### Revision History

<table>
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<th>Version</th>
<th>Date of Revision</th>
<th>Description of Revision</th>
<th>Revised By</th>
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<td>1.0</td>
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<td>Dr. Robert Tanguay</td>
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Important Information Before You Begin

The recommendations contained in this knowledge topic have been provincially adjudicated and are based on best practice and available evidence. Clinicians applying these recommendations should, in consultation with the patient, use independent clinical judgment in the context of individual clinical circumstances to direct care. This knowledge topic will be reviewed periodically and updated as best practice evidence and practice change.

The information in this topic strives to adhere to Institute for Safe Medication Practices (ISMP) safety standards and align with Quality and Safety initiatives and accreditation requirements such as the Required Organizational Practices. Some examples of these initiatives or groups are: Health Quality Council Alberta (HQCA), Choosing Wisely campaign, Safer Healthcare Now campaign etc.

Guidelines

This Clinical Knowledge Topic is based on the following guidelines(s):

- Alberta ODT Training Program. Module Five: Opioid Agonist Therapy¹
- Canadian Research Initiative in Substance Misuse (CRISM), 2018²

Keywords

- Buprenorphine
- Suboxone
- Opiate/Opioid Agonist Therapy
- OAT
- Opiate/Opioid replacement
- Opiate/Opioid withdrawal
- Opiate
- Narcotic withdrawal
- Opiate/Opioid Use Disorder
- OUD
**Decision Making**

**Goals**
- Complete a comprehensive assessment. Confirm a DSM-5 diagnosis of opioid use disorder (See Appendix A)
- Initiate opioid agonist treatment (OAT) with buprenorphine-naloxone whenever appropriate to reduce the risk of toxicity, morbidity and mortality, as well as to facilitate safer take home dosing.

**Decision Making Algorithm**

Note: Methadone, Slow – release oral morphine (SROM), and injectable opioid agonist therapy (iOAT) are all specialist-led approach
Scoring and Assessment Tools

Clinical Opiate Withdrawal Scale (COWS)\(^3,4\)

- Utilize the Clinical Opiate Withdrawal Scale (COWS) to assess withdrawal symptom severity.

Additional Decision Making Information

- Complete Medication Reconciliation and review medication PIN in Netcare
- Ideally plan induction for morning dosing, allowing for reassessment in the afternoon.
- Review risks and benefits of treatment. (See Common Contraindications)
- Critical to discontinue opioid use prior to the scheduled induction, emphasizing the need for opioid withdrawal to avoid risk of precipitated withdrawal.
- Emphasize that induction cannot take place during acute alcohol intoxication, and that there is an increased overdose risk if actively using alcohol, benzodiazepines or other sedative medications
- Obtain informed consent. Treatment Agreement forms will be completed in outpatient follow up clinic
Buprenorphine-naloxone (Suboxone) Induction Order Set:

**Order Set Keywords:** Buprenorphine, Suboxone, Opiate/Opioid Agonist Therapy, OAT, Opiate/Opioid replacement, Opiate/Opioid withdrawal, Opiate, Narcotic withdrawal, Opiate/Opioid Use Disorder, OUD

**General**

*Clinical Opiate Withdrawal Scale (COWS)*[^3][^4] Guidance

- Utilize the Clinical Opiate Withdrawal Scale (COWS) to assess withdrawal symptom severity.
- Patient should be experiencing moderate opioid withdrawal (COWS score greater than 12) before taking the first dose to reduce the risk of precipitated withdrawal. Precipitated withdrawal is the rapid onset of withdrawal symptoms when opioid antagonist or partial agonist medication is administered before the agonist effects of a previous opioid have subsided.
- Consider postponing induction until later in the day or the following day if COWS score less than 12.

Some patients take longer than others to show certain withdrawal symptoms, or show fewer withdrawal symptoms with longer abstinence periods. Initiation of buprenorphine-naloxone can occur if a patient has a lower COWS score, but clinical judgement, and patient awareness of risks is required.

