

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

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RE: Change in policy of epidural injections (CPT 62321, 62323, 64483, 64484)

Dear Dr. Patterson:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and the state societies of Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, Maryland, New Jersey, and Pennsylvania, we would like to bring your attention to an inaccurate LCD recently published. We are very much concerned with a revision of the policy which reduces the number of epidural injections which can be performed in a period of 6 months or a year for cervical/thoracic and lumbosacral spine by 50% or more. Novitas' recent policy, effective 1/1/2018, has been changed from lumbosacral epidural injections to include cervical/thoracic epidural injections. While this change is appropriate and appreciated, there is an inappropriate limitation introduced into this policy described under Utilization Guidelines of the policy. The limitations are described as follows:

1. A session is defined as all EIs (epidural injections), diagnostic selective nerve root blocks, or spinal injection procedures performed on a single day.
2. An injection is defined as the placement of a needle into the epidural space. Injecting one level bilaterally would be considered 2 injections. Injecting 2 levels, each unilaterally would be considered 2 injections. A maximum of 2 injections comprises a session, regardless of level, laterality or approach.

There are significant issues related to this definition. Traditionally the definition has always been that one session included one interlaminar epidural injection in one region or multiple unilateral or bilateral transforaminal epidural injections in one region.

The recently published LCD will change the entire dynamics of diagnosis and treatment considerably reducing appropriate and cost effective access to care. If a patient receives 2 bilateral transforaminal epidural injections, it will now be considered as 4 epidural injections, 2 level unilateral injections will be considered as 2 injections, reducing the number of procedures which can be performed on a person per year in the diagnostic and therapeutic phase significantly, thus reducing patient access and quality of life.

This is also in contrast to the earlier definition on guidance under the limitations, which considered as no more than 2 epidural injections for transforaminal to be considered as a single session either performed single level bilaterally or 2 levels unilaterally, which in itself is unusual as 2 bilaterals must be considered as 2 levels.

3. A diagnostic selective nerve root block (DSNRB) is identically coded as an epidural injection and constitutes one of the 2 injections allowed in a single session. Further, the policy describes that no more than 3 epidural injection sessions (6 injections) may be performed in a 6 month period and no more than 6 epidural sessions or 12 injections may be performed in all anatomic regions in a 12-month period regardless of the number of levels involved.

This policy is extremely problematic and also does not utilize standard of care.

It is also very confusing as the recently published LCD seems to suggest that injecting at multiple levels appears considered as multiple injections. Thus, it appears that 2 injections at one level may be considered as 2 sessions. However, if it is bilateral, it may be considered as 4 sessions. Bilateral injections are not commonly performed, but they are required on occasion.

The limit of 6 total epidural sessions for all anatomic regions is also inappropriate, interferes with continuity of care, and reduces access which in turn reduces the quality of life.

Another disturbing factor of this recently published change is that it appears that the policy has been applied retroactively through January 2017, even though the policy has been effective only on or after 5/4/2017 and physicians have only been noticing it recently.

It appears that the recently published policy has not been through the LCD consideration process as none of the members of CAC's of any involved state are aware of these changes. It is extremely unusual and unlikely that all the states would have missed this change. Further, the policy which was derived from Noridian MAC continues to be only for lumbar epidural injections which has been converted here to all epidural injections.

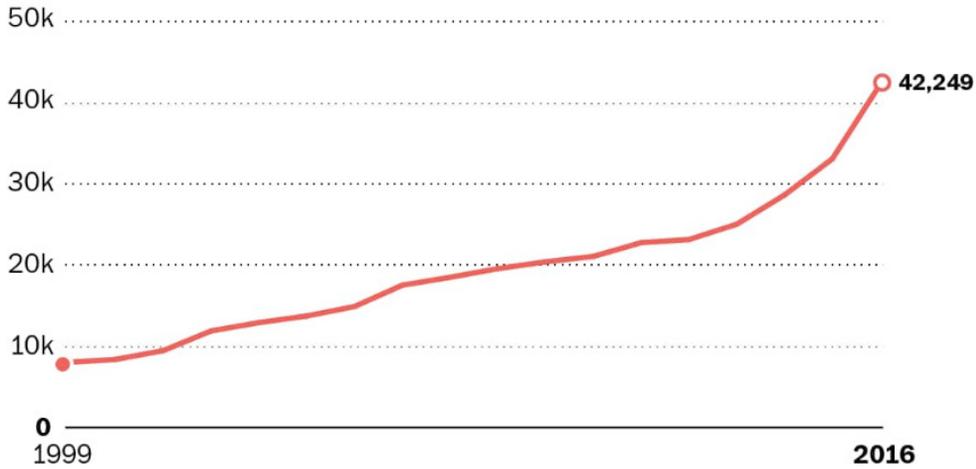
Now, considering that you have changed the policy for all epidural injections for all regions, it is very similar to facet joint interventions policy. Consequently, we can use the same language in reference to the frequency of the procedures as facet joint nerve blocks, which limits to a maximum of 5 per year with repeating them after 3 months of relief in the therapeutic phase.

