MEDICATION-ASSISTED TREATMENT
CENTERS OF EXCELLENCE

Integrating Medications for Addiction Treatment (MAT) into Office-Based Addiction Treatment:

An Evidence-Based Manual for Primary Care and Specialty Practices

New Jersey Medication-Assisted Treatment
Centers of Excellence

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NOTE: The NJ COE and NJ DMHAS gratefully acknowledge the original sources from which this manual was adapted:

1. Boston University School of Public Health / Albert Einstein College of Medicine / UCSF: Developed with funding from the Health Resources Services Administration Special Projects of National Significance: Integrating Buprenorphine Treatment for Opioid Use Disorder in Primary Care
2. Dartmouth/Hitchcock Knowledge map: Primary Care Based Treatment of Opioid Use Disorder

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Overview

This manual is designed to assist practitioners and their staff in supporting an office or clinic-based practice to prescribe medications for opioid use disorder, particularly buprenorphine and XR-naltrexone, as they are available in the community-based setting. While the manual should be useful for any office-based practitioner, it will be especially helpful for primary care practitioners who want to become providers in the NJ FamilyCare (Medicaid) Office Based Addiction Treatment (OBAT) initiative. The OBAT initiative includes a variety of provider types from office-based primary care and specialty clinics to addiction medicine programs that provide medications for addiction treatment (MAT) and other services for opioid use disorder (OUD) as part of their general medical practice.

See the NJ FamilyCare/Medicaid Newsletter (Volume 29, Number 18) for details about the initiative and the OBAT standards.

Studies show that MAT is especially beneficial when delivered in an office-based setting or in primary care clinics, such as certified community behavioral health clinics, federally qualified health care centers, and group family medicine practices. When medications for opioid use disorder are integrated into such settings, OUD can be treated as a chronic illness and patients can gain access to medical and addiction services under one roof. Furthermore, the 2020 American Society of Addiction Medicine OUD guidelines state that a patient's decision to decline psychosocial treatment (or the absence of available psychosocial treatment) should not preclude or delay pharmacotherapy for opioid use disorder. This statement further emphasizes the role that office-based providers have in starting and increasing access to MAT.

This manual refers to prescribing practitioners (e.g., physicians, advanced practice nurses, and physician assistants) and navigators (defined below).

To address any questions or to comment in regard to this manual, please contact the Northern NJ MAT Center of Excellence (COE) at coe@njms.rutgers.edu or the Southern NJ MAT Center of Excellence at southernnjcoe@rowan.edu. Please also visit our websites at bit.ly/mat-coe and snjmatcoe.org.

The New Jersey Medication-Assisted Treatment Model (NJ MATRx)

The NJ Division of Medical Assistance and Health Services, part of the New Jersey Department of Human Services, established the Medication-Assisted Treatment COEs to increase state-wide capacity to provide MAT through mentorship and education of community providers. One of the primary goals is to increase access to MAT for Medicaid recipients and to provide mentorship and support to MAT providers via ongoing engagement. Two centers were established: the Northern COE at Rutgers New Jersey Medical School in Newark, NJ, and the Southern COE as a joint partnership between Cooper Medical School of Rowan University in Camden, NJ and Rowan University School of Osteopathic Medicine in Stratford, NJ. See figure below for corresponding coverage of counties.

The MATRx model is centered on a care system consisting of the COEs, premier providers, and office-based treatment providers. This system can be thought of as a hub-and-spoke model with the COEs serving as a hub to provide clinical education and expertise on SUD management, as well as recommendations/suggestions for management of individual patients. Premier providers integrating both physical, behavioral, and substance use care while providing wrap-around services for patients. OBAT providers functioning as private office-based practices providing addiction medicine care. Patients may receive treatment from premier providers initially and then be referred to their primary care OBAT provider when their SUD condition is more stable. Likewise, those patients needing more treatment than the OBAT can provide may be referred to premier providers. At any point that clinical management recommendations are needed, the COEs can provide consultation for any provider and may be able to help with referrals.

This model works only when there are enough OBAT providers available and providing evidence-based care. The OBAT providers are office-based practice practitioners who are able to do the following:

- Provide MAT induction, stabilization and maintenance
- Participate in training or consultation offered through the COEs to demonstrate commitment towards evidence-based MAT care
- Maintain integrated care relationships
- Provide navigation services through employment of a patient navigator to help with psychosocial and non-medical needs

See section below for more information on the patient navigator

The intent of the OBAT is to integrate addiction medicine into general medical care, thereby allowing patients to receive addiction treatment from primary care. When

designated as an OBAT, practices are able to receive specific reimbursement rates for treating patients with OUD. They are able to provide or refer to behavioral health needs as they are required to have a patient navigator on-site to help with case management and non-medical needs. These providers can refer patients to premier providers, who can further support the OBAT providers through additional wrap-around services not provided by the OBATs. OBATs are able to use the referral network facilitated through ReachNJ (844-ReachNJ), which has the most updated information for OBATs and can refer callers directly to an OBAT for care. ReachNJ is a 24/7 addictions hotline for those suffering with SUD directly or friends and family calling on behalf of those suffering SUD to receive immediate assistance and support from live, New Jersey-based, trained addiction counselors. These counselors conduct a brief assessment with the patient to identify specific needs and link them with appropriate treatment for their addiction. The service can assist patients regardless of their insurance status. OBATs will also be able to use the network to refer patients to higher levels of care (see below on an overview of the levels of care).

As discussed, premier providers provide specialized treatment and wrap-around services that may not be available by the OBATs. Premier providers are independent clinics or DOH-licensed physician practices capable of providing fully integrated care (MAT, counseling and primary medical care). These include the following:

- Federally Qualified Health Centers (FQHCs)
- Opioid Treatment Programs(OTPs)
- Certified Community Behavioral Health Clinics (CCBHCs)
- Licensed ambulatory withdrawal management (AWM) providers
- Independent substance use disorder treatment services

In addition to outpatient services provided in office-based treatment settings, additional outpatient services are available to patients; these are defined within the American Society of Addiction Medicine Levels of Care. This describes treatment as “a continuum marked by four broad levels of services and an early intervention model. These four services include:

- Outpatient Services
- Intensive Outpatient/Partial Hospitalization Services
- Residential/Inpatient Services
- Medically Managed Intensive Inpatient Services

Within these services, “decimal numbers are used to further express gradations of intensity of services, which further explains why this model is a treatment continuum. When wrap-around services are needed or if patients need more intensive care (i.e., continued relapse despite patient’s goal of abstinence) than can be provided in the office-practice setting, this treatment continuum allows for providers to “conduct a multidimensional assessment” exploring the many risks and needs of each patient so that patients can be identified and placed in the treatment most appropriate for them.

Providers should understand the difference between outpatient services and the OBAT model as the OBAT model is referring specifically to care provided by the office-based, private practitioner. For more specific information on each of the 4 services above, please visit this guide from the American Society of Addiction Medicine.

The Centers of Excellence help to support the OBAT, providing education and mentorship for providers. COEs are able to provide training, consultation, and mentorship services for practitioners, especially through a 24/7 MAT "in-the-moment" hotline (1-844-HELP-OUD) for clinical questions. Mentorship also includes OBAT clinical support through technical assistance for new and established MAT clinics, and academic detailing through structured visits to healthcare providers, pharmacies, and community groups to provide tailored trainings on evidence-based practices. The COEs also educate on best practice guidelines, assist in making community connections for OBATs for adjunctive behavioral health services, and assist in workforce development by providing education/internship/fellowship opportunities for physicians and other health care professionals.

In rolling out this model, Medicaid beneficiaries will be able to have greater access to treatment for both medical and psychosocial needs, whereas Medicaid providers will have a greater incentive to see patients with substance use disorders, both important to tackling the opioid crisis.

Northern COE Counties

Southern COE Counties

OBAT Provider Classification

The Medicaid Newsletter (Volume 29, Number 18) states that OBAT providers consist of physicians, APNs, and PAs with a DATA 2000 waiver who meet established standards for participation. Until now, many providers have not participated in the treatment of substance use-related disorders (beyond referral) because of perceived barriers to providing treatment, lack of reimbursement, and/or a lack of experience/knowledge treating these conditions. The OBAT program is designed to enhance access and improve utilization of non-methadone MAT services for Medicaid beneficiaries by establishing additional supports and reducing administrative barriers for office-based providers providing these addiction services. These supports include increased rates for reimbursement for NJ FamilyCare providers, removal of prior authorization requirements, and allowing providers to bill the managed care plan for this substance use disorder (SUD) service when the beneficiary is covered by managed care.

OBAT providers must employ navigators. Navigators are available to work with the patient to establish a comprehensive, individualized treatment plan that addresses the non-medical, psychosocial factors that impact SUD treatment. Navigators can help individuals with logistics such as transportation and child care, and connect individuals to services such as counseling, employment or housing programs, etc. They ensure access and linkage to social service organizations, recovery supports and/or family education. When needed, they can make referrals to alternate levels of care. See the next section to learn about the qualifications for a navigator.

Preparing to Implement MAT in your Office Practice

The following activities should be completed before your MAT practice is implemented:

Develop job descriptions for key personnel

Job descriptions should be developed for DATA-waivered prescribing practitioners and for other key staff on the treatment team, which includes staff who will coordinate the patient's care (medical assistant, nurse, social worker, etc.) and/or a navigator (if an OBAT provider) or an addiction counselor.

NOTE: DATA-waivered prescribing practitioners can include: physicians, advanced practice nurses, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives)

Patient navigator – works with the patient to establish a comprehensive, individualized plan that supports the patient through the phases of their treatment and addresses non-medical factors that impact the overall care for OUD. They address psychosocial concerns and assist with the coordination of care. Click on the link here for a sample of a navigator care plan developed by the Camden Coalition of Healthcare Providers.

Initiation: provide system navigation, advocacy, community connections, support/education for treatment compliance, recovery planning
Stabilization: assist with patient follow-up for setting up and keeping appointments, facilitate community connections, employment and/or housing support, provide necessary education for treatment adherence
Maintenance: continued treatment system navigation, counseling, advocacy, and community connections

For upcoming events and trainings geared towards supporting your navigator, please visit the Camden Coalition of Healthcare Providers OBAT Events and Training Page
Additional information on the OBAT Model and billing, can be found here.

Prescriber - For a prescriber to qualify as an OBAT provider, she or he must have navigator services available. As per the Medicaid newsletter released in November 2019 Volume 29, 18, these are acceptable credentials to qualify as a navigator.

- Registered Nurse
- Licensed Practical Nurse
- Social Worker
- Medical Assistant with 4 years of clinical (practice-based) or lived experience (or 4 years combined)
- Bachelor's degree with 2 years of clinical or lived experience
- Associate degree with 4 years of clinical or lived experience (or 4 years combined).
    - *Lived experience is defined as direct or indirect use of a drug, such as through involvement with self-use, family, friends, etc.*
- Any licensed healthcare provider who is practicing within their scope of practice
    - This includes, but is not limited to, prescribers such as physicians, advanced practice nurses, and physician assistants. This provider, however, cannot serve both the prescriber and the navigator role simultaneously. Therefore, if a group practice has more than one prescriber, such as two APNs, one APN can function as the prescriber and the other as the navigator.

After the prescriber is approved to bill under Medicaid, navigators must also fill out this application with New Jersey Medicaid to confirm eligibility for being a navigator.

As of the November 2020 newsletter (Volume 30, 22), fee-for-service Medicaid providers must include a navigator credentialed by NJ FamilyCare AND enrolled as part of the prescriber's or group practice's NPI to be able to bill OBAT rates.