Ensure ALL inclusion criteria met

- Working diagnosis of opioid use disorder (OUD) according to the DSM V criteria
- Longer than 12 hours since last opioid use
  - At least 12 hrs since last short acting opioid (e.g. Heroin, crushed oxyCODONE [HYDROmorphine, morphine, Percocet])
  - At least 24 hrs since last oral long acting opioid (e.g. PO oxycodone [Oxycontin, Oxyneo], HYDROmorphine)
  - At least 72 hrs since last methadone dose
- *Caution is recommended in dosing for patients who are intoxicated

Opioid(s) last used: _________________ Route: ____________

Time opioid(s) last used: _________________ Route: ____________

**Patient Care**

**Monitoring**

*For alcohol withdrawal concerns, refer to Alcohol Withdrawal, Adult - Inpatient Order Set*

- Vital Signs every _____ hour
- Assess and document COWS every 30 to 60 minutes until score is greater than 12, then proceed with first dose of buprenorphine-naloxone.
  - Repeat COWS score 30 to 60 minutes after first dose
  - Notify prescriber if COWS scale increases by more than 2 or if patient is complaining of significant increase in withdrawal symptoms

**Psychosocial**

*Screen to be done on day 7 or discharge whichever comes first to assist with discharge planning*

- Depression screening (PHQ9)
- Anxiety screening (GAD 7)
- PTSD screening (PCL 5)
Laboratory Investigations On Admission

Hematology
- Complete Blood Count (CBC) with differential

Chemistry
- Creatinine
- Urea
- ALT
- Bilirubin Total
- Beta HCG

Urine
- Urine Drug Screen – Opioid Dependency Program Panel

Microbiology
- If symptoms suspected refer to the Sexually Transmitted Infection, Adult- Acute Care Clinical Knowledge Topic for the following order sets:
  - Suspected Sexually Transmitted Infection, Adult Male
  - Suspected Sexually Transmitted Infection, Adult Female
  - Suspected Sexually Transmitted Infestations and Lumps
  - Suspected Sexually Transmitted Genital Ulcers, Adult
  - Hepatitis/HIV Laboratory testing
    - Hepatitis B Post-Exposure Prophylaxis
    - Human Immunodeficiency Virus Post-Exposure Prophylaxis (HIV PEP)

Buprenorphine-Naloxone Initiation for Day 1

Contraindications:

Absolute:
- Allergy to buprenorphine, naloxone,

Relative:
- Pregnancy: Health Canada no longer lists pregnancy as a contraindication to its use. Clinicians treating pregnant women or women who become pregnant with established clinical stability on buprenorphine-naloxone are advised to continue treatment and consult an addiction medicine specialist. Buprenorphine without naloxone is safe in pregnancy and available through Special Access Program from Health Canada.
- Severe liver dysfunction or with cirrhosis and impaired function: Careful consideration advised when liver enzymes greater than 3 to 5 times normal upper limit.
- Severe respiratory distress
- Bowel obstruction
- Acute alcohol intoxication and/or Delirium tremens

The following is a general guideline only. Careful titration with senior populations as well as with youth is required. Prescribers are encouraged to access the Alberta OUD consult service.

*Buprenorphine-naloxone sublingual tablets can be halved and/or combined to achieve target doses.
Clinical Communication – Nurse to witness ingestion of buprenorphine-naloxone to ensure that the tablet is fully dissolved sublingually. Instruct patient to keep the tablet under their tongue until it dissolves, which may take up to 10 minutes, and to avoid swallowing, talking, eating, drinking, and smoking during this time.

Induction Day 1: Dose 1
The most common starting dose is 2 mg-0.5 mg (buprenorphine-naloxone). If the patient is experiencing severe withdrawal symptoms, starting dose may be increased to 4 mg-1 mg under supervised conditions

☐ buprenorphine-naloxone ______ mg sublingual once. Nurse to witness tablet dissolving sublingual
☑ Reassess COWS score in 30–60 minutes from the time of first dose
☐ Monitor for signs of precipitated withdrawal: COWS score significantly increased from initial score and/or patient complaining of worsening symptoms of opioid withdrawal within 30 minutes of the first dose of buprenorphine-naloxone. Refer to Medication for Withdrawal Symptoms below.

