SAMPLE LETTER OF MEDICAL NECESSITY FOR SUBLOCADE® (buprenorphine extended-release)

A letter of medical necessity may be requested by payers to support coverage for SUBLOCADE. Within this letter, there should be an explanation of why SUBLOCADE is medically necessary for the patient, and it should contain information that supports the need for SUBLOCADE for the patient, such as medical records, clinical treatment history, Prescribing Information, Medication Guide, and supporting literature. Submission of the letter may be in conjunction with a prior authorization request, with a claim form, or as a part of a response for additional documentation. Be sure to submit the letter of medical necessity on the practice letterhead, have it signed by the treating physician, and include patient-specific information.

This is a sample letter of medical necessity. This sample letter is intended to be an example for healthcare providers who have prescribed SUBLOCADE and who would like to request insurance coverage of SUBLOCADE for a patient. The [blue] text should be customized to provide specific information about your patient. The patient's insurance company may require additional information, and the sample letter may not include all topics required by the insurance company.

This sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when submitting for or appealing a coverage determination. Use of this template or the information in this template does not guarantee reimbursement or coverage. It is not intended to be a substitute for or to influence the independent clinical decision of the prescribing healthcare professional.

INDICATION

SUBLOCADE, with counseling and psychosocial support, is for moderate to severe opioid use disorder in those who have initiated treatment with a dose of transmucosal buprenorphine or are being treated with buprenorphine.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

[Date]
[Medical or Pharmacy Director]
[Insurance Plan or PBM]
[Address]
[City, State ZIP Code]

SAMPLE LETTER ONLY

Subject: Letter of Medical Necessity for SUBLOCADE® (buprenorphine extended-release) injection
Insured: [Patient Name]; Policy Number: [Policy Number]; Group Number: [Group Number]

Dear [Medicare or Pharmacy Director's Name]:

I am writing on behalf of my patient, [First Name] [Last Name], to request that [Insurance Plan/PBM Name] approve coverage for [Mr/Ms/Mrs/other title] [Last Name]'s treatment with SUBLOCADE® (buprenorphine extended-release) for their [first/second dose]. SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder as part of a complete treatment program that includes counseling and psychosocial support. Per the package insert, the second injection of SUBLOCADE may be administered as early as one week after the first injection. This letter outlines the rationale for approving this patient's [treatment with/second dose of] SUBLOCADE.

Patient Medical Overview and History

[Patient Name] is a[n] [age]-year-old patient born [MM-DD-YYYY] who was diagnosed with opioid use disorder on [date of diagnosis].

[Note: Exercise medical judgment and discretion when providing a diagnosis and characterization of the patient's condition. Consider including the following information:

- Patient's medical history with respect to current and past history of opioid use disorder
- Previous therapies or current therapies for opioid use disorder
- Response to previous or current therapies for opioid use disorder
- Description of patient's recent presentation, including psychosocial support
- Summary of professional opinion of likely prognosis without SUBLOCADE]

Rationale for Treatment

Given the patient's history, condition, and supporting clinical information, I believe treatment of [Patient Name] with SUBLOCADE is warranted, appropriate, and medically necessary. SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder as part of a complete treatment program that includes counseling and psychosocial support. SUBLOCADE is administered by a healthcare professional into the subcutaneous tissue in the abdomen, thigh, buttock, or back of the upper arm.

Treatment Plan

Since [Patient Name] [has been receiving transmucosal buprenorphine treatment, they {should be/have been} started with an initial SUBLOCADE dose of 300 mg]/[has not been receiving transmucosal buprenorphine treatment, they should receive an initial dose (eg, 4 mg) of transmucosal buprenorphine before administering the first injection of SUBLOCADE. After the initial injection of SUBLOCADE, patients should be monitored in a healthcare setting.] The second injection of SUBLOCADE may be administered as early as one week after the first injection. The recommended dose of SUBLOCADE is two initial doses of 300 mg followed by 100 mg monthly maintenance doses. Monthly doses of SUBLOCADE up to 300 mg may be considered if [Patient Name] tolerates SUBLOCADE but does not demonstrate satisfactory clinical response to the lower dose.

[Include necessary treatment rationale on dosage and timing.]

In summary, SUBLOCADE [indicate dosage and dose # if appropriate] is medically necessary and reasonable for [Patient Name]'s treatment of opioid use disorder. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,
[Treatment Provider's Signature]
[Treatment Provider's Name Typed]
[Treatment Provider's Phone Number]
Enclosures:
SUBLOCADE prescribing information
[Other supporting documents and/or medical records]

INDICATION

SUBLOCADE, with counseling and psychosocial support, is for moderate to severe opioid use disorder in those who have initiated treatment with a dose of transmucosal buprenorphine or are being treated with buprenorphine.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

CONTRAINDICATIONS: SUBLOCADE should not be administered to patients who are hypersensitive to buprenorphine or any component of the delivery system.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Buprenorphine is sought by people with opioid use disorder and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Risk of Life-Threatening Respiratory Depression and Concomitant Use of Benzodiazepines or Other CNS Depressants with Buprenorphine: Buprenorphine has been associated with life-threatening respiratory depression, overdose, and death, particularly when misused by self-injection or with concomitant use of benzodiazepines or other CNS depressants, including alcohol. Warn patients of the potential danger of self-administration of benzodiazepines, other CNS depressants, opioid analgesics, and alcohol while under treatment with SUBLOCADE. Counsel patients that such medications should not be used concomitantly unless supervised by a healthcare provider.

Use with caution in patients with compromised respiratory function (e.g., chronic obstructive pulmonary disease, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression).