Develop and assign responsibilities for MAT-related procedures, which include the following:

- Enrolling patients in MAT treatment
- Supporting the patient in MAT initiation, stabilization, and maintenance treatment (under supervision of the prescribers)
- Assisting in implementation of the plan of care
- Arranging for referrals to community providers if needed
- Getting insurance prior authorizations and troubleshooting other coverage-related issues

NOTE: Effective April 1, 2020, with the exception of DMAHS-defined safety edits, managed care organizations shall provide coverage for all generic MAT mediations, regardless of dosage form, for up to thirty-two (32) mg per day for oral/sublingual buprenorphine. Naltrexone XR (Vivitrol®), Sublocade®, and Probuphine® also do not require a prior authorization.

- Building relationships and linkages for counseling, other treatment (e.g., mental health care), and ancillary services (e.g., patient transportation)
- Sharing information with other members of the health care team
- Maintaining records and meeting requirements for a Drug Enforcement Administration (DEA) inspection

Develop clinical protocols for MAT

These should correspond to patient level of stability and to provider skill and confidence level in your office or clinic. Protocols are described in this manual for the following phases of treatment:

- Initial patient selection and assessment
- Preparing and educating patients for buprenorphine or extended-release naltrexone (XR-naltrexone) therapy and harm reduction with the co-prescribing of naloxone with the use of MAT
- Buprenorphine initiation (e.g., home versus office induction)
- Stabilization and maintenance treatment
- Tapering patients off buprenorphine (by their request; this is not recommended)
- Terminating treatment and transferring care

Create procedures to follow federal mandates for record-keeping practices

Keeping and maintaining a patient log for each prescriber; ensuring confidentiality of medical records, their storage, and their maintenance for DEA visits. For specific information, please utilize the PCSS resource on "How to Prepare for a Visit from the Drug Enforcement Agency (DEA) Regarding Buprenorphine Prescribing."

Create protocols for on-call and back-up systems that ensure patient access to a provider during nights and on weekends.

Require on-call staff to know how to manage patients who are prescribed MAT. If not, on-call staff need to know how to contact the buprenorphine prescriber on call. It may

be helpful for members of the treatment team to carry pagers or cell phones to field specific queries and concerns from participating patients, but this is not required.

Arrange for a clinical mentorship

If needed, MAT prescribers can request the assistance of a clinical mentor with expert knowledge and practical experience in MAT treatment. In NJ, two MAT Centers of Excellence (COE) have been established to provide training and mentorship to practitioners who are prescribing MAT for OUD; these include the Northern COE at Rutgers New Jersey Medical School to cover 12 northern counties, and the Southern COE in to cover 9 southern counties (see county maps). To contact a COE and request mentorship, please email the Northern NJ COE at coe@njms.rutgers.edu or the Southern NJ COE at SouthernNJCOE@rowan.edu. Prescribers can also participate in the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT) mentor program, a national training and mentoring project, to be assigned a mentor.

Develop protocols for accepting referrals (internal and external) for patients to receive buprenorphine treatment

Eligible patients may be identified by other providers at the clinic or patients may be self-referred or referred by another provider in the community. Using the referral protocol developed by your clinic in the pre-implementation phase, a member of the treatment team will contact the patient and make an appointment for the patient to meet with the prescribing provider for a patient assessment. It can be helpful to reserve some emergent appointment slots for these referrals, since long delays in starting MAT can result in an overdose and individuals are often in crisis when they are seeking MAT. Contact your respective COEs if you need assistance in making referrals to other levels of care.

Determine an individual who is responsible for documenting the types of insurance that the practice will accept and development of payment policies

Identify the individual at the clinic, such as your patient navigator, who will address prior authorization for insurance or Medicaid eligibility. This individual can also help patients apply for patient assistance programs. Your practice may also set payment plans for patients without insurance and specific payment policies that would be important for patients to be aware of.

Establish a working relationship with an on-site or community pharmacy to secure sustainable patient access to buprenorphine medication

While not required, it can be helpful to develop a relationship with a local pharmacy so that any issues with filling buprenorphine prescriptions can be addressed more easily. The treatment team can work with the pharmacy to ensure access to the various formulations of buprenorphine.

Establish or strengthen existing relationships with mental health and substance use treatment providers (on-site or in the community)

The OBAT program is designed to help facilitate transitions of care between the OBAT practice and higher levels of care. The patient navigator may help arrange for two-way referrals of individuals needing SUD services; examples of these types of care include counseling, mutual support groups, withdrawal management, inpatient treatment programs, outpatient treatment programs, and residential treatment. ReachNJ is a hotline (844-REACH NJ) that facilitates a referral network to help patients identify OBATs they can follow-up with for their opioid use disorder. A screening, brief intervention, and referral to treatment (SBIRT) is conducted during that call. ReachNJ uses the New Jersey Substance Abuse Monitoring System (NJSAMS) treatment directory to determine the providers available in the patient's community who prescribe MAT and take Medicaid. It also lists the agencies that can assist patients needing higher levels of care beyond the OBAT level of service. Alternative arrangements can also be made for referral of individuals needing specialty mental health care (see Appendices for the DMHAS Directory).

NOTE: It is helpful to strengthen professional relationships with the available services within your area to assist with the transitions of care process. The COEs co-host an MAT Lunch Hour every other Wednesdays from 12pm-1pm to facilitate collaboration and networking. For more information and for updates and announcements, please be sure to sign-up for the COE listserv and visit the COE websites at sites.rutgers.edu/mat-coe and snjmatcoe.org.

Implement policies that address and promote safe use of buprenorphine

Policies may include urine drug screens and checking the NJ Prescription Drug Monitoring Program (PDMP).

It is important to understand that urine drug screening is only ONE tool used to assess patient goals of treatment. As the ASAM consensus statement on the "Appropriate Use of Drug Testing in Clinical Addiction Medicine" states, drug testing should be used as a tool for supporting recovery rather than exacting punishment. The presence of opioids or other illicit drugs should NEVER be a rationale to withhold buprenorphine, especially if the urine drug screening confirms that the patient is taking buprenorphine.

The PDMP should be used to identify whether patients are filling their buprenorphine and to identify other prescribed controlled substances that may affect the treatment plan.

Maintain adequate number of prescribers to treat the numbers of patients being seen in the office or clinic

One year after obtaining waivers, practitioners should consider applying to the DEA to allow them to treat additional patients. During a public health emergency, SAMHSA is able to grant emergency buprenorphine waiver limit increases from 30 to 100 or from 100 to 275.

You can apply here.

Implement mechanisms for ongoing communication among treatment team members

When integrating buprenorphine treatment, communication strategies should include routine "huddles" and meetings involving the navigator, prescribers, and other treatment team staff.

Develop a training plan for clinic staff on addiction treatment

Training topics can include an overview of substance use disorders, urine toxicology screens, confidentiality issues, motivational interviewing and counseling, buprenorphine-specific topics, etc. Contact the COEs for assistance, if needed.

Counseling and Recovery Supports

Although this manual focuses on the use of implementing MAT in the OBAT model of care, practices should provide or arrange counseling and recovery support services for their patient population. All patients should be assessed as to the type and frequency of counseling that is indicated and this determination should be documented in patients' care plans. **Receiving MAT should NOT be contingent on patient engagement in counseling.**

As an alternative to individual counseling for patients who are stable, office-based practices may arrange for shared counseling appointments, in which counseling is provided in a group format that is co-led by the prescriber and another team staff. Clients should also receive brief interventions from staff on an as-needed basis.

If available, clients should be connected to the clinic's recovery support specialist or to peer support services outside of the practice. All clients should be educated about the critical role of recovery supports and information about the self-help and recovery supports programs in their geographic area. See the Appendices for information about these services.

Initial Referral and Patient Selection for MAT

An important first step to integrating buprenorphine treatment into OBAT settings (especially those integrating SUD care into a primary care practice) is to ensure that patients are screened and assessed to determine whether they may have an OUD.

An initial screening does not need to be comprehensive and can be conducted with a simple one-question universal screening tool of high validity, asking: **"How many times in the past year have you used an illegal drug or a prescription medication for nonmedical reasons?"** Should the patient answer 'yes,' a more comprehensive tool such as the DAST-10 screening tool can then be completed to determine severity of a possible SUD. Then, an assessment addressing SUD history and the DSM-5 OUD criteria can then formally diagnosis OUD. Please see the assessment section below.

Initially, when the treatment team is inexperienced with buprenorphine treatment, it may be ideal to select patients who are likely to have optimal outcomes with few complications. Once the treatment team gains experience, providing buprenorphine

treatment to more complex patients is warranted. Providers may contact the COE 24/7 MAT Provider Hotline for any "in-the-moment" advice or questions at 1-844-HELP-OUD.

Patients eligible for buprenorphine may be identified by other practitioners at the clinic, but some may be self-referred or be referred by a provider in the community.

Using the referral protocol developed by your clinic in the pre-implementation phase, a member of the clinical team should contact the patient to schedule an appointment as soon as possible with the prescribing provider for a patient assessment.

NOTE: Patients requesting buprenorphine treatment services are at risk of overdose death without medication. Therefore, it is paramount that patients receive medications as soon as possible.

Criteria for Buprenorphine Treatment

Inclusion Criteria

- OUD diagnosis, as determined by DSM-5 criteria
- Age ≥16 years or emancipated minor able to consent for medical and substance use treatment
- Able to comply with the program's buprenorphine treatment policies

Exclusion Criteria

- Known allergy/hypersensitivity to buprenorphine or naloxone
- Patients currently receiving methadone from an opioid treatment program (OTP)

NOTE: If the patient is asking to transition to buprenorphine, contact the OTP to collaborate on this transition to determine next steps.

Consider Risks vs. Benefits

The below is not an absolute contraindication to buprenorphine therapy; i.e., patients can be safely prescribed buprenorphine in the following conditions:

Significant concurrent use of alcohol and/or sedatives (e.g., benzodiazepines)

Patients should be assessed on admission for whether alcohol or sedatives will present a significant risk during buprenorphine treatment; the use of alcohol and sedative medications in conjunction with the intravenous misuse of buprenorphine has been associated with opioid overdose (this data is largely from Europe, where the mono-product buprenorphine is more available and there is a subpopulation of buprenorphine injectors; buprenorphine injecting appears to be much rarer in the U.S.). Therefore, prescribing buprenorphine is NOT an absolute contraindication for those who are currently drinking alcohol or other sedatives, but further assessment is warranted if the person's alcohol or sedative use is particularly severe.

The FDA released a MedWatch in 2017, stating that **buprenorphine should not be withheld from patients taking benzodiazepines or other central nervous system (CNS) depressants**. Although there are serious risks with combining these medicines, excluding patients from buprenorphine is not likely to stop them from using other CNS depressants and could result in more severe outcomes. Risks for concurrent use should be individualized and discussed with the patient.

Severe liver dysfunction (e.g., AST and/or ALT >3-5x upper limit of normal)

Studies show that liver dysfunction is generally due to an underlying condition such as hepatitis. It is good practice to get a baseline LFTs prior to initiating buprenorphine but this should NOT preclude therapy with buprenorphine if that is not possible. Consider the risks of continued illicit opioid use vs. therapy with buprenorphine. Contact the COE MAT provider (available 24/7 844-HELP OUD) hotline should you need additional assistance on this.

