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Buprenorphine—An Office-Based Treatment for Opioid Use Disorder

- **Buprenorphine treatment is a life-saving tool for patients with opioid use disorder (OUD).**
- **Increasing access to buprenorphine is urgently needed to address the opioid crisis in New York City.**
- **Incorporate buprenorphine treatment into your practice by**
  - **recognizing OUD,**
  - **prescribing buprenorphine after obtaining a waiver, and**
  - **providing ongoing management of patients with OUD.**

Opioid overdose deaths are a public health crisis in New York City (NYC). From 2010 to 2018, the rate of drug overdose death more than doubled, from 8.2 per 100,000 to 20.5 per 100,000. In 2018, opioids were involved in 80% of overdose deaths; fentanyl was the most common opioid (60%), followed by heroin (51%), methadone (14%), and opioid analgesics (11%).[1]

Effective treatment of opioid use disorder (OUD) can prevent overdose death. Buprenorphine and methadone are the most effective medications to treat OUD, reducing drug use and death and improving social wellbeing and functioning.[2,3] Because many New Yorkers do not receive effective treatment, there is an urgent need for NYC health care providers to offer medication to patients with OUD.

Buprenorphine is a safe and effective office-based treatment that can be integrated into primary care and other settings along with management of patients' other health issues (**Boxes 1** and **2**).[4–10]

To incorporate buprenorphine treatment into your practice:

1. Learn to recognize OUD.
2. Obtain training and a waiver to prescribe buprenorphine.
3. Prescribe buprenorphine to patients with OUD.
4. Provide ongoing management of patients with OUD.

Continuing education training, implementation guidance, and mentorship from experienced clinicians are also available (**Resources for Providers**).

STEP 1. LEARN TO RECOGNIZE OPIOID USE DISORDER

- Ask nonjudgmental, open-ended questions about a patient's drug use and their functioning with family, at work or school, and in social situations.
- Be aware of signs associated with opioid intoxication such as drowsiness, slurred speech, memory impairment, and pupillary constriction.[5]

WHAT ARE OPIOIDS?

- *Opioids* are drugs that bind to specific receptors in the brain and relieve pain. The group includes both heroin and opioid analgesics
- *Opioid analgesics* are pain-relieving prescription medications such as morphine, codeine, oxycodone, and hydrocodone

- Screen for drug use. Ask "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?"[11] If the response is ≥ 1, use one of several validated screening tools available, such as the DAST-10 (**Box 3**). See **Resources—Clinical Tools** for other options.

BOX 1. BUPRENORPHINE BASICS

Buprenorphine is a partial opioid agonist[5]

- Buprenorphine tightly binds to mu receptors in the brain, preventing other opioid agonists (ie, opioid analgesics, heroin, and methadone) from binding to and activating the receptor (**Figure**)
- Because buprenorphine activates the receptors only partially, it exhibits a ceiling effect on opioid activity; at an adequate dosage, buprenorphine reduces opioid withdrawal and craving but does not produce the euphoria and respiratory depression seen with full opioid agonists

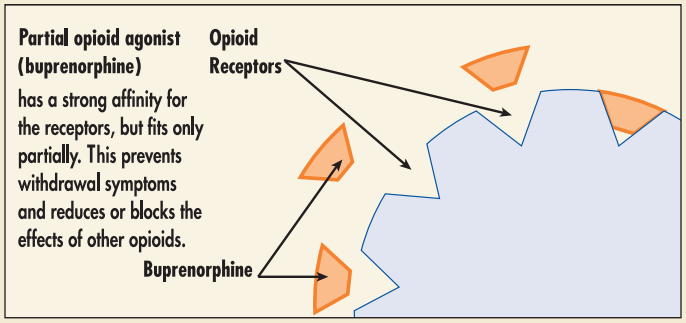
Buprenorphine has a low risk of overdose

- Buprenorphine's ceiling effect makes it less likely that a person will overdose on buprenorphine alone.[6] *Fatal overdose is still possible if other central nervous system (CNS) depressants, such as benzodiazepines or alcohol, are taken along with buprenorphine*

