

INDIAN HEALTH SERVICE National Pharmacy & Therapeutics Committee Formulary Brief: Update: MAT for Opioid Use Disorder

-August 2021-



Background:

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) reviewed Medication Assisted Treatment (MAT) for Opioid Use Disorder (OUD) at the Summer NPTC Meeting in August 2021 in an update to NPTC reviews on this topic completed in <u>August 2018</u> and <u>July 2020</u>. Practice guidelines and comparative data between MAT strategies, models of care and recent regulatory changes were evaluated. The evaluation included medications previously added to the National Core Formulary during the Summer NPTC meeting in August 2018 (*buprenorphine-naloxone, buprenorphine-restricted to treatment of OUD in pregnancy, and extended-release naltrexone*) as well as methadone, alpha-2-adrenergic agonists, and extended-release buprenorphine. Following the 2021 analysis, the NPTC voted to (1) <u>ADD</u> long-acting buprenorphine (any formulation, restricted to the treatment of OUD) to the National Core Formulary and to <u>MODIFY</u> the currently-approved buprenorphine language to read as (2) short-acting buprenorphine (any formulation, restricted to tDUD).

Discussion:

According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) 2019 National Survey on Drug Use and Health, 10.1 million Americans were estimated to have misused opioids in the last year.¹ This is 3.7% of the population. There is evidence that prescription opioids are the most frequent first opioid abused. Meanwhile, the incident use of heroin has more than doubled from 2007 to 2019 with over 1/2 of heroin users also reporting use of prescription opioids.² According to the 2019 SAMHSA Survey, an estimated 1.6 million Americans have an OUD due to either prescription opioids, heroin, or both.¹ According to data from the CDC, the epidemic of opioid overdose deaths is even more pronounced in Indian Country, with rural areas hit hardest.³

Findings:

The current opioid epidemic is multi-factorial, including the impact of prescription painkillers. The result has been a crisis of preventable deaths that has soared in recent years, rivalling the AIDS epidemic of the late 1980s. Meanwhile, the COVID-19 pandemic has only exacerbated the crisis. In 2020, the United States experienced the largest recorded single-year increase in overdose deaths.

On April 28, 2021, the Department of Health and Human Services issued <u>Practice Guidelines</u> for the Administration of Buprenorphine for Treating Opioid Use Disorder.⁴ This action was designed to address barriers and enhance access to buprenorphine for the treatment of OUD. The Practice Guidelines exempt eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives from the certification requirements related to training, counseling and other ancillary services (*i.e.*, psychosocial services) under federal statute. Specifically, the exemption allows these practitioners to treat up to 30 patients with OUD using buprenorphine without having to make certain training-related certifications and also allows practitioners to treat patients with buprenorphine without certifying as to their capacity to provide counseling and ancillary services. This exemption specifically addresses reported barriers of the training requirement. Providers are still required to submit an application designated as a "Notice of Intent" in order to prescribe buprenorphine for the treatment of OUD.

Last year, the Substance Abuse and Mental Health Services Administration published an <u>updated treatment</u> <u>improvement protocol</u> regarding medications for OUD.⁵ The SAMHSA guideline focuses on three medications; methadone, buprenorphine, and extended-release naltrexone, favoring an individualized approach to selection of a specific agent. While duration of therapy is not defined, the high rate of relapse after discontinuation of medication for treatment is noted and extended treatment is advocated. The guideline advises against using medically-supervised withdrawal alone, due to the high rate of relapse. When used as part of a broader treatment plan, methadone and buprenorphine are recommended along with medications for symptom control, including clonidine.

In March of last year, the American Society of Addiction Medicine issued a <u>focused update</u> of its 2015 National Practice Guideline for the use of medications in the treatment of addiction involving opioid use.^{6,7} Notably, the 2015 practice guideline highlighted the role of medication therapy plus psychosocial interventions as superior to withdrawal management followed by behavioral therapy alone. Among the various options for MAT, it advocated a shared decisionmaking approach, including variables such as patient preference and treatment venue. In a major revision, the 2020 focused update recommends that all FDA approved medications for the treatment of OUD should be available to all patients. Buprenorphine is a recommended treatment for patients with OUD who are able to give informed consent and have no specific contraindication for this treatment. Both office-based and home-based initiation are considered safe and effective when starting buprenorphine treatment. The guideline references that that FDA recently approved several new buprenorphine formulations for treatment of OUD and recommends that clinicians should use these products as indicated while being mindful of emerging evidence as it becomes available. Clinicians should take steps to reduce the chance of buprenorphine diversion. Recommended strategies may include frequent office visits (such as weekly in early treatment); drug testing, including testing for buprenorphine and metabolites; and recall visits for medication counts. Finally, there is no recommended time limit for pharmacological treatment with buprenorphine.

Actions:

In response to the crisis in opioid-related morbidity and mortality, the Department of Health and Human Services has made addressing the opioid abuse problem a high priority and is focused on implementing evidence-based approaches.⁸ In addition, to address the epidemic of OUD in Indian Country, the IHS Director issued a Special General Memorandum in June of 2019 to ensure and broaden access to MAT in the IHS service population.⁹ In order to support access to individualized medication assisted treatment options for OUD in Indian Country, the NPTC voted to add a long-acting formulation of buprenorphine and to remove the pregnancy restriction from short acting formulations of buprenorphine on the National Core Formulary.

If you have any questions regarding this document, please contact the NPTC at <u>IHSNPTC1@ihs.gov</u>. For more information about the NPTC, please visit the <u>NPTC website</u>.

References:

- 1. Substance Abuse and Mental Health Services Administration. 2019 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD.
- 2. Substance Abuse and Mental Health Services Administration; Center for Behavioral Health Statistics and Quality. <u>Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health.</u> Rockville, MD. 2020.
- 3. CDC MMWR. Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas United States. Surveillance Summaries / Vol. 66 / No. 19, October 20, 2017.
- Department of Health and Human Services; Office of the Secretary. <u>Practice Guidelines</u> for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 FR 22439. April 28, 2021.
- Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. <u>Treatment Improvement Protocol</u> (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.
- 6. American Society of Addiction Medicine. <u>National Practice Guideline</u> for the Treatment of Opioid Use Disorder, 2020 Focused Update. March 20, 2020.
- 7. Crotty K, Freedman K, et al. Executive Summary of the National Practice Guideline for the Treatment of Opioid Use Disorder. J Addict Med 14(2): 99-112, Mar/Apr 2020.
- 8. Office of the Surgeon General. <u>Surgeon General Priority: Opioids and Addiction.</u> Jan 2021.
- 9. Indian Health Service. Special General Memorandums (SGM 19-01): <u>Assuring Access to Medication Assisted Treatment for Opioid Use Disorder</u>. Published June 11, 2019