

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

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RE: Medically not necessary determination of percutaneous adhesiolysis CPT 62264

Dear Contractor Medical Directors of Palmetto GBA:

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP) and the state Societies of Interventional Pain Physicians of North Carolina, South Carolina, Virginia, West Virginia, Alabama, Georgia and Tennessee, we would like to thank you for continuously updating the LCDs. However, your recent update in relation to medically not necessary determination of percutaneous adhesiolysis is inappropriate, not based on evidence, does not follow Medicare Integrity Manual, and reduces access to appropriate treatment in patients with severe intractable recalcitrant low back and lower extremity pain. Your update, not only increases the cost of health care in general, but assists in escalating the opioid epidemic, but is in contrast to the overall philosophy of promoting nonopioid techniques as recommended by the National Academy of Medicine and 32 attorney generals of states requesting nonopioid modalities in managing chronic pain. Additionally, multiple committees in Congress and various departments of the Administration have also been promoting nonopioid techniques including interventional techniques.

Palmetto has determined epidural adhesiolysis as a not medically necessary procedure, despite substantial evidence available from multiple randomized controlled trials and high quality systematic reviews (1-3). The evidence has been extensive with multiple randomized controlled trials and systematic reviews specifically in post-surgery syndrome and spinal stenosis with recalcitrant pain and disability (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 from 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 treatment.

We are enclosing appropriate evidence synthesis based on systematic reviews (Attachments A-C).

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 (12).

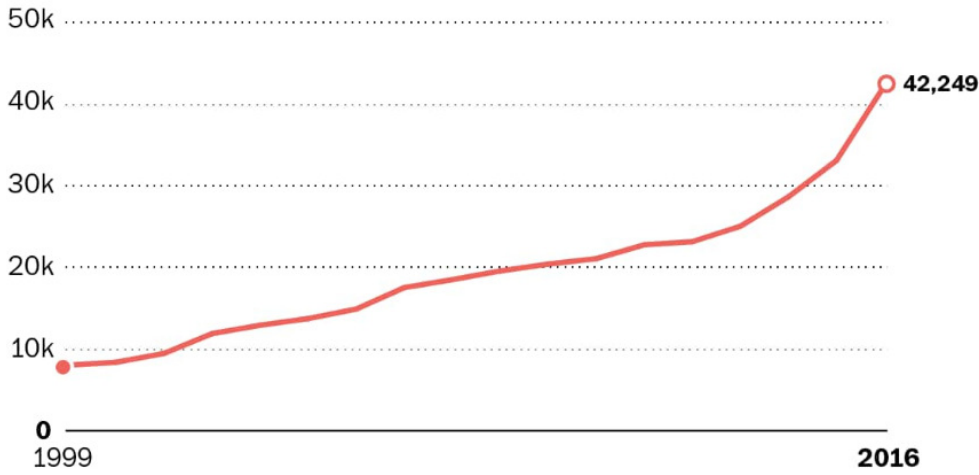
Interventional pain management techniques are minimally invasive procedures, including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (13).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (14).

Our comments are based on appropriate synthesis of evidence without bias or conflicts of interest to provide appropriate care, reduce utilization, and healthcare costs, and control the opioid epidemic. As you are well aware, the opioid epidemic continues to escalate. Despite the evidence that the 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. Even though, the reducing prevalence of opioid prescriptions, opioid deaths continue to increase (Figs. 1-3) (15-17). 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 (18) and 32 states attorney generals (19) have recommended the utilization of nonopioid techniques including interventional techniques. However, a recent analysis of utilization of various techniques, demonstrates a significant reduction in epidural injections and lumbar facet joint nerve blocks while there was a minimal increase in transforaminal epidural injections and a significant increase in radiofrequency neurotomy as shown in Figs. 4 and 5 (20-22). In addition to the modest declines in epidural injections and lumbar facet joint injections, extensive declines have been shown for adhesiolysis as shown in Fig. 6 (23). These factors must be taken into consideration in guideline development and policymaking, not only to control 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 (24-26).

