**Guidance For The Use Of Naltrexone In The Maintenance Of Abstinence in Formerly Opioid Dependent Adults By Clinicians Working Within NHS Grampian**

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<th>Lead Author/Co-coordinator:</th>
<th>Consultation Group:</th>
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<tr>
<td>NHS Grampian Substance Misuse Pharmacists</td>
<td>See relevant page in the Guidance</td>
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**Executive Sign-Off**

This document has been endorsed by the Director of Pharmacy and Medicines Management

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Author: Substance Misuse Pharmacists

Subject: Guidance

Key word(s): Guidance naltrexone opioid dependence substance misuse

Policy application: NHS Grampian – Substance Misuse

Purpose: This guidance advises all staff, involved in prescribing for substance misuse patients, on the recommended use of naltrexone in managing opioid dependency.

Responsibilities for implementation:

Organisational: Management Teams

Corporate: Senior Managers

Departmental: Substance Misuse Management Team

Area: General Practitioner Practices

Policy statement: It is the responsibility of supervisory staff at all levels to ensure that their staff are working to the most up to date and relevant guidance, policies, protocols and procedures. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this guidance act within their own level of competence.

Review: This policy will be reviewed at least every three years or sooner if current treatment recommendations change.
This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Responsible for review of this document: Substance Misuse Pharmacists

Responsible for ensuring registration of this document on the NHS Grampian Information/Document Silo: Pharmacy and Medicines Directorate, NHS Grampian

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Guidance for the use of naltrexone in the maintenance of abstinence in formerly opioid dependent adults by clinicians working within NHS Grampian

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Guidance For The Use Of Naltrexone In The Maintenance Of Abstinence In Formerly Opioid Dependent Adults By Clinicians Working Within NHS Grampian

1. Introduction

This guidance is intended for use by all clinicians involved in the management of substance misuse in NHS Grampian. It aims to provide guidance for the use of naltrexone in previously opioid dependent patients. Naltrexone is available for restricted use under specialist supervision (see Section 4.8). Treatment may be initiated in the community on the recommendation of a Consultant/Specialist in Substance Misuse.

2. Pharmacology

Naltrexone is a specific, high affinity, long acting competitive antagonist at opioid receptors and when taken regularly will prevent any other opioids binding to the opioid receptors. It has negligible opioid agonist activity. Tolerance does not develop with prolonged use.

3. Which Patients May Be Prescribed Naltrexone

Naltrexone is a treatment option in detoxified, formerly opioid-dependent people who are highly motivated to remain in an abstinence programme and who have remained opioid free for a minimum of 7-10 days. Prior to initiating treatment, consideration should be given to both benefits and risks associated with prescribing naltrexone. There is limited evidence to support its use in preventing relapse. This should be weighed up against the increased risk of overdose on relapse as tolerance to opioids will be low. Patients must be over 18 years of age.

4. Prescribing Information

4.1 Naltrexone should only be administered under adequate supervision to people who have been fully informed of the potential risks and adverse effects of treatment. It should be given as part of a programme of supportive care.

4.2 Patients should be warned that an attempt to overcome the blockade of opioid receptors whilst taking naltrexone could result in acute opioid intoxication, overdose and death as larger amounts of heroin/opioid will be required to achieve an effect and tolerance will be reduced. This is also the case for patients who miss doses/stop taking naltrexone and revert to opioid use. The patient’s motivation will be critical in the success of treatment. Prescribers should continue to assess this risk during treatment and advise accordingly.
4.3 Naltrexone is extensively metabolised by the liver and excreted predominantly in the urine. Therefore, caution should be observed in administering naltrexone to patients with impaired hepatic or renal function. Liver function tests should therefore be conducted prior to initiating treatment and repeated after one, three and six months of treatment. Where abnormalities are detected advice should be sought from the Specialist Substance Misuse Service prior to prescribing or continuing treatment. Naltrexone should not be given to patients with acute hepatitis or liver failure.