Consequently, we request that the recently published policy be reversed and changed to per region with a limit of 3 procedures per 6 months or revert to the traditionally followed older policy with 2 procedures in the diagnostic phase and 4 procedures per year in the therapeutic phase per region as utilized by CGS MAC.

Without such a change, substantial problems will be caused well into the future with unnecessary audits, appeals, straining physicians financially as well as with time consuming paperwork to add to already burned out physicians struggling to provide accessible high quality, cost effective diagnostic and treatment care to these patients. Further, reimbursements have been reduced substantially for epidural injections in recent years with removal of fluoroscopic coverage and reduction of payments in ambulatory surgery centers. Add to these, the opioid epidemic has been escalating with increasing deaths despite a reduction in prescriptions (Figs. 1-3) (1-3).

Opioid deaths surge in 2016

Number of opioid overdose deaths, 1999 to 2016



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Source: CDC

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 (1)

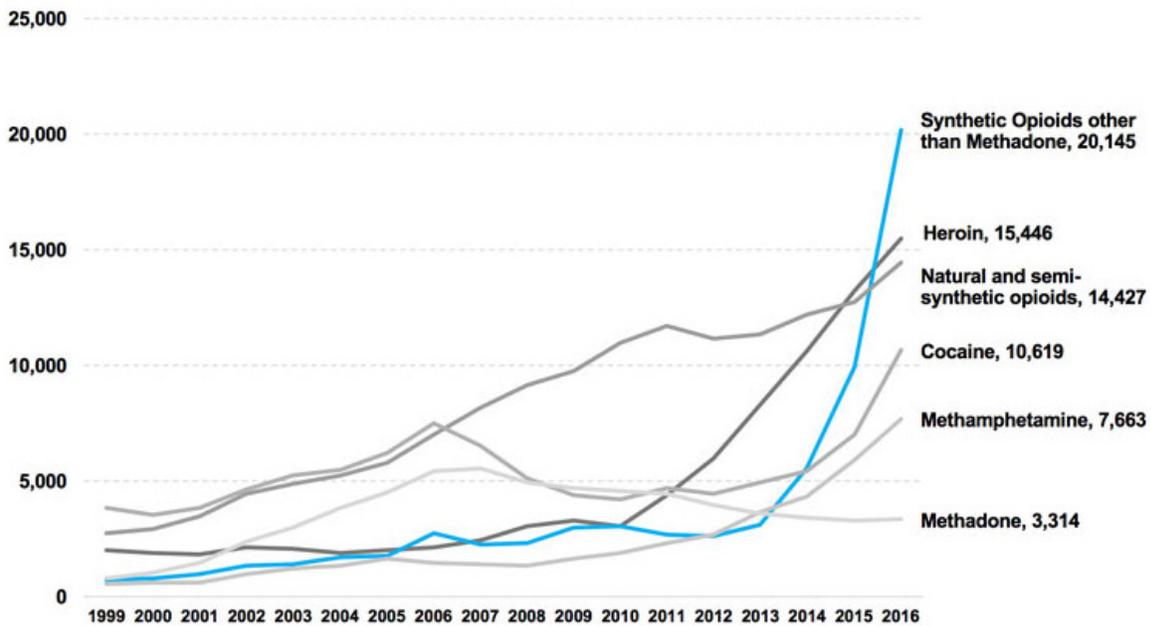


Fig. 2. Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.

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> (2).

