

OFFICE-BASED OPIOID TREATMENT (OBOT)

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Relevant Diagnoses

- Opioid use disorder

Related Clinical Policies & Guidelines:

- Opioid Treatment Program (maintenance)
- Optum Level of Care Guidelines: Substance-Related Disorders

INSTRUCTIONS FOR USE

This Behavioral Clinical Policy provides assistance in interpreting and administering behavioral health benefit plans that are managed by Optum and U.S. Behavioral Health Plan, California (doing business as OptumHealth Behavioral Solutions of California ("Optum-CA")). When deciding coverage, the member-specific benefit plan document must be referenced. The terms of the member-specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Behavioral Clinical Policy is based. In the event of a conflict, the member's specific benefit plan document supersedes this Behavioral Clinical Policy.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the COC/SPD prior to using this Behavioral Clinical Policy. Other Policies and Coverage Determination Guidelines may apply. Optum reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This Behavioral Clinical Policy is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

Additional Information

The lack of a specific exclusion for a service does not necessarily mean that the service is covered. For example, depending on the specific plan requirements, services that are inconsistent with Level of Care Guidelines and/or prevailing medical standards and clinical guidelines may be excluded. Please refer to the member's benefit document for specific plan requirements.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member-specific benefit document to determine benefit coverage.

COVERAGE RATIONALE

In accordance with national guidelines and clinical evidence, Office-Based Opioid Treatment (OBOT) is proven and medically necessary when the following criteria are met:

- Member is diagnosed with an opioid use disorder, according to current Diagnostic and Statistical Manual of Mental Disorders (DSM);
- Treatment is administered in a physician’s office, an intensive outpatient program (IOP), or a partial hospital program (PHP);
- Treatment is administered under an individualized treatment plan and in accordance with SAMHSA guidelines (SAMHSA 2014; SAMHSA 2012; SAMHSA 2004, etc);
- If a physician, the treating provider meets the following training and service requirements (SAMHSA 2014):
 - Demonstration of at least one of the following:
 - A subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology;
 - An addiction certification from the American Board of Addiction Medicine;
 - A subspecialty board certification in addiction medicine from the American Osteopathic Association;
 - At least 8 hours of training on the treatment of opioid dependence provided by a SAMHSA-approved organization, such as the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, or the American Psychiatric Association;
 - The securing of a registration number and unique identification number from the U.S. Drug Enforcement Administration (DEA) if administering buprenorphine (SAMHSA 2004);
 - A capacity to provide or refer members for necessary ancillary services, such as psychotherapy and recovery support services.
 - Medical/behavioral coordination of care is critical in the OBOT model so that patients get the full range of services needed to remain abstinent (SAMHSA 2014).
 - Staff members responsible for establishing linkages with other healthcare organizations and practitioners should be knowledgeable about pharmacotherapy treatment and actively seek patient consent to talk with other providers, including the patient’s primary care physician (SAMHSA 2015).
- *On July 22, 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law as Public Law 114-198. This law extends the privilege of prescribing buprenorphine in office-based settings to qualifying nurse practitioners (NPs) and physician assistants (PAs) until October 1, 2021 (SAMHSA 2017).*
 - CARA requires that NPs and PAs complete 24 hours of training to be eligible for a prescribing waiver. The training must address each of the topics in 21 USC 823(g)(2)(G)(ii)(IV) provided by one of the following organizations: The American Society of Addiction Medicine, American Academy of Addiction Psychiatry, American Medical Association, American Osteopathic Association, American Nurses Credentialing Center, American Psychiatric Association, American Association of Nurse Practitioners, American Academy of Physician Assistants, or any other organization that the Secretary of Health and Human Services determines is appropriate (SAMHSA 2017).
 - NPs and PAs who have completed the required training and seek to become DATA-waiver for up to 30 patients will be able to apply to do so by completing a hard copy of the Notification of Intent (NOI) and sending to SAMHSA, along with copies of their training certificate(s).
 - These waiver applications are forwarded to the DEA, which will assign the NP or PA a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the NP’s or PA’s regular DEA registration number.
 - SAMHSA shall review waiver applications within 45 days of receipt. If approved, NPs and PAs will receive a letter via email that confirms their waiver and includes their prescribing identification number.