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 (15)

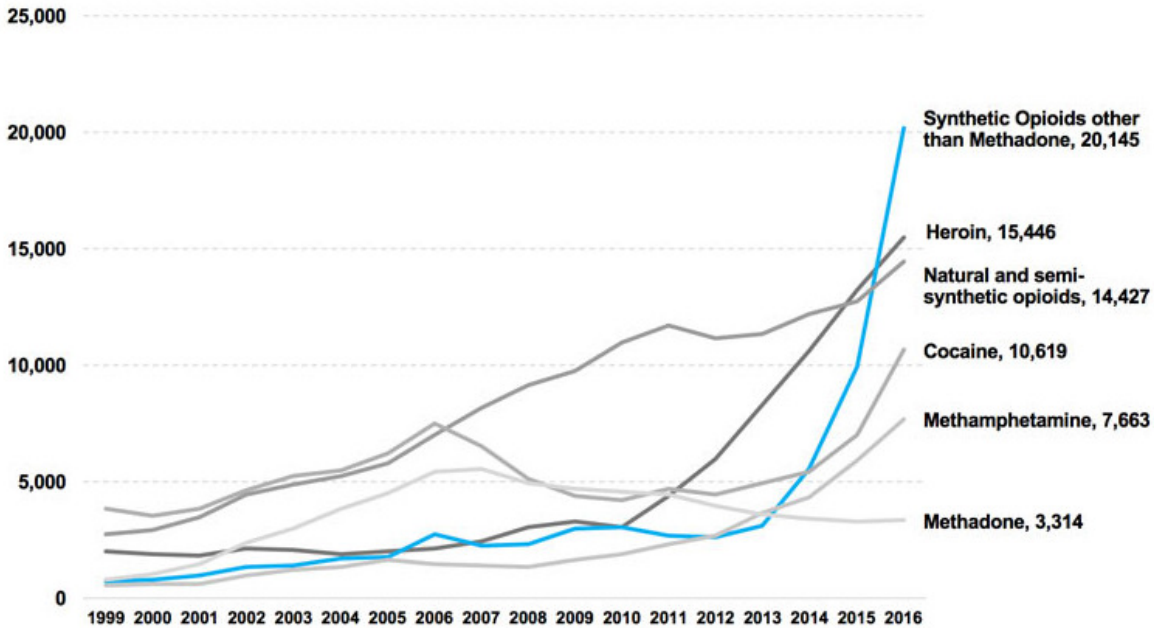


Fig. 2. Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.

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> (16).

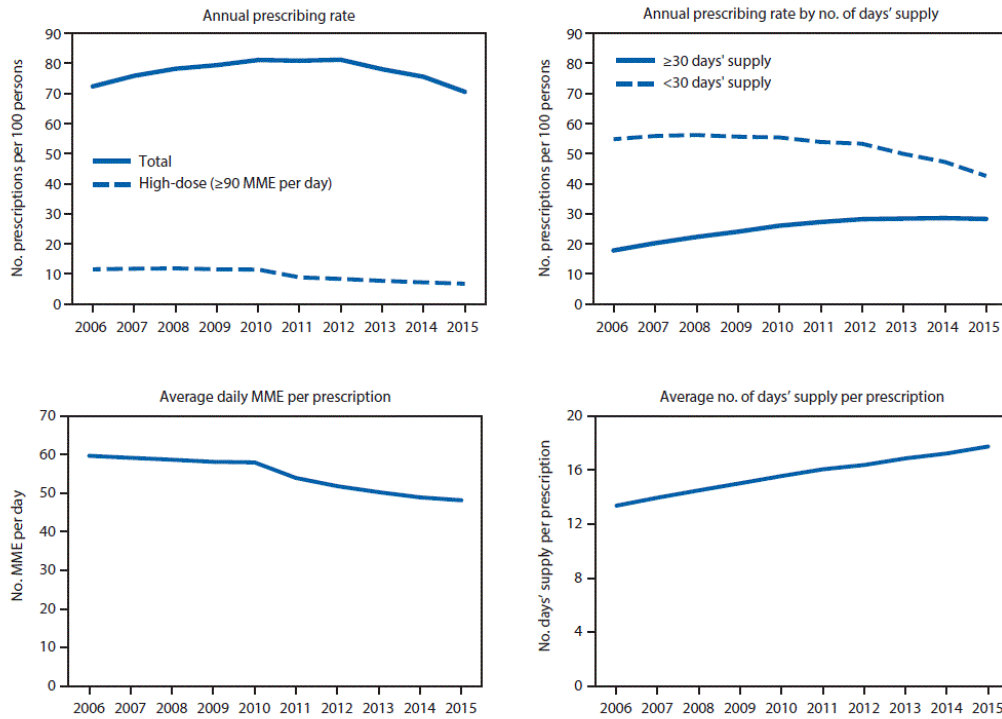


Fig. 3. Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.