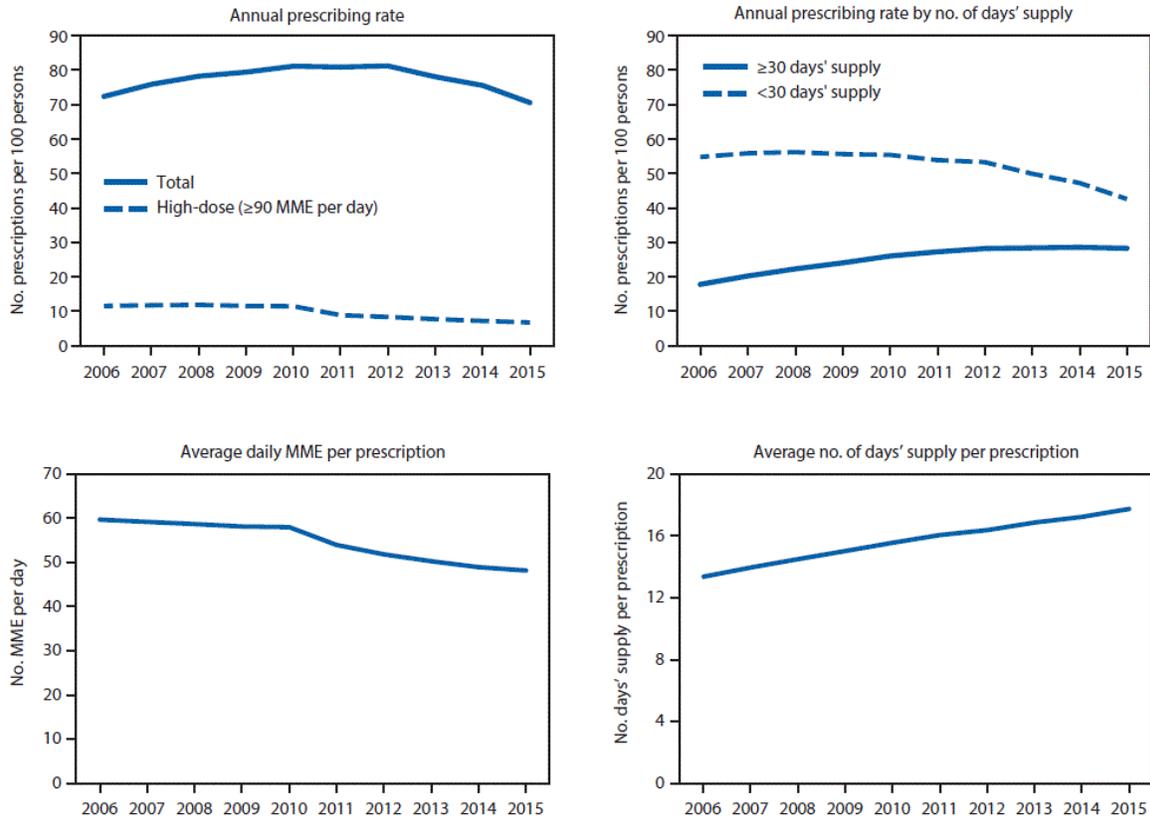


Fig. 3. Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.

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 (3).

What is crucial to understand is that non-coverage or undercoverage of nonopioid interventional pain modalities directly correlates with reimbursement policies and the decline in utilization of interventional techniques, specifically those of epidural injections.

Analysis of utilization of epidural injections has shown a significant reduction of interlaminar epidural injections with an extremely small increase of transforaminal epidural injections since 2009 to 2016 as shown in Figs. 4 and 5 (4,5). The discouragement of utilization of interventional techniques and also reductions in reimbursement, along with policies discouraging physicians to use nonopioid techniques, is in sharp contrast to the overall philosophy of promoting nonopioid techniques as recommended by the National Academy of Medicine and 32 attorney generals of various states, Congress, and the Administration. Meanwhile, the MACs following Noridian MACs also have shown lesser reductions, showing increasing utilization due to policy changes increasing from 2 procedures in the diagnostic phase per region, followed by 4 procedures in the therapeutic phase per year per region, to 3 epidural injection per year for 6 months with 6 per year. This policy developed by Noridian was followed in other jurisdictions including Novitas.