- **Serious/uncontrolled/untreated medical problems leading to altered mental status or delirium.**
- **Active suicidal ideation or any psychiatric impairment that impedes ability to provide informed consent to make decisions regarding their own care** (e.g., dementia, active psychosis, severe depression)

Buprenorphine may not be as effective in the following criteria but may be considered

Currently receiving methadone or opioid analgesic doses that exceed levels allowing for safe transition to buprenorphine (e.g., methadone >30-60mg). Patients who are switched to buprenorphine after experiencing withdrawal following the abrupt cessation of higher doses of methadone may not tolerate buprenorphine and have an increased risk of induction failure.

Chronic pain syndrome requiring chronic use of opioid analgesics. One modality can be to divide buprenorphine three to four times a day to enhance its analgesic effect.

Requiring a higher level of care than can be offered in the primary care clinic (i.e., outpatient substance use disorder treatment program, methadone maintenance, etc.).

NOTE: There are some clinical considerations that may require further patient assessment to determine appropriateness for buprenorphine. If patients have any of the criteria above and further assistance is needed to start buprenorphine, contact your COE via email or call the hotline, available 24/7 at 1-844-HELP-OUD. Patients may also be considered for other forms of MAT, such as injectable extended-release buprenorphine, methadone, or injectable extended-release naltrexone.

Criteria for XR-Naltrexone (Vivitrol®) Treatment

Inclusion Criteria:

- Patient must not be taking illicit opioids or prescription opioid medications for at least 7-10 days for short-acting opioids (e.g., heroin, oxycodone) or at least 10-14 days for long-acting opioids (e.g., methadone)
- Consistent and reliable urine drug screenings for opioids or for patients with recent opioid use, has negative results on screening or confirmatory opioid detection tests
- Undergone medically supervised withdrawal or self-withdrawal from opioids for a minimum of 7-10 days, as noted above.
- Patient is free of severe or active liver or kidney dysfunction (liver transaminases less than 5x ULN; bilirubin within normal limits; estimated or measured creatinine clearance 50 ml/min or greater)

PCSS has a useful step-by-step guide for initiating XR-naltrexone, available here. Should you have any questions for initiating XR-naltrexone, contact your COE via email or call the hotline, available 24/7 at 1-844-HELP-OUD.

Exclusion Criteria:

- Patients requiring opioid medication for therapeutic reasons.
- Contraindication to intramuscular injections.
- Conditions that impair peripheral absorption.
- Current physiologic opioid dependence or withdrawal.
- Failed naloxone or naltrexone challenge, patient self-report of opioid use in the past 7-10 days (or 14-21 days if a long-acting opioid like buprenorphine), or positive for any opioids on screening or confirmatory opioid detection tests. A naltrexone challenge is a small dose (12.5-25mg) of naltrexone provided to a patient who is subsequently observed for 90 minutes for an increase in COWS score. An increase in a COWS score of 2 or more suggests that more time is needed prior to starting XR-naltrexone. Alternatively, intramuscular naloxone may be used as a challenge.

Consider Risks vs. Benefits for the Following:

- Patients with severe hepatic impairment (Child-Pugh Class C/liver transaminases >5x ULN)
    - Hepatic impairment is generally due to an underlying disease. It is rare for naltrexone to induce liver injury.
- Moderate to severe renal impairment (estimated or measured CrCl <50 ml/min).

Patient Assessment

The objectives of the assessment are to determine the patient's clinical eligibility for MAT treatment, provide the basis for a treatment plan, and establish a baseline measure to evaluate a patient's response to treatment.

1. Using DSM-5 criteria (see Appendices) establish the diagnosis of OUD, including the duration and severity of opioid use.

2. Discuss patient's current opioid use and patterns, including level of tolerance, prior treatment experiences including experiences with opioid agonists, nature and severity of opioid withdrawal symptoms, time of last opioid use, and current withdrawal status (see form in Appendices).

3. Document opioid withdrawal symptoms using the Clinical Opiate Withdrawal Scale (COWS) to assess and document opioid withdrawal severity (see Appendix), including autonomic excitation (e.g., elevated blood pressure, increased heart rate, mydriasis, tremors, and agitation/restlessness), and the presence or absence of yawning, rhinorrhea, piloerection, diaphoresis, lacrimation, vomiting and muscle fasciculations.

- Assess for possible substance intoxication, including but not limited to patient disinhibition or other altered mental status.
- Observe for drug or needle use sequelae, including presence of track marks, abscesses, cellulitis.

4. Take a thorough history

- Ask about use of substances, including tobacco, alcohol, benzodiazepines, and other drugs.
- Ask about reason for substance use and any history of trauma.
- Detail current opioid use (e.g., type of opioid, method of administration, frequency of use, amount of use, last use).
- Ask about a history of mental health treatment and determine whether individual has a co-occurring mental health disorder (List any DSM-5 diagnoses, if known).
- Review past treatment experiences, including patient response to treatment, side effects, and perceived effectiveness.

- Determine patients' access to social supports, family, friends, employment, housing, finances, and legal assistance.
- Determine patients' readiness to participate in treatment and their goals for engaging in treatment.
- Ask about any legal issues (this can be concurrently addressed with the patient navigator) – legal matters may be reduced or repealed if drug-related and the patient is actively in treatment.

Medical Evaluation

Conduct appropriate physical examination.

Look for indications of substance use, such as needle track marks.

Identify comorbid medical conditions and psychiatric disorders and determine how, when, and where they will be addressed.

- Liver disease: Patients with decompensated cirrhosis may require close monitoring while on XR-naltrexone and slower titration of buprenorphine. Consider a hepatology consult/co-management for patients with chronic liver disease. See 'Conduct Lab Testing' section below for information regarding AST/ALT.
- Pain syndromes: Buprenorphine has analgesic properties with a duration of 6-8 hours, but may not be beneficial in patients with acute or chronic pain syndromes requiring high doses of full opioid agonist therapy (e.g., morphine, methadone, oxycodone, hydromorphone). Buprenorphine should be prescribed as TID or QID dosing for patients with co-occurring pain given that the analgesic effect wears off after 6-8 hours. When necessary, buprenorphine can be used simultaneously with low doses of short-acting full-opioid agonists provided that the patient is already taking buprenorphine and that the opioid is used sparingly and not for chronic use. XR-naltrexone cannot be used in these patients although there is some data demonstrating that low-dose naltrexone is beneficial for neuropathic pain.
- Medications: Buprenorphine is metabolized by the cytochrome P450 3A4 (CYP3A4) system and so medications that are CYP3A4 inhibitors or inducers (e.g., many psychiatric medications) may increase or decrease drug levels of buprenorphine. Most of these interactions, however, are not clinically significant, so consider weighing the benefits vs. risks of therapy. Naltrexone is not metabolized by CYP3A4 and so does not have any significant drug-drug interactions.

Conduct Lab Testing:

- Urine drug screening (UDS): Expect opiate-positive urine toxicology screens prior to initiating MAT treatment. Should UDS opiate screening be negative, further assessment of the patient may be warranted. Ensure that the testing parameters for the toxicology screen are understood; for example, synthetic opioids will not show up under an immunoassay for opiates, since the chemical structure is too unrelated (i.e., fentanyl will be negative on most "opiate" screens). A specific immunoassay for fentanyl or referral for confirmatory testing (LC/MS, GC/MS, etc.) would provide confirmation for synthetic opioids like fentanyl.

NOTE: Not having a UDS or the inability provide a UDS during evaluation should NOT preclude the initiation of buprenorphine if a full assessment confirms the diagnosis of an opioid use disorder.

- Pregnancy test (serum or urine HCG) for female patients of childbearing age. Assess and document use of birth control method for female patients of childbearing age, if applicable. If no contraception is used, engage in shared-decision making with the patient about the benefits of starting buprenorphine in those who are pregnant with OUD. Currently, it is not recommended to start XR-naltrexone in this population given lack of evidence and unknown harm. Starting medications for opioid use disorder is standard of care to reduce morbidity and mortality for both the mother and the neonate. Although there may be risks for neonatal abstinence syndrome, it can be treated. Consult with an OB-GYN provider for further management if needed.
- Liver Function: ALT, AST. Results over 5 times the normal upper limit may increase risk of buprenorphine-induced hepatitis but this is NOT an absolute contraindication for buprenorphine or naltrexone. Consider other comorbidities and other factors that may be leading to these values as studies have shown that elevated liver function is often not directly associated with buprenorphine or other forms of MAT.

Screen for HIV and viral hepatitis, including hepatitis A, and address any positive findings

After the patient has completed the assessment process, the prescriber will describe how MAT treatment is delivered in the clinic (including the roles of the physician and the team) and begin preparing the patient for treatment.

You can start by using this sample evaluation form.

Preparing the Patient for MAT

The steps to prepare a patient for treatment in an OBAT setting are performed by the prescribing physician, and include the following:

1. **Complete a treatment agreement.**
   This describes the goals of treatment, the risks and benefits of treatment, and the relationship between the patient and the treatment team (see Appendix for a sample agreement).

2. **Educate the patient about MAT treatment, harms of drug use, and how to properly administer the medication**, if the patient is to be taking sublingual formulations of buprenorphine, as well as how to safeguard and discard the medication; what they can expect to experience at each stage of treatment; and alternatives to buprenorphine treatment.
   - Useful information about what buprenorphine treatment is like and how to prepare for treatment initiation can be found on the ASAM website; this includes a pocket guide for patients and families (see Appendices for Patient Educational Resources). Contact your respective New Jersey MAT Center of Excellence for additional information.

   ↳ This sample OBAT support packet also includes this information.

   - Identify how the MAT treatment will be covered by Medicaid or other insurance.
   - Provide patient education on naloxone and provide access to a naloxone kit, if available. (see prescribetoprevent.org for patient info.)
   - Explain the risks associated with stopping MAT, and educate the patient about the use of techniques that can reduce the harms associated with substance use. When approaching patients who use drugs, it is important to come from the perspective that drug use is not "morally wrong" but to share with the patient that drug use has negative consequences on both the physical, medical, and social aspects of health.

   ↳ For assistance in guiding your encounter using the harm reduction approach, Dr. Jonathan Giftos, an addiction medicine specialist, developed a flow-chart. Education about today's drug supply likely containing highly potent synthetic opioids such as fentanyl should be discussed. Harms associated with drug use can include infection risk and overdose deaths. Techniques to address these may be the use of clean syringes, never using alone, always having

naloxone available for a friend/family member to administer to the patient, or the use of fentanyl test strips. For more information on these harm reduction tools and techniques, please refer to this guide on how to prevent and respond to an overdose. Additional information such as quick tips and a harm reduction template for documenting purposes can also be found by clicking the above links. Information on harm reduction centers where patients can access harm reduction tools can be found here.

3. **Explain to patients the potential need to communicate with other providers about the patient's treatment plan to integrate care,** especially with other substance use treatment or mental health and medical providers. This will require separate signed releases of information to exchange health information protected by federal 42 CFR Part 2 confidentiality regulations.

4. **Prepare patients to be in an opioid-free state and have mild-moderate symptoms of opioid withdrawal on the day of buprenorphine initiation.**

Patients should exhibit signs of at least mild withdrawal (COWS ≥ 8) prior to receiving their first dose of buprenorphine.

- Heroin withdrawal typically begins 8 to 24 hours after last use, peaks at 2 to 3 days, and lasts 5 to 7 days. Heroin use should be stopped at least 12 hours prior to buprenorphine initiation. Please see the note section as fentanyl has largely replaced heroin as the primary opioid purchased illicitly.

