

Vagus Nerve Stimulation

Vagus Nerve Stimulation (VNS) has been approved by the FDA and CMS for treatment resistant depression and epilepsy. Nonetheless, FDA approval, or even clearance for CRPS and other chronic pain conditions using VNS is a long way off.

As a CRPS patient, I am keenly interested in new therapies that can help our community. If they are FDA approved for other uses and have solid science behind them, want to see them approved for us as quickly as possible. FDA approval means insurance coverage and acceptance by the medical community.

As a healthcare professional, I am pragmatic as to the realities of how the health and regulatory systems work.

The reality about Vagus Nerve Stimulation being approved by the FDA and/or CMS to treat CRPS in specific will probably never happen. However, approval for treatment of chronic pain has a chance and that is the group in which we should be positioning ourselves to be included – starting now.

I did a deep dive on Vagus Nerve Stimulation with [ChatGPT](#) as my medical professional. ChatGPT is a conversational artificial intelligence that has passed multiple medical qualification boards. Combined with my own expertise, I hope that we have done a reasonable job.

What is Vagus Nerve Stimulation and how does it work?

Vagus nerve stimulation (VNS) is a medical procedure that uses a device similar to a pacemaker to deliver electrical impulses to the [vagus nerve](#), which is one of the largest nerves in the body. The vagus nerve that runs from the brainstem to the abdomen. VNS is presently FDA approved to treat epilepsy, depression, and migraines.

The stimulation is usually done in short bursts and the frequency, duration, and intensity of the stimulation is adjustable. The present method of fine-tuning for a patient is by trial and error to find what works best for them.

According to the [Cleveland Clinic](#), the procedure takes 60-90 minutes and is done under light sedation using a small incision in the buttocks or abdomen. A pulse generator is placed under the skin and connected to the vagus nerve. This generator sends small electrical pulses to the nerve, which can help reduce inflammation may reduce pain although the mechanism of how this works and why is not well understood. The procedure is non-invasive and *may* provide relief for those suffering from CRPS.

Vagus nerve stimulation is safe for most people according to the [Cleveland Clinic](#), however, it does have some risks, both from the surgery to implant the device and from the brain stimulation.

That VNS works for its approved uses is fairly well established. Why it works is much less certain. The consensus opinion is that VNS works by altering the activity of certain areas of the brain, which can lead to improvements in symptoms. For example, in the case of depression, VNS is thought to increase the release of neurotransmitters such as serotonin and norepinephrine, which can help improve mood.

It is important to note that VNS is typically used as a last resort for epilepsy, depression and migraines after other treatments have failed and is only done after careful consideration and discussion with a medical professional.

Has vagus nerve stimulation proven effective for chronic pain like complex regional pain syndrome?

There is limited evidence to suggest that vagus nerve stimulation (VNS) may be effective in treating chronic pain conditions such as complex regional pain syndrome (CRPS). Some studies have reported improvement in pain and other symptoms, but the results have been mixed and further research is needed to fully understand the effectiveness of VNS for this condition. Additionally, VNS is not commonly used for the treatment of CRPS, and other treatments such as physical therapy, pain medications, and nerve blocks are usually tried first.

Spinal cord stimulators remain a superior option.

Spinal cord stimulation (SCS) is a well understood and accepted treatment option for chronic pain conditions, including complex regional pain syndrome.

SCS has been shown to be effective in treating CRPS and has been widely used for many years. It works by delivering low-level electrical stimulation to the spinal cord, which can interfere with pain signals as they travel to the brain and reduce the perception of pain.

On the other hand, VNS has the potential of being able to treat a broader range of conditions, including depression and epilepsy, in addition to pain.

Spinal cord stimulation is a proven therapy and vagus nerve stimulation has only anecdotal support as a treatment for short term and chronic pain, including CRPS. Despite the hype and excitement, the exact mechanism by which vagus nerve stimulation (VNS) works for chronic pain is not fully understood. However, it is thought to work by altering the activity of certain areas of the brain involved in pain processing and perception.

One theory is that VNS can reduce pain by decreasing the activity of pain-related regions of the brain and increasing the activity of regions involved in pain modulation. The stimulation of the vagus nerve may also release neurotransmitters, such as [acetylcholine](#) and [norepinephrine](#), that help to modulate pain signals and reduce the perception of pain.

It is also thought that VNS may influence the immune system, reducing inflammation and reducing the production of pain-causing molecules.

Overall, the exact mechanism by which VNS works for chronic pain is still being studied, and further research is needed to determine the most effective ways to use VNS for this condition. However, some medical professionals and researchers are coming to believe that VNS may have a positive impact on various aspects of the pain experience and improve symptoms for some patients.

In Conclusion

There is work to be done to get approvals for VNS use to treat chronic pain like CRPS:

1. Double blind FDA approved clinical studies for chronic pain treatment using VNS. If the study(ies) show VNS to be effective, the manufacturers may shortcut FDA approval using a method called a 510k, relying on the already approved safety of the device and study results for effectiveness cutting years off of the process,

2. CMS approval, which is the clear pathway to commercial insurance approvals, can consume time after FDA approval if impact studies are not completed beforehand, and,
3. Private insurance approval is a must because the average cost for VNS is \$28,500 according to webmd.com. However, prices can range from a low of \$8,850 plus expenses if you choose to go to Turkey to a high of \$49,600 in New York and California. Obviously, the cost will vary depending on your location. Nonetheless, this is not an inexpensive procedure, particularly one with uncertain prospects of success.

It would make sense for the VNS manufacturers to be sponsoring studies and applying for 510(k) status for pain management for their devices since that is by far their largest market. While I could not find an active study, that does not mean that one or more are not underway.

Have a question for Jim and ChatGPT? Submit it to _____@rsds.org and you may see it in the next installment.

Jim is a CRPS patient with whole body involvement. Since medically retiring after 35 years in CEO roles in hospitals, medical device companies and value-based care providers, he stays active by advising healthcare companies and systems in the AI and analytics spaces. He also works to improve care and treatments for the rare disease community including the first initiative to use clinical and claims analytics to identify, diagnose and treat rare disease beginning with CRPS/RSD. As award winning novelists for "The Dyodyne Experiment," Dougeris is hard at work with his writing partner, V. Michael Santoro, on its sequel, "Sentience." He is also an active journalist writing articles and providing background and interviews on healthcare for national publications and news outlets.