NALTREXONE FOR RELAPSE PREVENTION GUIDELINE

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VALIDITY – should be accessed via the Trust intranet to ensure the current version is used.

CHANGE RECORD

Version	Date	Change details
1.0	*15 December 2016*	*New guidance.*
2.0	*12 November 2020*	*Reviewed and reformatted* *Initiation dose change for alcohol patients* *References added* *Prescriber referred to as doctor or NMP* *Trust logo updated*
3.0	*26 September 2024*	*Reviewed and addition of breath alcohol/drug test prior to starting medication. References updated. Approved at Drug and Therapeutics Group (26 September 2024).*

Contents

1. INTRODUCTION

NICE (2011) recommend that people who are opioid dependent progress from maintenance to detoxification and then abstinence. However relapse rates are high, and therefore detoxification should be supported by relapse-prevention strategies and psychological support.

The opioid antagonist Naltrexone can be used to help maintain abstinence and prevent relapses for people with opioid or alcohol dependence who are abstinent.

Naltrexone has been recommended by NICE (2007) Technology Appraisal guidance (TA115) and NICE (2011) Clinical guideline (CG115) for relapse prevention with opioid and alcohol dependence.

What is Naltrexone?
Naltrexone hydrochloride is used in combination with other medicines or therapy to help those who are dependent on drugs such as heroin (opioids), overcome their addiction.
It is indicated as supportive therapy in maintaining abstinence (self-denial) in alcohol-dependent patients.
Naltrexone acts by blocking receptors in the brain to block the action of opioids. Individuals will no longer experience the euphoria previously experienced after taking opioids.

From **Summary of product characteristics** (EMC, 2023)

Therapeutic Indication:

It is recommended that Naltrexone is an additional therapy within a comprehensive treatment program (including psychological therapy) for detoxified patients who have been opioid dependent or alcohol dependent to support abstinence.

The intended outcome is to support patients to stay abstinent of alcohol and/or opioids.

2. SCOPE

This document is applicable to all staff that work within Humber NHS Foundation Trust Addictions Services, East Riding Partnership (ERP). The Addictions service forms part of the Community Services Directorate.

The document is intended to support the use of appropriate, safe and effective prescribing of Naltrexone for relapse prevention for people who have been alcohol or opioid dependent and are now abstinent.

The document applies to all adults (aged 18 and over) with either alcohol or opioid dependence who are abstinent and would like a pharmacological intervention in combination with psychosocial interventions.

3. STATEMENT

This document sets out the standards of care that are expected when initiating Naltrexone treatment.

This document is part of a recovery focused addictions service options for interventions to prevent relapse.

This document supports the compliance with the Care Quality Commission Regulation 10, Outcome 16 - 'Patients who use the service will benefit from quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety'.

4. DUTIES AND RESPONSIBILITIES

The Addictions Service (ERP) clinical network group will disseminate this document to its staff for awareness. A copy will be published on the Trusts intranet.

Medical Doctors or Non-Medical Prescribers (NMP) with specialist knowledge of addictions would be responsible for initiation of the treatment of Naltrexone after clinical assessment and if this was agreed by the multi-disciplinary team to form part of an appropriate patient management plan.

5. PROCEDURES

5.1. Method of administration (Adults)

In accordance with national guidance the therapy should be initiated and supervised by a prescriber (Doctor or NMP) experienced in treatment of opioid-addicted and alcohol-addicted patients. When starting all new medications, the prescriber should go through the patient information leaflet on the drug with the patient, following clinical assessment.

Prior to first dose:
Breath alcohol to confirm no alcohol use.
Urine drug test to confirm no opioid class present.

Opioid dependence
The initial dose of Naltrexone hydrochloride should be 25 mg (half a tablet) for the opioid-dependent patient (BNF, 2023) followed by the usual dose of one tablet per day (50 mg Naltrexone hydrochloride).

Alcohol dependence
The initial dose of Naltrexone hydrochloride should be 25 mg (half a tablet) for the alcohol-dependent patient (BNF, 2023) followed by the usual dose of one tablet per day (50 mg naltrexone hydrochloride).

Dosage-regimen for both opioid and alcohol dependence
The Naltrexone dose can be modified in order to improve compliance to a three-times-a-week dosing schedule as follows: administration of 2 tablets (100 mg Naltrexone hydrochloride) on Monday and on Wednesday and 3 tablets (150 mg Naltrexone hydrochloride) on Friday. A dose of over 150 mg on any single day is not recommended, since this can lead to a higher incidence of side effects.

Important:

Naltrexone administered to currently using opioid-dependent persons can cause life-threatening withdrawal symptoms.

It must be verified that a patient has not taken opioids prior to starting naltrexone using a drug test.

Patients suspected of using opioids or being currently physically dependent on opioids must not start naltrexone until it has been confirmed that they have no opioid class in their urine drug test.

If a patient is suspected to be dependent on opioids currently or there are any further concerns, the prescriber may consider a naloxone challenge, as below.

However it is recommended to wait for a drug test confirming the presence of no opioids.

Naltrexone treatment must begin only when the opioid has been discontinued for a sufficiently long period (about 5 to 7 days for heroin and at least 10 days for Methadone) and this is negative on the urine drug test.

5.2. Length of treatment

As this is an adjunct to psychosocial treatment, no standard duration of treatment is stated but an initial three months should be considered. Prolonged administration may be necessary and can be done so with support of the patients GP, under a Shared Care Prescribing Framework.