Buprenorphine is available in several forms

- Buprenorphine is available as sublingual tablets and films, generally taken once daily, and as a monthly injection. The tablets dissolve within 5 to 10 minutes and the film dissolves even more rapidly. Buprenorphine is available as a monoproduct or in combination with naloxone. Implant forms are also available
- In the combination product, naloxone is included to act as a deterrent to intravenous use of buprenorphine. It precipitates withdrawal symptoms when injected but not when taken sublingually
- The buprenorphine/naloxone combination is preferable except when the patient is hypersensitive to naloxone (see **Review safety considerations**, page 4). See **Pregnancy** (page 4) for information on use in pregnancy

FIGURE. BUPRENORPHINE MECHANISM OF ACTION



- For patients who respond "Yes" to ≥ 3 questions on the DAST-10, assess for mild, moderate, or severe OUD with the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) criteria (**Box 4**).[12]

STEP 2. OBTAIN TRAINING AND A WAIVER TO PRESCRIBE BUPRENORPHINE

To prescribe buprenorphine, you must meet the following 3 criteria[13]:

1. Be a licensed prescriber (MD, DO, physician assistant [PA], or nurse practitioner [NP]). Depending on state-specific regulations, certified nurse midwives (CNM), clinical nurse specialists (CNS), and certified registered nurse anesthetists (CRNA) may also qualify.
2. Have any of the following credentials[13]:
   - completion of at least 8 hours of a specific continuing medical education training (online or in person) from an approved organization on prescribing buprenorphine; nonphysicians must complete the same 8 hours as physicians and an additional 16 hours of free online training (**Resources for Providers**),
   - subspecialty board certification related to addiction, or
   - investigator role in 1 or more clinical trials leading to US Food and Drug Administration (FDA) approval of a narcotic for drug maintenance or detoxification.

BOX 2. BUPRENORPHINE FAQS

Is buprenorphine as likely to be misused[a] as other opioids?

- No. Patients are less likely to misuse buprenorphine than they would a full opioid agonist
- The most common reasons for buprenorphine misuse are self-treatment of withdrawal symptoms and lack of access to treatment[7,8]
- Buprenorphine is co-formulated with naloxone to deter injection (**Box 1**)

Are patients treated with buprenorphine required to attend counseling?

- No. The Drug Addiction Treatment Act of 2000 (DATA 2000) mandates that buprenorphine prescribers must be able to refer patients for behavioral health services. Behavioral health support will benefit many patients, but it is not mandatory for the provider to refer all patients, or for patients to attend counseling
- In NYC, providers have the ability to refer patients to 888-NYC-WELL/888-692-9355, fulfilling the legal requirement (see **Resources for Providers**)
- The need for counseling should be determined on an individual basis.[5,9] In many cases, counseling may be successfully delivered by a primary care provider[10]

[a] *Using someone else's buprenorphine or using buprenorphine in ways other than prescribed*

3. Have the capacity to refer patients to counseling. In NYC, you can meet this criterion by referring patients to 888-NYC-WELL/888-692-9355.

If you meet all the criteria, you can obtain a waiver to prescribe buprenorphine from the Substance Abuse and Mental Health Services Administration (SAMHSA). The waiver allows you to have a maximum of 30 or 100 patients at any one time during the first year depending on the practice setting and meeting certain criteria. After 1 year following the initial notification, you can submit a second notification to enable you to treat up to 100 or 275 patients. More information is available from SAMHSA (at 866-BUP-CSAT/866-287-2728 or infobuprenorphine@samhsa.hhs.gov) or visit SAMHSA Training Materials and Resources for the most up-to-date information about the waiver process.