NOTE: Given that fentanyl is now often mixed with heroin, expect that withdrawal symptoms may last longer and can be delayed. Patients may need to wait longer than 12-16 hours prior to buprenorphine initiation (sometimes up to 24-36 hours). Therefore, initiation should be more dependent on the severity of withdrawal symptoms as determined by the COWS score. Contact the COEs if you have questions regarding the initiation of buprenorphine for patients who may be chronically using fentanyl.

- Methadone withdrawal typically begins 1 to 3 days after last use, peaks at 5 to 7 days, and lasts 14 to 21 days. For patients on methadone, tapering down to doses of 30-40 mg/day is recommended prior to buprenorphine initiation to reduce the risk of precipitated opioid withdrawal. Methadone administration should be stopped at least 48-72 hours prior to buprenorphine initiation (longer is always better; it is highly recommended to use alternative

medications for symptom relief, listed below, to allow patients to wait even longer).

NOTE: There are alternative strategies that may be used to initiate buprenorphine in patients who were previously on methadone. As of this writing, these strategies are based on case series. For more information, contact the COEs.

5. Consider prescribing/dispensing small quantities of medications for symptomatic relief of opioid withdrawal symptoms beforehand, if needed.

- Clonidine 0.1 mg PO q 6-8 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
- Loperamide 4mg at initial experience of diarrhea, then 2mg as needed for each episode of loose stool or diarrhea thereafter, not to exceed 16 mg/24h;
- Acetaminophen 500-1000 mg q 4-6 hrs PRN, ibuprofen 600mg PO every 6 hours as needed for myalgias or arthralgias.
- Ondansetron 4mg PO every 6 hours PRN nausea/vomiting
- Trazodone 100mg PO QHS PRN insomnia
- Gabapentin 600mg PO TID PRN moderate anxiety/restlessness

NOTE: This is NOT an all-inclusive list and other adjuncts may be warranted depending on the clinical scenario. Please contact the COE 24/7 hotline should you need further guidance.

Treatment Initiation and Stabilization of Buprenorphine

The goal of initiation and stabilization is to find the **appropriate dose** of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or cravings. This dose also should be sufficient enough to prevent the overcoming of the opioid receptor blockade in cases of relapse.

Because buprenorphine acts as a partial agonist at mu opioid receptors with an intrinsic activity of 40%, it may precipitate opioid withdrawal in a patient who has recently used opioids with full agonist activity. The duration of time in which opioids may stay in patients' system depends on the specific pharmacologic properties of the opioid and patients' liver function (because opioids are metabolized through the liver) and this might take from 8-24 hours to several days. For example, the mean clearance time for those who use fentanyl chronically may take a week or more, especially for those with renal impairment as fentanyl is cleared primarily via urine as metabolites. Patients should only be initiated on buprenorphine if they are showing objective signs of opioid withdrawal (unless they have been opioid-free for at least several days).

An initiation or induction phase beginning with a low (2mg or less) or a moderate dose (~8mg or more) that is followed by increasing doses over several days may be recommended for certain patients to minimize the likelihood of precipitating opioid withdrawal. Once a stable dose of buprenorphine is determined, patients are usually maintained at 16mg-24mg/day, which patients may take just once daily as buprenorphine is long-acting or may be divided to help with associated pain syndromes.

NOTE: There have been greater reports of precipitated withdrawal even in situations where patients are already experiencing nearly intolerable withdrawal prior to starting buprenorphine. This is due to fentanyl being the primary illicit opioid in the drug supply. Fentanyl easily equilibrates in the fat tissue and may appear as cleared when one experiences withdrawal. For an individualized approach to induction for your patient, please contact the COEs.

Determine whether to offer home and/or office-based inductions and review protocols for each.

Literature suggests that home-based induction is not any more or less effective than office-based induction. Given the mortality benefits of buprenorphine and the importance of removing barriers to ensure patient access, home induction has become a common approach to treatment, especially during the COVID-19 pandemic. Although

one may attribute precipitated withdrawal to the properties of buprenorphine, patient non-adherence to instructions for home induction is also a major, if not more important, cause for precipitated withdrawal. Therefore, ensuring that patients are appropriately counseled with teach-back will help to reduce risk of precipitated withdrawal due to patient error.

Most, if not all, patients are appropriate for home induction for buprenorphine except those who need a daily, highly structured program based on assessment, those who have failed previous induction(s) despite adherence to clinical instructions, and high-risk populations including, but not limited to, pregnant patients.

- Providers with experience in initiating patients on buprenorphine should have no difficulty providing buprenorphine for home induction.
    - Those providers who are newer to treating patients on buprenorphine may also provide buprenorphine for home induction but if in doubt or uncomfortable with any induction, please do not hesitate to contact the 24/7 COE clinical "in-the-moment" hotline.
- Patients who have previously taken buprenorphine, who know their withdrawal/craving symptoms and have demonstrated both comfort and skill at starting the medicine without clinical observation OR those who are motivated and able to understand and follow instructions regardless of whether they have previously taken buprenorphine are good candidates for home-based inductions.
    - During the COVID-19 pandemic, it may be more feasible to have patients initiate buprenorphine on their own at home.
- Patients' ability to tolerate opioid withdrawal symptoms should be considered. Patients who are very concerned or anxious about experiencing precipitated withdrawal, especially those who have failed buprenorphine induction in the past, may want to experience withdrawal and undergo induction within a clinical setting where they can be observed. Often patients with underlying anxiety may have difficulty differentiating their symptoms due to anxiety versus opioid withdrawal. In these cases, home induction may be challenging.
    - Assess whether the failed inductions were due to starting buprenorphine too early or other patient error, such as failure to follow planned instructions.
- Patients transferring from methadone to buprenorphine may have difficulties:
    - Patients may have not experienced opioid withdrawal symptoms in years (because of having received methadone treatment for years) and be quite fearful or anxious of experiencing opioid withdrawal.
    - Because methadone is so long-acting, they are at higher risk of precipitated withdrawal than patients who use opioids other than methadone. These patients are likely best suited for office-based inductions.

Home-based induction (Primary method for induction of buprenorphine)

Patient is given a prescription for buprenorphine at the prescriber intake visit and instructed to fill the prescription.

NOTE: Patients who have recently been released from prison or other restrictive, drug-free environments, may not demonstrate evidence of withdrawal. They may still be appropriate for treatment with buprenorphine to avoid relapse. For these patients, starting at a low-dose, and slowly titrating up may be an appropriate induction method. Patients who have been off opioids for at least 7-10 days may be candidates for injectable XR-naltrexone.

Prior to starting the medication at home, the patient is directed to monitor his/her withdrawal symptoms and may self-assess with the Subjective Opiate Withdrawal Scale (SOWS – see appendix). The patient is advised to have a caregiver/family member at home to also monitor signs and symptoms should precipitated withdrawal occur. Of note, most patients are often aware of when their opioid withdrawal is uncomfortable so may not necessarily use the SOWS scale to start buprenorphine. Thus, the use of SOWS is to help the patient with objectively identifying withdrawal to start buprenorphine, and may be of benefit for those patients who would like the additional guidance. The following is a guide to base dosing off of following the SOWS scale but patients may end up inducting themselves using an alternative, self-titrating method. The induction method used may vary as the induction period is individualized to patient withdrawal symptoms. The goal is to reduce withdrawal symptoms as much as possible during the induction period If you have any questions, please contact the 24/7 MAT provider hotline at 844-HELP OUD.

- If/when SOWS score is ≥ 11, 4mg-8mg of buprenorphine is administered depending on the level of withdrawal, with education on proper technique for the sublingual use. Err on the higher dose of 8mg especially for those patients who are anxious, uncomfortable, and have had previous failed inductions to reduce risk of precipitated withdrawal. The rationale for this is to ensure that there is enough buprenorphine to provide mu-agonistic effects to reduce the risk of precipitated withdrawal since lower doses may only be enough to displace the opioid of choice, which often leads to precipitated withdrawal. For more information, contact the COEs.

- Patients should wait 12-16 hours for short-acting opioid such as heroin, hydrocodone, oxycodone immediate release, 17-24 hours for intermediate acting opioids such as extended-release oxycodone (i.e. Oxycontin®), or 30-

48 hours for methadone and chronic fentanyl use prior to starting buprenorphine.

  - In practice, however, it is more important to focus on the LEVEL of withdrawal that a patient is experiencing rather than the number of hours since the last dose. The above hours represent the average number of hours that should elapse which is NOT definite for starting buprenorphine.

- If SOWS score is <11, the patient should wait until additional withdrawal symptoms appear. A good rule of thumb is to counsel patients that the withdrawal symptoms should be on the verge of being intolerable prior to starting buprenorphine.

- If the SOWS score worsens and the patient is experiencing precipitated withdrawal with altered mental status, agitation, or psychosis, advise patient or patient's caregiver to have the patient go to the nearest emergency room. Otherwise, the patient should take additional doses of buprenorphine to minimize the signs and symptoms of precipitated withdrawal.

NOTE: It is extremely important to educate patients that the treatment of precipitated withdrawal is with more buprenorphine. Quite often, patients go back to their opioid of choice to relieve the precipitated withdrawal and may be hesitant to try buprenorphine again.

NOTE: It is important to understand that the treatment of choice for precipitated withdrawal is to treat with more buprenorphine, as long as the patient is not experiencing severe withdrawal with elements of psychosis and agitation.

Patient observes his/her symptoms during the rest of the day, and SOWS is reassessed within 2-hour intervals.

- When the patient experiences a SOWS score of at least 8, they should take a second dose of 4mg-8mg buprenorphine every 2 hours as needed.
- The patient should continue to take additional doses of 4mg of buprenorphine to a maximum dose of 16mg-24mg for day 1.
  - There is no absolute maximum dose of buprenorphine, although buprenorphine tends to be not effective beyond doses of 32mg. It may be prudent to induct select patients up to 24mg on the first day. Some patients might even require 32mg on the first day. It is more important that patients are not under-dosed with buprenorphine and to help them avoid

withdrawal symptoms as much as possible. Contact the MAT provider hotline if you have any specific questions regarding induction of your patient.

- If needed, advise the patient they can take the following over-the-counter products for additional withdrawal symptom management if there are no contraindications for the patient:
  - Loperamide 4mg at initial experience of diarrhea, then 2mg as needed for each episode of loose stool or diarrhea thereafter (not to exceed 16 mg/24h);
  - Acetaminophen or ibuprofen for aches and pains
  - Diphenhydramine for insomnia

Explain how to track withdrawal symptoms using the SOWS scale and review the buprenorphine home induction instructions. Ensure that patients can teach-back the information.

NOTE: Most patients will know when they will need another dose of buprenorphine to reduce their withdrawal symptoms.

Review things that patients should not do, such as NOT to swallow buprenorphine (they should take it sublingually). This is because buprenorphine has poor bioavailability if swallowed.

Prescribe medication for induction; Provide enough buprenorphine such that patients can achieve a dose of 16-24mg per day until the next scheduled visit within 3-7 days. Therefore, the initial prescription should be at least 16mg of buprenorphine per day for a week. Steady state may not be achieved until 5-7 days of buprenorphine therapy. The important point is to ensure that the patient has an adequate supply of buprenorphine.

Office-Based Induction (Secondary method of induction)

The following induction protocol details the office-based procedures for assessing for symptoms of opioid withdrawal and starting and maintaining patients on buprenorphine. Office-based induction may be appropriate for patients who have had failed induction attempts in the past particularly with non-adherence to buprenorphine and those who may need an alternative induction requiring higher doses of buprenorphine, among other reasons. However, home induction may still be appropriate for the above reasons so individualizing the need for office-based induction from a patient-centered approach is important.