In accordance with national guidelines and clinical evidence, Office-Based Opioid Treatment is unproven and not medically necessary when the above criteria are not met.

The requested service or procedure must be reviewed against the language in the member's benefit document. When the requested service or procedure is limited or excluded from the member's benefit document, or is otherwise defined differently, it is the terms of the member's benefit document that prevails.

Per the specific requirements of the plan, health care services or supplies may not be covered when inconsistent with Level of Care Guidelines and/or evidence-based clinical guidelines:

Utilization Management Criteria

DEFINITIONS

Diagnostic and Statistical Manual of Mental Disorders (DSM): A manual produced by the American Psychiatric Association which provides the diagnostic criteria for mental health and substance-related disorders and other problems that may be the focus of clinical attention. Unless otherwise noted, the current edition of the DSM applies.

Proven Services: Services or technologies that, after a review of the evidence, demonstrate they can be safely and effectively administered to a defined patient population, under a set of specific conditions that are clearly identified. A service found to be proven does not necessarily indicate that the service is covered. The member's specific benefit plan must be referenced to determine coverage, limitations, and exclusions.

Scientific Evidence: The results of controlled clinical trials or other studies published in peer-reviewed, medical literature generally recognized by the relevant medical specialty community.

Unproven Services: Services including medications that are not consistent with prevailing medical research that has determined the services to not be effective for treatment of the condition and/or not to have the beneficial effect on behavioral health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed literature. Unproven services and all services related to unproven services are typically excluded. The fact that an unproven service, treatment, device, or pharmacological regimen is the only available treatment for a particular condition will not result in benefits if the procedure is considered to be unproven in the treatment of that particular condition.

DESCRIPTION OF SERVICES

Office-based opioid treatment is for members diagnosed with an opioid use disorder, and is administered in a physician's office, an intensive outpatient program (IOP), or a partial hospital program (PHP). In this form of medication-assisted treatment, an opioid is substituted with the medically-managed use of the following medications:

- Buprenorphine HCl sublingual tablets;
- Buprenorphine HCl with naloxone HCl dehydrate sublingual tablets (e.g., Suboxone®);
- Oral naltrexone;
- Extended-release injectable naltrexone (e.g., Vivitrol®).

Office-based opioid treatment is delivered either as a unique service, or as part of a larger comprehensive treatment plan. Community resources such as self-help, peer support groups, consumer-run services, and preventive health programs can augment medication-assisted treatments and support broader recovery/resiliency goals (SAMHSA 2014).

CLINICAL EVIDENCE

Summary of Clinical Evidence

The reviewed evidence demonstrates that buprenorphine, oral naltrexone, and extended-release injectable naltrexone can be administered safely and effectively in an office-based treatment setting. Follow-up studies of six months or greater have indicated a 50% or better retention rate, with a majority of dropouts occurring within the first month of treatment. National guidelines from professional societies recommend psychosocial treatment to be implemented in conjunction with the use of medications in the treatment of opioid use disorder.

Clinical Trials

Krupitsky and colleagues (2011) conducted a double-blind, placebo-controlled, randomized, 24-week trial of patients with opioid dependence disorder to assess the efficacy, safety, and patient-reported outcomes of an injectable, once-monthly extended-release formulation of the opioid antagonist naltrexone (XR-NTX). Patients aged 18 years or over who had 30 days or less of inpatient detoxification and 7 days or more off all opioids were enrolled at 13 clinical sites. Patients were randomly assigned to either 380mg XR-NTX (n = 126) or placebo (n = 124). Participants also received 12 biweekly counseling sessions. Participants, investigators, staff, and the sponsor were masked to treatment allocation. Primary endpoint was response profile for confirmed abstinence during weeks 5-24, assess by urine drug

tests and self-report of non-use. The median proportion of weeks of confirmed abstinence was 90% in the XR-NTX group, compared with 35% in the placebo group, and patients in the XR-NTX group self-reported a median of 99.2% opioid-free days, compared with 60.4% for the placebo group. Median retention was over 168 days in the XR-NTX group compared with 96 days in the placebo group. XR-NTX was well-tolerated. Two patients in each group discontinued due to adverse events. The authors conclude that XR-NTX represents a new treatment option that is distinct from opioid agonist maintenance treatment. XR-NTX in conjunction with psychosocial treatment might improve acceptance of opioid dependence pharmacotherapy and provide a useful treatment option for many patients.