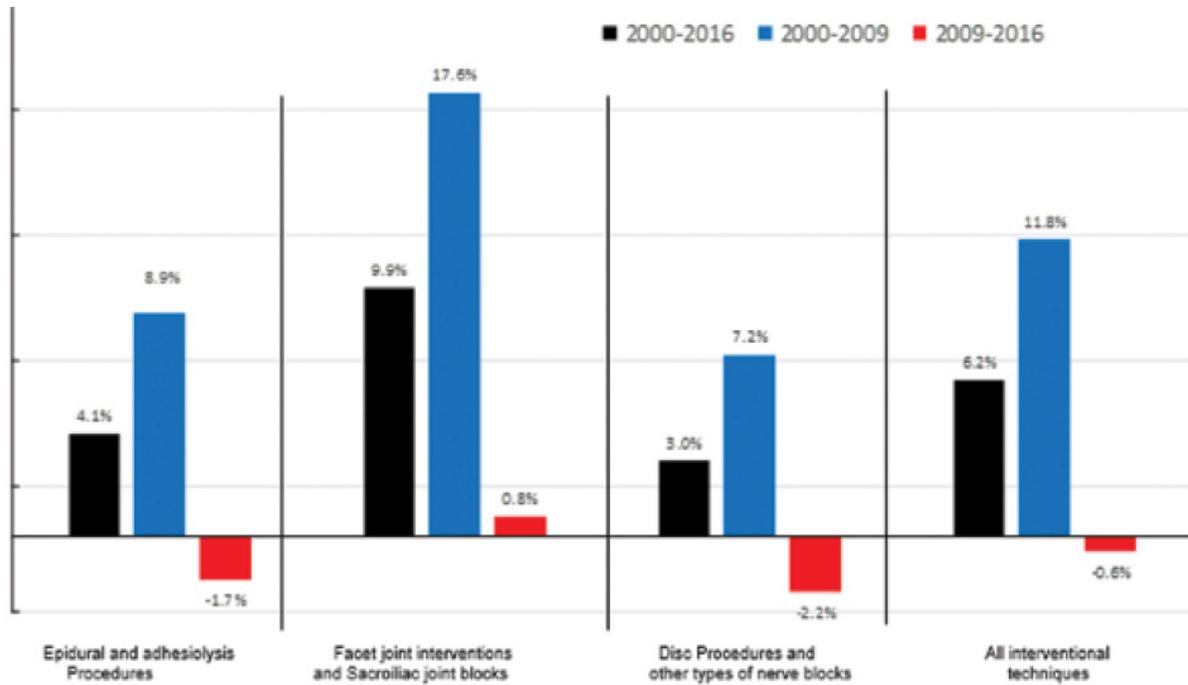


Fig 4. Comparative analysis of epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.

