

May 27, 2016

Re: Public Comment in Response to Proposed Official Disability Guideline (ODG) Recommendations

As physicians who specialize in treating chronic pain, we appreciate this opportunity to comment on the proposed ODG recommendations and to provide evidence in support of continued coverage for intrathecal drug delivery systems (IDDSs) in the treatment of chronic noncancer pain. We wish to preserve this effective treatment, which is endorsed by The American Society of Anesthesiologists, The American Society of Interventional Pain Physicians, The North American Neuromodulation Society, and <list additional organizations>. IDDS for chronic noncancer pain is currently covered by Medicare and most commercial health insurers.

Specifically, we wish to comment on the proposed ban of any new IDDS implants, low-dose therapy for newly initiated IDDSs, and patient-controlled therapy devices. We are aware that patients can experience persistent pain that is not well managed, and that chronic pain has clinical, psychological, and social consequences (1). We also understand that opioids are associated with serious risks of overdose or opioid use disorder. Yet the independent and highly regarded ECRI Institute found that IDDS provides clinically relevant pain relief for noncancer pain and is associated with a decrease in the amount of other drugs taken or in the proportion of patients taking other drugs (2).

Because intrathecal drug delivery is specifically targeted to pain receptors, it requires much lower effective doses than used orally, and IDDSs remain under continual physician management of dosing and refills. IDDS patients were less likely than those taking oral opioids to discontinue treatment due to adverse events (8.9% vs. 22.9%, respectively), or insufficient pain relief (7.6% vs. 10.3%, respectively), according to a Cochrane review of thousands of patients (2). In addition, improvements in safety, efficacy, compliance, and cost can be achieved by reducing or eliminating concomitant oral opioids in patients treated for chronic noncancer pain. New low-dose intrathecal therapy protocols focus on discontinuing systemic opioids either before or very soon after implant.

Best practices for reducing morbidity from intrathecal therapy were addressed by an international multi-specialty work group in 2014. Their publication created awareness of higher risk practices that if eliminated should markedly reduce morbidity (3). **It is important to note that the risk of IDDS must be compared to the alternative of treating severe intractable pain with systemic opioids.**

During a time when the United States is facing a prescription opioid crisis, the proposed guidelines would remove a vital alternative to systemic opioid use for patients with severe intractable pain.

Patients in IDDS studies have typically endured debilitating pain for years—often more than 5 years(4,5)—and so IDDS is not undertaken lightly. Furthermore, a preimplant trial allows the patient and physician to assess the therapy before permanent implant. IDDS provides a means to administer considerably lower doses of medications by an alternative route, thereby reducing the burden of systemic use and decreasing the patients' exposure to systemic doses and their associated risks. IDDS can also provide nonopioid medications via the pump.

Ziconotide is a nonopioid Food and Drug Administration-approved medication for use in the pump for pain. The Polyanalgesic Consensus Conference (PACC) has been regularly updating treatment algorithms for more than a decade that incorporate the use of nonopioid medications as part of IDDS for pain (6,7). A newly revised algorithm is in process and planned for publication shortly (8). **Once again, it is important to underscore the need for and availability of treatments for pain that do not employ systemic opioids at a time when we are facing a crisis regarding systemic opioid use.** We feel that eliminating the use of IDDS for pain is extremely inappropriate because it removes one alternative to systemic opioid use at a time when we are facing this crisis.

The accompanying *Targeted Intrathecal Drug Delivery* document presents evidence to support our contention that IDDS is a valuable pain treatment therapy. With recent evidence in mind, it is difficult to justify suspension of IDDS therapy, which has proven both safe and effective. *Targeted Intrathecal Drug Delivery* includes clinical trials of IDDS that are not in the ODG documents, and would give the public, insurers, and physicians an opportunity to evaluate what is known *today* about IDD for non-cancer pain.

Sincerely,



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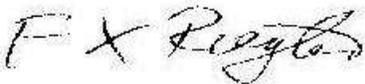
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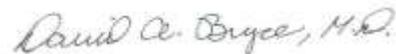
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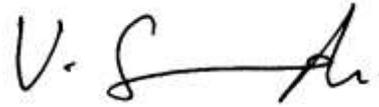
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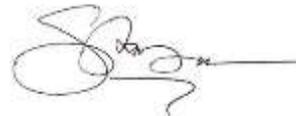
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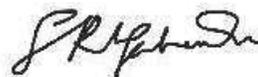
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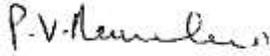
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American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Society of Anesthesiologists
Arkansas Society of Interventional Pain Physicians
Connecticut Pain Society
Delaware Society of Interventional Pain Physicians
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Georgia Society of Interventional Pain Physicians
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Minnesota Society of Interventional Pain Physicians
Mississippi Society of Interventional Pain Physicians
Missouri Society of Interventional Pain Physicians
The Montana Center for Wellness & Pain Management
New Hampshire Society of Interventional Pain Physicians
New Jersey Society of Interventional Pain Physicians
New York Society of Interventional Pain Physicians
North American Spine Society
Ohio Society of Interventional Pain Physicians
Oklahoma Society of Interventional Pain Physicians

Oregon Society of Interventional Pain Physicians
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Society of Interventional Pain Physicians of Louisiana
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¹ Dowell D, Hagerich TM, Chou R. Centers for Disease Control and Prevention. *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*. *MMWR*. 2016;65(1):1-50.

² Noble M, Treadwell J, Schoelles K, Sun F. HTA final report. *Implantable Infusion Pumps for Chronic Noncancer Pain*. Plymouth Meeting, PA: ECRI Institute; 2008. Health Technology Assessment performed for Washington State Health Care Authority.

³ Prager J, Deer T, Levy R, et al. Best practices for intrathecal drug delivery for pain. *Neuromodulation*. 2014;17(4):354-372; discussion 372.

⁴ Hamza M, Doleys DM, Saleh IA, Medvedovsky A, Verdolin MH, Hamza M. A prospective, randomized, single-blinded, head-to-head long-term outcome study, comparing intrathecal (IT) boluses with continuous infusion trialing techniques prior to implantation of drug delivery systems (DDS) for the treatment of severe intractable chronic nonmalignant pain. *Neuromodulation*. 2015;18(7):636-648; discussion 649.

⁵ Caraway D, Walker V, Becker L, Hinnenthal J. Successful discontinuation of systemic opioids after implantation of an intrathecal drug delivery system. *Neuromodulation*. 2015;18(6):508-515; discussion 515-506.

⁶ Deer T, Krames ES, Hassenbusch SJ, et al. Polyanalgesic Consensus Conference 2007: recommendations for the management of pain by intrathecal (intraspinous) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2007;10(4):300-328.

⁷ Deer TR, Prager J, Levy R, et al. Polyanalgesic Consensus Conference 2012: recommendations for the management of pain by intrathecal (intraspinous) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2012;15(5):436-464; discussion 464-436.

⁸ Deer TR, Pope J, Hayek S, et al. The Polyanalgesic Consensus Conference (PACC) recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation*. 2016; in press.