



Institute for Research, Education
& Training in Addictions

Neuromodulation Devices for Opioid Withdrawal: Frequently Asked Questions

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Neuromodulation Devices for Opioid Withdrawal: FAQ

1. What are neuromodulation devices?

The International Neuromodulation Society defines therapeutic neuromodulation as “the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body.” In other words, neuromodulation devices stimulate parts of the nervous system to control, or modulate, how those areas work and reestablish neural balance. This can improve symptoms caused by brain or nerve problems and help the body work normally.

2. How do they work to reduce opioid withdrawal?

Neuromodulation devices are designed to help ease opioid withdrawal by stimulating the auricular (ear) branch of the vagus nerve, a neural pathway believed to regulate the body’s stress response. Small, wearable devices send low-level electrical pulses to electrodes placed in front of and behind the ear. Depending on the design, stimulation reaches the nerve either through the skin (transcutaneous) or just beneath it using tiny, acupuncture-like needles (percutaneous). Stimulating the vagus nerve is thought to calm autonomic hyperarousal, the prolonged, heightened stress response that makes withdrawal feel so intense.

3. Are these devices FDA-approved?

No. The FDA has reviewed six devices for use in opioid withdrawal to help reduce symptoms. As a novel device, the first was “granted” FDA permission to be legally sold in the US by demonstrating that the device has probable benefits and can control probable risks, based on results from a single open-label, uncontrolled study of 73 patients.^{1,2} While the results are promising, the lack of a control group means that we are unsure whether the symptom reduction was due to the device, the natural resolution of withdrawal over time, the placebo effect, or something else. Later devices were FDA “cleared” for sale in the US based on their similarity, or “substantial equivalence,” to the first device. The process to get FDA “approval” is much more rigorous, and manufacturers need strong evidence from well-designed clinical trials.

No device is currently granted, cleared, or approved as a stand-alone treatment for opioid withdrawal, only as an “aid”³ to reduce symptoms and “in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms.”⁴ There are also no devices granted, cleared, or approved as treatments for opioid use disorder (OUD).

4. Are these devices effective in treating opioid withdrawal symptoms?

The evidence for the effectiveness of these devices is limited. Currently, three peer-reviewed studies, all sponsored by neuromodulation device manufacturers, have examined their effect on withdrawal symptoms, with mixed results.^{2,5,6} After an hour of active device use, participants reported a slightly greater decrease in withdrawal symptoms on the Clinical Opiate Withdrawal Scale (COWS)⁷ compared to those using a deactivated “sham” device. Whether the difference was statistically significant (not due to random chance) seemed to depend on how the change in COWS score was calculated. Regardless, the clinical significance appeared modest: active device use decreased withdrawal scores by 2.3 to 2.6 points more than sham devices,^{5,6} less than the 6-point change patients have identified as clinically meaningful.⁸ While this early evidence is promising and shows potential for nerve stimulation to reduce withdrawal symptoms, the overall evidence remains limited.

A follow-up study also examined the effect of active vs. sham stimulation during residential treatment on self-reported illicit opioid or psychostimulant use in the 12 weeks after discharge. Randomization to active device stimulation did not lead to significantly fewer use-days of these substances.⁹

5. What are effective treatments for managing opioid withdrawal symptoms?

The American Society of Addiction Medicine (ASAM) recognizes two main strategies for managing opioid withdrawal: starting patients on methadone or buprenorphine before gradually tapering the dose, or prescribing FDA-approved lofexidine during the acute withdrawal period (usually lasting 7 to 10 days after symptoms start).¹⁰ Methadone and buprenorphine prevent acute withdrawal symptoms and reduce opioid craving.¹¹ Lofexidine is highly effective at counteracting acute withdrawal symptoms.¹² These strategies can be used together and in combination with medications to treat specific symptoms such as anxiety, diarrhea, pain, nausea, and insomnia.