4.4 Initiating Treatment - Prior to initiating naltrexone the clinician should be certain that the patient is opioid free. Patients should be advised of the risk of precipitated withdrawal which can occur rapidly: the first symptoms can occur within 5 minutes, the last after 48 hours. Where there is uncertainty about a patient’s current opioid intake, it may be that naltrexone is not the most appropriate treatment option. There are tools which can be used to support the assessment process.

These include:

- A urine screen or oral fluid test which is negative for opioid drugs. If there remains doubt that the patient is free of opioid drugs the initiation of naltrexone should be delayed.

- Alternatively if the patient and clinician feel appropriate, a naloxone challenge can be considered. A withdrawal syndrome precipitated by naloxone will be of shorter duration than one precipitated by naltrexone.

Naloxone challenge should be undertaken by a specialist clinician in substance misuse as per the Summary of Product Characteristics (SPC) advice for naltrexone.

The recommended procedure is as follows:

(i) An initial dose of 0.2mg naloxone should be administered by intravenous injection.

(ii) Subcutaneous or intramuscular routes may be used where the intravenous route is not feasible however the onset of action and thus precipitation of withdrawal will be slower and thus the period of observation will be longer. The intravenous route is the preferred option and should be used wherever feasible.

(iii) If after 30 seconds no adverse reactions occur, a further intravenous injection of 0.6mg naloxone may be administered.

(iv) Continue to observe the patient for withdrawal effects for a further 30 minutes.

(v) If doubt exists that the patient is opioid-free, the challenge may be repeated with a naloxone dose of 1.6mg.

(vi) If there is no evidence of a reaction, naltrexone administration may be initiated with 25mg (half a tablet) by mouth.
4.5 The initial dose of naltrexone 25mg (half a tablet) on day 1 should be followed by 50mg (one tablet) daily. If the daily dose is tolerated there is the potential for the patient to take the regime at a higher dose on three days a week, e.g. 100mg Monday, 100mg Wednesday and 150mg Friday. The recommended maximum daily dose is 150mg. The total weekly dose should not exceed 350mg. It is worth considering the increased incidence of gastro-intestinal side-effects that may result and the likelihood of concordance with this regimen prior to prescribing.

4.6 Patients should be provided with adequate information on naltrexone and its effects, including its effect on opioid pain relief. A fact sheet is available (Appendix 1) and should be printed off and given to each patient. “Drug misuse and dependence: UK guidelines on clinical management” recommends that patients are given a card indicating that they are maintained on naltrexone.

4.7 During the first month of treatment the patient should be offered weekly appointments for relapse prevention, a psychological treatment designed to further maintain abstinence and increase the chance of naltrexone being successful.

4.8 LFTs should be re-checked one month after initiation of the prescription. At this point, prescribing may be continued by the GP, with their agreement and support from specialist service. An overview of the treatment plan should be provided.

4.9 An initial treatment period of three months should be considered. Continuation of treatment beyond three months is a decision for the prescriber in consultation with the patient based on review and discussion of the relative risks and benefits, in particular the risk of relapse to opioid misuse.

4.10 Discontinuation of treatment should be considered if there is evidence of misuse or continued illicit opioid use.

4.11 Naltrexone should not be prescribed in isolation but as part of a programme. This programme should be tailored to the individual patient’s needs and include appropriate psychosocial interventions.

5. Contraindications, Cautions And Side Effects For The Use Of Naltrexone

The BNF and/or Summary of Product Characteristics should be consulted for full and up to date information on contraindications, cautions and side effects. Key points to note:

5.1 Naltrexone should not be given to patients currently dependent on opioids since an acute withdrawal syndrome may ensue.

5.2 Concomitant administration of naltrexone with an opioid-containing medication should be avoided. In an emergency requiring opioid analgesia an increased dose of opioid may be required to control pain. The patient should be closely monitored for evidence of respiratory depression or other adverse symptoms and signs.
6. Pregnancy And Breastfeeding

Because of absence of documented clinical experience naltrexone should only be given to pregnant women when, in the judgement of the attending physician, the potential benefits outweigh the possible risks. Naltrexone should be avoided in breast feeding mothers due to potential toxicity.

