Local Coverage Determination in All Jurisdictions

SUMMARY

Based on the 21st Century Cures Act of 2016, the updated LCD process with greater transparency, consistency, and patient engagement for procedures which are medically reasonable and necessary is being developed in conjunction with National Contractor Advisory Meeting consisting of experts from various disciplines.

The proposed policy has numerous issues, which may result in explosion of opioid epidemic, increasing health care costs and hampered access to care. We are asking your assistance for significant revisions and amendments in four (4) important areas:

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 LHNP, then the patient should wait no longer than 2 weeks for the first ESI and no longer than 2 weeks for a second and or third ESI, 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.

Introduction

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 when the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency
- Ordered and furnished by qualified personnel

The National Contractor Advisory meeting consisting of experts from multiple areas performed evidence synthesis in which American Society of Interventional Pain Physicians (ASIPP) participated. 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.

Percutaneous Adhesiolysis

There was an LCD request for percutaneous adhesiolysis at CGS. Subsequently, it was incorporated into multijurisdictional committee assessment as an epidural intervention. Percutaneous adhesiolysis is an epidural intervention, which differs from epidural injections with additional involvement of catheter-based adhesiolysis. It fits the criteria of the epidural intervention as described in evidence-based guidelines. Based on multiple moderate to high-quality RCTs and systematic reviews, the evidence was shown to be Level I to II with strong to moderate recommendation in evidence-based guidelines for long-term improvement of post lumbar surgery syndrome, spinal stenosis and recalcitrant disc herniation, after failure of conservative management and fluoroscopically-guided epidural injections. The evidence for lumbar central spinal stenosis based on relevant, moderate to high-quality RCTs, observational studies, and systematic reviews was Level II with moderate to strong recommendation in patients nonresponsive to conservative management and fluoroscopically guided epidural injections.

Lack of addition to this procedure will be significantly consequential. As of now, Noridian and Palmetto have issued non-coverage determinations (NCDs). In other jurisdictions, this procedure is offered; however, with the publication of epidural policy it may encourage other jurisdictions to do the same. Now which is a differential decline in access will become a universal decline in access. In addition, percutaneous adhesiolysis procedure, which is performed only after failure of fluoroscopically directed epidural injections, may reduce other expensive modalities including repeat surgical interventions, spinal cord stimulation, intrathecal infusion systems, and increased opioid prescriptions. The cost utility analysis have shown similar cost utility compared to other modalities. This may also lead to utilization and continuation of transforaminal epidural injections, which cost the same to Medicare or less with approval of percutaneous adhesiolysis.

Covered Indications

The covered indications may be appropriate for transforaminal epidural injections with appropriate language revisions to radicular pain.

Local Coverage Determination In All Jurisdictions *(continued)*

However, the indications for interlaminar and caudal epidural injections should be expanded.

Radiculopathy should be replaced with radicular pain. Often these terms are used interchangeably. All types of procedures have been shown to be effective in managing radicular pain, even though the evidence is somewhat better for transforaminal epidural injections and transforaminal epidural injections are indicated only when there is radicular pain. However, there is no evidence of any of the procedures in managing radiculopathy.

We request the addition of disc herniation and degenerative disc disease as causative factors.

Discogenic pain without facet joint or sacroiliac joint pain has been shown to be well managed with epidural injections. Clinical and cost utility analysis show similar effectiveness as in disc herniation or spinal stenosis or post lumbar surgery syndrome. Consequently, degenerative disc disease without radicular pain, spinal stenosis without neurogenic claudication, post surgery syndrome without radicular pain, and discogenic pain without facet joint or sacroiliac joint pain must be covered. Failure to do so will leave majority of the patients without any further treatment. Based on facet joint policy, patients not achieving 80% relief on 2 consecutive comparative local anesthetic blocks will be judged as negative for facet joint pain and will be positive and responsive to interlaminar or caudal epidural injections, as shown in the literature, systematic reviews and guidelines, with a multi-jurisdictional committee score of 3.43.

Duration of Relief During the Initial Phase

Pain duration of at least 4 weeks and the inability to tolerate non-invasive conservative care or medical documentation of failure to respond to 4 weeks of non-invasive conservative care should be eliminated for acute radicular pain, similar to acute herpes zoster. Acute radicular pain and acute herpes zoster may be treated after 1-2 weeks of non-invasive conservative care.

Multiple Treatments

The policy states no multiple treatments can be performed. We can understand that in a single region there may not be multiple procedures; however, when these are performed in different regions there is no basis for this. In general, literature shows that 60% of the patients with spinal pain have more than one region involved. Consequently, this will significantly restrict the access. It also causes patient inconvenience, provider increased workload and costs, and finally it is more expensive to the program with payment of 200% instead of 150%.

Unintended consequence of this will include Medicare Advantage Plans going to the same with high co-pays and deductibles doubling the pain.

Further, all government plans, Medicaid, commercial payers also follow this. Apart from expense, it will result in significant lack of access, with expenses, family involvement with transportation, and multiple COVID tests. In addition, we also have concerns with regards to long-term treatment and restrictions.

Treatments Exceeding 12 Months

This limitation is unreasonable and the requirements add significant documentation burden, and also affects the access. The LCD already has sufficient guardrails in place to prevent overuse or abuse of the procedure while outlining appropriate use and thus we request that this limitation be removed.

To request policy changes, please contact:
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ABOUT ASIPP AND SIPMS

The American Society of Interventional Pain Physicians (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 49 state societies of Interventional Pain Physicians, including Puerto Rico and the affiliated Texas Pain Society, excluding Connecticut.

The Society of Interventional Pain Management Surgery Centers (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 or solely or an overwhelming majority of interventional pain management services.

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