American Society *of* Interventional Pain Physicians®
"The Voice of Interventional Pain Management"
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RE: Epidural Procedures for Pain Management: Proposed Local Coverage Determinations in all MAC Jurisdictions

Dear Ms. Jensen, Mr. Ward, Ms. Evans, and Ms. Truong:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), the Society of Interventional Pain Management Surgery Centers (SIPMS), and 49 state societies of Interventional Pain Physicians, including Puerto Rico and the affiliated Texas Pain Society, excluding Connecticut, we would like to thank you for your courtesy and assistance you have provided over the years with implementation of local coverage determinations (LCDs) and changes of 21st Century Cures Act of 2016, the updated process to provide greater transparency, consistency, and patient engagement.

Since we have discussed multiple issues with you in 2018, several changes have been occurring, the majority of them seem to be good as you have inferred in reference to implementation of 21st Century Cures Act of 2016. We will continue to face significant issues related to coverage of medically and necessary services, transparency and evidence development, and policy coordination and implementation.

In reference to LCDs, we have applied for new LCDs for cervical epidural injections and percutaneous adhesiolysis, with CGS based on non-coverage policies of Noridian and Palmetto, all Medicare Advantage

Plans and various others including Medicaid and commercial insurers. We held meetings, but they were never brought to consideration.

We were pleased when they added both the procedures for consideration with epidural interventions. However, while cervical epidural stayed in and coverage policies were developed, percutaneous adhesiolysis appears to have been removed after evidence synthesis was performed.

Following this, facet joint policy was developed in which all groups were involved. We continue with some issues related to this policy, based on misunderstandings. The major issue with Facet Joint Interventions for Pain Management in all MAC jurisdictions is related to **MULTIPLE PROCEDURES:**

> It has been our understanding that multiple procedures are not allowed in the same region; however, MAC contractors are now interpreting that these procedures cannot be performed in separate regions also in the same session. This is creating major issues with access. This may lead to explosion of opioid epidemic, increased expenses to Medicare program with payment of 200%, rather than 150% when they are performed in the same session, and unintended consequences with extensive copays and deductibles for Medicare Advantage Plans, non-coverage by Medicaid Managed Care contractors, all government programs, and finally it is spreading to commercial insurers. Finally, this will lead to use more expensive and invasive treatments.

Apart from these, today we are writing to ask for your assistance in requiring significant revisions and amendments in four (4) important areas of Proposed Local Coverage Determination of Epidural Procedures for Pain Management in all MAC jurisdictions.

1. Inclusion of percutaneous adhesiolysis, which has been discussed in multijurisdictional committee with a score of 3.21 of 5, supported by randomized controlled trials, systematic reviews and guidelines with evidence levels of I to II with strong to moderate recommendation.

2. Revision of indications with the replacement of terminology of radiculopathy with radicular pain and limiting these indications for transforaminal epidural injections with addition of disc herniation to present indications. In addition, the covered indications must include degenerative disc disease, spinal stenosis, post surgery syndrome, and discogenic pain without evidence of facet joint or sacroiliac joint pain as they have been covered in the previous LCDs with an abundance of evidence.

3. Revision of procedural limitations and outcomes assessment with duration of relief, with expansion, similar to the previous LCD, with 2 procedures in the diagnostic or initial phase with 4 and 6 weeks apart after first and second procedures per spinal region, followed by 4 epidural injections per spinal region in a rolling year, initiated with a third procedure. If the patients' condition includes an acute lumbar herniated nucleus pulposus, then the patient should wait no longer than 2 weeks for the first epidural steroid injection and no longer than 2 weeks for a second and or third epidural steroid injection, if indicated. Additionally, to provide a second epidural after 3 months of sustained 50% pain relief is not supported by the literature. An overwhelming evidence shows that the first procedure provides less than 6 weeks of relief on average and the second procedure provides 10 weeks of relief on average.

4. Coverage for multiple procedures in separate regions in the same session when reasonable and necessary.

During the evidence development, some subject matter experts were used who were openly totally negative of coverage of any type of epidural procedures or any interventional techniques and they had no clinical experience other than providing negative and extremely biased evidence. Unfortunately, these are also government experts paid by tax dollars. Further, roll out has been hampered with multiple issues as CAC members were not informed and even for us, it took 3 weeks to find out that a policy was released. Some

of the jurisdictions had open CACs and members were not even aware of the release of the policy until the day of the presentation. Better late than never, really is not optimal for transparency and participation. It will be appropriate to provide proper instructions in these areas.

If these changes are not implemented, failure to provide appropriate care to these patients will lead to more expensive treatments and hinder the access and may fuel opioid epidemic in addition to explosion of modalities such as spinal cord stimulation, intrathecal infusion system implantables, PILD procedure, interspinous prosthesis implants, and finally surgical interventions. In addition to this, it will increase the expenses to the program as described earlier and also reduce the access significantly, not only to Medicare patients, but also Medicare Advantage, all governmental programs, Medicaid, and finally commercial insurers. It will cause substantial inconvenience to the patients with multiple copays, difficulties with drivers bringing them to the procedures, and multiple COVID tests. In essence, this policy will hurt the most vulnerable, namely the elderly, economically disadvantaged, and minority population which is quite opposite the goals of Medicare program.

BACKGROUND

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. ASIPP is comprised of 50 affiliated state societies, and the Puerto Rico Society of Interventional Pain Physicians.

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 (http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf).

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 (http://medpac.gov/docs/default-source/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0).

SIPMS is a not-for-profit professional organization founded in 2005, with membership involving surgical centers focusing on interventional pain management, dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic pain. There are approximately 500 surgery centers across the nation approved by Medicare providing solely, or an overwhelming majority, of interventional pain management services.

Medicare

Based on the 21st Century Cures Act of 2016, the LCD process is updated to provide greater transparency, consistency, and patient engagement.

Medicare covers medically reasonable and necessary services. If the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency in terms of whether the service or item is:

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the beneficiary's medical needs and condition;
- Ordered and furnished by qualified personnel

Further, LCD development process must assure beneficiary access to care.

The National Contractor Advisory meeting consisting of national experts, geographic representation, academic and clinical practice, various specialties that perform are involved in the procedure, have performed evidence-based review. American Society of Interventional Pain Physicians through its multiple CAC members and subject matter experts, have participated in National Contractor Advisory Committee meeting for policy development. Based on the hierarchy of evidence review, an overwhelming majority of the procedures received recommendations based on randomized controlled trials, appropriately performed systematic reviews and meta-analysis, and evidence-based clinical practice guidelines, rather than consensus based guidance.

We are enclosing a generic comment letter, which has been customized to each MAC for your consideration, along with a fact sheet, which have been provided to our membership and members of the Congress.

At this time, we are not engaging patients. There is a major cry in reference to access issues, which can become very difficult to handle with patient involvement.

We are hoping that keeping in the spirit of 21st Century Cures Act of 2016, Medicare would consider for patient safety and to preserve the access based on evidence-based guidance to facilitate appropriate revisions and amendments.

If you have any questions, please feel free to contact us.

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Thank you again,

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