Soeffing and colleagues (2009) assessed one-year outcomes of patients who were prescribed sublingual buprenorphine in a primary care practice, and to identify factors associated with favorable outcomes. All 255 patients who were given at least one prescription for buprenorphine over a four year period at a primary care practice were included. Patients were classified as "opioid-positive" or "opioid-negative" each month based on patient report, urine toxicology, and provider assessment. After 12 months, 145 (57%) patients remained in treatment, and 64.7% of their months were opioid-negative. About half of all dropouts occurred within the first month. Patient using prescription opioids were more likely to be opioid-negative (compared to patients using heroin). The authors note that while the results were limited to a single practice, many patients benefited from this treatment. They conclude that this study adds to a growing body of evidence that office-based treatment of opioid dependence with sublingual buprenorphine is safe and effective in the primary care setting.

Mintzer and colleagues (2007) conducted a cohort study to examine the efficacy and practicality of buprenorphine-naloxone treatment in primary care settings. A total of 99 consecutive patients enrolled in buprenorphine-naloxone treatment for opioid dependence at 2 urban primary care practices were studied. Primary outcome measure was sobriety at 6 months, judged by the treating physician based on periodic urinal drug tests, frequent physical examinations, and questioning of the patients about substance use. Results found that 54% of patients were sober at 6 months. There was no significant correlation between sobriety and site of care, drug of choice, or dose of buprenorphine-naloxone. Sobriety was correlated with length of treatment and attendance at self-help meetings. The authors conclude that opioid-addicted patients can be safely and effectively treated in non-research primary care settings with limited on-site resources.

Comer and colleagues (2006) conducted a randomized, placebo-controlled trial to evaluate the safety and efficacy of a sustained-release depot formulation of naltrexone in treating opioid dependence. This 8-week trial, conducted at 2 medical centers consisted of 60 heroin-dependent adults. Participants were stratified by sex and years of heroin use and then randomized to receive placebo, 192 mg of depot naltrexone, or 384mg of depot naltrexone. Doses were administered at the beginning of weeks 1 and 5. All participants received twice-weekly relapse prevention therapy, provided observed urine samples, and completed other assessments at each visit. Main outcome measures were retention in treatment and percentage of opioid-negative urine samples. Results found that retention in treatment was dose-related, with 39%, 60%, and 68% of patients in the placebo, 192mg, and 384mg groups, respectively, remaining in treatment at the end of 2 months. Time to dropout had a significant main effect of dose, with mean time to dropout of 27, 36, and 48 days for placebo, 192mg, and 384mg groups, respectively. Adverse events were minimal and generally mild. The authors conclude that this formulation of naltrexone was well-tolerated and produced a robust, dose-related increase in treatment retention.

Stein and colleagues (2005) conducted an observational cohort study of patients prescribed buprenorphine/naloxone and followed for 6 months to assess the rate and predictors of treatment retention for primary care patients with opioid dependence prescribed buprenorphine. A total of 41 patients with a mean duration of opioid use of 15.7 years were enrolled. At 24 weeks of treatment, 59% remained in treatment. Nearly half of the dropouts occurred in the first 30 days of treatment, and those with opiate-positive toxicologies at week 1 were more likely to drop out of treatment. Additionally, employment and addiction counseling during treatment were significantly associated with treatment retention. The authors conclude that retention rates in this real world, primary care-based buprenorphine maintenance practice reflect those reported in clinical trials. Abstinence during the first week of treatment and receipt of counseling were considered critical to patient retention.