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 (17).

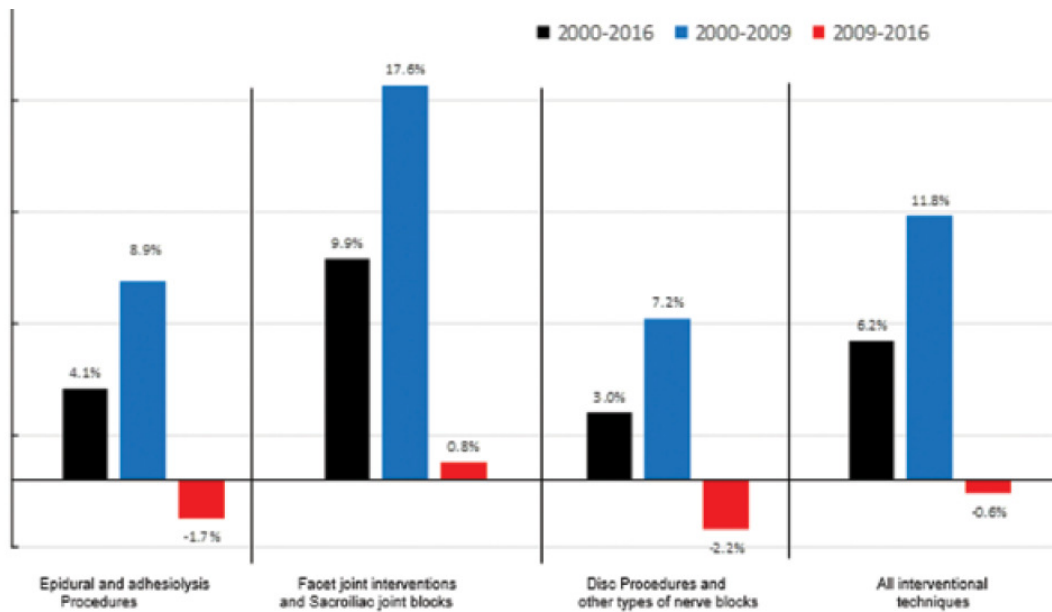


Fig 4. Comparative analysis of epidural and adhesionolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.

