ASIPP®
American Society of
Interventional Pain Physicians
THE VOICE OF INTERVENTIONAL PAIN MANAGEMENT

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Re: Clinical Policy: Caudal or Interlaminar Epidural Steroid Injections CP.MP.164
Date of Last Revision: 09/21

Clinical Policy: Selective Nerve Root Blocks and Transforaminal Epidural Steroid Injections CP.MP.165
Date of Last Revision: 08/21

Dear Dr. Ken Yamaguchi & Ms. London:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), 49 state societies and affiliates including Puerto Rico Society of Interventional Pain Physicians, as well as the membership of ASIPP, we thank you for your updates and revisions of epidural policies.

Multiple members in various states have brought attention to the above policies on Caudal or Interlaminar Epidural Steroid Injections, Selective Nerve Root Blocks and Transforaminal Epidural Steroid Injections. There are significant concerns about some of the recent changes supposedly made based on Medicare guidelines. These changes however do not reflect the final determination by Medicare. Revisions of the Centene policy were established prior to the final effective date of the Medicare policy. Consequently, we are requesting that you change your policy in reference to treatment beyond 12 months or more than 4 therapeutic injections to reflect the Medicare LCD indicating that a primary care physician must be informed as to the specific reasons for continued treatment.

The criteria includes:

1. Pain is severe enough to cause a significant degree of functional disability or occasional disability.
2. The epidural steroid injection provides at least 50% sustained improvement of pain and/or 50% objective improvement in function using the same scale as baseline.
3. Rationale for the continuation of the epidural steroid injection, including, but not limited to:
   - Patient is a high risk surgical candidate
   - The patient does not desire surgery

- Recurrence of pain in the same location relieved with epidural steroid injections for at least 3 months
- Finally, the requirement has been changed to notify the primary care provider.

Based on the available evidence, we request that the policy eliminates "not medically necessary" or modifies its restrictions so that if one of the conditions is met, patient treatment can be continued after 12 months.

As background information on the long-term use of injections, your literature search and the text is appropriate. You have quoted the manuscript by Manchikanti et al comparing caudal, interlaminar and transforaminal epidural injections in disc herniation (1) which included a description of 3 randomized, double blind controlled trials, involving 360 patients publishing results over a 2-year follow-up (2-4).

However, it appears that you may have missed 2 studies evaluating interlaminar epidural injections in the cervical and thoracic spine with a 2-year follow-up (5,6) that included a total of 230 patients.

In addition, Manchikanti et al also have evaluated the role of caudal and interlaminar epidural injections in spinal stenosis with a 2-year follow-up (7,8) involving a total of 220 patients.

Manchikanti et al also have published caudal and interlaminar epidural injections in the cervical spine related to post surgery syndrome with a 2-year follow-up, in randomized, double-blind, controlled trials with inclusion of a total of 256 patients (9,10).

In addition to this, 2-year follow-ups were also performed for discogenic pain with caudal, and interlaminar epidurals in the lumbar and cervical spine incorporating 3 randomized, double-blind, controlled trials, with a total of 380 patients having chronic persistent pain after ruling out discogenic and facet joint pain (11-13).

Knezevic et al (14), in a systematic review and meta-analysis, evaluated 15 manuscripts, of which 12 provided a 2-year follow-up. Their search included studies from 1966 through December 2019. Outcome measures in their analysis included a hard endpoint for the primary outcome, defined as the proportion of patients with 50% pain relief and improvement in function. Secondary outcome measures, or soft endpoints, were pain relief and/or improvement in function. The results based on qualitative analysis, quantitative analysis with conventional meta-analysis, and single-arm meta-analysis showed Level II, moderate evidence, for short-term and long-term improvement in pain and function with the application of epidural injections with local anesthetics, with or without steroid, in managing spinal pain of multiple origins. These injections included caudal, lumbar, thoracic and cervical interlaminar epidurals and lumbar transforaminal epidural injections. Of these, 12 of the 15 studies met the inclusion criteria at 24 months. The summary data of significant improvement at 24 months with $\geq$ 50% pain relief and improvement in function is shown in Table 1. These were highly selected patients known as responsive patients, reporting pain relief from disc herniation ranging from 77% to 86% in these patients. Pain relief with spinal stenosis ranged from 51% to 85% of patients. Very good outcome results were also reported in discogenic pain and post surgery syndrome. This is the only systematic review which by assessing studies having a 2-year follow-up addressed results extending beyond 1 year.

Table 1. *Significant improvement at 24 months – significant improvement (≥ 50%) of pain and function.*