Opioids can cause sleep-related breathing disorders, e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at the time SUBLOCADE is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone. Emphasize the importance of calling 911 or getting emergency help, even if naloxone is administered.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Risk of Serious Injection Site Reactions: The most common injection site reactions are pain, erythema and pruritus with some involving abscess, ulceration, and necrosis. Some cases resulted in surgical depot removal, debridement, antibiotic administration, and SUBLOCADE discontinuation. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration. Carefully review injection technique.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. NOWS may be life-threatening if not recognized and treated in the neonate. Newborns should be observed for signs of NOWS and managed accordingly. Advise pregnant women receiving opioid addiction treatment with SUBLOCADE of the risk of neonatal opioid withdrawal syndrome.

Adrenal Insufficiency: Adrenal insufficiency has been reported with opioid use. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off the opioid.

Discontinuation of SUBLOCADE Treatment: Due to the long-acting nature of SUBLOCADE, if treatment is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Inform patients that they may have detectable levels of buprenorphine for a prolonged period of time after treatment with SUBLOCADE. Considerations of drug-drug interactions, buprenorphine effects, and analgesia may continue to be relevant for several months after the last injection.

Risk of Hepatitis, Hepatic Events: Because cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving buprenorphine, monitor liver function tests prior to treatment and monthly during treatment.

Hypersensitivity Reactions: Hypersensitivity to buprenorphine-containing products have been reported most commonly as rashes, hives, and pruritus. Some cases of bronchospasm, angioneurotic edema, and anaphylactic shock have also been reported.

Precipitation of Opioid Withdrawal in Patients Dependent on Full Agonist Opioids: Buprenorphine may precipitate opioid withdrawal signs and symptoms in persons who are currently physically dependent on full opioid agonists if administered before the effects have subsided, at least 6 hours for short-acting opioids and 24 hours for long-acting opioids. Verify that patients have tolerated transmucosal buprenorphine before administering the first injection of SUBLOCADE.

Risks Associated With Treatment of Emergent Acute Pain: When patients need acute pain management, or may require anesthesia, treat patients receiving SUBLOCADE currently or within the last 6 months with a non-opioid analgesic whenever possible. If opioid therapy is required, patients may be treated with a high-affinity full opioid analgesic under the supervision of a physician, with particular attention to respiratory function, as higher doses may be required for analgesic effect and therefore, a higher potential for toxicity exists with opioid administration.

Advise patients of the importance of instructing their family members, in the event of emergency, to inform the treating healthcare provider or emergency room staff that the patient is physically dependent on an opioid and that the patient is being treated with SUBLOCADE.

Use in Opioid Naïve Patients: Because death has been reported for opioid naïve individuals who received buprenorphine sublingual tablet, SUBLOCADE is not appropriate for use in opioid naïve patients.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Use in Patients With Impaired Hepatic Function: Because buprenorphine levels cannot be rapidly decreased, SUBLOCADE is not recommended for patients with pre-existing moderate to severe hepatic impairment. Patients who develop moderate to severe hepatic impairment while being treated with SUBLOCADE should be monitored for several months for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

QTc Prolongation: QT studies with buprenorphine products have demonstrated QT prolongation ≤ 15 msec. Buprenorphine is unlikely to be pro-arrhythmic when used alone in patients without risk factors. The risk of combining buprenorphine with other QT-prolonging agents is not known. Consider these observations when prescribing SUBLOCADE to patients with risk factors such as hypokalemia, bradycardia, recent conversion from atrial fibrillation, congestive heart failure, digitalis therapy, baseline QT prolongation, subclinical long-QT syndrome, or severe hypomagnesemia.

Impairment of Ability to Drive or Operate Machinery: SUBLOCADE may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Caution patients about driving or operating hazardous machinery until they are reasonably certain that SUBLOCADE does not adversely affect their ability to engage in such activities.

Orthostatic Hypotension: Buprenorphine may produce orthostatic hypotension.

Elevation of Cerebrospinal Fluid Pressure: Buprenorphine may elevate cerebrospinal fluid pressure and should be used with caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased. Buprenorphine can produce miosis and changes in the level of consciousness that may interfere with patient evaluation.

Elevation of Intracholedochal Pressure: Buprenorphine has been shown to increase intracholedochal pressure, as do other opioids, and thus should be administered with caution to patients with dysfunction of the biliary tract.

Effects in Acute Abdominal Conditions: Buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Unintentional Pediatric Exposure: Buprenorphine can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it.

ADVERSE REACTIONS: Adverse reactions commonly associated with SUBLOCADE (≥5% of subjects) during clinical trials were constipation, headache, nausea, vomiting, increased hepatic enzymes, fatigue, and injection site pain and pruritus. This is not a complete list of potential adverse events. Please see the full Prescribing Information for a complete list.

DRUG INTERACTIONS

CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under-dosing.

Serotonergic Drugs: If concomitant use with serotonergic drugs is warranted, monitor for serotonin syndrome, particularly during treatment initiation, and during dose adjustment of the serotonergic drug.

Consult the full Prescribing Information for SUBLOCADE for more information on potentially significant drug interactions.

IMPORTANT SAFETY INFORMATION (CONTINUED)

USE IN SPECIFIC POPULATIONS

Pregnancy: Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Lactation: Buprenorphine passes into the mother's milk. Advise breastfeeding women to monitor the infant for increased drowsiness and breathing difficulties.

Fertility: Chronic use of opioids may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Geriatric Patients: Monitor geriatric patients receiving SUBLOCADE for sedation or respiratory depression.

To report a pregnancy or side effects associated with taking SUBLOCADE or any safety related information, product complaint, request for medical information, or product query, please contact PatientSafetyNA@indivior.com or 1-877-782-6966.

Sublocade®
(buprenorphine extended-release) injection for subcutaneous use Ⓒ 100mg·300mg