Dorsal root ganglion stimulation

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Policy contains: Dorsal root ganglion stimulation; spinal cord stimulation.

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Coverage policy

Dorsal root ganglion stimulation for spine pain management is investigational/not clinically proven and, therefore, not medically necessary.

Limitations
No limitations were identified during the writing of this policy.

Alternative covered services

- Conventional spinal cord stimulation.
- Epidural steroid injections.
- Facet joint injections.
- Trigger point injections.
Background

Spine pain is a common disorder, associated with improper position or movement of the vertebrae and connecting muscles, nerves, and bones in the spinal column. It may originate from within the spinal column, or manifest as referred pain from another organ. Most cases of spine pain are acute, and will resolve within weeks without major medical interventions — often without knowing the cause. Some cases can be chronic, and require medical intervention.

A number of therapies can be used for spine pain. Many treatments are non-invasive, including heat treatments, cold compression, medications, exercises, stress reduction, and massage. Other cases can be treated with chiropractic manipulation, acupuncture, laser therapy, various types of injections, and electrotherapies such as transcutaneous electrical nerve stimulation. Those who do not respond to these treatments may be candidates for surgery.

One approach to treatment is spinal cord stimulation, which has become more widely used in managing chronic pain unresponsive to more conservative therapies (Jeon, 2012). This approach can involve several modalities, including burst stimulation, high-frequency stimulation, and dorsal root ganglion stimulation (Wong, 2017).

A ganglion is a nerve cell cluster comprising small, smooth, round swellings of thick jelly-like material in the autonomic nervous system and sensory system (Harding, 2016). Dorsal root ganglia are located between spinal nerves and the spinal cord, and contain cell bodies of sensory neurons, carrying neural signals from the central to the peripheral nervous system. Dorsal nerve roots control pain and temperature, and can lead to numbness. Causes of dorsal root pain include injury, degenerative disc disease, herniated disc, and bulging disc (Laser Spine Institute, 2017). Spinal nerves in the dorsal root ganglion branch out from the dorsal column to different parts of the body.

The stimulator of the dorsal root ganglion treats chronic pain, especially in difficult areas like the hand, chest, abdomen, foot, knee, and groin, as well as the spine. It threads electric leads into the epidural space and into the intervertebral foramen; each lead is tipped by four electrode contacts placed over the ganglion. After surgery, leads can be programmed to stimulate different parts of the dorsal root ganglia, based on a pain pattern, and patients are sent home with a hand-held controller (Deer, 2016).

The U.S. Food and Drug Administration cleared dorsal root ganglion spinal stimulation for chronic nerve pain associated with complex regional pain syndrome and/or peripheral causalgia in the groin and lower limb in February, 2016 (Deer, 2016). The St. Jude Medical Asium™ Neurostimulator system for dorsal root ganglion stimulation was the first of these products to be approved (NeuroNews, 2016). In August, 2016, the Food and Drug Administration cleared the Freedom Spinal Cord Stimulator for marketing to treat intractable pain in the trunk and/or lower limbs, including dorsal root ganglion stimulation.

Findings

A guideline from the American Society of Interventional Pain Physicians on ways to manage chronic spinal pain does not mention dorsal root ganglion stimulation (Manchikanti, 2013). The International Association for the Study of Pain’s Neuropathic Pain Special Interest Group mentioned dorsal root ganglion stimulation and cited several randomized controlled trials, but made no recommendation on use of this technique (Dworkin, 2013). The American Society of International Pain Physicians issued a guideline on continuing pain from angina in 2007.
and updated it in 2011 and 2013; spinal cord stimulation was included in recommendations, but dorsal root ganglion stimulation was not specifically mentioned (Anderson, 2007; Anderson, 2011; Anderson, 2013).

In September 2018, the Neuromodulation Appropriateness Consensus Committee produced a compendium of best practices for dorsal root ganglion stimulation to improve patient selection, guide surgical methods, improve post-operative care, and make recommendations for management of patients treated with dorsal root ganglion stimulation (Deer, 2019).