Fudala and colleagues (2003) conducted a multicenter, randomized, placebo-controlled trial to study the efficacy and safety of office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. The trial involved 326 opiate-addicted persons who were assigned to office-based treatment with sublingual tablets consisting of buprenorphine in combination with naloxone, buprenorphine alone, or placebo given daily for four weeks. Primary outcome measures were percentage of urine samples negative for opiates, and subjects' self-reported craving for opiates. The trial was terminated early because buprenorphine and naloxone in combination and buprenorphine alone were found to have greater efficacy than placebo. Rates of adverse events were similar in the active-treatment and placebo groups. The authors concluded that buprenorphine and naloxone in combination and buprenorphine alone are safe and reduce the use of opiates and the craving for opiates among opiate-addicted persons who receive these medications in an office-based setting.

Systematic Reviews/Meta-Analyses

Thomas and colleagues (2014) reviewed the research available on buprenorphine maintenance treatment (BMT), including meta-analyses, systematic reviews, and individual studies. A total of sixteen randomized controlled trials (RCTs) and seven systematic reviews or meta-analyses were included. The review found that overall, a high level of evidence was found for the effectiveness of BMT in increasing treatment retention and decreasing illicit opioid use. When the medications are dosed similarly, BMT appears to be as effective as methadone maintenance treatment (MMT) in reducing illicit opioid use. Some studies suggested that MMT might have better treatment retention than BMT. However, buprenorphine has a better safety profile than methadone, and the ability to prescribe it in office facilities as opposed to only opioid treatment programs improves access to care and earlier initiation of treatment. Both BMT and MMT were found to reduce illicit drug use during pregnancy. Further areas for study include impact of BMT on secondary outcomes, appropriate dosing to enhance treatment outcomes, improved induction protocols, and examination of BMT use in specific subpopulations.

Kahan and colleagues (2011) conducted a clinical review on the use of buprenorphine for opioid-addicted patients in primary care. Controlled trials, meta-analyses, and large observational studies were reviewed. Results from the review found that buprenorphine has a much lower risk of overdose than methadone and is preferred for patients at high risk of methadone toxicity, those who might need shorter-term maintenance therapy, and those with limited access to methadone treatment. The authors conclude that buprenorphine is an effective treatment of opioid addiction and can be safely prescribed by primary care physicians.

Johansson and colleagues (2006) conducted a meta-analytical review to assess the efficacy of naltrexone in the reduction of illicit opioid use, and determine the potential moderating role of treatment retention. Eligible studies were randomized controlled trials (RCTs) with a minimum duration of 4 weeks, which compared naltrexone maintenance with control, another treatment, or with psychosocial or psychopharmacological treatment plus naltrexone maintenance. A total of 15 RCTs were included in the review, with the duration of intervention ranging from 8-38 weeks. All eligible studies had to enroll at least 20 outpatients. Efficacy outcomes included opioid-positive urines, craving, and psychiatric symptoms. Overall, no statistically significant difference was found in retention levels between naltrexone groups and comparison groups, while the outcomes of opioid-positive urines showed a result which favored naltrexone. An analysis of variance showed naltrexone to be significantly more effective in studies with high retention levels than in studies with low retention levels for all outcomes except psychiatric symptoms. The authors conclude that retention is an important moderator of the effectiveness of naltrexone in the treatment of opioid dependence, and that naltrexone is an effective treatment if the retention rate is above a certain level.

Professional Societies

American Psychiatric Association (APA): A 2006 clinical guideline from the APA for the treatment of patients with substance use disorders states that routine office-based pharmacological treatment with buprenorphine has considerable promise based on research studies and the growing clinical experience with this form of treatment in the United States.

