Department of Health Government of Nunavut	**Medical Directives and Delegation** **Community Health Nursing**		
TITLE:		**SECTION:**	**POLICY NUMBER:**
Naltrexone use for Alcohol Dependency		Pharmacy	09-021-00
EFFECTIVE DATE:	**REVIEW DUE:**	**REPLACES NUMBER:**	**NUMBER OF PAGES:**
Feb 15, 2022	Feb 15, 2025	New Policy	6
APPLIES TO:			
Community Health Nurses (CHN), Mental Health Nurse (MHN)			

1. BACKGROUND:

The Department of Health (Health) is committed to providing Nunavummiut with treatment options that align with current research and best practices.

Naltrexone is a safe and evidence-based pharmaceutical option for patients with alcohol dependency which improves both reduction and cessation outcomes. Naltrexone is not an aversive pharmacotherapy, but acts to decrease cravings.

This medical directive provides an authorising mechanism for Community Health Nurses (CHNs) and Mental Health Nurses (MHNs) to dispense a 14-day course of Naltrexone for alcohol dependency until a prescription can be obtained from a physician or nurse practitioner (NP). It is important for the client to have timely access to Naltrexone when they are seeking help. Delays in access to Naltrexone may negatively influence the client's willingness to adhere to this treatment and its success.

2. MEDICAL DIRECTIVE:

2.1. CHNs or MHNs may initiate and dispense up to a maximum of a 14-day course of Naltrexone for the treatment of reducing and abstaining from alcohol in clients with dependency.

2.1.1. Naltrexone is available as 50 mg tablets and is dispensed to allow a dose of 25 mg orally once a day x 3 days, then increased to the therapeutic dose of 50 mg orally once a day x 11 days.

2.2. Each time this medical directive is initiated, the CHN or MHN is responsible for reviewing the case (either by email or phone) with the community physician/NP or covering psychiatrist to obtain a prescription beyond the 14 days.

3. AUTHORIZED IMPLEMENTERS:

3.1. CHNs or MHNs who possess the knowledge, judgment, and skill to do so, refer to Appendix A. For CHNs lacking the knowledge, judgement and skill, supplemental education is available on Naltrexone provided by the Department of Addictions and Mental Health.

3.2. Sub-delegation is not permitted to another health care provider or staff.

4. ELIGIBLE CLIENTS

4.1. Adult clients 18 years of age or older with alcohol dependency meeting the DSM-5 criteria of moderate or severe (score of 4 or greater) alcohol use disorders. Refer to Appendix B for a template of the DSM-5 alcohol use disorder questionnaire.

4.2. Clients consenting to taking the medication and actively seeking assistance to reduce and/or abstain from alcohol.

4.3. Clients are ineligible for CHN or MHN initiated Naltrexone therapy if the client has received opioids in the past 7 days; has a medical history of acute hepatitis, liver failure or severe renal failure (eGFR < 20); ALT/AST great than three times the upper limit of normal; or pregnant.

5. NALTREXONE SAFETY PROFILE, CONTRAINDICATIONS, AND ADVERSE EFFECTS:

5.1. Safety Profile:

5.1.1. The client does not need to abstain from alcohol before starting Naltrexone.

5.1.2. Naltrexone is safe to continue to take even if the client continues to consume alcohol.

5.1.3. There is minimal risk to the client in the case of unintentional or intentional overdose.

5.2. Contraindications:

5.2.1. Concomitant opioid use or in acute opioid withdrawal. Since Naltrexone acts as a competitive antagonist at opioid receptors, this medication is contraindicated in clients who are actively on opioids. **The client must be opioid free for a least 7 days prior to the start of Naltrexone treatment.** If there is any doubt that your client is not opioid free, do not proceed with a Naltrexone start.

5.2.2. Acute Hepatitis or Liver Failure. Caution if

5.2.3. Severe Renal Failure (eGFR < 20) as naltrexone and its primary metabolite are excreted primarily in the urine (use with caution advised in Canada).

5.2.4. Transaminases (AST/ALT) greater than three times the upper limit of normal.

5.2.5. Pregnancy (a relative contraindication due to the lack of human studies).

5.3. Adverse Effects:

5.3.1. Nausea (10%)

5.3.2. Headache (7%)

5.3.3. Dizziness (7%)

5.3.4. Insomnia or sleepiness (5%)

5.3.5. Vomiting (4%)

5.3.6. Suicidal thoughts, attempted suicide and depression have been reported post-marketing, however, there is no statistical correlation (Incidence of suicidal ideation reported: Naltrexone group 0-1% & Placebo group 1-3%. Incidence of depression reported: Naltrexone group 0-15% & Placebo group 0-17%). Health Canada has no official warnings linking suicidality and Naltrexone. A theoretical risk exists. It is recommended to monitor for depression and/or suicidal thoughts.

Practice Point: Alternative pharmaceutical options should be explored with a physician or NP for clients with acute hepatitis, liver failure severe renal failure or on opioids. Pregnancy is a relative contraindication due to lack of human studies and the physician or NP should be consulted to weigh the risks vs benefits.