6. What are some of the potential risks of using neuromodulation devices to treat opioid withdrawal?

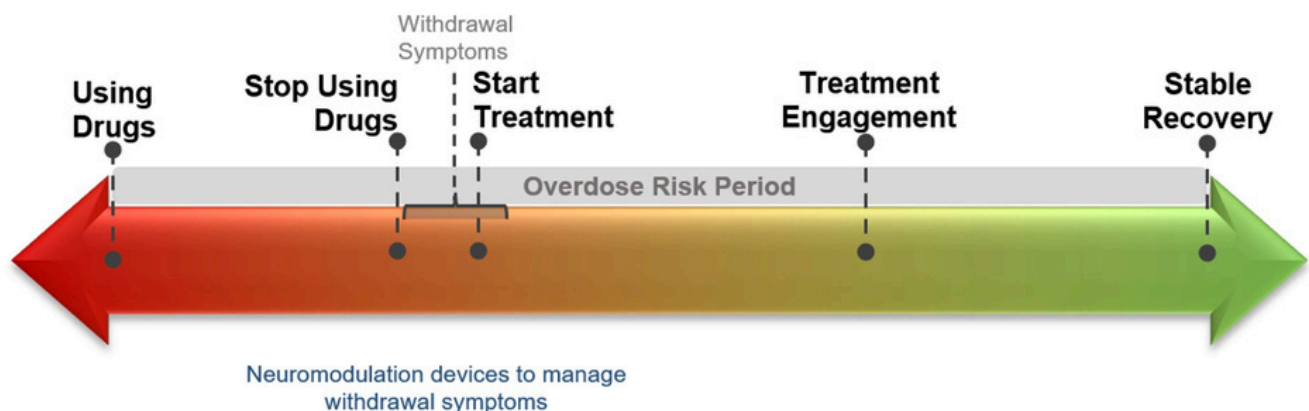
There may be some risks following treatment with a neuromodulation device associated with the return of withdrawal symptoms. A promotional flyer for one device states that, after treatment with the device, “...your [drug] tolerance will be much lower. Using the same amount as before could cause a fatal overdose.”¹³ Other risks of device use are minor and relate to pain and skin irritation where the electrodes are attached to the body.

7. How much do these devices cost compared to other options?

A course of treatment with one device costs \$5,500 per person.¹⁴ The total cost for 16 mg/day of buprenorphine over 10 days of acute withdrawal ranges from \$25 to \$267, based on the retail price for 30 sublingual tablets of 8 mg buprenorphine listed on GoodRx.com. Similarly, lofexidine ranges in cost from \$167 to \$389 retail for 10 days at 2.52mg/day, still significantly less than the cost of the cited device. Additionally, most Medicaid and other insurance plans provide coverage for these medications. Given the very small effects on withdrawal symptom severity and lack of evidence on preventing relapse and overdose, a medication like buprenorphine might provide more “bang for your buck” than the devices currently on the market.

8. Where might these devices fit in the overdose prevention, treatment, and recovery continuum?

OUD treatment and stable recovery involve much more than managing withdrawal symptoms, as shown in the graphic below. Withdrawal symptoms appear during a relatively brief period after a person discontinues active drug use.



There are no devices that have been granted, cleared, or approved by the FDA for the treatment of OUD. Once the withdrawal period is over, there is no application for neuromodulation devices in the treatment of OUD.

Gold-standard treatment for OUD involves the use of FDA-approved medications such as buprenorphine and methadone.¹⁵⁻²¹ Claims of “unmedicated opioid treatment” are misleading and may increase the risk of relapse and overdose. Additionally, remaining engaged in counseling treatment and recovery support can be effective strategies that help some people get well and stay in recovery.

Neuromodulation devices may be helpful in settings where medications to treat withdrawal symptoms are not readily available or when a patient’s other health conditions prevent them from being able to take approved medications. However, these devices were FDA-cleared to help with withdrawal symptoms in addition to standard medications, not instead of them.

Takeaways

- Neuromodulation devices are not treatments for OUD. OUD treatment and stable recovery involve much more than managing withdrawal symptoms.
- Withdrawal symptoms can be effectively managed with medications such as lofexidine or buprenorphine, and this may be more cost-effective than neuromodulation devices.
- Neuromodulation devices may be a promising treatment for opioid withdrawal symptoms, however, the evidence for their effectiveness is limited. They were FDA-cleared to treat opioid withdrawal symptoms along with standard medications.
- Buprenorphine and methadone are considered the gold-standard treatments for OUD, proven to significantly reduce withdrawal symptoms, improve treatment engagement, and reduce the risk of overdose.