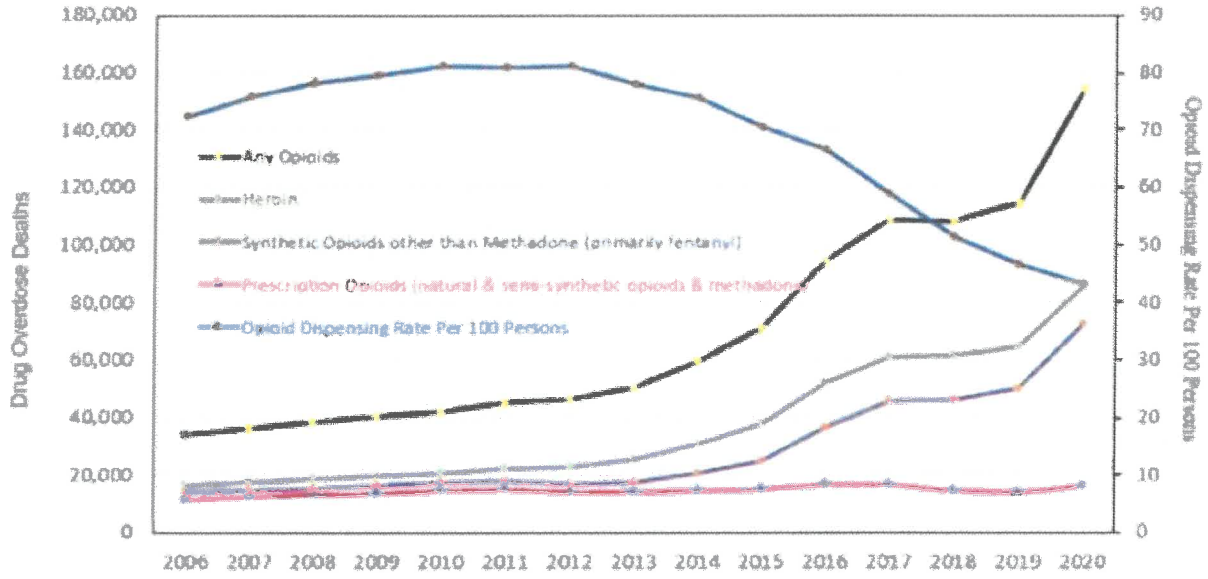
Study	All patients			Responsive Patients		
	Lidocaine Only	Lidocaine + Steroids	Difference	Lidocaine Only	Lidocaine + Steroids	Difference
Disc herniation						
Manchikanti et al (2)	60% (36/60)	65% (39/60)	0.5732	77% (36/47)	76% (38/50)	0.9081
Manchikanti et al (7)	60% (36/60)	70% (42/60)	0.2528	72% (36/50)	71% (42/59)	0.9087
Manchikanti et al (5)	72% (43/60)	68% (41/60)	0.6340	77% (41/53)	80% (40/50)	0.7126
Manchikanti et al (6)	71% (39/55)	80% (44/55)	0.2747	80% (39/49)	86% (44/51)	0.4263
Manchikanti et al (4)	65% (39/60)	57% (34/60)	0.3710	80% (39/45)	73% (33/45)	0.4361
Pooled#	65% (193/295)	68% (200/295)	0.4405	77% (191/248)	77% (197/255)	1.0000
Discogenic pain						
Manchikanti et al (11)	54% (32/60)	60% (36/60)	0.5086	84% (28/33)	73% (30/41)	0.4856
Manchikanti et al (13)	72% (43/60)	67% (40/60)	0.5536	78% (42/54)	70% (38/54)	0.3455
Manchikanti et al (12)	73% (44/60)	70% (42/60)	0.7170	78% (43/55)	75% (42/56)	0.7107
Pooled	66% (119/180)	66% (118/180)	0.9204	80% (113/142)	73% (110/151)	0.1592
Spinal stenosis						
Manchikanti et al (7)	38% (19/50)	44% (22/50)	0.5439	51% (19/37)	57% (21/37)	0.6071
Manchikanti et al (8)	72% (43/60)	73% (44/60)	0.9028	84% (43/51)	85% (45/53)	0.8885
Pooled	56% (62/110)	60% (66/110)	0.5487	70% (62/88)	73% (66/90)	0.6584
Post-surgery syndrome						
Manchikanti et al (9)	47% (33/70)	58% (39/70)	0.1941	62% (33/53)	69% (39/56)	0.4440
Manchikanti et al (10)	69% (40/58)	71% (41/58)	0.8150	74% (39/53)	79% (37/47)	0.5590
Pooled	57% (73/128)	63% (80/128)	0.3281	68% (72/106)	74% (76/103)	0.3406

ASIPP guidelines also provided with appropriate evidence for long-term follow-up (15).

There is Level I evidence for caudal epidural injections, lumbar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections with a strong recommendation for long-term effectiveness. Level II to III evidence was established for spinal stenosis with a moderate to strong recommendation for caudal and interlaminar epidural injections. The guidelines also reflect Level II evidence with a moderate to strong recommendation in post-surgery syndrome.

Thus, there is relevant evidence to continue epidural injections beyond 12 months when specific indications are met.

Lack of coverage for essential interventional techniques can cause significant issues related not only to a deterioration in patient function and an inability to be productive citizens, but this dearth in coverage can also exacerbate the already escalating fourth wave of the opioid epidemic. Without access to necessary pain management therapies either employing interventional techniques with or without non-opioid medications or by providing treatment through adequate opioid dosage patients will be forced into illicit drug use, which in the long run, will devastate the patient and their family, and will cause extensive damage to both insurers and society. Figure 1 shows the paradox of the opioid epidemic with an escalating fourth wave (16).



Source:
https://www.cdc.gov/nchs/products/databriefs/db428.htm
https://www.cdc.gov/drugoverdose/rxrate-maps/index.html Accessed on 1/25/2022

Fig. 1. *The opioid paradox. Opioid prescriptions are declining while opioid overdose deaths are increasing.*

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 49 state societies of Interventional Pain Physicians, including Puerto Rico.

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 (The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. 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 (Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December 2001. http://medpac.gov/docs/default-source/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0)

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

Thank you,

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To view some of Dr. Manchikanti's publications go to:
https://pubmed.ncbi.nlm.nih.gov/?term=Manchikanti+L%5BAuthor%5D&sort=date

"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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