6. PROCEDURE:

6.1. The CHN or MHN is responsible for determining if the conditions of this directive have been met

before enacting it. The CHN will refer to the FNIHB Clinical Practice Guidelines (CPGs) on alcohol abuse in chapter 15 for additional alcohol related considerations outside the scope of this medical directive.

6.2. The CHN or MHN completes the DSM-5 Criteria for alcohol use disorder questionnaire with the client. Clients scoring 4 or greater and actively seeking assistance with a reduction or abstinence of alcohol meet the eligibility criteria for starting Naltrexone.

6.3. The CHN or MHN then reviews the list of contraindications outlined in section 5.2 to ensure all are excluded.

6.4. The CHN or MHN is responsible for outlining to the client the benefits, risks and adverse effects of starting Naltrexone and obtaining verbal consent.

6.5. Up to three times the upper limit of normal for transaminases is an acceptable range for a Naltrexone start (acceptable range includes: AST of 108 and ALT of 156). If AST and ALT have not been tested in the previous 6 months, they should be tested within one week of starting Naltrexone ordered by the CHN. A repeat AST and ALT follow-up is required at 1 month after treatment is initiated and the physician or NP is notified if transaminases exceed three times the upper limit of normal.

6.6. Caution is advised with an eGFR less than 20, consequently if a serum creatinine with eGFR have not been tested in the previous 6 months, it should be tested within one week of starting Naltrexone ordered by the CHN.

6.7. After reviewing the most up-to-date Nunavut Drug Formulary and the Dispensing Medication Policy # 09-005-00, the CHN may dispense a 14-day course of Naltrexone (25 mg orally once a day x 3 days, then increased to the therapeutic dose of 50 mg orally once a day x 11 days).

6.8. Naltrexone is available in the community health centres as a 50 mg scored tablet formulation. A medication bottle is prepared with three ½ tablets and 11 full tablets of Naltrexone. The CHN will follow the Labelling Pharmaceutical Agents Policy #09-011-00 and include the following on the medication label:

- 6.8.1. Client's name
- 6.8.2. Date
- 6.8.3. Medication name and strength
- 6.8.4. Dose, route, frequency, duration, amount dispensed
- 6.8.5. Nurse's initials who prepared the medication

6.9. Each time this medical directive is initiated, the CHN will then review the case (either by email or phone) with the community physician/NP or covering psychiatrist to obtain a prescription beyond 14 days. *The ideal duration of treatment should be at least 6 months.

6.10. An attempt should be made to engage the client with mental health counselling. A combination of counselling with pharmacotherapy provides the greatest efficacy over medication alone.

*Practice Point: Relapses are to be expected, but do not mean treatment failure. Have a treatment plan that addresses options and relapse management.

7. DOCUMENTATION:

7.1. The following must be documented in the client's health record in addition to following the Documentation Standard Policy (06-008-00) and Administering or Dispensing Pharmaceuticals – Documentation Policy (09-006-00)

- Reason for enacting this medical directive including the client's eligibility criteria along with contraindications excluded.
- Documentation that a verbal informed consent was obtained.

- Documentation of AST and ALT results within the past 3 months which are below the three times the upper limit of normal range.

8. RELATED POLICIES, PROTOCOLS AND LEGISLATION:

Community Health Nursing Manual:	09-011-00	Labelling Pharmaceutical Agents
Community Health Nursing Manual:	09-006-00	Administering or Dispensing Pharmaceuticals - Documentation
Community Health Nursing Manual:	09-005-00	Dispensing Medications
Community Health Nursing Manual:	09-001-00	Documentation of Allergies
Community Health Nursing Manual:	09-002-00	RN Initiated Drug Therapy
Community Health Nursing Manual:	07-001-00	Community Health Nursing
Community Health Nursing Manual:	06-008-00	Documentation Standard

9. APPENDICES

APPENDIX A: Decision-Making Model for Performing Additional Functions and Transferred Functions
APPENDIX B: DSM-5 Criteria for Alcohol Use Disorders