The stimulation of the dorsal root ganglion is a pulse. In an early study of 76 patients with chronic lumbosacral radicular pain, 70% who received pulsed frequency to the dorsal root ganglion/nerve had successful pain reduction after two months. For those initially receiving pulsed frequency, 82% had such a reduction; the difference between the two were not statistically significant (Simopoulos, 2008).

Well-designed studies on effectiveness of dorsal root ganglion stimulation are limited (Liem, 2015). A group of Dutch researchers contend that the critical role of the dorsal root ganglion in pain has been overlooked, and that more studies might reveal effective new options for pain management (Liem, 2016). Another group from the Hospital of the University of Pennsylvania notes that spinal cord stimulation has been shown to be superior to conservative medical management after failed back surgery, and thus preliminary results of newer stimulation technologies (including dorsal root ganglion stimulation) find promising results for even better outcomes (Song, 2014). Although there is some evidence on efficacy of this technique, studies are needed to better understand long-term effects (Forget, 2015).

A meta-analysis of four reviews (n = 67), use of pulsed radiofrequency on dorsal root ganglion stimulation helped alleviate cervical radicular pain, which was previously unresponsive to other therapies. However, the small size of the analysis should be taken into consideration (Kwak, 2018).

One systematic review identified six studies on neurostimulation of the dorsal root ganglion (compared to seven other studies of other forms of intraspinal stimulation), noting that dorsal root stimulation of the spinal cord provides less than optimal pain relief for certain pain syndromes (Chang Chien, 2017). Another systematic review of 16 studies that compared three approaches to reduce chronic pain via the dorsal root ganglion found limited information to draw conclusions (Pope, 2013).

A systematic review of post-herpetic neuralgia cautioned about any use of dorsal root ganglion stimulation because of its “destructive properties” (Lin, 2019).

A systematic review of 29 studies, just one of which was randomized and controlled, with a median of six participants, concluded that electrical field stimulation of dorsal root ganglion may help highly selected participants who have failed other treatments. Authors caution about drawing conclusions due to the limited number of subjects (Vuka, 2019).

A systematic review of 12 studies (n = 980) concluded that compared with medical therapy, spinal stimulation significantly increased the odds of reducing pain by 50% or more in three trials. Three types of spinal stimulation (high-frequency 10 kilohertz, Burst, and dorsal root ganglion) were associated with increased odds of pain relief (Lamer, 2019).

A summary of the literature on dorsal root ganglion stimulation states that there is Class A randomized clinical trial evidence that dorsal root ganglion stimulation provides superior pain relief to spinal cord stimulation for neuropathic pain (Harrison, 2018).

A recent randomized controlled trial of 152 persons with complex regional pain syndrome or causalgia in the lower extremities compared pain relief of those undergoing dorsal root ganglion stimulation to those given conventional spinal cord stimulation. The percentage of subjects who had greater than 50% pain relief after three months was significantly greater for the dorsal root ganglion group: 81.2% versus 55.7%, P < .001 (Deer, 2017).
A randomized controlled trial of 50 patients showed that as a means of controlling lumbosacral radicular pain, pulsed radiofrequency stimulation on the dorsal root ganglion can be used for controlling lumbosacral radicular pain. After three months of treatment, decreases in pain intensity over 50% were observed and were significantly greater for patients bipolar (76%) versus monopolar (50%) pulsed radiofrequency groups (Chang, 2017).

Another randomized trial of 38 patients with spinal pain who were administered either epidural steroid injections or dorsal root ganglion stimulation showed both resulted in greatly reduced pain intensity scores after 12 weeks, but one treatment was not significantly greater than the other (Lee, 2016).

One study analyzed the impact on pain of implanted dorsal root ganglion devices for persons with intractable pain in the back and/or lower limbs. After 12 months, pain was reduced by 56%, and 60% of subjects reported at least a 50% improvement in pain. Measures of quality of life and mood also improved. Authors speculate this technology yields comparable results to traditional spinal cord stimulation (Liem, 2015). Results were comparable to earlier findings after six months in the same study, with 32 subjects enrolled (Liem, 2013).

References

On October 1, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were dorsal root ganglion stimulation, spinal cord stimulation. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


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1/2020: Three policies added, four removed.