SHARED CARE GUIDELINE FOR THE MANAGEMENT OF PATIENTS ON NALTREXONE FOR OPIOID DEPENDENCE

INDICATION

Naltrexone is a pure opiate antagonist licensed as an adjunctive prophylactic therapy in the maintenance of detoxified, formerly opioid-dependent patients. Relapse of opiate use is most likely to occur in the early stages following detoxification; the use of naltrexone at this point will block the effects of opiates thus preventing the reinforcing effects of drug taking behavior

NICE TA 115 states:

- Naltrexone is recommended as a treatment option for people who have been opioid dependent but who have stopped using opioids, and who are highly motivated to stay free from the drugs in an abstinence programme.
- It should only be given to people who have been told about the problems associated with treatment, and with proper supervision. Treatment with naltrexone should be given as part of a support programme to help the person manage their opioid dependence.
- Healthcare professionals should regularly review how well naltrexone is working to help people stay off opioids. If there is evidence that the person has been using the drugs again then healthcare professionals should consider stopping naltrexone treatment.

The British Association of Psychopharmacology Guidelines; 2012 suggest that oral naltrexone treatment should be considered for formerly opioid-dependent people who are highly motivated to remain abstinent.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of naltrexone can be shared between the specialist setting and the patient's GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

REFERRAL AND INITIATION

- Treatment will be initiated within secondary care, the prison service or appropriate specialist service in agreement with the patient's support worker as part of a structured programme.
- Liver function tests should be completed before treatment. Practice should be pertinent to local protocols.
- Patients should have been opiate free for 7 to 10 days prior to treatment being started. A negative drug screen confirms this on the day of first treatment.

- When the person is established on a stable dose pattern without side effects and has shown a clear commitment to continue with treatment for an agreed period then the case will be discussed with the person's GP with a view to continued prescribing in primary care.
- Agreement will be reached on whether personal support to the patient will be provided by the local specialist drug and alcohol service or non-statutory drug service. Patients who do not continue under the care of the specialist drugs and alcohol service may be referred back for reassessment of treatment outside of any waiting list.
- Treatment rarely continues beyond 6-12 months, although some individuals may request more extended protection.

Specialist Responsibilities	
1.	To assess patient for suitability for prescribing naltrexone, including undertaking a drug screen and baseline LFTs prior to initiating therapy.
2.	To ensure the patient is given a naltrexone warning card and told to keep it on their person.
3.	To advise patients that an attempt to overcome the opioid block caused by naltrexone could result in acute opioid intoxication/death.
4.	To write to the GP requesting shared care ensuring specialist service treatment contract is signed by all relevant parties (Specialist nurse, GP and Patient).
5.	To advise when it might be appropriate for treatment to be stopped.
6.	To provide leaflets and consent forms on request.
7.	To ensure that that the patient can access on-going psychosocial support where appropriate.
8.	Specialist nurse to arrange and monitor (if appropriate) appointments at specialist central prescribing services

General Practitioner Responsibilities	
1	Initially to refer the patient for specialist advice.
2	Where appropriate to continue to prescribe naltrexone as part of a shared care arrangement when treatment has been initiated and stabilised by a specialist service and shared care has been agreed.
3	To provide support to enhance compliance.
4	To continue prescribing naltrexone and to re-refer the patient or seek specialist advice from the psychiatrist or specialist team as necessary.
5	To perform LFTs every 4 months or more frequently if required.
6	To regularly monitor the patients' health and wellbeing and for adverse drug reactions. It is recommended that the patient be seen monthly for the first 3 months and then 3 monthly thereafter
7	To contact local drug team for any aspect of the patients care which are of concern to the GP.
8	To deal with the general health issues of the patient

Patient's role (or that of carer)	
1	To take naltrexone regularly and not take/use opioids.
2	Report any adverse effects to their GP/specialist service nurse whilst taking naltrexone.
3	To ensure they have a clear understanding of their treatment.
4	To carry the naltrexone warning card on their person.
5	To attend the necessary appointments with specialist services.
6	To actively remain in a structured care programme for the duration of their treatment with naltrexone.

SUPPORTING INFORMATION

Monitoring

Baseline liver function tests should be performed before commencing treatment, and then monitored every four months during treatment. Greater caution is required for those with Hepatitis B or C status: monitor more frequently for changes in transaminase levels, e.g., monthly for patients with normal LFTs; two weekly for patients with moderately raised transaminase levels, as per local guidance.

Dosage and Administration

The initial dose of naltrexone should be 25mg (half a tablet). Following stabilisation the usual dosage is 50 mg daily. The half-life of naltrexone allows thrice weekly dosing (e.g. 100 mg on Monday and Wednesday with 150 mg on Friday).

Contraindications.

Naltrexone is contraindicated:
• In patients with acute hepatitis or liver failure.
• In patients currently dependent on opioids since an acute withdrawal syndrome may ensue.
• In any patient who has a positive screen for opioids or who has failed the naloxone challenge test.
• In combination with methadone
• In conjunction with an opioid containing medication
• In patients who have demonstrated hypersensitivity to naltrexone hydrochloride or any of the excipients
• Severe renal failure
Use in pregnancy should only be considered if the potential benefit outweighs the risk. There is little information on its use in breast feeding which, in general, should be avoided

Cautions

Liver function tests needed before and during treatment, test for opioid dependence with Naltrexone before treatment. Avoid concomitant use of opioids but increased dose of analgesic may be required for pain, see below (monitor for opioid intoxication).
Patients should be warned that an attempt to overcome the blockade of opioid receptors but overdosing could result in acute opioid intoxication.

Side effects

- Incidence > 10% - difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea, vomiting, low energy, joint/muscle pain and headache.
- Incidence < 10% - loss of appetite, diarrhoea, constipation, increased thirst, increased energy, feeling down, irritability, dizziness, rash, delayed ejaculation, decreased potency, chills, chest pain, increased sweating and increased lacrimation.
- Occasionally – liver function abnormalities.

Interactions

Naltrexone blocks the effects of all opioids.
The SPC states:
"Association to be taken into account: barbiturates; benzodiazepines, anxiolytics others than benzodiazepines (i.e. meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserin, trimipramine), sedative antihistaminics H1, neuroleptics, (droperidol).
There have been reports of cases of lethargy and somnolence following concomitant administration of naltrexone and thioridazine."

Special Recommendations

If the patient requires analgesia for mild pain then a non-opioid analgesic should be used. If the patient requires opiate analgesia consider specialist anaesthetic assessment as the doses required to obtain adequate pain relief are such that the resulting respiratory depression may be deeper and prolonged.

Drug cost

At 350mg weekly dose, monthly cost = £22.34
(BNF 68, Sept 2014)

This list is not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

References

1. Nalorex ® (Bristol Myers Squibb) Summary of Product Characteristics. Updated 19-Mar-2014
2. Naltrexone for the management of opioid dependence. NICE TA 115. Published Jan 2007 http://www.nice.org.uk/guidance/ta115
3. British Association for Psychopharmacology updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity: recommendations from BAP. Journal of Psychopharmacology 0(0) 1-54
4. British National Formulary no 68. Sept 2014-March 2015

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