5.3. Contraindications

- Hypersensitivity to the active substance or its constituents
- Severe renal impairment
- Severe hepatic impairment
- Acute hepatitis
- Opioid addicted patients with a current abuse of opioids
- Positive screening result for opioids (or after failure of the naloxone challenge test)
- For use in conjunction with an opioid – containing medication – e.g. codeine
- In combination with Methadone.

5.4. Special warnings and precautions for use

- Risk of overdose - high dose opioid intake with Naltrexone can lead to overdose.
- Patients must be warned against the concomitant use of opioids.
- Liver Function tests - Abnormal liver function tests have been reported with Naltrexone. Therefore Liver Function Tests (LFT) before and during treatment are required.
- Naltrexone is extensively metabolised by the liver and excreted predominantly in the urine. Therefore, caution should be observed in administering to patients with impaired hepatic or renal function.
- If the patient needs opioid treatment, e.g. opioid analgesia in emergency situations, the dose needed may be higher than normal. The patient will require specific attention and care in these situations.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- Patients might be more sensitive to opioid containing medicines after treatment with Naltrexone.

5.5. Pregnancy and lactation

Data from animal studies have shown reproductive toxicity. The data is insufficient to establish clinical relevance. The potential risk for humans is unknown. Naltrexone should only be given to pregnant women when, in the judgement of the prescriber, the potential benefits outweigh any possible risk.

During treatment breast feeding is not recommended.

5.6. Naloxone challenge procedure (for information)

1. The patient must have the result of recent (within 4 weeks) liver function tests available at the time of the challenge. These must be reviewed and signed off by the supervising doctor (see point 5.4).
2. The patient must be opiate free i.e. from Methadone for 10 days, heroin for 7 days and Buprenorphine for 4 days prior to the challenge.
3. The patient will need to be in the building for at least 1½ hours and a prescriber (doctor or NMP) must be present during this time.

4. A doctor or nurse must be available for monitoring pulse and blood pressure.
5. Before commencing, the patient must be given a full explanation of the Naloxone Challenge; particularly that withdrawals may be severe if they have used opiates in the previous 4-10 days (see point 5.1). Document in notes that this information has been given.
6. Test a fresh sample of urine to test for the presence of opiates. If positive or the patient admits to using opiates within the time periods specified, abandon the test and arrange for the patient to be reassessed. If urine test negative, proceed with the challenge.

The Naloxone Challenge

1. Check baseline blood pressure (BP) and pulse

Give Naloxone 200micrograms I/M injection

2. Repeat BP and pulse after 5 minutes

3. Repeat BP and pulse after further 25 minutes, If no signs of opiate withdrawal, then

Give Naloxone 600micrograms I/M injection

1. Repeat BP and pulse after 5 minutes

2. Repeat BP and pulse after further 55 minutes

Give Naltrexone 25mg (½ tablet orally)

Interpretation of the Naloxone Challenge Test
If opiate withdrawal symptoms occur, the onset is within a few minutes and peaks within 10 minutes. The following symptoms may occur:

I. Piloerection (palpable and lasting>30 seconds)
II. Rhinorrhoea, lacrimation and yawning (> 3 times)
III. Sweating (wet rather than moist)
IV. Vomiting

A positive test (i.e. the patient is still dependent on opiates) occurs if there is:

I. One or more marked symptoms
II. Two or more milder symptoms

Piloerection is the most decisive sign. Restlessness may also occur.

What to do after a Naloxone Challenge Test
I. Test Negative – Start naltrexone 25mg that day, 50mg daily thereafter. Follow the guideline for the prescribing of Naltrexone.
II. Test mild Positive or patient has subjective discomfort – Repeat challenge 2-3 days later.
III. Test Positive with severe withdrawals – Symptomatic relief for withdrawals.

6. EQUALITY AND DIVERSITY

An Equality and Diversity Impact Assessment (EIA) has been carried out on this document using the Humber Teaching NHS Trust approved EIA tool.

7. MENTAL CAPACITY

The Trust supports the following principles, as set out in the Mental Capacity Act and has applied them in the development of this document:

1. A person must be assumed to have capacity unless it is established that they lack capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because they make an unwise decision.
4. An act completed, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in their best interests.
5. Before the act is completed, or the decision made, regard must be had as to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

8. IMPLEMENTATION

This document will be disseminated by the method described in the Policy and Procedural Documents Development and Management Policy.

This document does not require additional financial resource.

9. MONITORING AND AUDIT

Monitoring and Audit of adherence to this guideline will occur utilising the clinical record system (SystmOne) every two years. Results will be shared with staff via ERP Clinical Network meeting members.

10. REFERENCES/EVIDENCE/GLOSSARY/DEFINITIONS

BNF (2023) British National Formulary https://bnf.nice.org.uk/drug/naltrexone-hydrochloride.html

EMC (2023) Electronic Medical Compendium Naltrexone Hydrochloride 50 mg Film-coated Tablets SmPC https://www.medicines.org.uk/emc/product/6073/smpc#gref

https://www.medicines.org.uk/emc/product/8968/smpc

NICE (2007) Technology Appraisal guidance (TA115) Naltrexone for the management of opioid dependence

NICE (2011) Clinical guideline (CG115) Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence