Shared Care Protocol –remains open to review in light of any new evidence
***Amber** = To be initiated and titrated to a stable dose in secondary care with follow up prescribing and monitoring by primary care.*

Naltrexone

Shared Care Guideline for treatment of alcohol dependence and opioid dependence

Introduction

Indication/Licensing information
Naltrexone is licensed for use as an additional therapy within a comprehensive treatment program including psychological guidance for detoxified patients who have been opioid-dependent and/or alcohol dependent to support abstinence.

NICE recommends After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) focused specifically on alcohol misuse.

Naltrexone is recommended as a treatment option in detoxified formerly opioid-dependent people who are highly motivated to remain in an abstinence programme.

Pharmacology
Naltrexone is an opioid-receptor antagonist

Dosage and administration

- Relapse prevention in opioid dependence, ADULT over 18 years (initiate in specialist clinics only or by GP's in the Shared Care scheme), 25 mg initially then 50 mg daily; total weekly dose (350 mg) may be divided and given on 3 days of the week for improved compliance (e.g. 100 mg on Monday and Wednesday, and 150 mg on Friday)
- Relapse prevention in alcohol dependence, ADULT and CHILD over 16 years [unlicensed under 18 years], 25 mg [unlicensed dose] on first day, increased to 50 mg daily if tolerated

As naltrexone hydrochloride is an adjunctive therapy and the full recovery process from alcohol or opioid dependence is individually variable, no standard duration of treatment can be stated; an initial period of three months for opioid clients and 6 months for alcohol clients should be considered. However, prolonged administration may be necessary.

Responsibilities of the specialist initiating treatment

Summary

- To assess the suitability of the patient for treatment.
- To discuss the benefits and side effects of treatment with the patient/carer and the need for long term monitoring if applicable.
- To perform baseline tests and if appropriate routine tests until the patient is stable.
- To prescribe for the first 12 weeks of treatment
- To ask the GP whether they are willing to participate in shared care.
- To provide the GP with a summary of information relating to the individual patient to support the GP in undertaking shared care (See Shared care request form in Appendix A).
- To advise the GP of any dosage adjustments required, monitoring required, when to refer back, and when and how to stop treatment (if appropriate).
- To advise the GP when the patient will next be reviewed by the specialist.
- To monitor the patient for adverse events and report to the GP and where appropriate Commission on Human Medicines/MHRA (Yellow card scheme).
- To provide the GP with contact details in case of queries.

Baseline Tests
LFTs – would not recommend prescribing if ALT >x2 limit
Urine drug screen for people with a history of opioid dependence
Routine Tests
LFTs
Disease monitoring
Patient should be monitored for abstinence every 6 months

Responsibilities of other prescribers

Acceptance of Responsibility by the Primary Care Clinician
It is optional for GPs to participate in taking on responsibility for shared care for the patient. GPs will take on shared care only if they are willing and able.

Summary

- To reply to the request for shared care as soon as possible.
- To prescribe and adjust the dose as recommended by the specialist.
- To ensure there are no interactions with any other medications initiated in primary care.
- To continue monitoring as agreed with secondary care (guideline should include details of monitoring requirements and what to do when each of the defined parameters alters).
- To refer back to the specialist where appropriate. For example:
  - Patient or general practitioner is **not** comfortable to continue with the existing regime due to either change in condition or drug side effects.
  - Advice in respect of concordance.
  - Special situations, (e.g. Pregnancy)
- Discontinue the drug as directed by the specialist if required
- To identify adverse events if the patient presents with any signs and liaise with the hospital specialist where necessary. To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme).