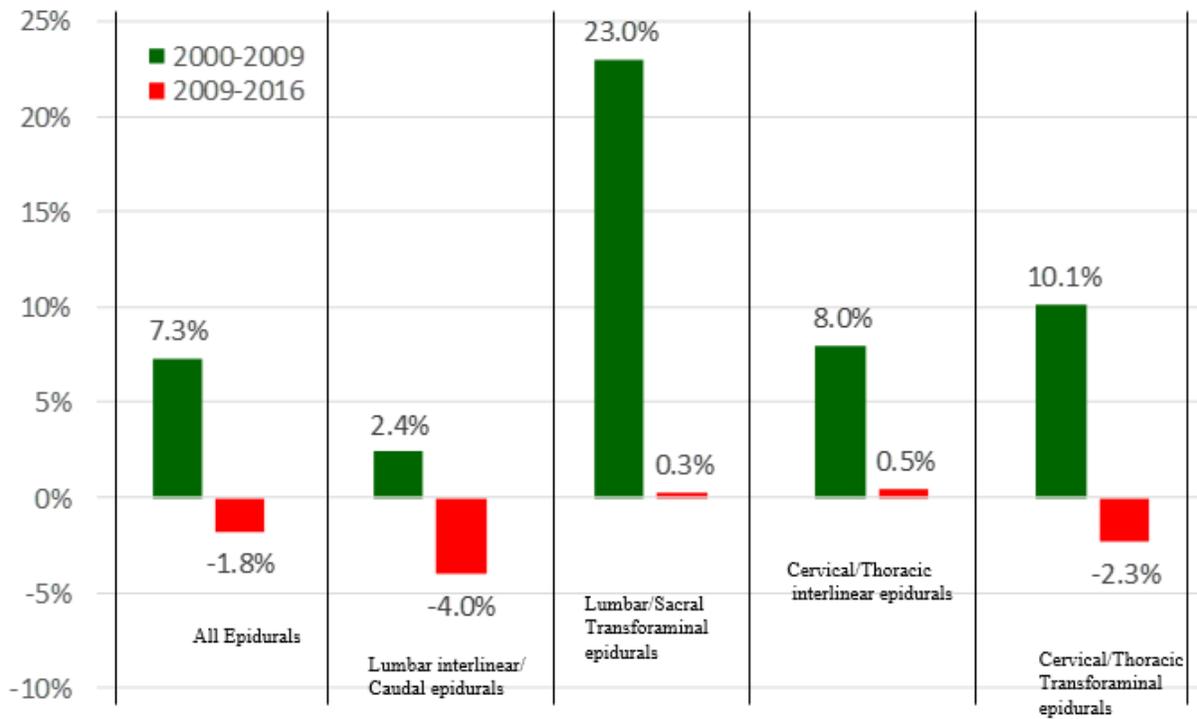


Fig 5. Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.

The literature is replete with multiple indications and effectiveness studies for epidural injections, including: central spinal stenosis with or without claudication; foraminal stenosis with or without radicular pain; discogenic pain (after an appropriate diagnostic workup eliminating facet joint pain, sacroiliac joint pain and other conditions); and, finally, post surgery syndrome (6-46). The majority of the studies showed positive evidence for fluoroscopic epidural injections when performed appropriately with repeated procedures in patients who were responsive to the initial 2 procedures. Further, the misunderstanding of placebo and flawed methodology has been discussed extensively (11,13,45,47). The comprehensive evidence provided by Kaye et al (7) utilizing best evidence synthesis from Level I to V showed the following, after reviewing 52 trials that met inclusion criteria:

- The evidence in managing lumbar disc herniation or radiculitis is Level II for long-term improvement, either with caudal, interlaminar, or transforaminal epidural injections with no significant difference among the approaches.
- The evidence is Level II for long-term management of cervical disc herniation with interlaminar epidural injections.
- The evidence is Level II to III in managing thoracic disc herniation with an interlaminar approach.
- The evidence is Level II for caudal and lumbar interlaminar epidural injections with Level III evidence for lumbar transforaminal epidural injections for lumbar spinal stenosis.
- The evidence is Level II for cervical spinal stenosis management with an interlaminar approach.
- The evidence is Level II for axial or discogenic pain without facet arthropathy or disc herniation treated with caudal or lumbar interlaminar injections in the lumbar region; whereas it is Level II in the cervical region treated with cervical interlaminar epidural injections.
- The evidence for post lumbar surgery syndrome is Level II with caudal epidural injections and for post cervical surgery syndrome it is Level II with cervical interlaminar epidural injections.

Further, not only clinical efficacy evidence, but also significant evidence of cost utility has been provided thus far for caudal and lumbar interlaminar epidural injections for disc herniation, discogenic pain, and spinal stenosis, and caudal epidural injections for post surgery syndrome (48,49). The cost utility analysis was performed using highly regarded surgical literature from an analysis of Spine Patient Outcomes Research Trial (SPORT) data (50,51). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall the cost effectiveness of disc herniation surgery (50) 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 (51). More importantly, these studies showed direct costs without medication 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 indirect costs at 60% and highest indirect cost of 40%, the cost utility of caudal epidural injections is estimated to be \$3,628 with multiplication of the procedural cost by 1.67. This procedure can be used to treat disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome with some variations (48). Further, cost utility analysis of lumbar interlaminar epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and axial or discogenic low back pain, utilizing the extrapolation method of surgical interventions of direct cost, showed an average cost of \$3,301 per QALY (49).

Thus, the guidance and evidence assessment provide not only the clinical effectiveness, but also value with lower expenses than surgical interventions per one year of QALY and well below \$20,000 or \$50,000 threshold utilized by many authorities.

Consequently, we request that the recently published policy be reversed and appropriate coverage provided interventional pain physicians provide minimally invasive diagnostic and treatment services with an excellent risk/benefit ratio and may be the only reasonable option for nonopioid pain relief, thus addressing in a realistic way the current opioid crisis. Given the reality of intractable chronic pain, interventional procedures offer the most compassionate, comprehensive, cost effective option which can preserve access to care, continuity of care, and improve the quality of life, while minimizing the risks of the opioid epidemic and avoiding the poor outcomes of invasive surgeries.

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 (52).

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 discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (53).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (54).

Thank you again in advance for your consideration of our request. If you have any further questions, please feel free to contact us.

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