It is also important to monitor patients who are naïve to buprenorphine for signs of allergic reaction
☐ Monitor for allergic reaction: hives, difficult breathing, swelling of your face, lips, tongue, or throat) for 30-60 minutes following first dose buprenorphine-naloxone

Induction Day 1: Dose 2
Once it has been established that the initial dose is well tolerated the dose can be increased fairly rapidly to a dose that provides stable effects for 24 hours and is clinically effective

1. If withdrawal symptoms are well controlled with the initial dose, a second dose may not be required. If withdrawal symptoms return then a second dose is appropriate.
2. If symptoms are not adequately relieved, monitor and repeat dosing until symptoms are relieved or 12 mg-3 mg (buprenorphine-naloxone) is reached in the first 24 hours.
3. If symptoms persist despite reaching the 12 mg-3 mg (buprenorphine-naloxone) maximum recommended first day dose, consider contacting addiction medicine supports (local or through the AHS Opioid Use Disorder Telephone Consultation Line) for additional recommendations.

☐ Repeat buprenorphine-naloxone 2 mg- 0.5 mg sublingual every 1 hour until relief of symptoms or maximum of 12 mg – 3mg is reached in the first 24 hours.
☐ OR
☐ Repeat buprenorphine-naloxone 4 mg-1 mg sublingual dose every 1 hour until relief of symptoms or maximum of 12 mg-3 mg is reached in the first 24 hours.

Medications for Withdrawal Symptoms
Precipitated withdrawal can occur when the first dose is administered to an individual using full agonist opioids (e.g., heroin, fentanyl, oxyCODONE).

- Buprenorphine- naloxone rapidly displaces any full agonist opioid that is present at the receptor resulting in a dramatic decrease in overall opioid effects resulting in precipitated withdrawal.
• In patients who have used full agonist opioids recently, the sudden replacement can precipitate significant opioid withdrawal symptoms.

**Precipitated Withdrawal: Intervention**

In the event that a patient develops precipitated withdrawal, clinicians may either continue or stop the induction.

- Both options require supportive treatment, reassurance that symptoms will resolve, and careful explanation of what has occurred to patients.
- Deciding between these two options can be guided by patient preference, severity of precipitated withdrawal and clinician experience.

**Option 1: Continue Induction (preferred)**

- Obtain informed consent to continue with induction.
- **Prescribers are encouraged to access the Alberta OUD consult service for guidance regarding**
  - Administration of adjunct medications (i.e. cloNIDine, gabapentin, QUETiapine)
  - Administration of additional doses of buprenorphine-naloxone
  - Offer non-opioid symptomatic treatment for withdrawal

**Option 2: Stop Induction (not preferred)**

- Obtain informed consent to stop induction.
- Provide reassurance that symptoms will resolve as opioid withdrawal runs its course.
- Offer non-opioid symptomatic treatment for withdrawal
- Plan for another trial of induction on a future date, preferably the next day if possible.

References:
Canadian Research Initiative in Substance Misuse (CRISM), 2018; British Columbia Centre on Substance Use (BCSSU) and B.C. Ministry of Health, 2017a; American Society of Addiction Medicine, 2015.

Limit administration of benzodiazepines to no more than 72 hours

- cloNIDine 0.1 to 0.2 mg PO every 4 hours PRN for restlessness, tachycardia, diaphoresis. Hold if SBP is less than 90 (maximum dose of 0.6 mg per 24 hours)
- dimenhyDRINATE 50 mg PO/IV every 6 hours PRN for nausea
- loperamide 4 mg PO x1 PRN for diarrhea and then 2 mg PO PRN after each loose stool to maximum of 16 mg in 24 hours
- ibuprofen 600 mg PO every 6 hours PRN
- acetaminophen 1000 mg PO every 4 hours PRN to a maximum of 4 doses or 4000 mg in 24 hours
- gabapentin 200 mg to 400 mg TID PRN
  May choose ONE of:
  - clonazePAM 0.25 mg to 0.5 mg PO BID PRN
  OR
  - LORazepam 0.5 mg to 1 mg PO sublingual every 6 hours PRN
Buprenorphine-Naloxone Initiation for Day 2

**Induction Day 2: Dose 1**

*If no withdrawal symptoms since last dose:*

- Continue a once-daily dose equal to the total amount administered on the previous day. Titrate up as needed in subsequent days.