American Society of Addiction Medicine (ASAM): A 2015 national practice guideline for the use of medications in the treatment of addiction involving opioid use notes that buprenorphine is recommended for treating opioid use disorder, and that an important feature of buprenorphine is its ability to be prescribed in office-based treatment settings. The guideline recommends that psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder. The guideline also notes that naltrexone is a recommended treatment in preventing relapse in opioid use disorder; oral formula naltrexone may be considered for patients in whom adherence can be supervised or enforced, while extended-release injectable naltrexone may be more suitable for patients with adherence issues. Psychosocial treatment is also recommended in conjunction with naltrexone treatment.

A 2011 literature review and consensus statement from ASAM synthesized the most current evidence on the use of buprenorphine in an office-based setting. Over 375 articles published in peer-reviewed journals were submitted to a consensus panel composed of researchers, educators, and clinicians in the field of addiction medicine and with specific expertise in the use of office-based opioid treatment (OBOT). The panel found that therapeutic outcomes for patients who self-select OBOT with buprenorphine are comparable to those seen in patients treated with methadone programs. While there are few absolute contraindications of buprenorphine use, experience and skill level of the treating physician can vary. Therefore it is important a targeted assessment of each patient occur to confirm the provider has adequate resources to meet the patient's needs.

National Institute on Drug Abuse (NIDA): In a research-based guide (last revised 2012), NIDA states that buprenorphine and naltrexone (including the long-acting formulation) are effective in helping individuals addicted to heroin or other opioids stabilize their lives and reduce their illicit drug use, especially when combined with counseling and other behavioral therapies. The guide states that buprenorphine is safe and effective for treating opioid addiction when used as directed.

Substance Abuse and Mental Health Services Administration (SAMHSA): In a 2015 brief guide on the clinical use of extended-release injectable naltrexone in the treatment of opioid use disorder, SAMHSA notes that extended-release injectable naltrexone appears to be reasonably well tolerated. The guide notes that while no definitive research supports which patients benefit most from extended-release injectable naltrexone, it may include those who have not had treatment success with methadone or buprenorphine, those with a high degree of motivation for abstinence, and those who have been successful on opioid agonists who wish to discontinue agonist therapy or those not interested in agonist therapy to treat their opioid use disorder.

A 2004 Treatment Improvement Protocol (TIP #40) by SAMHSA recommends that buprenorphine/naloxone combination be used for induction treatment (and for stabilization and maintenance) for most patients in the treatment of opioid addiction. Prior to embarking on the provision of office-based addiction treatment services, medical practices should undertake certain preparations to ensure the highest quality experience for patients, providers, and staff. Providers and practice staff should have an appropriate level of training, experience, and comfort with this form of treatment. Linkages with other medical and mental health professionals should be established to ensure the availability of comprehensive community-based treatment services.

U.S. Veterans Affairs / Department of Defense (VA/DOD): In their 2015 clinical practice guideline for the management of substance use disorders, the VA/DOD recommends individualizing choice of appropriate treatment setting (OTP or OBOT), considering patient preferences, for patients with opioid use disorder for whom buprenorphine is indicated. For patients with opioid use disorder for whom opioid agonist treatment is contraindicated, unacceptable, unavailable, or discontinued and who have established abstinence for a sufficient period of time, extended-release injectable naltrexone is recommended. The VA/DOD notes that there is insufficient evidence to recommend for or against oral naltrexone for treatment of opioid use disorder. The guideline notes that choice of psychosocial intervention should be made considering patient preferences and provider training/competence.

World Health Organization (WHO): In its 2009 guidelines for the psychosocially assisted pharmacological treatment of opioid dependence, the WHO recommends that average buprenorphine maintenance doses should be at least 8mg per day, that buprenorphine doses be directly supervised in the early phase of treatment, and that psychosocial support be offered routinely in association with pharmacological treatment for opioid dependence.

U.S. FOOD AND DRUG ADMINISTRATION

The U.S. Food and Drug Administration (FDA) has approved:

- Buprenorphine for use in treating opioid addiction in the physician's office (2002).
- Naltrexone for the treatment of addiction to drugs such as heroin, morphine, and oxycodone (1984).
- Extended-release injectable naltrexone (Vivitrol) to treat people with opioid dependence (2010).