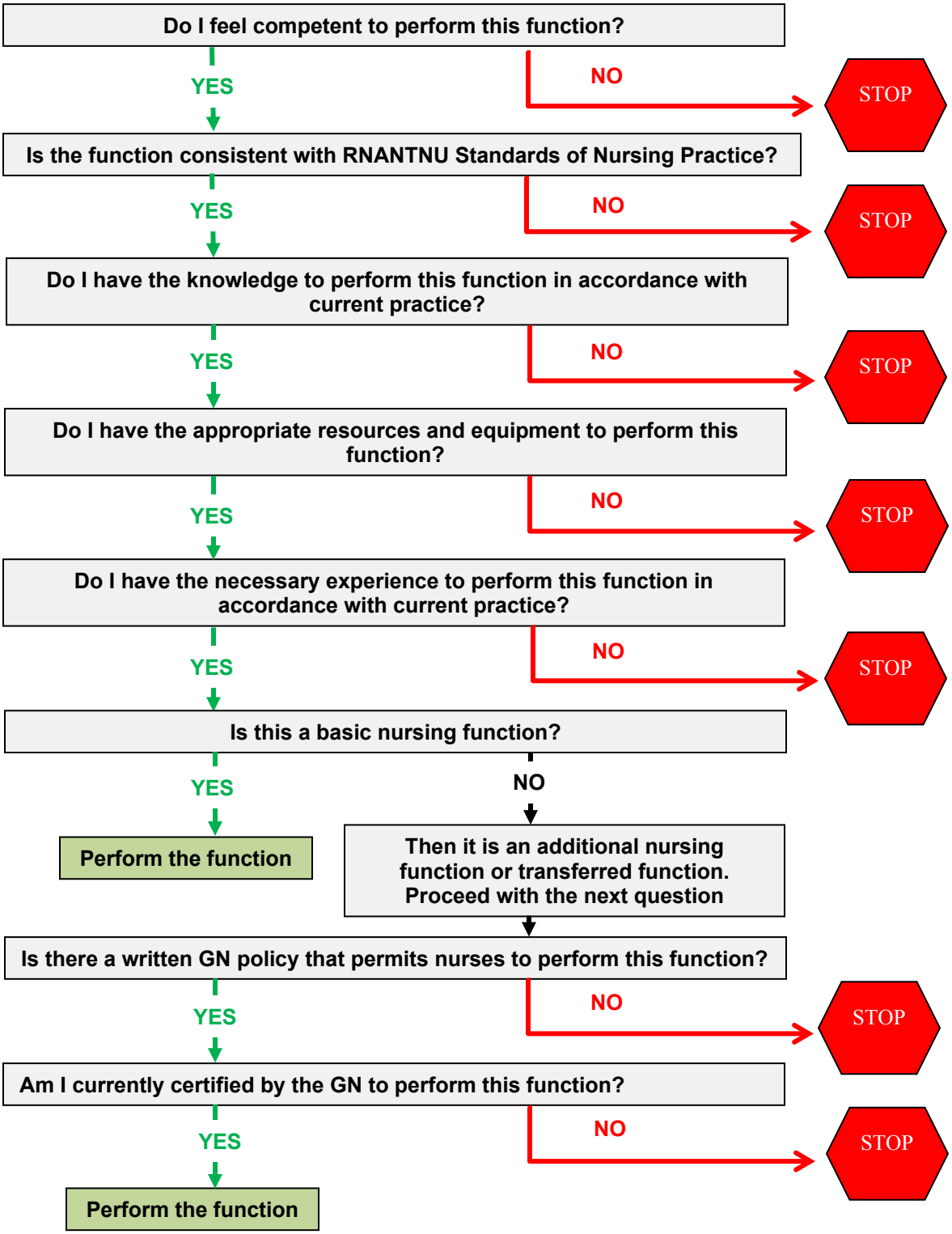
10. REFERENCES:

1. Alcohol Use Disorder (AUD) Tool. https://cep.health/clinical-products/alcohol-use-disorder/. September 2019.
2. Revia (Naltrexone) Product Monograph. Teva Canada Limited; 2020 Jul 16.
3. RxFiles Alcohol Use Disorder (AUD): Drug Comparison Chart Aug 2021.
4. Salsbury E et al. Pharmacotherapy for Alcohol Use Disorder. Therapeutic Tips and Trends 2021 Early Winter; 6(1): 1-8.

11. APPROVALS:

Approved By: Jennifer Berry	Date: 2022-02-15
Jennifer Berry, Assistant Deputy Minister – Health Operations	
Approved By: Jenifer Bujold	Date: Feb 15, 2022
Jenifer Bujold, a/Chief Nursing Officer	
Approved By:	Date: Feb 15, 2022
Dr. Chelsey Sheffield, a/Territorial Chief of Staff	

APPENDIX A: Decision-Making Model for Performing Additional Functions and Transferred Functions



RNANT/NU (2010). *Scope of Practice for Registered Nurse*

Appendix B: DSM-5 Criteria for Alcohol Use Disorders

DSM-5 Criteria for alcohol use disorders: 2-3 positive questions indicate mild alcohol use disorder; 4-5 positive questions indicate moderate alcohol use disorder; and 6+ positive questions indicate severe alcohol use disorder. In the past 12 months have you:

- ☐ Had times when you ended up drinking more, or longer than you intended?
- ☐ More than once wanted to cut down, stop drinking, or tried to, but couldn't?
- ☐ Spent a lot of time drinking? Or being sick/getting over the after effects?
- ☐ Experienced craving — a strong need, or urge to drink?
- ☐ Found that drinking or being sick from drinking often interfered with taking care of your home or family? Or caused job troubles? Or school problems?
- ☐ Continued to drink even though it was causing trouble with your family or friends?
- ☐ Given up or cut back on activities that were important or interesting to you, or gave these activities to drink?
- ☐ More than once gotten into situations during or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in dangerous area, unsafe sex)?
- ☐ Continued to drink even though it was making you feel depressed, anxious or adding to another health problem? Or continued to drink after having had a blackout?
- ☐ Had to drink much more than you once did to get a desired effect? Or found that your usual number of drinks had much less effect than before?
- ☐ Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, irritability, anxiety, depression, restlessness, nausea, or sweating? Or sensed things that were not there?