BOX 3. DRUG USE QUESTIONNAIRE (DAST-10)

"Drug use" refers to (1) the use of prescribed or over-the-counter drugs in excess of the directions, and (2) any nonmedical use of drugs

The various classes of drugs may include cannabis (marijuana, hashish), solvents (eg, paint thinner), tranquilizers (eg, Valium), barbiturates, cocaine, stimulants (eg, speed), hallucinogens (eg, LSD), or narcotics (eg, heroin). The questions do not include alcoholic beverages

Please answer every question. If you have difficulty with a statement, then choose the response that is mostly right

These questions refer to drug use in the past 12 months. Please answer No or Yes		
1. Have you used drugs other than those required for medical reasons?	No	Yes
2. Do you use more than one drug at a time?	No	Yes
3. Are you always able to stop using drugs when you want to?	No	Yes
4. Have you had "blackouts" or "flashbacks" as a result of drug use?	No	Yes
5. Do you ever feel bad or guilty about your drug use?	No	Yes
6. Does your spouse (or parents) ever complain about your involvement with drugs?	No	Yes
7. Have you neglected your family because of your use of drugs?	No	Yes
8. Have you engaged in illegal activities in order to obtain drugs?	No	Yes
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	No	Yes
10. Have you had medical problems as a result of your drug use (eg, memory loss, hepatitis, convulsions, bleeding, etc)?	No	Yes

See Drug Abuse Screening Test (DAST-10) for more information

STEP 3. PRESCRIBE BUPRENORPHINE TO PATIENTS WITH OPIOID USE DISORDER

The treatment goals for OUD are to prevent overdose, alleviate physical symptoms of withdrawal and cravings, and help patients meet their goals for functioning in their personal, work, and community lives.

Talk with your patient

Buprenorphine may be a good choice for patients who[5]

- meet the DSM-5 criteria for OUD,
- can be expected to be reasonably adherent to the treatment plan,

BOX 4. DSM-5 CRITERIA FOR OPIOID USE DISORDER (OUD)[12]

Ask opioid users if they have experienced these symptoms in the past year:

- Taking the substance in larger amounts or for longer than you meant to
- Wanting to cut down or stop using the substance but not managing to
- Spending a lot of time getting, using, or recovering from use of the substance
- Cravings and urges to use the substance
- Not managing to do what you should at work, home, or school because of substance use
- Continuing to use, even when it causes problems in relationships
- Giving up important social, occupational, or recreational activities because of substance use
- Using substances again and again, even when it puts you in danger
- Continuing to use, even when you know you have a physical or psychological problem that could have been caused or made worse by the substance
- Needing more of the substance to get the effect you want (tolerance). **Note:** This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision
- Development of withdrawal symptoms, which can be relieved by taking more of the substance. **Note:** This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision

2–3 symptoms: mild OUD
4–5 symptoms: moderate OUD
6+ symptoms: severe OUD

- have been educated about the risks and benefits of buprenorphine treatment,
- are willing to follow safety precautions for buprenorphine treatment, and
- have agreed to buprenorphine treatment after a review of treatment options.

Draft a treatment agreement

- A written agreement (**Resources for Provider**s) will help establish mutual trust and clarify expectations of patient and provider involvement in buprenorphine treatment.[5]

Assess severity of withdrawal

Typically, patients must experience at least mild withdrawal symptoms before beginning buprenorphine or they risk developing a precipitated or severe withdrawal.[5] A score of ≥ 5 on the standardized Clinical Opiate Withdrawal Scale (COWS) (**Resources for Providers**) is the recommended threshold[14]; higher scores reduce the chances of precipitating withdrawal.

Determine location of treatment initiation

Studies have established the safety of starting treatment at home, which is a common practice. Patients are prescribed a limited number of days of buprenorphine with careful instructions and follow-up. Office-based prescribers will likely find that initiating treatment at home is more feasible and also preferable to many patients. Published guidance is available.[5, 15–17]

Determine optimal dosage

Buprenorphine dosage between 4 mg and 24 mg a day usually controls symptoms of withdrawal and craving and results in improved stability.[5] The once-monthly injection dosage is 100 mg or 300 mg. Dosage should be individualized. Underdosing could cause patients to drop out of treatment and may contribute to polysubstance use.[18,19] Dosages that are too high can cause sedation.