1. Assessment: Patients already will have been assessed for treatment appropriateness, including confirmation of diagnosis of moderate-to-severe OUD and other clinical criteria (as described above).

- Assess the level of opioid withdrawal that patients are experiencing. Use the COWS to score the patient's opioid withdrawal as mild, moderate, or severe.
- Patients should exhibit signs of at least mild withdrawal (COWS ≥ 8) prior to receiving their first dose of buprenorphine.
- If patients appear intoxicated or exhibits no signs of withdrawal, then they should not be started on buprenorphine at this visit. They should be rescheduled for a later date or time and counseled regarding the need to present when they are experiencing at least mild opioid withdrawal. An exception may be made for patients who have gone through medically supervised withdrawal management (e.g. inpatient withdrawal management program) or non-medical detoxification (e.g. jail) and now present opioid-free and with drug craving.
- In addition to assessing signs and symptoms of opioid withdrawal, also assess for possible substance intoxication, including but not limited to alcohol odor, nystagmus, patient disinhibition, or other altered mental status.
- Urine will be collected on the first day of initiation and sent to the lab for routine toxicology or tested in the clinic using a point-of-care test kit. Urine drug testing can be done frequently if needed (e.g., weekly) during stabilization period.

2. Follow the initial buprenorphine dose instructions as listed under buprenorphine home induction, except utilize the COWS score (rather than SOWS), to determine the appropriate time to begin.

3. Re-evaluate the patient after 30-60 minutes.
If there is no change in symptoms (no worsening), or symptoms are somewhat improved, an additional dose of buprenorphine 4-8 mg SL may be given. Reassess the patient again in 30-60 minutes for symptom relief. This process of providing an additional dose and reassessment may occur again, or the patient may be counseled to take two additional 4 mg doses at home should withdrawal or-marked craving recur in the evening. The total amount of buprenorphine that is typically provided on the first day of dosing is up to 16mg-24mg.

A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates precipitated withdrawal. Discuss with patient and review time of last opioid use. Give additional 4-8mg of buprenorphine hourly until symptoms resolve (higher doses for greater symptoms of withdrawal). As an adjunct AFTER administering the 2nd dose of buprenorphine, may give other medications for symptom management (clonidine, loperamide, acetaminophen or NSAIDS) and instruct to return the following day for re-evaluation.

4. Patients should return to clinic in the next 1-2 days for re-evaluation and upward dose titration.

Some patients who are well-engaged in care or have prior experience with this medication can be given a week's worth of medication on the day of induction and are able to be re-evaluated over the telephone during the first week of induction.

NOTE: Titrating up too slowly may needlessly prolong withdrawal - either of these situations may result in patient relapse or other treatment non-adherence. Therefore, alternative methods to rapidly induct patients on buprenorphine are available. These methods are not evidence-based as of this writing and must be individualized to the patient. Should you require assistance, please contact the COE.

Typical doses during the induction are as follows:

- First 24 hours: Typically, 16 mg total; usually should not exceed 24mg.
- Days 2-3: if symptoms of opioid withdrawal continue, increase daily dose by 4-8 mg depending on severity of opioid withdrawal (e.g., add 2 mg for mild withdrawal or 4mg for moderate-severe withdrawal). Typical dose is 16-24mg, some patients may require up to 32mg.

Stabilization Encounters After Initiating Buprenorphine

Stabilization encounters are suggested but not required after initiating buprenorphine. These may be done to follow-up on buprenorphine induction prior to the next prescriber visit. The patient navigator can conduct these encounters and notify the provider of any concerns related to signs and symptoms of withdrawal or cravings. Your practice should do what works for you and your patients.

Follow-up with the patient to identify what buprenorphine dose the patient is taking and whether the patient is still experiencing any patient-reported signs and symptoms of withdrawal or cravings. Patients may be monitored either daily (for unstable patients) or once or twice weekly (stable patients) by the navigator, and these encounters may occur over the phone. Typically, the next prescriber visit should occur within 2 weeks to ensure that the patient has an adequate supply of buprenorphine available. Thus, the stabilization encounters may occur over 2 visits for stable patients, typically around day 3-7 and again around day 10-14 (see visit schedule below).

Criteria for Dose Increases

- Significant opioid craving (especially towards end of dosing period)
- Significant opioid withdrawal symptoms (especially towards end of dosing period)
- Urine toxicology persistently positive for opioids

Target Dose is the dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms and cravings. The median expected dose is 16 mg daily, although higher doses such as 24 mg may be required. Very few patients will find 8mg daily sufficient as this dose is generally suboptimal. The total daily dose of buprenorphine is generally 16 mg or more to be effective.

Most patients reach their target dose within the first two weeks of treatment. Review with patients that diversion or misuse of buprenorphine may result in closer monitoring to ensure appropriate therapy with buprenorphine. Make sure that patients have an adequate supply of medication until their next visit.

Maintenance Visits

When a stable buprenorphine dose is achieved, patients enter the maintenance phase of treatment. Some patients may reach their target dose and progress to the maintenance stage of treatment within 2 weeks while others may take much longer, which may be influenced by the patient's treatment goals. If patients relapse or destabilize, they should return to more frequent monitoring.

Frequency of visits after induction

Generally, patients can be seen on a monthly basis if they are stable:

- Taking medication as directed, (e.g., no requests for early refills, lost/stolen prescriptions, adequate buprenorphine and norbuprenorphine levels present in UDS)
- No unexpected illicit substance use by patient report or UDS.

NOTE: Patients may report use of other illicit substances or continued opioid use that may indicate a need to increase frequency of visits, NOT to stop treatment. Ensuring that a treatment plan is made to address the other SUD would be important in these cases.

- No use of sedative hypnotic drugs (e.g., benzodiazepines) unless prescribed or heavy alcohol
- No unexplained or otherwise concerning findings on query of the PDMP
- Cravings under reasonable control

If the UDS shows the presence of illicit substances including the use of sedative hypnotic drugs, increase the frequency of visits to follow-up on the patient's goal of therapy. Help patients understand that relapse is part of the recovery process but continued use of illicit substances justifies closer monitoring of therapy. Consider false-positives on UDS and send confirmatory drug screenings, if applicable.

Stable patients can transition to visits every 4 weeks. Patients being seen every 4 weeks who do not meet the above criteria, or adhere to the treatment agreement, should be seen more frequently with at most a 2-week interval. After at least 6 months of stability, the interval can be lengthened to every 12 weeks supplemented by occasional random urine testing. The minimum schedule for stable patients should be to see the prescribing practitioner at least every 3 months.

Use of Extended-Release Buprenorphine Subcutaneous Injection (Sublocade®)

Background

Extended-release buprenorphine injection (Sublocade®) is a once-monthly subcutaneous injection for patients with moderate-to-severe OUD. Sublocade® is equivalent to approximately 16-24 mg/day of sublingual buprenorphine. Patients should be treated with a transmucosal formulation of buprenorphine for at least 7 days and on stable doses of buprenorphine 8-24mg/day before starting Sublocade®. Sublocade® may be a good option for patients in whom adherence or diversion is a concern. Use of Sublocade® can also help with patient concerns such as having their prescription bottles stolen or needing to store their medication safely away from children.

NOTE: There is new literature suggesting that patients can be started on extended-release buprenorphine without being stable on a transmucosal formulation of buprenorphine for at least 7 days. For more information, please contact the MAT Hotline Provider line at 844-HELP OUD or contact your Center of Excellence (coe@njms.rutgers.edu or southernnjcoe@rowan.edu.)

Dosing

Patients should be able to tolerate 8-24 mg of transmucosal buprenorphine before starting Sublocade®. This is to ensure sufficient opioid tolerance to avoid adverse events such as excessive sedation or nausea with Sublocade®. The recommended dose of Sublocade® is 300 mg monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly. Some patients may require sublingual buprenorphine during initiation of Sublocade®. The maintenance dose may be increased to 300 mg monthly for patients who continue to experience withdrawal and/or craving symptoms or continue to use opioids on the 100 mg maintenance dose. A patient who misses a dose

should receive the next dose as soon as possible. The minimum number of days between doses is 26 days. Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect. If Sublocade® is discontinued, plasma levels decrease slowly over time and may be detectable for 12 months or longer. Therefore, patients should be monitored for several months for signs of opioid withdrawal after stopping treatment.

Administration

Sublocade® is injected subcutaneously into the abdomen by a healthcare provider. The injection site should have adequate subcutaneous tissue free of nodules or lesions and the area should not be irritated, reddened, bruised, infected, or scarred in any way. The medication should be at room temperature for 15-30 minutes prior to injection to increase patient comfort. Patients should be educated that they will have a lump present for several weeks that will decrease in size over time.

Providers can obtain Sublocade® for their patients in two ways: (1) Through a certified specialty pharmacy that directly delivers the medication to the office or clinic for administration to the patient, or (2) Order directly from a distributor (healthcare setting must first become certified in the Sublocade® REMS Program). It is important to note that different plans contract with different specialty pharmacies to process Sublocade® orders. There are many steps for getting Sublocade® to the office for administration to the patient, including submission of the prescription and patient information to the specialty pharmacy, processing of the prescription by the pharmacy, and obtaining verbal authorization from patients to ship Sublocade® to the office. Obtaining consent may prove challenging for some patients who are difficult to reach or do not have access to a telephone. In these instances, staff may call the specialty pharmacy while patients are in the office for their visit. It is important to establish a clinic process and designated team member(s) to facilitate processing of new Sublocade® orders and refills and troubleshoot issues so that minimal delays between injections occur. If you have any questions about the use or procurement of Sublocade® for your patients, please contact your COE via email or call the hotline.

Monitoring for Adherence and Misuse

Routine monitoring should include frequent office visits (weekly in early treatment), UDS, and the state PDMP. Monitoring may include pill/film count or observed ingestion, especially those in which there is evidence of non-adherence to buprenorphine. Urine toxicology should be able to detect buprenorphine in addition to drugs of concern and be collected in a manner that ensures it is unadulterated and belongs to the patient. **Emphasize that the collection of UDS is not meant to be punitive but instead used as a measure to monitor safety and efficacy of treatment.**

Frequency of testing should be guided by the stability of the patient. The practitioner can have the patient bring his or her medication container to each appointment to show

that the medication is being taken as directed. Observed ingestion (having the patient take the medication in front of the practitioner or a trained monitor) **at the beginning of buprenorphine therapy** can help the practitioner ensure that the patient knows how to take the medication. Later in therapy, observing ingestion periodically can help patients adhere to therapy. Providers, however, should not use observed ingestion with a punitive intent as the goal is to reduce/eliminate stigma. PDMPs help physicians monitor whether patients are obtaining the prescribed medication, obtaining prescriptions for controlled substances from other prescribers, or refilling prescriptions early.

NOTE: It is important for providers to become familiar with the UDS available in their health care systems. It is ideal to include buprenorphine testing in the UDS, along with opiates, oxycodone, and methadone. Other substances included in the UDS (cannabinoids, methamphetamines, benzodiazepines, cocaine, etc.) may depend on particular labs and local patterns of substance use.

Practitioners need to continually acknowledge and reinforce a patient's adherence to treatment, reduction of illicit drug use, and positive life changes. Practitioners may also respond to progress by reducing the frequency of office visits and/or increasing the patient's responsibility for his or her medication.

Preventing misuse of buprenorphine

The great majority of patients misusing buprenorphine are self-medicating to manage cravings and withdrawal symptoms when they do not have access to opioids. Further, while misuse of buprenorphine is serious, the risks associated with this are much lower than those of heroin and other opioids.

