

For the Treatment of Spinal Pain

Spinal Pain—The Scope of the Problem

Spinal pain (lumbar and cervical pain) is, simply stated, a quagmire for health plans, employers, physicians, and patients. It is estimated that low back pain alone affects 30-40 million people in the United States and costs our society \$100 billion annually.¹ In this country, the condition is responsible for the loss of an estimated 150 million workdays each year, and it is the second most common cause of absence from work in adults under 55 years of age.²

Shortcomings of Conventional Treatment

There are many precipitating causes of spinal pain. Because it is so varied, identifying the cause can be very difficult. As a result, effectively treating spinal pain is an ongoing challenge for physicians. Patients typically undergo non-invasive therapies such as chiropractic care, transcutaneous electrical nerve stimulation (TENS), and a host of pharmaceutical agents. If the pain does not resolve, patients then proceed to more invasive procedures, such as injections and surgeries. There is a significant void in available treatments between these two pathways (see Figure 1). In addition, once patients start down a

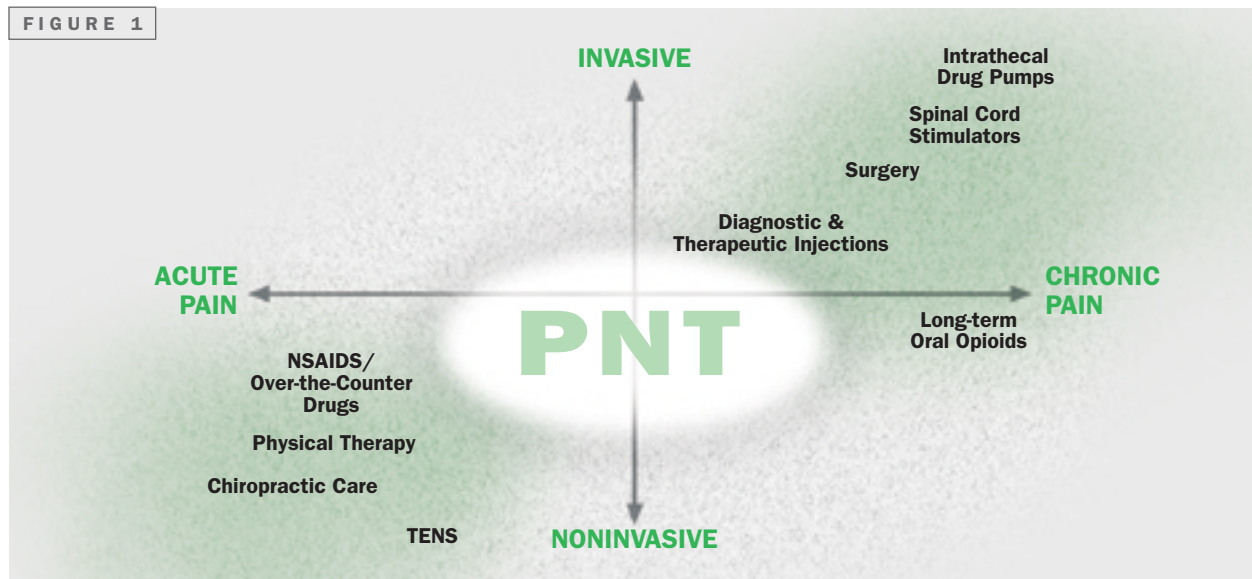
more invasive pathway, they tend to experience multiple procedures. A recent review of claims from a national actuarial firm found that low back pain patients experience an average of two to six invasive procedures once they begin undergoing invasive procedures.³

Invasive therapies represent an enormous commitment, not only for patients and their families, but also for the physicians who treat these patients and the payers who cover the procedures. Average costs for therapy can range from \$15,000-20,000 (plus \$2,500 per year) for patients undergoing implantation of a spinal cord stimulator, to \$18,000–25,000 for a fusion procedure.^{4,5} Other costs can include an estimated \$3,250 per year for medication and \$1,000–1,500 per epidural steroid injection.⁴