- Initiate treatment according to the package insert.
- Monitor patients for approximately 2 weeks after initiating therapy until you've determined the adequate buprenorphine dosage.

For patients who are switching from methadone, coordinate to taper the patient to 30 to 40 mg of methadone before starting buprenorphine.[5]

INTEGRATE BUPRENORPHINE TREATMENT INTO PRACTICE WORKFLOW

- Identify champions with clinical and institutional knowledge to facilitate implementation
- Request staff training, technical assistance, and mentoring from the NYC Health Department
- Explore practice models to determine which is the best fit for your setting
- Assign a staff member such as a nurse or clinical pharmacist to coordinate the buprenorphine program, keep an electronic registry of buprenorphine patients, and manage refill requests
- Plan for referral or on-site psychosocial counseling
- Ensure coverage by a waivered prescriber during vacations to minimize disruptions in treatment
- Incorporate feedback from patients

Review safety considerations[a]

- **Polysubstance use:** Even if patients are using other substances, they will likely have less risk of opioid overdose if they continue taking buprenorphine than if they are discharged from care.
  - Some patients who use multiple substances might need a higher level of care, such as a specialized addiction treatment program; others may benefit from continued management with buprenorphine in the general medical setting.
- **Benzodiazepines and other CNS depressants:** FDA guidance states that buprenorphine should not be withheld from patients taking benzodiazepines or other central nervous system (CNS) depressants whether prescribed or illicitly obtained.[20] The combined use of these drugs increases the risk of serious side effects, including overdose and death. However, the harm caused by continued use and untreated OUD, if care is denied or if a patient is discharged from care, can outweigh these risks. Risks can be mitigated by careful medication management and educating patients about the serious risks of combined use. If a patient is sedated at the time of evaluation, the cause of sedation should be evaluated.
- **Hepatic impairment:** Buprenorphine carries a low risk of hepatoxicity. Consider monitoring liver function during treatment for patients with predisposing risk factors for hepatic injury.[21]
- **HIV:** Buprenorphine is associated with reduced opioid use, increased initiation of antiretroviral therapy, and increased CD4 counts,[22] and has been effectively and safely integrated into HIV treatment settings.[23] Clinical data have not shown hepatotoxicity or pharmacodynamic interactions when buprenorphine is used with antiretroviral therapy, including atazanavir/ritonavir,[24] despite increased plasma concentrations of buprenorphine and its metabolite norbuprenorphine.[25]
- **Pregnancy:** Methadone has been considered the standard of care in the United States. Recent evidence also supports the use of buprenorphine during pregnancy.[26] Current recommendations, based on theoretical concerns, are to use the buprenorphine monoproduct in pregnancy; however, recent safety data on use of the combination product during

pregnancy suggest no adverse effects and similar outcomes compared with the monoproduct.[26]

- **Lactation:** Breastfeeding should be encouraged in women who are stable on buprenorphine and who do not have other contraindications. While small amounts of buprenorphine and norbuprenorphine are secreted into breast milk, adverse events have not been reported among breastfed infants of mothers treated with sublingual buprenorphine.[26,27]
- **Adolescents:** Buprenorphine is approved for use in patients aged 16 years and older. It is recommended that pediatricians consider prescribing buprenorphine or refer to others who can.[28]
- **Adverse events:** The most common adverse events are rashes, hives, and pruritus. Bronchospasm, angioneurotic edema, and anaphylactic shock have also been reported. Buprenorphine products should not be given to those who are hypersensitive to buprenorphine or naloxone.[5]

[a]*See product information for full safety information.*

STEP 4. PROVIDE ONGOING MANAGEMENT OF PATIENTS WITH OPIOID USE DISORDER[5]

