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 refill. IDD 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 IDD studies have typically endured debilitating pain for years—often more than 5 years(4,5)—and so IDD 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. IDSS 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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Other Organizations and Institutions Endorsing this Comment Letter:

- 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
- Department of Anesthesiology, University of Kentucky College of Medicine
- Florida Society of Interventional Pain Physicians
- Georgia Society of Interventional Pain Physicians
- Iowa Society of Interventional Pain Physicians
- Maine Society of Interventional Pain Physicians
- Massachusetts Society of Interventional Pain Physicians
- Michigan Society of Interventional Pain Physicians
- 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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