

Prescribing Framework for Naltrexone in Alcohol Relapse Prevention

Patients Name:..... NHS Number:

Patients Address:.....(Use addressograph sticker)

GP's Name:.....

Communication

We agree to treat this patient within this Prescribing Framework	
Specialist Prescriber's Name.....	Prof Reg. No.
Specialist Prescriber's Signature.....	Date:.....
<i>Where prescriber is <u>not</u> a consultant:</i>	
Consultant's Name:	GMC No
Consultant's Signature	Date:.....
GP's Signature:.....	Date:.....
GP's Name (if different from listed above).....	

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and send **back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at : <http://www.hey.nhs.uk/amber.htm>

SHARED CARE FRAMEWORK FOR CLINICAL INFORMATION ONLY. Drug and alcohol treatment services in Hull and East Riding are directly commissioned by Public Health with specialists and GPs, who prescribe treatment for opioid/ alcohol dependence as part of this locally commissioned Public Health service. GPs prescribing outside of these arrangements using this framework should do so in accordance with NICE guidance.

1. Background

Naltrexone is an opioid-receptor antagonist but is useful as an adjunct in the treatment of alcohol dependence **after** a successful withdrawal. Treatment should be initiated by a specialist and continued under specialist supervision. Treatment should be reviewed monthly for the first six months, and then at reduced intervals. Naltrexone should be stopped if drinking continues for 4-6 weeks after starting treatment.

After a successful withdrawal for people with moderate and severe alcohol dependence, Acamprosate or oral Naltrexone can be considered in combination with an individual psychological intervention specifically on alcohol misuse. Disulfiram can be considered in those patients for whom Acamprosate and Naltrexone are not suitable

These guidelines aim to provide a framework for the prescribing of Naltrexone as an adjunct for alcohol relapse prevention by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements. This framework is supportive of NICE CG115 *Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence*

This document should be read in conjunction with the guidance “Responsibility for prescribing between Primary & Secondary/Tertiary Care” <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>

2. Indication

Naltrexone is indicated as an adjunct to prevent relapse in formerly alcohol-dependent patients. Treatment should be initiated and supervised by an appropriate specialist. It should only be used as part of an integrated programme including psychological interventions

3. Dose

Adults and Children over 16 years (unlicensed under 18 years): 25mg (unlicensed dose) on first day, increased to 50mg daily if tolerated.
Treatment should commence after assisted withdrawal

4. Duration of treatment

Naltrexone should usually be prescribed for up to 6 months, or longer for those benefiting from the drug who want to continue with it. It should be stopped if drinking persists 4–6 weeks after starting the drug.

5. Contraindications / cautions

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 combination with methadone
- in conjunction with an opioid containing medication

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- in patients who have demonstrated hypersensitivity to Naltrexone hydrochloride or any of the excipients
- in severe renal failure

Cautions:

Liver function tests are needed before and during treatment.

It may be prudent to test for opioid dependence with Naloxone before treatment.

Concomitant use of medications containing an opioid should be avoided, although an increased dose of an opioid analgesic can be given for pain if needed – monitor for opioid intoxication.

6. Adverse effects

Major adverse events are rare. Side effects are common but tend to be mild, transient and improve with time.

- Side effects with an incidence >10%

insomnia	asthenia	joint/muscle pain
anxiety	headache	nervousness
abdominal pain	nausea	vomiting
restlessness		

- Side effects with an incidence <10%

chills	increased energy	loss of appetite
diarrhoea	constipation	irritability
increased lacrimation	delayed ejaculation	decreased potency
increased thirst	skin rashes	increased sweating
Dizziness	feeling down or tired	Chills
tachycardia	palpitations	

- Rare but potentially serious side effects

Liver function abnormalities (dose dependent elevation of liver enzymes)
Idiopathic thrombocytopenic purpura

7. Interactions

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.

Insulin requirements of a patient may rise by about 30% when treated with Naltrexone

Extreme lethargy may occur in patients on Thioridazine

Effects of other opioid-containing medications may be blocked

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Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Monitoring:

Before starting treatment with oral Naltrexone conduct a comprehensive medical assessment (baseline urea and electrolytes and liver function tests including gamma glutamyl transferase [GGT]). In particular, consider any contraindications or cautions (see the SPC), and discuss these with the service user.

Service users taking oral Naltrexone should stay under supervision, at least monthly, for 6 months, and at reduced but regular intervals if the drug is continued after 6 months.

Monitor LFT every 6 months, and discuss any abnormal results with specialist team.

If the service user feels unwell advise them to stop the oral naltrexone immediately.

9. Information to patient

Patients will be provided with specific information relating to their treatment.

Ensure patients are aware of the impact of Naltrexone on opioid-based medication. Ensure patients are aware that some common medicines contain opiates and these may not work when taking Naltrexone. Patients should be advised to contact their GP or pharmacist if they need medicines to relieve a cough, cold, pain or diarrhea since these may contain opiates.

10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	<ul style="list-style-type: none"> • Naltrexone induction must be undertaken by a specialist service • LFTs and urinalysis • Naloxone challenge if appropriate • Provide patient with written and verbal information about Naltrexone • Advise patient to carry a Treatment Card at all times, as treatment with Naltrexone renders opioid analgesia ineffective for pain control in the event of emergencies. • Provide regular counselling and support for the patient. • Following the initial four week period, the specialist team will liaise with the patient's GP to discuss the transfer and advice on dose and duration of prescribing (e.g. a period of six months). 	<ul style="list-style-type: none"> • Liaise with the specialist team

Maintenance	<ul style="list-style-type: none"> Regular support and advice available to the GP from the appropriate specialist team. Arrangement for continuous patient support and aftercare. Treatment should be reviewed monthly for the first six months, and then at reduced but regular intervals Patient must be in receipt of continuing therapeutic intervention from a specialist team 	<ul style="list-style-type: none"> Take over the prescribing of Naltrexone after the first month Monitor response to treatment and adverse effects every three months (Psychiatric co-morbidity may occur in patients with a history of alcohol abuse). Monitor alcohol intake – in any alcohol intake, stop treatment and refer back to specialist team. Refer to the specialist team where necessary Six monthly liver function tests and any abnormal results discussed with the specialist team
Review and discharge	<ul style="list-style-type: none"> Review patient after 1 year and discharge from service or stop treatment. • Advise GP of when and how treatment should be discontinued 	<ul style="list-style-type: none"> Continue treatment as recommended. • Co-operate with the specialist during discontinuation

Contact Details:

Contact Specialist as per clinic letter

During office hours:	Out of hours:
Humber Teaching NHS Foundation (HTFT) Baker Street (01482 336562)	Victoria House and ask for the on-call consultant 01482 223191
CGL ReNEW Hull Trafalgar House, 41-45 Beverley Road Hull, HU3 1XH 01482 620013 earlyhelp.hull@cgl.org.uk	

APPROVAL PROCESS

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