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501-c3 non-profit organization

## LONG-ACTING INJECTABLE NALTREXONE IS NOT A FIRST-LINE TREATMENT FOR MOST INDIVIDUALS WITH MODERATE OR SEVERE OPIOID USE DISORDER

May 8, 2023

**EXCERPT:** (Full document is at [https://bit.ly/naltrexone\\_secondline](https://bit.ly/naltrexone_secondline))

Stop Stigma Now (SSN; [www.StopStigmaNow.org](http://www.StopStigmaNow.org)) and Doctors For America (DFA; <https://doctorsforamerica.org>) confirm that long-acting injectable naltrexone (XR-NTX) is a second-line treatment option for most individuals with moderate or severe opioid use disorder (OUD) based on currently available information, and that methadone or buprenorphine (opioid agonist therapy or OAT) are first-line treatments for most such individuals.

Health agencies and medical providers who treat opioid use disorder should communicate this to individuals considering treatment, and should also inform such individuals about all FDA-approved pharmacologic options, that the choice among available treatment options should be a shared decision between the clinician and the patient, and that any approved pharmacologic therapy may be recommended preferentially based on individual circumstances.

This position is based on the fact that, unlike OAT, injectable naltrexone has not been clearly demonstrated to reduce fatal overdose deaths (1 - 6), and has been associated with lower retention in treatment compared with OAT in some studies (7) (8). This position is also consistent with the published statements reproduced below.

The 2021 Veterans Administration/Dept of Defense guideline on the Management of Substance Use Disorder recommends using either methadone or buprenorphine/naloxone as first line treatment for OUD as a strong recommendation, and suggests offering extended-release naltrexone when treating OUD as a weak recommendation (9).

The 2023 American Society of Addiction Medicine (ASAM)'s publication 'Pocket Addiction Medicine' states that methadone and buprenorphine are 1<sup>st</sup> line treatments, and that extended-release naltrexone is a "2<sup>nd</sup> line option for patients who have been counseled on risks vs. benefits and prefer it to agonist medication" (10).

OVER

MEDICATION TREATMENT FOR OPIOID ADDICTION SAVES LIVES

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ASAM's Policy Statement on Treatment of Opioid Use Disorder in Correctional Settings states that "For individuals who do not want to be treated with methadone or buprenorphine, extended-release injectable naltrexone is an alternative option for relapse prevention during detainment and after release." (11)...

OAT has been described in recent peer-reviewed reports as the "gold standard" or most effective treatment for OUD, or that XR-NTX is appropriate for those who are unable to, or choose not to, use OAT (14 – 26).

The Food and Drug Administration (FDA) Prescribing Information for Vivitrol, the brand name of XR-NXT, notes that "... Any attempt by a patient to overcome the antagonism by taking opioids is especially dangerous and may lead to life-threatening opioid intoxication or fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade" (27). The Risk Evaluation and Mitigation Strategy (REMS) for Vivitrol required by the FDA states that "Using large amounts of opioids, such as prescription pain pills or heroin, to overcome effects of Vivitrol, can lead to serious injury, coma, and death" (28).

Nevertheless, XR-NTX is an important option that may be more appropriate than OAT for particular individuals. For example, XR-NTX may be appropriate for individuals with relatively brief durations of OUD, mild OUD, those who strongly prefer it or who decline OAT, or when OAT is not available. SSN and DFA endorse the availability of all FDA-approved medications for OUD: methadone, buprenorphine, and XR-NTX.

Also, XR-NTX should be considered for individuals who have undergone medically managed withdrawal off of OAT. This should be accompanied by an explanation that, unlike OAT, it is a second-line agent for most people with moderate or severe OUD.

For the reasons noted, injectable naltrexone is currently a second line OUD treatment option, after OAT, for most individuals seeking treatment for moderate or severe OUD, and methadone or buprenorphine should be considered as first line treatments for most of these individuals.

**(See the full document at [https://bit.ly/naltrexone\\_secondline](https://bit.ly/naltrexone_secondline) for annotated references)**