CENTERS FOR MEDICARE AND MEDICAID SERVICES

A National Coverage Determination (NCD) exists for *Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic*.

UTILIZATION MANAGEMENT CRITERIA

Prior authorization may be required for Medication Assisted Treatment.

Before using this section, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

Admission Criteria

- See "Common Criteria and Best Practices for All Levels of Care", available at: <https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locg.html>
AND
- The criteria from the [Coverage Rationale](#) section of this document are met, unless otherwise mandated by regulation or customer contract.
AND
- Patients should be assessed for a range of biopsychosocial needs (including medical and psychiatric care, and social assistance) in addition to opioid use and addiction, and treated or referred for help in meeting these needs (Kraus et al 2011).
AND
- The factors leading to admission suggest that there is imminent or current risk of mild withdrawal (opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal before taking a first dose of buprenorphine to reduce risk of precipitated withdrawal (ASAM 2015)).

AND

- Medical complications, if present, can be safely managed.
 - The member has no known contraindications to buprenorphine or naltrexone treatment.
 - The member is not dependent on high doses of benzodiazepines or other central nervous system depressants, including alcohol.

AND

- The member is not in imminent or current risk of harm to self, others, and/or property.

AND

- A comprehensive patient assessment, which is considered essential to determine the appropriateness of office-based or other opioid agonist treatment (SAMHSA 2004), has been completed.

Buprenorphine (SAMHSA 2004)

- During the induction phase, the member is transitioned from the opioid of abuse to buprenorphine.
- Buprenorphine is first administered during induction after the member has abstained from using opioids for 12-24 hours, and is in the early stages of opioid withdrawal.
- Induction is initiated in the physician's office using 4mg, followed by up to 4mg after 4 hours, if needed.
 - Day 1 should not exceed 8mg.
 - 4mg buprenorphine and 1mg naloxone in 2-4 hours, with additional 4mg buprenorphine and 1mg naloxone, if indicated, for buprenorphine/naloxone is recommended.
- Induction continues in the physician's office with daily administration of increasing dosages of buprenorphine until a therapeutic dose is achieved.
- During induction, the physician monitors the member's response to treatment and continued motivation to participate in comprehensive treatment that includes psychosocial interventions alongside buprenorphine treatment.

Oral Naltrexone

- Oral naltrexone is indicated when:
 - The patient has remained free of opioids for at least 7-10 days and is not showing withdrawal signs or reporting withdrawal symptoms (SAMHSA 2016a; SAMHSA 2014);
 - The member is medically clear (e.g., normal liver functioning tests, negative toxicology screenings);
 - The member is motivated, or has a responsible person who is willing to monitor the member's compliance with treatment; naltrexone is used primarily in well-motivated patients (SAMHSA 2014);
 - The member is not anticipating surgery or has a medical condition for which opioids may be prescribed;
 - The member is willing to participate in psychosocial treatment, as the efficacy of naltrexone use in conjunction with psychosocial treatment has been established (ASAM 2015; SAMHSA 2014; SAMHSA 2012).
- The initial oral naltrexone dose is 50mg/day, or three times weekly in two 100mg doses followed by one 150mg dose (SAMHSA 2016a; ASAM 2015; SAMHSA 2014).
 - For members at risk (e.g., women, younger members, members with shorter abstinence), safety precautions should be considered.

Extended-Release Injectable Naltrexone (Vivitrol)

- Extended-release injectable naltrexone is indicated when:
 - The member and provider have determined naltrexone products would be the optimal selection of agents used for treatment of opioid dependence, based on member characteristics or preferences.
 - In addition, naltrexone products may be considered for situations in which the member has not responded to other pharmacological and/or non-pharmacological forms of treatment, or not able to comply with oral naltrexone treatment (SAMHSA 2012);
 - The member has remained free of opioids for at least 7-10 days and is not showing withdrawal signs or reporting withdrawal symptoms (SAMHSA 2016a; SAMHSA 2014; SAMHSA 2012);
 - The member is medically clear (e.g., normal liver functioning tests, negative toxicology screenings);
 - The member does not have a bleeding disorder or condition that prevents deep IM injections;
 - The member is not anticipating surgery or has a medical condition for which opioids may be prescribed;
 - The member is willing to participate in psychosocial treatment, as the efficacy of naltrexone use in conjunction with psychosocial treatment has been established (ASAM 2015; SAMHSA 2014; SAMHSA 2012).
- Naltrexone is administered by intramuscular (IM) gluteal injection at a dose of up to 380mg.

