Medical Necessity Letter – Example Template

PLEASE NOTE: This template letter is provided by Orexo as an example only for patients who have been prescribed ZUBSOLV® (buprenorphine and naloxone) sublingual tablet (CIII). No healthcare provider is required to use this template and it is not intended as a substitute for a prescriber's independent medical judgment.

This letter should be customized by the prescriber (or the prescriber's office staff) for each patient to reflect that patient's medical history, diagnosis, treatment recommendations, and other relevant information. The prescriber is responsible for ensuring the accuracy of all information provided. This template may not include all information required to support a prior authorization request or a request for additional treatment information. Requirements for each health plan may vary. Please refer to the full Prescribing Information for ZUBSOLV, including the Important Safety Information, when determining whether ZUBSOLV is medically appropriate for an individual patient. Orexo does not guarantee coverage or reimbursement for ZUBSOLV.

[Insert on Healthcare Provider's Letterhead]

[Date]
[Contact Name or Department]
[Insurance Company Name]
[Street Address]
[City, State Zip]
[Policy Number]

Re: Letter of Medical Necessity for [Patient First Name] [Patient Last Name] for ZUBSOLV® (buprenorphine and naloxone) sublingual tablets (CIII)

Dear [Name or Contact]:

This is a formal Letter of Medical Necessity requesting coverage for ZUBSOLV for [Insert Patient First Name and Last Name] for the treatment of [his or her] opioid dependence.

As the treating healthcare provider, it is my clinical judgment that [Patient Name] is a medically appropriate patient for ZUBSOLV based on the FDA-approved indication, diagnosis of opioid dependence, and history of therapies that have been tried and failed. Since my patient is still suffering from [his or her] opioid dependence, I am requesting ZUBSOLV be a covered therapy. I have provided additional information regarding my patient's medical history and summary of my treatment rationale.

Patient History and Diagnosis

[Patient First Name] is a [age]-year-old [male or female] who has been treated for opioid dependence since [Date]. [Patient Name] has been in my care since [Date].

As a result of my patient's opioid dependence, [Enter Description of Patient History, including Relevant symptoms]. [Patient Name] has tried [Previous Therapies] and [Describe Outcomes].

Based on the above information, it is my medical recommendation that ZUBSOLV is indicated and medically necessary for [Patient's Name]. To support this request, I have enclosed the following documentation for your review:

- [PATIENT'S PROGRESS NOTES OUTLINING DIAGNOSIS OF OPIOID DEPENDENCE]
- [TREATMENT HISTORY, PAST THERAPIES PRESCRIBED, AND OUTCOMES]
- [OTHER RELEVANT MEDICAL INFORMATION]

Sincerely,

[Treating Provider's Name and Signature]
[NPI Number]
[Contact Information]

Enclosures:

- ZUBSOLV Prescribing Information
- Patient Medical Records
- [Other documentation as appropriate]

Indication

ZUBSOLV® (buprenorphine and naloxone) sublingual tablet (CIII) is indicated for the treatment of opioid dependence. ZUBSOLV should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Treatment should be initiated under the direction of healthcare providers who meet certain qualifying requirements under the Drug Addiction Treatment Act of 2000, and who have been assigned a unique identification number ("X" number).

Important Safety Information

Contraindications

- ZUBSOLV is contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone, as serious adverse reactions, including anaphylactic shock, have been reported.

Warnings and Precautions

- Addiction, Abuse, and Misuse: Buprenorphine can be abused in a similar manner to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.
- Risk of Life-Threatening Respiratory and Central Nervous System (CNS) Depression: Life-threatening respiratory depression and death have occurred in association with buprenorphine use. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with ZUBSOLV.
- Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose: Strongly consider prescribing naloxone for the emergency treatment of opioid overdose, both when initiating and renewing treatment with ZUBSOLV, and consider prescribing naloxone if the patient has household members (including children) or other close contacts at risk for accidental ingestion or opioid overdose.
    - Advise patients and caregivers that naloxone may also be administered for a known or suspected overdose with ZUBSOLV itself.

    - 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.
- Managing Risks from Concomitant Use of Benzodiazepines or Other CNS Depressants: Concomitant use of buprenorphine and benzodiazepines or other CNS depressants increases the risk of adverse reactions including overdose and death. As a routine part of orientation to buprenorphine treatment, educate patients about the risks of concomitant use of benzodiazepines, sedatives, opioid analgesics, and alcohol. Develop strategies to manage use of prescribed or illicit benzodiazepines or other CNS depressants at initiation of buprenorphine treatment, or if it emerges as a concern during treatment.
    - Before co-prescribing benzodiazepines, ensure that patients are properly diagnosed and consider alternative treatments to address anxiety or insomnia.
    - Take measures to confirm that patients are taking their medication as prescribed and are not diverting or supplementing with illicit drugs, including toxicology screening to test for prescribed and illicit benzodiazepines.
- Unintentional Pediatric Exposure: Store ZUBSOLV safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal respiratory depression in children.
- Neonatal Opioid Withdrawal Syndrome (NOWS): Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy.
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patients off of the opioid.
- Risk of Opioid Withdrawal with Abrupt Discontinuation: If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.
- Risk of Hepatitis; Hepatic Events: Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.
- Precipitation of Opioid Withdrawal Signs and Symptoms: An opioid withdrawal syndrome is likely to occur with parenteral misuse of ZUBSOLV by individuals physically dependent on full opioid agonists or by sublingual administration before the agonist effects of other opioids have subsided.
- Risk of Overdose in Opioid-Naïve Patients: ZUBSOLV is not appropriate as an analgesic. There have been reported deaths of opioid-naïve individuals who received a 2-mg sublingual dose of buprenorphine.
- Dental Adverse Events: Cases of dental caries, some severe (i.e., tooth fracture, tooth loss), have been reported following the use of transmucosal buprenorphine-containing products. Educate patients to seek dental care and strategies to maintain or improve oral health while being treated with ZUBSOLV.
- QTc Prolongation: Thorough QT studies with buprenorphine products have demonstrated QT prolongation ≤15 msec. The risk of combining buprenorphine with other QT prolonging agents is not known. Consider these observations in clinical decisions when prescribing ZUBSOLV to patients with QT-related risk factors.

Use in Specific Populations

- Lactation: Buprenorphine passes into mother's milk.
- Geriatric Patients: Monitor for sedation and respiratory depression.
- Moderate and Severe Hepatic Impairment: Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment.

Adverse Reactions & Drug Interactions

- Adverse events commonly observed with the sublingual administration of ZUBSOLV are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.
- Benzodiazepines: Use caution in prescribing ZUBSOLV for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse.
- CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over or under dosing.
- Antiretrovirals: Patients who are on chronic buprenorphine treatment should have their dose monitored if NNRTIs are added to their treatment regimen. Monitor patients taking buprenorphine and atazanavir with and without ritonavir, and reduce dose of buprenorphine if warranted.
- Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue ZUBSOLV if serotonin syndrome is suspected.

This is not a complete list of potential adverse events associated with buprenorphine/naloxone tablets. For additional safety information, please see Full Prescribing Information.