Buprenorphine can be misused by patients in many ways, as follows: selling prescribed medication, stockpiling medication for use later or in a higher dose to treat cravings, insufflating (snorting), injecting, or rectal use (plugging) of medication intended for sublingual use. Often though, as evidenced in the literature, most patients are not abusing buprenorphine but using it sublingually.to self-treat withdrawal. Other signs of misuse include inadequately storing buprenorphine (e.g., open medicine cabinet, carried in purse, left in glove compartment, on desk, etc.), losing pills, or failing to ensure safekeeping of pills from children/others, doctor shopping, with multiple prescribers, or forged prescriptions, and supplementing legitimate prescriptions with street drugs.

Clinic staff should be aware of the warning signs of inappropriate use of buprenorphine, which are as follows. Address these concerns with patients using motivational interviewing.

- Unexpected toxicology screens
- Requests for early refills
- Sudden request for dose increases in a previously stabilized patient
- Lost prescriptions, multiple prescribers, and prescription forgery
- Close acquaintances (e.g., significant others, spouse, friends) with opioid dependence who are not in treatment

Treatment Duration

There is no ideal duration of buprenorphine treatment. It may take a few years for the brain to recover from opioid use disorder. Therefore, treatment may last years or for a lifetime due to the risk of relapse. Because OUD is a chronic illness without a cure, long-term management is generally warranted. Depending on patients' specific situations, long-term management may or may not involve opioid agonist medication. However, studies consistently demonstrate that longer duration of opioid agonist treatment is associated with better outcomes.

In deciding whether to taper and discontinue buprenorphine, consider that the optimal situation for this is when the patient is socially stable, has developed supportive relationships with persons not using drugs, has discovered alternative ways of dealing with the precipitants to drug use, and is confident and motivated to taper off opioid agonist therapy. For most patients, tapering and discontinuing buprenorphine leads to a heightened risk of relapse.

Buprenorphine-maintained patients who are clinically stable and who want to discontinue treatment should be tapered slowly (e.g., decrease their buprenorphine dose by 10-25% each month). Slow tapers have been shown to be more successful than rapid tapers. The pace of a voluntary taper should be determined by the patient and could be halted or reversed at the patient's request.

Terminating Treatment and Transferring Care

Serious infractions that place the patient or others at risk can result in a patient's discharge from the clinic. These may include: an act or threat of violence against a patient or clinic staff; possession of weapons; violations of the program or clinic policies and regulations; harassment of other patients or staff on the basis of gender, ethnicity, or sexual orientation; stealing or other illegal acts on the clinic grounds; duplicate treatment in opioid agonist treatment programs (e.g., receiving methadone and buprenorphine); and tampering with urine toxicology samples. If safe and appropriate,

providing a small supply of medication to their new treatment facility may be considered. Note that continued use of opioids while on buprenorphine is NOT a serious infraction and should NEVER warrant cessation of medications for opioid use disorder as continued use is a part of the chronic, relapsing nature of addiction. Closer follow-up and understanding the patient's goal of therapy is warranted. Ensure that harm reduction strategies are implemented, which include the prescribing of naloxone for all patients, clean syringes for those use inject drugs, fentanyl test strips, and referrals to the closest harm reduction center.

Information on the harm reduction centers, which are community-based programs that provide a safe and welcome space for people who use drugs to access sterile syringes, needles, injection equipment, life-saving drug naloxone, along with education on safer use, overdose prevention, and safe disposal of used equipment.

Lack of significant improvement or worsening clinical course may be due to progression of the illness, additional physical or psychological stressors, inadequate or inappropriate treatment, or noncompliance with treatment. The treatment team should work closely with patients during these times to help identify contributing factors and strategies to overcome them. The frequency of monitoring and counseling should be increased or the patient should be referred to a higher level of care.

Transfer to a higher level of SUD services (e.g., outside providers for intensive case management, partial care, or residential treatment) should be considered and offered. Transfer from office-based buprenorphine to more structured methadone treatment is an option.

Patients on Buprenorphine Who Become Pregnant

Remaining on pharmacotherapy is the recommended standard of care and best option for a pregnant woman with OUD. This will help the patient avoid a return to substance use, which has the potential for overdose or death. A decision to withdraw from pharmacotherapy is not recommended and should be made with great care on a case-by-case basis as there are risks associated with neonatal abstinence syndrome. Opioid withdrawal also puts patients at risk for premature delivery.

No consensus exists on whether a woman on buprenorphine/naloxone for OUD who states the intention to become pregnant or is in the early stages of pregnancy should be switched from the combination buprenorphine/naloxone product to the buprenorphine-only product. Experts do agree that any change from buprenorphine/naloxone to the buprenorphine-only product or a decision to continue on a buprenorphine/naloxone product during pregnancy should be made only when informed by the patient's specific needs and concerns. In either case, the patient's fully informed consent should be obtained after review of the risks and benefits of the course of treatment selected. There is insufficient information about the safety of XR-naltrexone during pregnancy. There is

a lack of agreement on whether women on naltrexone should continue it during pregnancy, but one should consider benefits vs. risks, especially those doing well and stable on naltrexone. Women stable on naltrexone prior to pregnancy may be offered treatment with buprenorphine or methadone; however, this transition must be done carefully as patients on long-term antagonist therapy are no longer opioid tolerant.


For details, see SAMHSA Guidelines

Patients on Buprenorphine Who Require Treatment for Pain

Since buprenorphine has excellent analgesic properties, acute pain can be managed by temporarily increasing the total dose of buprenorphine and scheduling in divided doses.

If non-narcotic medications (e.g., acetaminophen and NSAIDs) do not reduce pain, temporarily increasing the buprenorphine dose and dividing the dosing may be effective for mild-moderate acute pain.

Because buprenorphine has a higher affinity for opioid receptors than most opioids, pain control with other mu agonists requires careful attention and titration. The decision to use another opioid for pain should only be made in consultation with a pain specialist.


Recent guidelines recommend that for most (if not all) patients, buprenorphine should be continued at the pre-operative dose during the perioperative period. Only in cases where patients are predicted to have high opioid requirements post-operatively should buprenorphine be dose reduced, and usually only to 16mg. If in the rare situation should buprenorphine be discontinued (which should only be done only in consultation with pain management/anesthesia), this should occur 24-36 hours in advance of surgery (substituting 15 mg BID of sustained release morphine) and re-induction restarted postoperatively when the need for full opioid agonist analgesia has passed.

Treatment Initiation and Stabilization of XR-Naltrexone

General Information for Initiation

XR-naltrexone, unlike buprenorphine, is an opioid antagonist. It works by blocking the effects of opioids on the opioid receptors due to its high affinity and thus, can restore endogenous levels of opioids. Due to its high affinity for the opioid receptor, it also has the risk of precipitating opioid withdrawal. Precipitated withdrawal that occurs after extended-release naltrexone intramuscular administration can be life-threatening and may cause severe hemodynamic instability and agitated delirium. It is important that an opioid antagonist challenge be conducted and that patients should be opioid-free for at least 7 days (longer if on a long-acting opioid) prior to initiating naltrexone ER.

Initiation

If a patient is deemed to be an appropriate for XR-naltrexone and the patient is willing to take XR-naltrexone, it is important to first conduct an initial assessment as you would do in the patient history and initial mediation evaluation. Getting a history of the drug use (type, amount route) and treatment history (medications, response, adherence) are important. The initial readiness assessment should include the following:

- Vital signs
- Urine toxicology (screen for all opioids including buprenorphine, oxycodone, and methadone)
- Recent opioid use history
- Pregnancy test
- Assess for contraindications (see above section regarding exclusion criteria for XR-naltrexone)

If the patient has not used any opioids within the past 10-14 days, and there is good evidence of opioid abstinence in the past 2 weeks, no withdrawal symptoms, and opioid-negative toxicology, then the patient can receive their first XR-naltrexone dose.

If the patient has used an opioid within the past 14 days, but not in the past 7 days, evaluate initiation of XR-naltrexone with the COWS scale. If COWS>4, treat withdrawal with adjunctive medication and revaluate in 1-2 days. If the COWS scale is 4 or less and opioid-negative toxicology, perform an intramuscular naloxone challenge or use 25mg naltrexone orally x1 to determine risk for precipitated withdrawal. Monitor the patient for 90 minutes and if the COWS scale increase is less than 2, proceed with XR-naltrexone

injection. If the challenge is positive, treat the withdrawal using adjunctive medications and re-evaluate on another day.

If a patient has used within the past 7 days, the patient likely is still physically dependent on opioids even with opioid-negative toxicology. Treat the patients' withdrawal with adjunctive medication (see adjunctive medication section) and postpone evaluation until at least 7 days of no opioid use. In case of daily opioid use, recommend cessation and conduct buprenorphine-assisted withdrawal management.

For more information, refer to this guide from PCSS, which provides a step-by-step protocol to initiating XR-naltrexone.

Maintenance

Patients should receive XR-naltrexone once every 4 weeks. It is administered into the upper outer quadrant of the gluteal area intramuscularly. Patients must ensure adherence to XR-naltrexone since XR-naltrexone is an antagonist of the opioid mu-receptor and will therefore lower tolerance to opioids. Given the growth of highly potent synthetic opioids such as fentanyl, one may be at much higher risk of overdose if XR-naltrexone is not administered timely within a month. There are also reports that its efficacy may wane even after 3 weeks after the injection. Therefore, some may need an injection sooner than once a month, depending on the patient's risk for overdose. In any case, the importance of adherence is critical while on XR-naltrexone to reduce the risk of overdose death.

Treatment Duration

Similar to buprenorphine treatment, there is no ideal duration of treatment. The pivotal study for XR-naltrexone followed patients on average for a duration of 24 weeks. Generally, it takes at least two years for the brain to recover from opioid use disorder. Therefore, treatment may last years or for a lifetime due to the risk of relapse. Because OUD is a chronic illness without a cure, long-term management is generally warranted. Depending on patients' specific situations, long-term management may or may not be medication-assisted treatment. However, studies consistently demonstrate that longer duration of treatment is associated with better outcomes.

NOTE: Patients who discontinue medications for opioid use disorder, especially those who have not relapsed while on XR-naltrexone, and resume opioid use should be warned about the increased risk of death from opioid overdose due to lowered tolerance.

Switching Between Different Forms of MAT

Switching from buprenorphine to naltrexone

In general, when switching from buprenorphine to naltrexone, at least 10-14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure the patient is not physically dependent on opioids before starting naltrexone.

For patients who have been stable on buprenorphine and are requesting to be tapered off of buprenorphine OR would like to switch to naltrexone, a slow taper of buprenorphine is generally required over a period of 3-6 months. Patients should be warned regarding the risk of relapse associated with lower total daily doses of buprenorphine as more mu-opioid receptors become available for other opioids. If the patient is successful with tapering off buprenorphine and is NOT experiencing any withdrawal during this process, the patient should then be off of all opioids for a period of 10-14 days before starting naltrexone (XR-naltrexone is recommended). Again, the patient should be counseled on the risk of relapse during this time, and high risk of overdose due to desensitization of the mu-opioid receptors. If the patient is successful, the patient can then be started on XR-naltrexone. For more information, contact your COE or call the MAT hotline for further assistance.

Switching from naltrexone to buprenorphine

Switching from an antagonist (naltrexone) to a partial agonist (buprenorphine) is generally less complicated because there is no physical dependence with antagonist treatment and no possibility of precipitated withdrawal. Patients may be switched when a significant amount of naltrexone is out of their system (about 1 day for oral naltrexone and 30 days for XR-naltrexone).