Clinical Particulars

BNF therapeutic class	Drugs used in substance misuse – alcohol and opioid dependence https://doi.org/10.18578/BNF.269764922
Cautions and Contraindications	Ensure opioid dependence has been excluded by taking a history, drug testing and, if possible, consideration of a naloxone challenge or test dose before starting treatment. Avoid concomitant use of opioids but increased dose of opioid analgesic may be required for pain (monitor for opioid intoxication)
Adverse Drug Reactions	Nausea, vomiting, abdominal pain, diarrhoea, constipation, reduced appetite, increased thirst, chest pain, anxiety, sleep disorders, headache, increased energy, irritability, mood swings, dizziness, chills, urinary retention, delayed ejaculation, decreased potency, joint and muscle pain, increased lacrimation, rash, increased sweating; *rarely* hepatic dysfunction, depression, suicidal ideation, tinnitus, speech disorders; *very rarely* hallucinations, tremor, idiopathic thrombocytopenia, exanthema
Monitoring	Liver function tests needed before and during treatment; urine drug screen for people with a history of opioid dependence.
Interactions	Presently, clinical experience and experimental data on the effect of naltrexone on the pharmacokinetics of other substances are limited. Concomitant treatment with naltrexone and other medicinal products should be conducted with caution and should be followed carefully.

Communication

Specialist to GP
The specialist will inform the GP when they have initiated drug naltrexone. When the patient is near completing the satisfactory initiation period, the specialist will write to the GP to request they take over prescribing and where possible give an indication as to the expected length of treatment. The Specialist will also send a Shared care request form to support the GP in undertaking shared care. (Appendix A)

GP to specialist
If the GP has concerns over the prescribing of drug naltrexone, they will contact the specialist as soon as possible.

Contact names and details

Contact Details	Telephone number	Email
Dr Fleur Ashby Consultant Clinical Director, Barnsley Recovery Steps	01226 779066	Amanda.Ashby@humankindcharity.org.uk
Chris Lawson, Head of Medicines Management, NHS Barnsley CCG	01226 433798	chris.lawson@nhs.net

References

- SPC Naltrexone updated 05/03/14. Available at: http://www.medicines.org.uk/emc/medicine/25878 Accessed 12.08.20
- BNF. Available at: https://www.medicinescomplete.com/mc/bnf/current/index.htm Accessed 12.08.20
- NICE Clinical Guideline 115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. Available at: http://guidance.nice.org.uk/CG115 Accessed 12.08.20
- NICE Technology Appraisal Guidance (TA 115): Naltrexone for the management of opioid dependence. Available at: https://www.nice.org.uk/guidance/ta115/chapter/4-Evidence-and-interpretation Accessed 12.08.20
- Choice and Medication website (information about mental health conditions, treatments and medications). Available at: https://www.choiceandmedication.org/humankind/

Development Process

This guidance has been produced following an AMBER classification status of Naltrexone by the Barnsley Area Prescribing Committee. This guideline has been subject to consultation and endorsement by the Area Prescribing Committee on 14th October 2020.

Appendix A – Shared Care request form (Amber)

- Specialist to complete when requesting GP to enter a shared care arrangement.
- GP to return signed copy of form.
- Both parties should retain a signed copy of the form in the patient's record.

From (**Specialist**): _____ **To** (**GP**): _____

Patient details

Name: _____ ID Number: _____

Address: _____ DOB: _____

Diagnosed condition: _____

Amber Drug details

Drug name: _____ Dose: _____

Date of initiation: _____ Length of treatment: _____

The patient will be reviewed by the Consultant on: _____

The patient should be reviewed by the GP by: _____

Monitoring

The following monitoring should be undertaken by the GP:

Parameter	Date next test due	Frequency
LFT		6 monthly

Communication

Consultant/ Non-Medical Prescriber/ Shared Care GP

Telephone number: _____ Fax number:_____

Email address: _____

Confirmation of acceptance of shared care

Specialist (Doctor/Nurse) name: _____

Specialist (Doctor/Nurse) signature: _____ Date: _____

I, Dr ……., can confirm I :

☐ accept the request to participate in shared care for the patient named above.

☐ reject the request to participate in shared care for the patient named above. The reason for this being ……..

GP signature: _____ Date: _____

To save resources you have been sent appendix A of the shared care document. The full document (Naltrexone Shared Care Guideline for treatment of alcohol dependence and opioid dependence, date approved October 2020) can be accessed on the Barnsley BEST website at the following link: http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/

Or via the Barnsley Area Formulary www.barnsleyformulary.nhs.uk