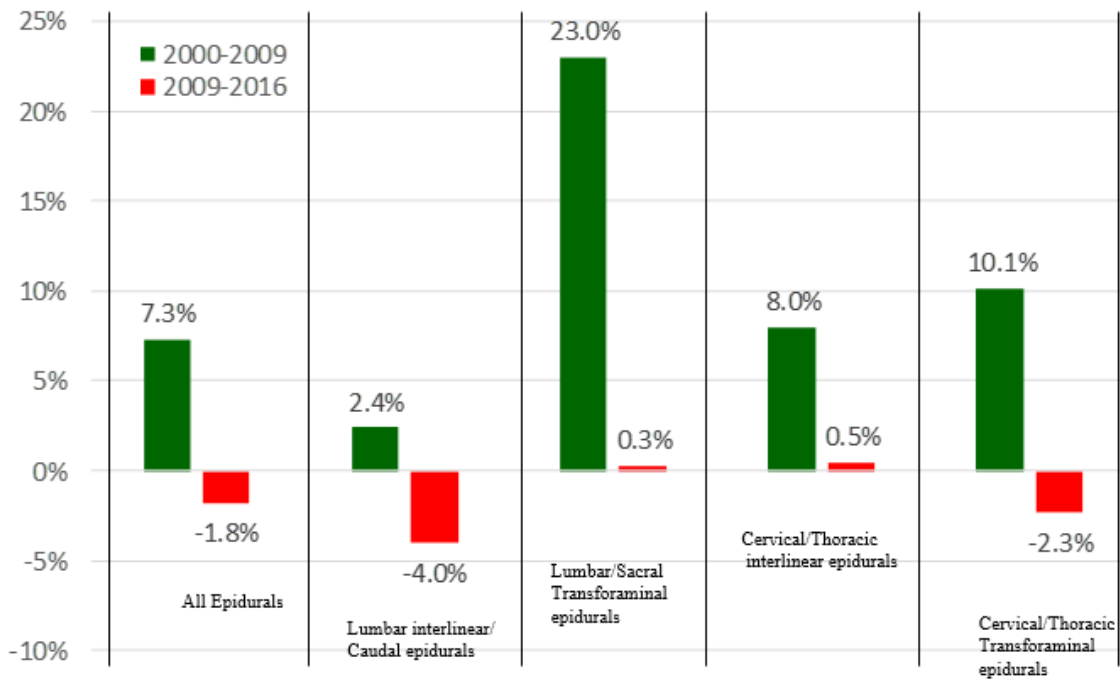


Fig 5. Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.

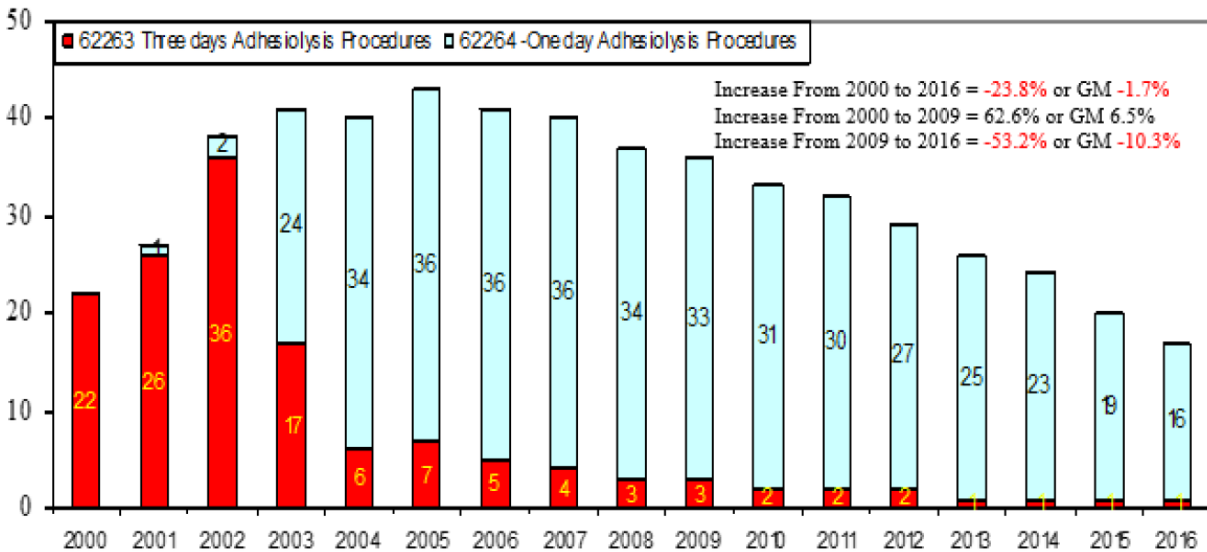


Fig 6. Frequency of utilization of 3-day and 1-day adhesiolysis procedures from 2000 to 2016, in Medicare recipients.

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 (23).

Hopefully, you will reverse your recent update decision and resume the previous coverage before we face significant access issues. As you are well aware, utilization of adhesiolysis has declined significantly over the years because of the policies instituted by Noridian and others attempting to follow them. Further, lack of an LCD also is hindering coverage by Medicare Advantage Plans and others. At this time, we also are requesting that you issue an LCD for percutaneous adhesiolysis and other interventional techniques which are commonly performed including cervical epidural injections and sacroiliac joint injections.

Once again, thank you for providing us with the opportunity to respond to these important issues. If you have any questions, concerns, or need any further information, please feel free to contact us.

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