*If withdrawal symptoms present since last dose:*

- Administer dose equal to the total amount administered on previous day, plus an additional **Buprenorphine-naloxone 4 mg-1 mg**. The target dose on Day 2 is 16 mg-4 mg. **If symptoms are relieved after 2 to 3 hours**, prescribe this target dose for the next day.

  - Buprenorphine-naloxone ______ mg sublingual once. Nurse to witness tablet dissolving sublingual.
  - Nurse to reassess and repeat COWS score every 2 to 3 hours if clinically indicated.

**Induction Day 2: Dose 2**

After the first dose, if symptoms are not relieved after 2–3 hours, a second of 4 mg-1 mg dose of buprenorphine-naloxone can be administered. Current guidelines recommend the total dose on Day 2 should not exceed 16 mg-4 mg (without consultation from addiction specialist).

- If symptoms resolve 2–3 hours after the second additional dose, prescribe this total daily dose for the following day.

- **If symptoms persist 2–3 hours and target 2\textsuperscript{nd} day dose of 16 mg-4 mg has been reached:**
  - Prescribers are encouraged to access the Alberta OUD consult service for guidance on prescribing beyond target 2\textsuperscript{nd} day dosing (i.e. 18 mg to 24 mg).
  - Manage withdrawal symptomatically for the remainder of Day 2

**Note:** If withdrawal symptoms are not relieved with initial or repeated buprenorphine-naloxone doses, it is important to confirm that tablets are being taken and/or administered correctly (i.e., placing under tongue, waiting for tablet(s) to dissolve completely, no swallowing, eating, drinking, or smoking until tablet has fully dissolved).

  - Buprenorphine-naloxone ______ mg sublingual once. Nurse to witness ingestion

**Induction Day 3+**

On the 3\textsuperscript{rd} and subsequent induction days, if withdrawal symptoms, craving, or illicit opioid use persists:

- Titrate as needed to achieve an optimal stable dose that can sustain an entire 24-hour dosing interval with no withdrawal symptoms and no medication-related intoxication or sedation
- Target dose is generally **16 mg-4 mg daily** (buprenorphine-naloxone) by the end of the first week,
- For fentanyl, this may be different and up to a dose of **24 mg-6 mg daily** may be required.

**Doses Greater than 24 mg-6 mg**

- Doses greater than 24 mg-6 mg daily have not been demonstrated to provide clinical advantage.
- **However US guidelines support, and clinical practice has shown some patients may require doses up to 32 mg-8 mg daily.**
- Prescribers are encouraged to access the Alberta OUD consult service for guidance on prescribing beyond a dose of 24 mg-6 mg daily.
Clear documentation and justification should be included in the patient record for doses that do exceed 24 mg-6 mg buprenorphine-naloxone.

If symptoms persist for 2 to 3 hours and target 2\textsuperscript{nd} day dose of 16 mg-4 mg has been reached or if 3\textsuperscript{rd} dose of 24 mg-6 mg daily is reached. Prescribers are encouraged to access the Alberta Opioid Dependency Program (ODP) e-Consult line and/or eReferral to speak with an addiction medicine specialist for guided management of precipitated withdrawal.

- Buprenorphine-naloxone ______ mg sublingual daily

Transitions and Referrals

- Consult Addiction Services, if available
- Consult Psychiatry, if available
- Social Worker - To confirm patient has drug coverage for Buprenorphine-Naloxone in community
- Consult outpatient prescriber
- Opioid Dependency Telephone Consult or eReferral to Alberta Opioid Dependency Program (ODP) consult service for guidance
  
  [https://www.albertahealthservices.ca/info/page15558.aspx](https://www.albertahealthservices.ca/info/page15558.aspx)

