



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

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March 23, 2023

Dear BCBS of Tennessee medical policy panel:

We have reviewed proposed LCD **Implanted Peripheral Nerve Stimulation Devices as a Treatment for Pain**. The American Society of Interventional Pain Physicians (ASIPP) is very alarmed that the proposed LCD demonstrates a serious lack of understanding of peripheral nerve stimulation.

Specifically, we are concerned that this policy, even in the very first paragraph, has completely confused multiple types of stimulation, conflating PNS (peripheral nerve stimulation, where a stimulator is placed directly on a nerve) with PNFS (peripheral nerve field stimulation, where a wire is placed “somewhere in the vicinity of a nerve”). There is also no understanding of the difference between the implantation of an internal power generator (IPG), where the battery is placed inside the body, and wireless stimulation, where the power is transmitted through the skin to a receiver. Perhaps this illustration will help:

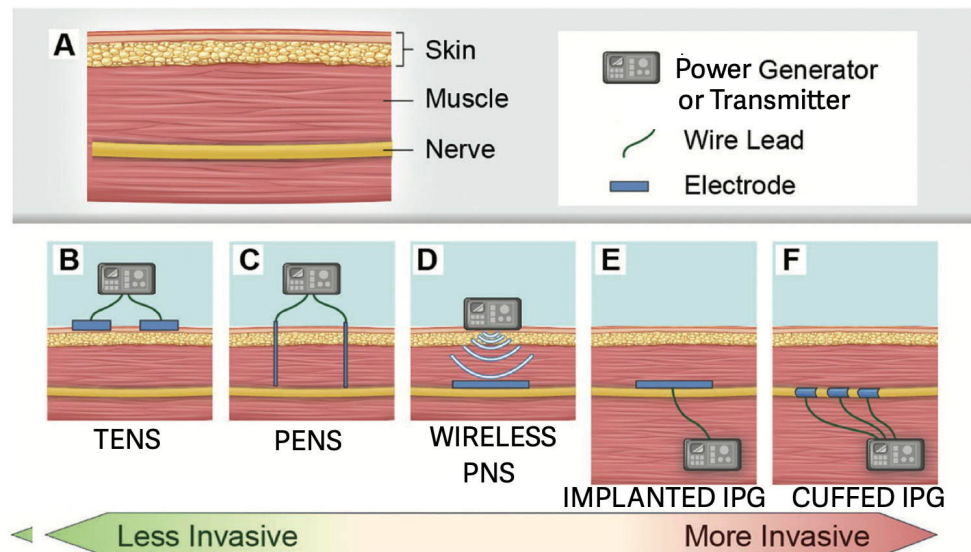


Illustration by Cleveland FES Center

Review of your references is very lacking. For instance, in the same *Biomedicine* volume as the Char, et al(1) reference that you site, there is a much more specific and nuanced review of upper extremity stimulation(2). When you say that there has been no long-term evidence, the wireless devices have only been FDA approved since 2016, but there are several retrospective studies reviewing 2-year data.

However, you can use complex regional pain syndrome (CRPS) as one of the reviews. Chmiela et al. described a retrospective review over a 30-year period involving 165 patients with CRPS Type I or II.(3); a total of 51% of patients reported functional improvement, and chronic opiate use amongst the cohort decreased from 62% at baseline to 41% with treatment. And this was using open dissections and antiquated technology, which would be considered barbaric today.

The literature is exploding with new studies, including one from February of this year; Abd-Elseyed and Moghim(4) looked at 57 PNS patients implanted in a wide range of sites, noting pain decreases from about 8/10 to about 2/10 at 24 months ($p \leq 0.001$) and a significant decrease in opioid use. There were only 2 patients explanted and 1 lead migration.

Other recent reports include a case series by Chahadeh, Rich, Wiederholz et al. (5) who followed 11 patients with a variety of sites implanted. Over the 6-month review period, the patients noted an 87% improvement in pain with no complications, and their Patient Global Impression of Change (PGIC) score was 7 of 7 (“a great deal better”). One patient stopped all opioids, and the rest decreased their medication by at least 50%.

Omitted also were the recent systematic review by Helms et al.(6) that concluded “*While the vast majority of the reviewed studies were of small samples, collectively they reveal significant improvement in pain utilizing PNS for treatment of neuropathic pain conditions*” as well as the recent PNS guidelines (7).

Of note, you include reviews by Ni et al. (8) and Sarica et al. (9) regarding peripheral stimulation (including field stimulation – see above) of the trigeminal nerve. Please note that PNS devices are FDA approved for named peripheral nerves from the neck down but not craniofacial pain.

We notice that many of your references (Gilligan times several, NICE, NASS, Hayes) are for a low back pain treatment using a motor stimulator system that causes muscle contraction to strengthen the muscle rather than interfering with pain signals. This is a rehabilitation device but not a peripheral stimulator, and therefore not appropriately included in this policy.

We would therefore suggest that appropriate coverage should include:

- Peripheral nerves in upper and lower extremities affected by complex regional pain syndromes (type 1 and 2), as well as pain due to peripheral nerve injury, post-surgical scar formation, nerve entrapment, and painful mono-neuropathies.
- Intercostal and ilioinguinal nerves for post-surgical and post-traumatic neuropathic pain involving these nerve distributions.

We believe that this proposed policy should not be approved as it is in direct conflict with current standards of care, as well as recent actions by the AMA CPT determinations, supporting PNS and its coding.

In this age of cost containment, we understand that the knee-jerk response to a new cost center is to claim that it is “experimental”, thus relieving you of any need to provide coverage. However, such a policy will result in a renewed explosion of opioid misuse, as desperate patients in pain reach for any option. The cost of hospitalizations, useless physical therapy, and ineffective surgeries as well as the cost of addiction treatment will be much more in the long run than these minimally invasive devices that are trialed (and thus confirmed effective) before use.

We and our experts request a conference call with you and leadership to address more specifically the catastrophic consequences and adverse impact this policy will have on patient care, including a concomitant increase in opioid use and deaths and additional strain on limited resources.

Sincerely,

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