Switching from methadone to buprenorphine

Some patients who are on methadone may prefer to be on buprenorphine for a variety of reasons, as buprenorphine is available in pharmacies. Some may prefer buprenorphine as it may provide the patient more control of their dosing, while others may prefer the switch due to side-effects. For others, there may be a medical need for switching due to drug interactions and other clinical situations. Generally, methadone should be titrated down to a dose of 30-60mg at a rate not faster than 10% per week. Patients who may need a faster titration off of methadone may need to be hospitalized to facilitate this switch to

buprenorphine. Thus, a slow titration is generally recommended. After achieving a dose of 30-60mg (with the lower, the better) AND without uncomfortable withdrawal symptoms, patients are then stopped altogether for at least 48-72 hours. During this period, patients may be provided adjunctive withdrawal medications (see the section of “Preparing the Patient for MAT Treatment”). Use the appropriate withdrawal scale as described in the buprenorphine induction section to start patients on buprenorphine. There are various methods to induct with buprenorphine in patients who have been on methadone, as methadone is a long-acting opioid. Traditional modes of induction as described previously in this document may lead to increased risk of precipitated withdrawal. Therefore, methods including microdosing and high-dose buprenorphine are available in the literature beyond the scope of this manual. For more information on these, contact your COE for further information.

Miscellaneous (Treating OUD with Telehealth)

Given the relaxed telehealth regulations on the prescribing of controlled substances during the COVID-19 pandemic, telehealth encounters have been used for initial and follow-up. Both the Drug Enforcement Agency (DEA) and SAMHSA regulate the practice of telehealth but the DEA promulgates telehealth regulations under the Ryan Haight Act as it pertains to using buprenorphine via telemedicine. This act states that practitioners must have conducted at least one in-person medical evaluation of the patient before providing controlled substances to patients with several exceptions, one of which exempted this requirement because of the COVID-19 pandemic.

See this valuable resource on Extending Pandemic Flexibilities For Opioid Use Disorder Treatment: Telemedicine and Initiating Buprenorphine Treatment from the George Washington University Regulatory Studies Center.

Since overdose deaths have skyrocketed during the COVID-19 pandemic, with over 93,000 overdose deaths in 2020, it is apparent that further access to medications for opioid use disorder is needed. SAMHSA encourages the use of telehealth for buprenorphine and opioid use disorder treatment and specifically for the pandemic, has permitted the use of audio-only technology for telehealth consultations.

These relaxed regulations may change after the end of the COVID-19 pandemic so please be sure to follow the latest information on both the DEA COVID-19 and SAMHSA COVID-19 websites.

it's the COE's position that technologies like telehealth (I prefer telemedicine), may provide improved MOUD access to our rural and difficult to reach communities (and it's our position it should remain after COVID.) The NJ MAT Centers of Excellence support the use of telehealth for the treatment of OUD during the COVID-19 pandemic, especially for patients who are at high-risk for contracting COVID-19. Continue to use best practices as you would for an in-person visit. Should you have any questions about documenting for a telehealth appointment, please contact your respective NJ MAT Center of Excellence or contact our 24/7 hotline provider number.

Miscellaneous (Outpatient Tx of Alcohol Use Disorder)

Alcohol use disorder is associated with significant morbidity and mortality. It also associated with poorer treatment outcomes in those who have active opioid misuse. There are three FDA-approved medications recommended for relapse prevention in those with moderate-severe alcohol use disorder, which include naltrexone, acamprosate, and disulfiram. These medications, compared to medications for opioid use disorder, have NOT been shown to reduce mortality but only to reduce heavy drinking or support abstinence from drinking. Both naltrexone and acamprosate are considered the first-line options for alcohol relapse prevention.

Naltrexone is best used to reduce drinking, especially relapse to heavy drinking. Patients who have co-occurring opioid and alcohol use disorders may be candidates for the use of the injectable XR-naltrexone but they must be opioid-free for at least 7-10 days (past the acute opioid withdrawal phase) and must be adherent to their monthly injection. This is because patients on naltrexone have lower opioid tolerance, which subjects them to a higher risk of overdose. In addition, data has not shown that naltrexone reduces mortality in opioid use disorder compared to those on buprenorphine or methadone. Therefore, treatment with XR-naltrexone in patients with both opioid and alcohol use disorders should be for patients who are highly motivated, likely to be adherent, and with low risk for relapse/recurrence for opioid use disorder. Oral naltrexone should not be used for treatment in those with opioid use disorder.

Disulfiram is only used to support complete alcohol abstinence. Potential serious adverse events of disulfiram include acute cardiovascular disease, liver toxicity, and psychosis. This does not include the nausea, vomiting, and diarrhea that occurs when patients drink alcohol while taking disulfiram. This leaves acamprosate as the main option for those who have co-occurring opioid and alcohol use disorders on opioid agonist therapy such as buprenorphine or methadone. Acamprosate, however, is best for promoting initial abstinence and is therefore more effective in those who have a period of abstinence than in those who are actively drinking. It is also taken three times a day and requires dosage adjustment for renal impairment.

Evidence-based psychosocial interventions, such as cognitive behavioral therapy, should be provided in all patients with alcohol use disorder. Medications are recommended and should be offered in combination with psychosocial interventions in those with moderate-severe alcohol use disorder. Medications should NOT be withheld from patients who decline psychosocial interventions. For more information on managing alcohol use disorder, please contact the Centers of Excellence or call the 24/7 hotline for "in-the-moment" clinical questions.

For additional information, please also refer to the American Psychiatric Association's alcohol use disorder treatment guidelines and SAMHSA's guide for using medications for the treatment of alcohol use disorder.

NOTE: In patients with concurrent, active opioid and moderate-severe alcohol use disorders not already on treatment for either disease, initiating evidence-based medications for opioid use disorder should be the priority given their mortality reducing benefits and the correlation between opioid misuse and heavier and/or frequent drinking.

APPENDICES

Resources

NJCARES
Real-time dashboard of N.J. opioid-related data (e.g., overdoses, naloxone administrations, and opioid prescriptions).

https://www.njoag.gov/programs/nj-cares/

Medication Assisted Treatment Resources for Practitioners

The American Society of Addiction Medicine (ASAM) National Practice Guideline: For the Use of Medications in the Treatment of Addiction Involving Opioid Use
https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline

The American Psychiatric Association's Practice Guideline for The Pharmacological Treatment of Patients with Alcohol Use Disorder:
https://psychiatryonline.org/doi/book/10.1176/appi.books.9781615371969

SAMHSA's Treatment Guide: Medication for the Treatment of Alcohol Use Disorder:
https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4907.pdf

Providers Clinical Support System (PCSS-MAT) – Medication Assisted Treatment
Provides evidenced based training and resource materials and videos on MAT and related issues.
https://pcssnow.org/

Clinical Guidance for Treating Pregnant Women and Parents with Opioid Use Disorder and Their Infants (SAMHSA)
https://store.samhsa.gov/product/Clinical-Guidance-for-Treating-Pregnant-and-Parenting-Women-With-Opioid-Use-Disorder-and-Their-Infants/SMA18-5054

Medications for Opioid Use Disorder For Healthcare Providers and Addiction Professionals, Policymakers, Patients, and Families (SAMHSA TIP 63)
https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Executive-Summary/PEP20-02-01-005

Medicaid Billing Information for Providers:
Provider Enrollment 609-588-6036

Provider Services Call Center:
1-800-776-6334
www.njmmis.com

The state released this newsletter to detail changes made to the OBAT program. In particular, the newsletter delineates requirements for who qualifies as a navigator.

Consumer and Family Resources on Substance Use Treatment Services

Opioid Addiction Treatment: a guide for Patients, Families and Friends:
Brochure and other patient resources from ASAM.
https://www.asam.org/resources/patient-resources

Parent-to-Parent Coalition:
Offers support and other services to families struggling with addiction.
http://parent2parentnj.org/index.php

NJ Connect For Recovery:
Substance Use Treatment counselors and peer recovery specialists answer callers' questions about substance use disorder treatment and support services)
https://www.njconnectforrecovery.org/

Naloxone and Overdose Prevention

Substance Abuse and Mental Health Services Administration (SAMHSA) Opioid Overdose Toolkit: Provides detailed information for first responders, treatment providers, and those recovering from substance use about emergency response and naloxone use.

Also has information for communities and local governments about policy development around these issues (toolkit available as free download).
https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742

Prescribe to Prevent:
Tools for overdose prevention, including patient videos.
https://prescribetoprevent.org/

DMHAS website:
Information about how individuals can obtain free naloxone kits and training (updated on a monthly basis).
http://www.state.nj.us/humanservices/dmhas/initiatives/naloxone.html

Harm Reduction Resources:

We Keep Us Safe: How to Prevent and Respond to an Overdose (For Patients)

Quick Tips: Harm Reduction

Harm Reduction Template

NJ Dept. of Health: Harm Reduction Centers

National Harm Reduction Coalition

A Harm Reduction Approach to Patients Who Use Drugs by Jonathan Giftos, MD

Smoking Cessation Resources

NJ Quitline:
Online smoking cessation counseling and resources
(866) NJSTOPS / (866) 657-8677

Consumer and Family Resources on Mental Health Services

NJ MentalHealthCares:
Behavioral care specialists provide information to callers and connect them to the behavioral health and services they need, such as: legal, housing, employment, rehabilitation, inpatient and outpatient, self-help and more. Also provides supportive counseling, psycho-education, advocacy and telephone case management to ensure every caller is linked to their desired service.

1-866-202-HELP (4357) (TTY 1-877-294-4356) — for free, confidential mental health information and referral.

https://www.njmentalhealthcares.org/about-us/

NJ Division of Mental Health and Addiction Services (DMHAS) Website:
Directories of mental health and addictions programs by county and by service type

Mental Health Services Directory
Substance Abuse Treatment Services Directory

Suicide Prevention - NJ HOPELINE:
24-hour telephonic suicide prevention hotline. Also offers web-based anonymous and confidential Live Chat support services.

