DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (05/2024)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
DHS 134.31(3)(o)
DHS 94.03 & 94.09
§§ 51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.
This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)	ID Number	Living Unit	Date of Birth
,			

Name – Individual Preparing This Form	Name – Staff Contact	Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Opiate partial agonist	Subutex® (sublingual buprenorphine)	4 mg to 24 mg sublingually once daily	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.
Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.
This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)
Include DSM-5 diagnosis or the diagnostic impression ("working hypothesis").

2. Alternative mode(s) of treatment other than OR in addition to medications include
Note: Some of these would be applicable only in an inpatient environment.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

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4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects: Constipation, nausea, vomiting, xerostomia, abdominal pain, infectious disease

Less Common Side Effects: Prolonged QT interval, tachycardia, hypotension, sweating, diarrhea, toothache, constipation, ALT/SGPT level raised, gamma-glutamyl transferase above reference range, arthralgia, backache, creatinine kinase level above reference range, miosis, anxiety, depression, urinary tract infection, pain in throat, pneumonia, respiratory depression, respiratory distress or failure, dehydration, substance withdrawal

Rare Side Effects: Atrial fibrillation, chest pain, coronary arteriosclerosis, hypotension, non-cardiac chest pain, orthostatic hypotension, syncope, bradyarrhythmia, hypertension, tachycardia, bowel obstruction, cholecystitis, infection of tooth, liver function tests outside reference range, ankle fracture, osteoarthritis, cerebrovascular accident

Caution

Precautions:

- **Addiction**
  Use cautiously in patients with personal or family history of substance abuse or mental illness due to high potential for abuse, dependence, and misuse; dependence may occur with recommended doses.
- **Alcoholism**
  Use cautiously in patients with acute alcoholism and delirium tremens.
- **Cardiovascular**
  QTc prolongation has been reported; increased risk in patients with hypokalemia, bradycardia, recent conversion from atrial fibrillation, congestive heart failure, digitalis therapy, baseline QT prolongation, subclinical long-QT syndrome, or severe hypomagnesemia. Orthostatic hypotension may occur in ambulatory patients, particularly in patients with reduced blood volume and with concurrent administration of CNS depressants (e.g., general anesthetics, phenothiazines). Syncope may occur in ambulatory patients, particularly in patients with reduced blood volume and with concurrent administration of CNS depressants (e.g., general anesthetics, phenothiazines). Avoid use in patients with circulatory shock.
- **Endocrine and metabolic**
  Adrenal cortical insufficiency (e.g., Addison disease). Myxedema or hypothyroidism. Opioids may rarely lead to adrenal insufficiency due to inadequate amounts of cortisol.
- **Gastrointestinal**
  May obscure diagnosis or clinical course of patients with a head injury.
- **Hepatic**
  Sphincter of Oddi spasm may occur with morphine use; monitor patients with biliary tract disease, including pancreatitis. Use cautiously in patients with biliary dysfunction; increased intracholedochal pressure has been reported. Cytolytic hepatitis and hepatitis with jaundice have been reported, with increased risk in patients with preexisting liver enzyme abnormalities, hepatitis B or C, concomitant use of hepatotoxic drugs, and ongoing injection drug use.
- **Immunologic**
  Hypersensitivity may occur, including bronchospasm, angioneurotic edema, and anaphylactic shock.
- **Musculoskeletal**
  Kyphoscoliosis.
- **Neurologic**
  Increased intracranial pressure may occur in susceptible patients (e.g., brain tumors or head injury) due to decreased respiratory drive and carbon dioxide retention; monitoring recommended, especially with initiation and titration of therapy. Avoid use with impaired consciousness or coma. Potentially life-threatening serotonin syndrome may occur, particularly with concomitant use of serotonergic drugs. New or worsening seizures may occur; monitoring recommended in patients with history of seizure disorders. Opioid-induced hyperalgesia (OIH) may occur and has been reported with short-term and longer-term use of opioid analgesics.
- **Psychiatric**
  Use with caution in patients with toxic psychoses.
- **Renal**
  Prostate hypertrophy or urethral stricture.
- **Reproductive**
  Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility.
- **Respiratory**
  Life-threatening or fatal respiratory depression may occur, particularly in the elderly, cachectic, or debilitated patients, those with chronic obstructive pulmonary disease or cor pulmonale, and patients with substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression. Sleep-related breathing disorders including central sleep apnea and sleep-related hypoxemia may occur and risk increases in a dose-dependent fashion.

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- **Special populations (Beers Criteria)**
  Avoid opioids in patients with or at high risk for delirium, as may induce or worsen delirium. Avoid opioids in patients with a history of fractures or falls (excludes pain management for severe acute pain) as ataxia, syncope, impaired psychomotor function, or additional falls may occur. If use is necessary, consider reducing use of other CNS-active agents that increase risk of falls and fractures and implement other strategies to reduce risk of falls.
- **Special populations (Beers Criteria - Concomitant Use)**
  Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls and fractures, and avoid concomitant use of any benzodiazepine due to increased risk of adverse events and overdose. Avoid concomitant use of gabapentin or pregabalin due to increased risk of severe sedation-related adverse events including respiratory depression and death (unless when transitioning away from opioid therapy or with goal of reduced opioid use, although such uses require caution).

Warning
Black Box Warnings:

- **Buccal (Film)**
  Addiction, Abuse, and Misuse. Because the use of buprenorphine hydrochloride exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.
- **Life-Threatening Respiratory Depression**
  Serious, life-threatening, or fatal respiratory depression may occur with use of buprenorphine hydrochloride, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of buprenorphine hydrochloride are essential. Misuse or abuse of buprenorphine hydrochloride by chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in the uncontrolled delivery of buprenorphine and pose a significant risk of overdose and death.
- **Accidental Exposure**
  Accidental exposure of even one dose of buprenorphine hydrochloride, especially in children, can result in a fatal overdose of buprenorphine.
- **Risks From Concomitant Use with Benzodiazepines or Other CNS Depressants**
  Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of buprenorphine hydrochloride and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- **Neonatal Opioid Withdrawal Syndrome (NOWS)**
  If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Syndrome Note
Neonatal abstinence syndrome: May occur with prolonged use during pregnancy. Advise pregnant women of fetal risk- potentially life-threatening to the fetus without diagnosis and treatment. Monitor newborns for symptoms.

See standard reference text for an all-inclusive list of side effects.

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Medication: Subutex® – (sublingual buprenorphine)

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES		**DATE SIGNED**
Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client ☐ Self ☐ Parent ☐ Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	

Client / Parent of Minor / Guardian (POA-HC) Comments

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____