Continued Service Criteria

- See "Common Criteria and Best Practices for All Levels of Care", available at:
<https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locq.html>

AND

- The member's current condition can continue to be safely, efficiently, and effectively assessed and/or treated.

Buprenorphine (SAMHSA 2004)

- During the stabilization phase:
 - The provider monitors the member's response to treatment and level of motivation.
 - The frequency of office visits lessens, and the member may be transitioned to a prescription for use at home.
 - The standard dose is 12-16mg per day, although some members may need up to 32mg per day, particularly if the member experiences withdrawal symptoms or feels compelled to use opioids.
 - Some patients may prefer or may respond better to less-than-daily dosing regimens of buprenorphine; administration of up to 24mg on alternate days may be indicated when the member's condition has stabilized.
 - Use of buprenorphine at home is indicated when:
 - The member abstains from using drugs and alcohol;
 - The member has regularly participated in office-based opioid treatment;
 - There are no significant behavioral problems;
 - There is no evidence of criminal activity;
 - There are no psychosocial or environmental problems;
 - The member can safely store the buprenorphine;
 - There is no risk that the buprenorphine will be diverted;
 - The member is participating in psychosocial interventions per the treatment plan.
- During the maintenance phase:
 - The member is on a stable dose of buprenorphine;
 - The member is no longer experiencing withdrawal, side effects, or cravings for opioids;
 - Psychosocial issues are addressed as part of the comprehensive treatment plan.
 - The provider continues to monitor the member's response to treatment and level of motivation.
 - The frequency of office visits is further reduced, and if indicated, the member continues to self-administer buprenorphine.

Oral Naltrexone

- There are no clear guidelines on the duration of oral naltrexone maintenance. Careful clinical evaluation of relapse risk should be done prior to the decision to discontinue naltrexone (Kleber 2007).

Extended-Release Injectable Naltrexone (Vivitrol)

- Naltrexone is administered by intramuscular (IM) gluteal injection every 4 weeks at a dose of up to 380mg. If a dose is delayed or missed, the next injection is administered as soon as possible.

Psychosocial Treatment

- Pharmacotherapy alone is rarely sufficient treatment for drug addiction, and treatment outcomes demonstrate a dose-response effect based on the level or amount of psychosocial treatment services that are provided (SAMHSA 2004);
 - For most patients, drug abuse counseling (individual or group) and participation in self-help programs are considered necessary (SAMHSA 2004).
 - The ability to provide counseling and education within the context of office-based practice may vary considerably, depending on the type and structure of the practice (SAMHSA 2004).
 - Providers considering making buprenorphine available to their patients should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities (SAMHSA 2004).

Discharge Criteria

- see "Common Criteria and Best Practices for All Levels of Care", available at: <https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locq.html>
- Staff members should have a capacity to provide or refer members for necessary ancillary services, such as psychotherapy and recovery support services.
 - Staff members responsible for establishing linkages with other healthcare organizations and practitioners should be knowledgeable about pharmacotherapy treatment and actively seek patient consent to talk with other providers, including the patient's primary care physician (SAMHSA 2015).

Buprenorphine

- When the end of treatment is indicated, tapering occurs over a 2-3 week period. If significant withdrawal symptoms emerge, doses are split into 2-3 smaller doses until buprenorphine can be safely discontinued (SAMHSA 2004).

Oral Naltrexone

- Discontinuation is not associated with withdrawal, so it is not necessary to taper the dose (ASAM 2015; SAMHSA 2014). Patients who discontinue therapy and resume opioid use should be made aware of the increased risks associated with an opioid overdose (ASAM 2015).