855-NJ-HOPELINE or (855) 654-6735

https://njhopeline.com/talk-to-us-by-chat/

Integrated Family Supports Services (IFSS):
Available free and offered statewide to families of individuals with mental illness, IFSS provides a range of supportive activities that include advocacy and education, multi-family groups educational conferences, referral, and linkage services

https://www.naminj.org/support/professional/ifss/

NJ National Alliance on Mental Illness- New Jersey (NAMI NJ):
Provides education, support, and systems advocacy to empower families and persons with mental illness

http://www.naminj.org/

BUPRENORPHINE TREATMENT AGREEMENT

Patient Agreement

As a participant in buprenorphine treatment for opioid use disorder, I freely and voluntarily agree to accept this treatment agreement, as follows:

- ✓ I understand that the goal of treatment is reduce drug use with the ultimate goal of abstinence from all use of illicit drugs. I agree to notify the clinic immediately in case of relapse, and to be open and honest about my treatment goals and relapses during appointments. ____ (initial)

- ✓ I understand that medication alone may not be adequate treatment for my disease. I may be recommended to participate in patient education, substance use disorder counseling and relapse prevention programs, including acceptance of referral to more intensive levels of care, if needed. I understand that I will not be forced to participate but will make every attempt to do so, if recommended to, as I will be invested in reaching my goals of treatment. ____ (initial)

- ✓ If indicated, I also agree with a plan for treating co-occurring medical or psychiatric conditions, as well as other substance use disorders, including tobacco. ____(initial)

- ✓ I agree to keep, and be on time to, all my scheduled appointments, to not arrive at the clinic intoxicated or under the influence of drugs, and to conduct myself in a courteous manner in the clinic. It is my responsibility to call the clinic if I will be late or need to reschedule my appointment. ____ (initial)

- ✓ I agree to take my medication as instructed. I agree not to sell, share or to give any of my medication to another person. I understand that such mishandling of my medication is a crime and a serious violation of this agreement. ____ (initial)

- ✓ I agree that my prescriptions can be given to me at my appointments, and during conditions when appropriate at the discretion of my provider. Missed appointments may result in my not being able to get medication until the next scheduled visit. ____ (initial)

- ✓ I agree that it is my responsibility to keep my medication in a safe and secure place that is out of the reach of children at all times. Lost or stolen medication will be replaced at the discretion of my clinician. My medication should be kept in a container that displays the prescription label. ____ (initial)

- ✓ I agree not to obtain medications from any physicians or other sources without informing my treating team and first discussing it with my primary physician. I recognize that use of buprenorphine with benzodiazepines (e.g., Valium/diazepam, Librium/ chlordiazepoxide, Ativan/lorazepam, Xanax/alprazolam, etc.) may be dangerous if not prescribed by a doctor. ____ (initial)

- ✓ I agree to sign a consent for release of information to allow my primary care team to exchange information with my outside counselor, treatment program, or probation/parole officer. ___ (initial)

- ✓ The treatment team will periodically access the State Prescription Drug Monitoring Program (PDMP) to ensure I am taking my buprenorphine as directed, and ensure its safe use with other controlled substances that I may be taking. ____ (initial)

- ✓ If I am female of child bearing age and become pregnant while on buprenorphine/naloxone I will immediately alert my health provider so they can assist me in the proper steps to keep me and my unborn baby safe. ____ (initial)

- ✓ I agree to allow my primary care team to discuss the amount and timing of medication dispensed with the pharmacy (pharmacy name): _____ ____(initial)

- ✓ Failure to comply with the above may result in intensification of monitoring and treatment or discharge from the clinic, depending on the severity or frequency of the issue.

- ✓ The procedures to treat my condition have been explained to me. I understand that it will involve my taking the prescribed buprenorphine on the schedule determined by the prescriber.

My goals for treatment are as follows:

_____

_____

_____

_____

_____ _____

Patient's Printed Name Date Patient's Signature Date

_____ _____

Prescriber's Printed Name Date Prescriber's Signature Date

Buprenorphine Home Induction Instructions for Patients

Buprenorphine works to reduce withdrawal symptoms and craving, while lessening the effect (high) of using another opioid drug. Since it is not as strong as other opioids, buprenorphine can cause withdrawal if taken while other opioids are still in your system. Therefore, the first dose should not be taken until you feel significant symptoms of withdrawal: anxiety, restlessness, cramps, nausea, diarrhea, shakes, goosebumps, yawning, sweating, and fast heartbeat. The worse you feel when you begin the medication, the better it will make you feel after a dose.

Buprenorphine is not absorbed well if swallowed, so it is taken sublingually (allowed to dissolve under the tongue).

Dosing Instructions:

Day 1: Take 4-8 mg of buprenorphine as directed by your doctor under the tongue when you feel significant withdrawal. Be sure to let this dissolve completely under your tongue and DO NOT eat or drink anything while it is dissolving.

1. Wait at least 1 hour. If you still have symptoms of withdrawal you can repeat this dose, but don't take more if you're feeling ok.
2. If withdrawal symptoms are still present after waiting another hour, or if symptoms return later- take another dose. Repeat as needed up to a maximum of 24 mg on day 1.

Day 2: Take the total number of mg used over the first day and divide the dose in 2 when you wake in the morning. If, after an hour or more, you feel withdrawal, take another 4mg every 2 hours as needed to a maximum total dose for day 2 is 24 mg.

Day 3: Take the total number of mg used over day 2 and divide the dose in 2 when you wake in the morning. If, after an hour or more, you feel withdrawal and your morning dose was under 16mg, take an additional 4mg dose every 2 hours as needed to a maximum total dose for day 3 is 24 mg.

Day 4 and beyond: Take the total mg from day 3 and divide the dose in 2 or 3.

Caution: If you have bad withdrawal symptoms in spite of taking buprenorphine as directed above, contact your primary care clinic. You can take acetaminophen or ibuprofen for pain (unless told not to) and loperamide (Imodium) for diarrhea. Clonidine can be prescribed for bad anxiety or jitters.

Avoid taking other opioids or benzodiazepines like alprazolam and clonazepam (sedating medicine) unless they are prescribed and you are monitored closely by a physician.

Avoid drinking alcohol while on buprenorphine.

If you feel sleepy or impaired do not drive or operate a mechanical object or vehicle.

Be sure to store your medication in a safe place where children and others will not have access to it.

Clinical Opiate Withdrawal Scale (COWS)

APPENDIX 1
Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date and Time ____/____/____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	**GI Upset**: *over last 1/2 hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating: *over past 1/2 hour not accounted for by room temperature or patient activity.* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor** *observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness *Observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	**Yawning** *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or Irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

This version may be copied and used clinically.

Journal of Psychoactive Drugs Volume 35 (2), April - June 2003

Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *J Psychoactive Drugs*, 35(2), 253–9.

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: We want to know how you're feeling. In the column below today's date and time, use the scale to write number from 0-4 about how you feel about each symptom right now.

Scale: **0 = not at all** **1 = a little** **2 = moderately** **3 = quite a bit** **4 = extremely**

DATE						
TIME						
SYMPTOM		**SCORE**	**SCORE**	**SCORE**	**SCORE**	**SCORE**
1	I feel anxious					
2	I feel like yawning					
3	I am perspiring					
4	My eyes are tearing					
5	My nose is running					
6	I have goosebumps					
7	I am shaking					
8	I have hot flushes					
9	I have cold flushes					
10	My bones and muscles ache					
11	I feel restless					
12	I feel nauseous					
13	I feel like vomiting					
14	My muscles twitch					
15	I have stomach cramps					
16	I feel like using now					
TOTAL						

Mild Withdrawal = score of 1 – 10
Moderate withdrawal = 11 – 20
Severe withdrawal = 21 – 30

Sample Prescriber Intake Form:

Patient Demographics:	
Patient Name:	
Date of Birth:	
Age:	
MRN:	
Referral Source:	

Chief Complaint:

History of Present Illness
[Patient Name] is a [age] yo *** who is being seen and evaluated for substance use disorder. **HPI:** First Substance(s) used: Age at first substance used: Progression of use: **Current Use:** **(**Substance(s) used/Amount Used/Frequency of Use/Route of Use): Nicotine Use: Complete Substance History: **Alcohol:** Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use : **Cannabinoids (natural/THC/marijuana or synthetic/K2)** Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use : **Opioids (oxycodone, heroin, kratom):** Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use : **Sedatives (Benzodiazepines, barbitruates)** **Hallucinogens (LSD, mushrooms/psilocybin):** Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use :

Club Drugs and Synthetics(GHB, GHB derivatives, MDMA, molly, etc): Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use :
Dissociative: Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use :
Stimulants (cocaine, methamphetamine, khat, cathinones/bath salts, other amphetamines): Never used/ type used/ amount used/ duration of use/ frequency of use/ route of use (intranasal, inhaled, injected, ingested, other)/ current use :

Medical / Legal / Social Problems from Substance Use:

Treatments for Substance Use Engagement in the past: Medication/Rehab/Detox/IOP/etc.

Outcomes from each treatment episode:

Longest amount of sober time achieved for each substance:

History:

Social History:
Living Situation:
Insurance status:
Current Relationships:
Using Friends/Acquaintances/Family Members :
Sober Supports:
Employment Status:
Education:
Transportation Barriers:
Food Stability:

Family History:
Family history of alcohol or substance use disorder:
Family history of mental illness:

Past Medical History:

Psychiatric History
Diagnoses:
Treatment:
Current symptoms:
History of hospitalizations
History of suicide attempts:

Allergies: ***

Current Medications:

Review of Systems:

Physical Exam:	
Vitals:	
Constitutional:	
Eyes:	Pupils:
ENMT:	
Neck:	
Respiratory:	
Cardiovascular:	Murmurs:
Gastrointestinal:	Bowel sounds: distension:
Musculoskeletal:	
Skin:	Injection sites/scars/abscesses/venous sclerosis/ piloerection
Neurologic:	
Psychiatric:	
Lymphatic:	

Results:	
Pertinent Lab Results:	***

New Jersey Prescription Monitoring Program results : ***

Assessment and Plan:
[Patient Name] is a *** yo *** with a PMH of ***, who was seen and evaluated for *** use disorder. Assessment and recommendations are as follows: Patient meets the criteria for *** use disorder with the following in the last 12 months: (DSM 5 Criteria) Plan: *** - Naloxone Spray 4mg, prn overdose, #1 (two-pack), 3 refills

Sample Navigator Intake Form:

EXAMPLE: OBAT Navigator Psychosocial Care Plan

Intake Care Plan

Patient Name		DOB	
Medicaid Plan		ID Number	
PCP		OBAT Navigator	
Date MAT Service Initiated:			
Phase of Medical Care (Initiation, Stabilization, Maintenance)		Weeks in Phase	
Care Plan Last Updated:			

Background:
Connecting Tasks with Vision: What is your patient's motivating goal (s) / vision for their life? (why do they want to be in recovery)
Patient strengths / resources:

Top priorities / barriers the patient wants to work on? (up to three)			
Need	***Next Steps*** *(for navigator and patient depending on patient's ability to self-navigate)*	***Timeframe*** *(if applicable)*	**Notes**
	Navigator: ***Patient:***		
	Navigator: ***Patient:***		
	Navigator: ***Patient:***		
Identified needs to work on later:			
Other Providers, Community Resources, etc. the patient is working with:			

Patient Education

- **Harm Reduction Resources Discussed YES NO**
  (*Depending on SUD dx may involve referrals to local harm reduction centers, syringe exchange programs, training on how to administer Narcan, etc)*

  Notes:

- **Emergency Resources Discussed YES NO**
  (*Who to call/where to go if have a medication issue after hours, crisis hotlines, 211 for emergency housing, etc)*

  Notes:

Date:

Visit Notes:

Subsequent Visit Notes:

Patient Name		DOB	
Medicaid Plan		ID Number	
PCP		OBAT Navigator	
Date MAT Service Initiated:			
Phase of Medical Care (Initiation, Stabilization, Maintenance)		Weeks in Phase	
Care Plan Last Updated:			

Current Need	***Next Steps*** *(for navigator and patient depending on patient's ability to self-navigate)*	***Timeframe*** *(if applicable)*	**Notes**
	Navigator: ***Patient:***		
	Navigator: ***Patient:***		
	Navigator: ***Patient:***		

Date:

Visit Notes:

Any identified needs to work on later?

Completed Goals Tracking

Completed Goals	**Notes**

Clinical References

1. Lintzeris N, Monds LA, Rivas C, et al. Transferring Patients from Methadone to Buprenorphine: The Feasibility and Evaluation of Practice Guidelines. *J Addict Med.* 2018 May-Jun;12(3):234-40.

2. Clinical Opiate Withdrawal Scale. Accessed from: https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf

3. Subjective Opiate Withdrawal Scale. Accessed from: https://www.asam.org/docs/default-source/education-docs/sows_8-28-2017.pdf?sfvrsn=f30540c2_2

4. Sublocade® [package insert]. North Chesterfield, VA: Indivior, Inc. 2019.

5. Vivitrol® [package insert]. Waltham, MA: Alkermes, Inc. 2010.