (1) and Al-Kaisy et al (2) showed significant improvement from baseline in patients receiving HF10 therapy, along with potential superiority over conventional spinal cord stimulation. Further, the Senza system is capable of and FDA-labeled to provide the same SCS operating frequencies as other recommended spinal cord stimulation devices. It is the only device that is approved to deliver HF10 therapy. The FDA indications for use are similar to previously approved devices with an additional possibility of better results to traditional SCS when configured to deliver paraesthesia-free therapy at 10,000 Hz. Additionally, the Centers for Medicare and Medicaid Services (CMS) has stated that the device met the CMS requirement of "substantial clinical improvement" as compared to traditional SCS, through the transitional pass-through payment process.

Consequently, CMS and FDA have determined that high frequency stimulation is neither experimental, nor investigational, and this procedure meets Medicare criteria with safety and effectiveness and it is as beneficial as an existing and available medically appropriate alternative (4). As you are well aware, a technology is deemed experimental and investigational if there are insufficient outcomes data in the peer reviewed medical literature, or FDA approval has not been obtained, or a relevant and large medical society or regulatory agents deems it experimental based on available evidence. Since none of these issues are applicable to high frequency stimulation, it is our contention that classification of experimental and investigational is inappropriate and not based on evidence.

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CMM-210 IMPLANTABLE INTRATHECAL DRUG DELIVERY SYSTEMS

CMM-210.1: Definitions

Definitions are appropriate.

CMM-210.3: Indications

Indications are appropriate.

CMM-210.4: Non-Indications

Non-indications are appropriate.

CMM-210.5: Replacement

Replacement is appropriate.

CMM-204 PROLOTHERAPY

The guidance is appropriate as a non-covered procedure.

Thank you again for asking for our input. We hope that this has been helpful.

Following the above recommendations will improve patient access and ease the opioid crisis, and finally save insurers money instead of increasing the costs.

Thank you,

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