Admission/Transfer/Discharge Planning

1. Considerations for Discharge/Transfer
   - At time of Discharge Instruction
     - Fax triplicate prescription providing up to 7 days prescription for buprenorphine-naloxone for patients (observed daily dosing at pharmacy)
     - Physician to provide discharge instructions
     - Contact follow up provider if symptoms worsening
     - Follow up information given
     - Naloxone kit with education on use or resources for training
     - Fax referral to ____________ clinic
   - Contact and arrange urgent appointment for outpatient prescriber
   - Bridging prescription (triplicate) faxed to outpatient pharmacy

2. Outpatient follow-up
   - Referral to outpatient addiction treatment
   - Referral to harm reduction services
   - Discharge home with a naloxone kit and review instruction
   - Ensure patient is connected with outpatient services or family physician for continued care

3. Patient and Caregiver education and discharge instructions (under development)
References
2. Canadian Research Initiative in Substance Misuse (CRISM), 2018.
3. British Columbia Centre on Substance Use (BCSSU) and B.C. Ministry of Health, 2017.

Additional Resources
Appendix A  DSM 5 Diagnostic Criteria for Opioid Use Disorder

<table>
<thead>
<tr>
<th>A</th>
<th>A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by <strong>at least 2 of the following</strong>, occurring within a 12-month period:</th>
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<tbody>
<tr>
<td>1</td>
<td>Opioids are often taken in larger amounts or over a longer period than was intended</td>
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<td>2</td>
<td>There is a persistent desire or unsuccessful efforts to cut down or control opioid use</td>
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<td>3</td>
<td>A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects</td>
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<td>4</td>
<td>Craving, or a strong desire or urge to use opioids</td>
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<td>5</td>
<td>Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home</td>
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<tr>
<td>6</td>
<td>Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids</td>
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<tr>
<td>7</td>
<td>Important social, occupational, or recreational activities are given up or reduced because of opioid use</td>
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<tr>
<td>8</td>
<td>Recurrent opioid use in situations in which it is physically hazardous</td>
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<td>9</td>
<td>Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance</td>
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<td>10</td>
<td><strong>Tolerance</strong>, as defined by either of the following:</td>
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<td>a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect</td>
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<td>b. A markedly diminished effect with continued use of the same amount of an opioid</td>
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<td><strong>Note:</strong> This criterion is not considered to be met for those taking opioids solely for appropriate medical supervision</td>
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<td>11</td>
<td><strong>Withdrawal</strong>, as manifested by either of the following:</td>
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<td>a. The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal)</td>
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<td>b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms</td>
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<td><strong>Note:</strong> This criterion is not considered to be met for those taking opioids solely for appropriate medical supervision</td>
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**Specify Severity as:**
- Mild: Presence of 2 to 3 symptoms
- Moderate: Presence of 4 to 5 symptoms
- Severe: Presence of 6 or more symptoms

**Specify Remission as:**
- Early Remission: After full criteria for opioid use disorder were previously met: None of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception of "Craving, or a strong desire or urge to use opioids")
- Sustained Remission: After full criteria for opioid use disorder were previously met: None of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception of "Craving, or a strong desire or urge to use opioids")

**Specify if:**
- On Maintenance Therapy: Use if the individual is taking a prescribed agonist medication such as methadone or buprenorphine and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone
- In a controlled environment: Use if the individual is in an environment where access to opioids is restricted

### Clinical Opioid Withdrawal Scale (COWS)

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 ______/_______/__________ |
| Reasons for this Assessment: | |

**Resting Pulse Rate:**
- 0 pulse rate 80 or below
- 1 pulse rate 81 - 100
- 2 pulse rate 101 - 120
- 4 pulse rate greater than 120

**Gl 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

**GI Upset:** 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

**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 observables
- 4 gross tremor or muscle twitching

**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 observables
- 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 I 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.

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

We would like to acknowledge the contributions of the Provincial Clinical Knowledge Working Group members as follows. Your participation and time spent is appreciated.

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<td>On behalf of Provincial Nutrition and Food Services</td>
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Strategic Clinical Network

Addiction and Mental Health Strategic Clinical Network

Clinical Informatics Leads

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**Additional Contributors**

Thank you to all provincial stakeholders who participated in the review process for this topic. Your time spent reviewing the knowledge topics and providing valuable feedback is appreciated.

For questions or feedback please contact ClinicalKnowledgeTopics@ahs.ca.