Percutaneous Neuromodulation Therapy

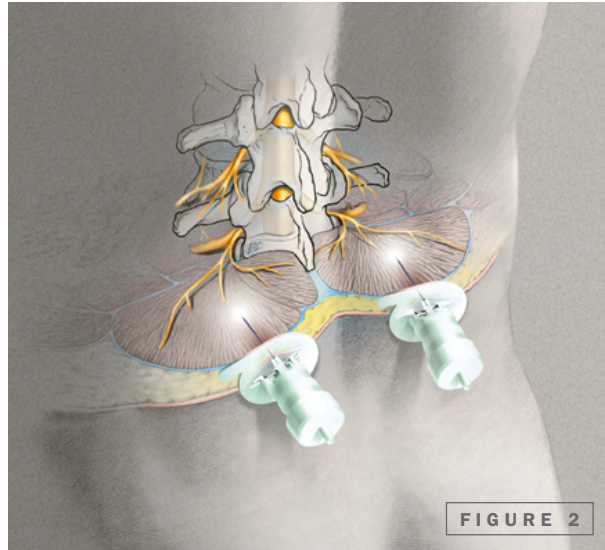
The Percutaneous Neuromodulation Therapy (PNT) System is a minimally invasive, office-based therapy for the treatment of low back and cervical pain. Vertis Neuroscience™, a medical device company based in Seattle, developed the technology, which has been reviewed and cleared by the U.S. Food and Drug

FIGURE 1



Administration based on compelling clinical evidence. The PNT System was developed specifically for post-acute spinal pain patients whose pain has not been adequately controlled.

The PNT System fills a critical void in the treatment of spinal pain and represents the next generation of neurostimulation technology. The unique system is based on an innovative dimension of the new and growing field of neurotechnology—the application of electrical therapies to treat diseases and disorders that affect the central nervous system. The PNT System delivers electrical stimulation via fine-gauge filament electrodes (250 micron diameter) that are housed in unique sharps-safe casings called Safeguides. The Safeguides are used to temporarily insert the electrodes to a depth of three centimeters for the lumbar application and two centimeters for the cervical application. These Safeguide electrodes enable the delivery of electrical stimulation directly to the deep tissues in order to reach the nerve pathways that lead to the dorsal horn of the spinal column, where pain signals are processed and transmitted to the brain (see Figure 2). Researchers believe that the stimulation delivered through PNT modulates the hypersensitivity of the nerve cells that give rise to persistent pain.⁶



Studies have shown PNT to be effective for many patients in reducing pain, improving activity levels, decreasing reliance on pain medications, and enhancing sleep.⁷⁻¹⁰ For the vast majority of patients, the therapy is well tolerated, with little to no discomfort and few side effects. Typically, four treatments with PNT are necessary to determine patient response.^{7,8} If the patient is experiencing benefit, the therapy regimen typically requires up to ten treatments.

Benefit to Health Plans and Employers

PNT represents an important advance in the treatment of one of society's most pervasive, debilitating, and costly healthcare problems. This minimally invasive technology has been proven to reduce pain, aid in the restoration of function, and improve quality of life for patients suffering from spinal pain. As such, PNT offers the potential for significant clinical and economic benefits when used as an alternative to more invasive and/or expensive options for post-acute spinal pain.

We invite you to visit www.pnthealth.com for more information about PNT. For specific information about physicians utilizing PNT in your health plan's area, please call the PNT Support Line at 1.800.585.0195.



Vertis Neuroscience
14301 SE First St.
Vancouver, WA 98684

800.597.2695
360.882.2317 Fax
www.pnthealth.com

1. Cherkin DC, Deyo RA, Wheeler K, Ciol MA. Physician variation in diagnostic testing for low back pain. Who you see is what you get. *Arthritis Rheum.* 1994
2. Guo HR, et al. Back pain prevalence in U.S. industry and estimates of lost workdays. *American Journal of Public Health.* 1999
3. Evidence of Value Model[®] developed by Strategic Health Resources[®]. January 2001
4. Bell GK, et al. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *Journal of Pain and Symptom Management.* 1997
5. Turk, DC. Treatment of chronic pain: clinical outcomes, cost-effectiveness, and cost benefits. *Drug Benefit Trends.* 2001
6. Hanai, F. Effect of electrical stimulation of peripheral nerves on neuropathic pain. *Spine.* 2000
7. Seroussi R, Gliner BE, Steinintz, Schmitt S, Gamburd R, Firlik AD. Effectiveness of percutaneous neuromodulation therapy (PNT) for patients with chronic and severe low back pain. Accepted for publication. *Pain Practice.* Volume 3, Issue 1, March 2003
8. Borg-Stein J, Seroussi RG, Schmitt S, et al. Safety and efficacy of percutaneous neuromodulation therapy (PNT) in the management of subacute radiating low back pain. *Pain Practice.* In Press. 2002
9. Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. *JAMA.* 1999;281:818-23
10. White PF, et al. Percutaneous Neuromodulation Therapy: Does the location of electrical stimulation effect the acute analgesic response? *Anesth Analg.* 2000;91:949-54.