7. Supervision Of Consumption

There is currently no funded facility in NHS Grampian to support the supervised consumption of naltrexone in community pharmacy. However, it can still be prescribed in instalments or dispensed to a named other, e.g. patient’s partner or relative, who may be able to provide support and/or supervise administration.

8. Consultation

Steve Beason  Psychiatriest, NHSG Substance Misuse Service
Bruce Davidson  Consultant Psychiatrist and Clinical Lead, NHSG Substance Misuse Service
Sharin Garden  Clinical Psychologist, Royal Cornhill Hospital
Richard Legg  GP with Special Interest in Substance Misuse
Alison Mearns  GP with Special Interest in Substance Misuse
Lesley Thomson  Lead H&SCP Pharmacist, Aberdeenshire
CPN Clinical Leads  NHSG Substance Misuse Service
CPN Team Leads  NHSG Substance Misuse Service
NHS Grampian Mental Health Operational Medicines Management Group

9. References


Appendix 1 – Fact Sheet - Naltrexone

FACT SHEET - NALTREXONE

(Naltrexone may be called Nalorex® or Opizone®)

What is naltrexone and why is it prescribed?

Naltrexone blocks the sites in the body where opioids such as heroin and methadone would work. It helps prevent the effects of opioids taken at the same time. This means it blocks the “high” or euphoria you would otherwise get from a dose of an opioid.

Naltrexone is used to help a person who has been detoxified from opioids, e.g. heroin or methadone, to maintain a drug free state. It is usually used in combination with counselling or other supportive therapy.

Is naltrexone safe to take?

Naltrexone is usually started 7-10 days after a person has undergone ‘detox’, because otherwise it will trigger withdrawal symptoms.

If you begin treatment with naltrexone and are still using opioids you will probably experience withdrawal effects (nasal stuffiness, runny nose, excessive tears, yawning, sweating, tremor, abdominal cramps, vomiting, ‘goose bumps’, joint pain and skin crawling). These may start within five minutes and last for up to 48 hours. They are not pleasant, so it is better to tell your doctor if you have taken any opioids before you begin treatment on naltrexone. Remember some cough and cold remedies and pain killers may contain opiates, e.g. co-codamol.

There may be occasions when healthcare professionals need to give you an opioid, such as in an emergency. It is therefore important that you inform medical professionals treating you that you are on naltrexone.

What to do if a dose is missed?

If you forget to take a dose, take it as soon as you remember, as long as it is within a few hours of the usual time. Do not take two doses at the same time.

For how long will it have to be taken?

Treatment with naltrexone is recommended for at least three months. Your prescriber will discuss continuation of treatment with you and in particular your risk of relapse.
What about other drugs and medications?

Although naltrexone blocks the effects of opioids, large doses of these drugs can overcome this. **This can result in overdose and may cause death.**

What about alcohol?

Naltrexone does affect your ability to drive or perform skilled tasks. This effect is made worse by alcohol or any other sedating or sleep-inducing medicines.

Do these medicines have side effects?

Like all medicines, side effects may occur. These vary from person to person and may wear off over time.

Side effects of naltrexone treatment include:

- Difficulty sleeping, anxiety, nervousness
- Abdominal pain/cramps
- Nausea and/or vomiting
- Low energy
- Joint and muscle pain
- Headache.

If you experience any of these side effects and they cause you concern, let your doctor, nurse or pharmacist know.

Further information about this medicine is contained in the Patient Information Leaflet. This is written by the pharmaceutical company and is included in the pack with the medicine.

Tell your doctor if you are, or intend to become pregnant

If you need further details contact your doctor or pharmacist

This leaflet has been prepared by the Specialist Pharmacists in Substance Misuse, NHS Grampian adapted from NHS Forth Valley information.

This leaflet can only give you some information about your medicine. It is not intended to substitute for the expertise or judgement of a doctor, pharmacist or other healthcare professional. It is not an official manufacturer’s Patient Information Leaflet and you should refer to this for more information. You might find some other leaflets or books relating to this medicine, or the Internet might have more information. Remember the Internet is not always accurate.