- Discuss treatment goals in a nonjudgmental manner, respecting patient autonomy and collaborating in decision-making as much as possible.
- Tailor frequency of return visits to the individual patient and degree of clinical stability. Weekly or more frequent visits may be needed for a patient early in treatment or during unstable periods. Longer visit intervals, such as monthly or more, may be appropriate for patients who are stable. At follow up visits, routinely:
  - assess the treatment plan, including urine toxicology, as appropriate to assess drug use, the presence of drug adulterants, and buprenorphine adherence;
  - assess for mood, anxiety, or personality disorders.
- Treatment should be individualized and continued for as long as the patient benefits and agrees to care. Because longer treatment is generally associated with better outcomes, avoid blanket limitations on treatment duration.[3]
- Offer referral, as needed, to counseling or a 12-step program, but not as a condition of treatment. These services can help the patient manage psychological or psychosocial problems that could affect treatment.
- Provide a clear protocol for refilling prescriptions to ensure continuous treatment.
- Remain attentive to frequent requests for early refills or reports of lost medication. These could be signs of misuse, which might indicate self-treatment of opioid withdrawal or cravings and a need to increase prescribed dosage. Requests for more medication could also signal diversion to individuals who do not have access to a buprenorphine prescription.[8,29,30]
- If the patient continues to misuse opioids during maintenance treatment,
  - discuss treatment goals in a nonjudgmental manner, emphasizing a collaborative relationship.
  - intensify treatment by reducing follow-up intervals, reassessing the medication dosage, and referring for more intensive psychosocial counseling or specialized addiction treatment.

Reducing dosage and discontinuing treatment

Make the decision to discontinue buprenorphine treatment in partnership with the patient based on their individual needs and circumstances. People who've been opioid dependent for short periods may be able to discontinue buprenorphine therapy; those who've been using opioids over long periods will likely need long-term treatment.[31]

Longer treatment is associated with better outcomes. Abrupt discontinuation or rapid dosage taper may result in discomfort from craving and opioid withdrawal, so work closely with

EMERGING TRENDS IN BUPRENORPHINE PRACTICE

- Emergency department initiation for patients who present with an opioid-related diagnosis or wanting treatment for OUD. Patients are given buprenorphine (if in withdrawal) or a short-term prescription to start at home as a bridge to quick outpatient follow-up[31,32]
- Buprenorphine group sessions for patients stable in care where the prescriber meets with each patient separately during the group to assess treatment[33]
- Integrating buprenorphine treatment into HIV/AIDS and hepatitis C treatment settings. Stabilization on buprenorphine is likely to improve adherence to treatment and other indicators for HIV, HCV, and other chronic conditions[34–36]
- Integrating buprenorphine treatment into standard hospital care (eg, starting buprenorphine for patients with OUD during acute hospitalizations with linkage to outpatient care at discharge)[37]
- Providing buprenorphine treatment in correctional settings[38]
- Initiating buprenorphine treatment as close to the time of a patient's request as possible to enhance opportunity for patient engagement in care. Because of the relatively low risk profile of buprenorphine, a prescription for a limited number of days after a focused evaluation may be appropriate, except when there are clear contraindications. Further testing and evaluation can be completed at follow-up visits

RESOURCES FOR PROVIDERS

Clinical tools and guidance

- DAST-10: https://cde.drugabuse.gov/sites/nida_cde/files/DrugAbuseScreeningTest_2014Mar24.pdf
- ASSIST: https://www.who.int/substance_abuse/activities/assist_v3_english.pdf
- NIDA Quick Screen and NIDA-Modified ASSIST: https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/nida-quick-screen
- Clinical Opiate Withdrawal Scale (COWS): http://www.naabt.org/documents/COWS_induction_flow_sheet.pdf
- Subjective Opiate Withdrawal Scale (SOWS): https://www.ncbi.nlm.nih.gov/books/NBK143183

General information and guidance on buprenorphine

- Substance Abuse and Mental Health Services of America (SAMHSA). Buprenorphine: https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine
- SAMHSA. TIP 63: Medications for Opioid Use Disorder – Full document: https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-006.pdf

Buprenorphine waiver training

- NYC prescribers: Contact: buprenorphine@health.nyc.gov for up-to-date information on the NYC Health Department's free, monthly trainings
- Substance Abuse and Mental Health Service Administration (SAMHSA): www.samhsa.gov, 866-BUP-CSAT/866-287-2728
- Providers Clinical Support System (PCSS): https://learning.pcssnow.org
  - Buprenorphine waiver information: https://pcssnow.org/medication-assisted-treatment
  - 8 Hour Online MAT Waiver Training: https://learning.pcssnow.org/p/onlinematwaiver
  - Calendar of buprenorphine waiver trainings: https://pcssnow.org/calendar-of-events
- American Academy of Addiction Psychiatry: www.aaap.org
- American Osteopathic Academy of Addiction Medicine: https://education.aoaam.org
- American Psychiatric Association: https://www.psychiatry.org/psychiatrists/education/signature-initiatives/buprenorphine-prescriber-training
- American Society of Addiction Medicine: https://www.asam.org/education/live-online-cme/waiver-training

Buprenorphine waiver application process

- Substance Abuse and Mental Health Service Administration (SAMHSA): 866-BUP-CSAT/866-287-27280
  - SAMHSA Training Materials and Resources: https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources
  - For practitioners: https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver
  - For buprenorphine waiver application (notification): https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php

Physician-patient sample treatment agreement

- SAMHSA. TIP 63: Medications for opioid use disorder – full document: https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-006.pdf

Mentoring program for prescribers

- NYC Health Department mentoring for NYC prescribers: buprenorphine@health.nyc.gov
- PCSS mentoring: https://pcssnow.org/mentoring

Referral resources

- NYC WELL, a free, 24/7 confidential hotline for mental health and substance use concerns, with information for patients and providers:
  - Call: 1-888-NYC-WELL (1-888-692-9355); all languages
  - Visit: nycwell.cityofnewyork.us
  - Chat: https://nycwell.cityofnewyork.us/en/get-help-now/chat-with-a-counselor-now
  - Text: "WELL" to 65173

Opioid overdose prevention resources

- Contact NYC WELL to locate an opioid overdose prevention program where naloxone is available for free, including those offering syringe services
- Download the Stop OD NYC app for overdose prevention education and how to obtain naloxone

Other resources and guidance

- NYC Health Department. Information about buprenorphine: https://www1.nyc.gov/site/doh/providers/health-topics/treating-opioid-addiction.page
- New York State Department of Health and Office of Addiction Services and Support. Implementing Transmucosal Buprenorphine for Treatment of Opioid Use Disorder Best Practices: https://www.health.ny.gov/diseases/aids/consumers/prevention/buprenorphine/docs/bupe_best_practices_2019.pdf
- University of California, San Francisco Substance Use Warmline: https://nccc.ucsf.edu/clinician-consultation/substance-use-management 1-855-300-3595, Monday–Friday, 9 am–8 pm ET *Clinically supported advice on substance use management for healthcare providers*
- Providers Clinical Support System (education and materials and resources): www.pcssnow.org

For Technical Assistance and Other Questions (for NYC prescribers): buprenorphine@health.nyc.gov

the patient on a tapering schedule. Plan for additional patient support and overdose prevention during this time. Refer to the package insert for full prescribing information, including dosing and safety. Be prepared to reinitiate treatment if necessary.[7]

SUMMARY

Buprenorphine is a life-saving office-based treatment for OUD. Integrating buprenorphine prescribing into your practice can be very rewarding and will make treatment for OUD more available to those who need it and reduce stigmatization that may deter people from seeking care. ◆

RESOURCES FOR PATIENTS

- NYC Health Department. General information about buprenorphine and where to find treatment:
  Go to nyc.gov/health and search "opioid treatment medication," then click the "how to find treatment" tab
- New York State Department of Health information about buprenorphine and where to find treatment: https://www.health.ny.gov/diseases/aids/consumers/prevention/buprenorphine
- SAMHSA Buprenorphine Treatment Practitioner Locator: https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator

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