Extended-Release Injectable Naltrexone (Vivitrol)

- There is no clearly defined duration of treatment with IM naltrexone, however, a provider may consider discontinuation once the member's condition has stabilized, the member is able to maintain abstinence, has a support and recovery plan, and there is a reduced risk of relapse.
- The provider should remind the member that opioid medications should not be taken for at least 30 days following discontinuation; patients who discontinue therapy and resume opioid use should be made aware of the increased risks associated with an opioid overdose (ASAM 2015).

Relapse Prevention (SAMHSA 2014):

- Strategies that target relapse prevention should be part of any comprehensive treatment program.
- The possibility of relapse should be explained to patients who want to dose taper, especially those who are not stable on their current dosage, as part of the informed-consent process.
- Patients who choose tapering should be monitored closely and taught relapse prevention strategies.
- Relapse prevention techniques should be incorporated into counseling and other support services both before and during dosage reduction.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
90791	Psychiatric diagnostic evaluation
90792	Psychiatric diagnostic evaluation with medical services
90832	Psychotherapy, 30 minutes with patient
90833 + E/M Code	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service
90834	Psychotherapy, 45 minutes with patient
90836 + E/M Code	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service
90837	Psychotherapy, 60 minutes with patient
90838 + E/M Code	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service
90846	Family psychotherapy (without patient present), 50 minutes
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes
90853	Group psychotherapy (other than of a multiple-family group)
90863	Pharmacologic management, including prescription and review of medication, when performed with other psychotherapy services
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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HCPC Code	Description
H0001	Alcohol and/or drug assessment
H0002	Behavioral health screening to determine eligibility for admission to treatment program
H0003	Alcohol and/or drug screening; laboratory analysis of specimens for presence of alcohol and/or drugs
H0004	Behavioral health counseling and therapy, per 15 minutes
H0005	Alcohol and/or drug services; group counseling by a clinician
H0014	Alcohol and/or drug services; ambulatory detoxification
H0015	Alcohol and/or drug services; intensive outpatient (treatment program that operates at least 3 hours/day and at least 3 days/week and is based on an individualized treatment plan), including assessment, counseling; crisis intervention, and activity therapies or education
H0031	Mental health assessment, by nonphysician
H0032	Mental health service plan development by nonphysician
H0033	Oral medication administration, direct observation
H0034	Medication training and support, per 15 minutes
H0035	Mental health partial hospitalization, treatment, less than 24 hours
H0047	Alcohol and/or other drug abuse services, not otherwise specified
J0571	Buprenorphine, oral, 1 mg
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine
J2315	Injection, naltrexone, depot form, 1 mg
T1016	Case management, each 15 minutes

ICD-10 Diagnosis Code	Description
F11.10 – F11.19	Opioid abuse
F11.20 – F11.29	Opioid dependence
F11.90 – F11.99	Opioid use

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ADDITIONAL RESOURCES

Clinical Protocols

Optum maintains clinical protocols that include the Level of Care Guidelines and Best Practice Guidelines which describe the scientific evidence, prevailing medical standards, and clinical guidelines supporting our determinations regarding treatment. These clinical protocols are available to Covered Persons upon request, and to Physicians and other behavioral health care professionals on www.providerexpress.com.

Peer Review

Optum will offer a peer review to the provider when services do not appear to conform to this policy. The purpose of a peer review is to allow the provider the opportunity to share additional or new information about the case to assist the Peer Reviewer in making a determination including, when necessary, to clarify a diagnosis.

Second Opinion Evaluations

Optum facilitates obtaining a second opinion evaluation when requested by an member, provider, or when Optum otherwise determines that a second opinion is necessary to make a determination, clarify a diagnosis or improve treatment planning and care for the member.

Referral Assistance

Optum provides assistance with accessing care when the provider and/or member determine that there is not an appropriate match with the member's clinical needs and goals, or if additional providers should be involved in delivering treatment.

HISTORY/REVISION INFORMATION

Date	Action/Description
03/14/2017	• Version 1 (Approved by UMC)