Citations

1. U.S. Food and Drug Administration, Center for Devices and Radiological Health. NSS-2 BRIDGE De Novo DEN170018 decision summary. Published online November 15, 2017. Accessed August 18, 2025. http://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf
2. Miranda A, Taca A. Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: A multisite, retrospective assessment. *Am J Drug Alcohol Abuse*. 2017;44(1):56-63. doi:10.1080/00952990.2017.1295459
3. U.S. Food and Drug Administration, Center for Devices and Radiological Health. NSS-2 BRIDGE De Novo DEN170018 classification order. Published online November 15, 2017. Accessed August 18, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170018.pdf
4. U.S. Food and Drug Administration, Center for Devices and Radiological Health. Sparrow Therapy System 510(k) K201873 premarket notification summary. Published online January 2, 2021. Accessed August 18, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201873.pdf
5. Tirado CF, Washburn SN, Covalin A, et al. Delivering transcutaneous auricular neurostimulation (tAN) to improve symptoms associated with opioid withdrawal: Results from a prospective clinical trial. *Bioelectron Med*. 2022;8(12). doi:10.1186/s42234-022-00095-x
6. Greenwald MK, Arfken CL, Winston JR. A randomized, sham-controlled clinical trial to evaluate the NET Device™ for reducing withdrawal symptom severity during opioid discontinuation. *Front Psychiatry*. 2025;16. doi:10.3389/fpsy.2025.1510428
7. Wesson DR, Ling W. The clinical opiate withdrawal scale (COWS). *J Psychoactive Drugs*. 2003;35(2):253-259. doi:10.1080/02791072.2003.10400007
8. Dunn KE, Bird HE, Bergeria CL, Ware OD, Strain EC, Huhn AS. Operational definition of precipitated opioid withdrawal. *Front Psychiatry*. 2023;14. doi:10.3389/fpsy.2023.1141980
9. Greenwald MK, Arfken CL, Winston JR. Post-discharge use of opioids, psychostimulants, and treatment medications following residential opioid discontinuation with NET Device™ monotherapy. *Front Psychiatry*. 2025;16. doi:10.3389/fpsy.2025.162726
10. American Society of Addiction Medicine. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. *J Addict Med*. 2020;14(2S Suppl 1):1-91. doi:10.1097/ADM.0000000000000633
11. Volkow ND, Blanco C. Medications for opioid use disorders: Clinical and pharmacological considerations. *J Clin Invest*. 2020;130(1):10-13. doi:10.1172/JCI1134708
12. Urits I, Patel A, Zusman R, et al. A comprehensive update of lofexidine for the management of opioid withdrawal symptoms. *Psychopharmacol Bull*. 2020;50(3):76-96.
13. Jeff Tindall Oldham County Jailer. Facing Withdrawal? There's a Better Way Than Cold Turkey NET Recovery flyer. Facebook. August 8, 2025. Accessed August 8, 2025. <https://www.facebook.com/100074976836011/posts/love-oldham-county-detention-centers-relationship-with-net-recovery-please-reach/778093194699901/>
14. Clark County Fiscal Court. September 25, 2025 Regular Meeting of the Fiscal Court [Video]. YouTube. Published September 25, 2025. Accessed October 22, 2025. <https://www.youtube.com/watch?v=rE31swa2eVE>

15. Yarbrough CR, Cooper HLF, Beane S, et al. State Medicaid policies governing access to medications for opioid use disorder (MOUD) and MOUD treatment use in a large sample of people who inject drugs in 20 U.S. states. *Subst Use Misuse*. 2025;60(4):531-541. doi:10.1080/10826084.2024.2440365
16. Wakeman SE, Larochelle MR, Ameli O, et al. Comparative effectiveness of different treatment pathways for opioid use disorder. *JAMA Netw Open*. 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622
17. Wyse JJ, Shull S, Lindner S, et al. Access to medications for opioid use disorder in rural versus urban Veterans Health Administration facilities. *J Gen Intern Med*. 2023;38(8):1871-1876. doi:10.1007/s11606-023-08027-4
18. Moore KE, Roberts W, Reid HH, Smith KMZ, Oberleitner LMS, McKee SA. Effectiveness of medication assisted treatment for opioid use in prison and jail settings: A meta-analysis and systematic review. *J Subst Abuse Treat*. 2019;99:32-43. doi:10.1016/j.jsat.2018.12.003
19. Tsui JI, Evans JL, Lum PJ, Hahn JA, Page K. Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA Intern Med*. 2014;174(12):1974. doi:10.1001/jamainternmed.2014.5416
20. Woody GE, Bruce D, Korhuis PT, et al. HIV risk reduction with buprenorphine–naloxone or methadone: Findings from a randomized trial. *JAIDS*. 2014;66(3):288-293. doi:10.1097/QAI.0000000000000165
21. Centers for Disease Control and Prevention. SUDORS dashboard: Fatal drug overdose data. CDC’s state unintentional drug overdose reporting system (SUDORS), preliminary data. August 7, 2025. Accessed September 30, 2025. <https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html>

Appendix

FDA Reviews of Medical Devices for Opioid Withdrawal

Device Name	FDA Submission #	Device Manufacturer	FDA Decision	Decision Year	Publications
NSS-2 BRIDGE	DEN170018	Innovative Health Solutions, Inc. Versailles, IN 47042	Granted	2017	1 open-label uncontrolled chart review (n=72) ²
Drug Relief	K173861	DyAnsys, Inc. San Mateo, CA 94401	Cleared, SE to NSS-2 BRIDGE	2018	
Drug Relief v1	K221231 & K21197	DyAnsys, Inc. San Mateo, CA 94401	Cleared, SE to Drug Relief	2021 & 2022	
Sparrow Therapy System	K201873	Spark Biomedical, Inc. Dallas, TX 75252	Cleared, SE to NSS-2 BRIDGE	2021	1 RCT (n=31) ⁵
Sparrow Ascent	K230796	Spark Biomedical, Inc. Dallas, TX 75252	Cleared, SE to Sparrow Therapy System	2023	
NET Device	K233166	Net Recovery Corp Anaheim Hills, CA 92808	Cleared, SE to Sparrow Therapy System	2024	1 RCT (n=108) ⁶ 1 observational (n=103) ⁹

RCT = Randomized Controlled Trial; SE = Substantial equivalence

This FAQ is available online at <https://ireta.org/resources/neuromodfaq/>.

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