Manchester Mental Health and Social Care Trust

Shared Care Guideline for	Reference Number
Prescription and monitoring of Naltrexone Hydrochloride in alcohol dependence	
Author(s)/Originator(s): (please state author name and department)	**To be read in conjunction with the following documents:** Current Summary of Product characteristics (http://www.medicines.org.uk)
Dr Daly - Consultant Psychiatrist, Alcohol Services Dr Donnelly – Consultant Psychiatrist MMHSCT	BNF
Date approved by Medicines Management Committee: 10th September 2013	**Review Date: 31st November 2016**

1. Licensed Indications	Maintenance of abstinence in alcohol dependence *Please note Naltrexone is now licensed for use in alcohol dependence as an adjunct to prevent relapse.*
2. Therapeutic use & background	Naltrexone is used as an adjunct to psychological interventions to support those who are trying to remain abstinent. It helps to reduce the risk of relapse to heavy drinking by reducing the desire for alcohol. A large database of high quality evidence was reviewed by NICE and it was felt that in moderate to severe alcohol dependence Naltrexone is effective in reducing the rate of relapse. Naltrexone is recommended in a review of the effectiveness of treatment for alcohol problems by the NTA 2006. NICE Alcohol use disorder : Diagnosis, assessment and management of harmful drinking and alcohol dependence (NICE Clinical Practice Guideline 115 Feb 2011) recommend the use of naltrexone as first line treatment after successful withdrawal from alcohol (Recommendation 8.3.6.7). Naltrexone is a long acting competitive opiate antagonist. It's mode of action is thought to be via reducing the pleasurable and rewarding effects of alcohol. Naltrexone achieves this by blocking the effects of opioids released on consumption of alcohol therefore preventing the enhanced dopamine release in the mesolimbic system. Naltrexone is metabolised by the liver and excreted by the kidneys.
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	- Patients currently dependent on opiates (causes acute withdrawal) - Acute hepatitis - Acute liver failure/Severe hepatic impairment (ALT>2Xnormal range) - Severe renal failure - Hypersensitivity to Naltrexone HCl

<table>
<tr><td>4. Prescribing in pregnancy and lactation</td><td colspan="3">There is little data on safety in breastfeeding or pregnancy. Manufacturers advise only use in pregnancy if the risk outweighs the benefit. It is unknown if Naltrexone or its metabolites are excreted into human breast milk and should not be used in lactating female.</td></tr>
<tr><td rowspan="8">5. Dosage regimen for continuing care</td><td colspan="3">Route of administration Oral</td></tr>
<tr><td colspan="3">Preparations available Available as 50mg f/c scored tablets (either Nazorex or Opizone)</td></tr>
<tr><td colspan="3">Please prescribe: Day one: 25mg initial test dose,
Day two : 50mg daily continue at this dose</td></tr>
<tr><td>Is titration required</td><td>Yes ✓</td><td>No</td></tr>
<tr><td colspan="3">Adjunctive treatment regime

Adjunctive psychosocial intervention</td></tr>
<tr><td colspan="3">Conditions requiring dose reduction

None</td></tr>
<tr><td colspan="3">Usual response time

Immediate, peak plasma concentration is reached within 1 hour.</td></tr>
<tr><td colspan="3">Duration of treatment

6-12 months</td></tr>
<tr><td colspan="3">Treatment to be terminated by

Either GP or the specialist. Treatment should be terminated if a full relapse (return to heavy drinking for 4-6 weeks) has happened, lack of efficacy or intolerable side effects.</td></tr>
<tr><td rowspan="2">6.Drug Interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics</td><td colspan="3">Opiates - the opioid dose needed to achieve the desired therapeutic effect may be larger than normal. This increases the risk of respiratory depression and circulatory effects making them more pronounced and long lasting.</td></tr>
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7. Adverse drug reactions

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF

Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.

Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
Common >10% Headache, sleep disorders, restlessness, nervousness, abdominal pain and cramps, nausea, weakness and joint/muscle	Generally mild and self limiting, if analgesia is required use non-opiates. If continuous and severe may require cessation.	GP
Common 1-10% Loss of appetite, diarrhoea, constipation, increased thirst, increased energy, feeling down, irritability, dizziness, skin rash, delayed ejaculation, decreased potency, chills, chest pain, increased sweating and increased lacrimation.	Generally mild and self limiting. If continuous and severe may require cessation.	GP
Rare <0.1% Liver abnormalities	Monitor LFT's if continued elevation of ALT to >3X normal limit then stop medication.	GP/Specialist
Rare <0.1% Depression, suicidal ideation and self harm	Seek advice from psychiatric services and stop medication	GP/Specialist/A+E
Very Rare <0.01% Idiopathic thrombocytopaenia	Stop medication and seek advice from haematologist.	GP/Specialist/Haematologist

	Very Rare <0.01% Euphoria, hallucinations	Stop medication and seek advice from specialist..	GP/Specialist
	The patient should be advised to report any of the following signs or symptoms to their GP without delay: Signs of liver failure such as jaundice and easy bruising, signs of ITP such as excessive bleeding and easy bruising, any rapid mood changes or suicidal thoughts.		
	Other important co morbidities: None		
	Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.		
8.Baseline investigations	**List of investigations / monitoring :** - prior to commencing LFT's		
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?**	**Yes or No (if yes complete following section)**	

	Monitoring	**Frequency**	**Results**	**Action**	**By whom**
	Efficacy and side effects	6 weekly	Ensure engagement with psychosocial intervention and CAT.	Contact CAT	CAT/GP
	Monitor LFT	*3 monthly*	*If ALT> 3x normal consider stopping*	*Contact Specialist at Brian Hore Unit for advice*	*GP/ BHU/ CAT*

10. Pharmaceutical aspects	No special considerations required.
11. Secondary care contact information	**If stopping medication or needing advice please contact:**
	Dr ___Chris Daly_____

	Contact number: __0161 217 4166_____
	Hospital: __Brian Hore Unit_____
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been initiated and established by the secondary care specialist. ▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements

13. Responsibilities of initiating specialist	Initiate treatment or to advise the GP to initiate treatment as appropriate Monitor patient's initial reaction to and progress on the drug. Ensure that the patient has an adequate supply of medication until GP supply can be arranged (Unless GP is initiating treatment after advice from specialists). Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before review. Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient *or* inform GP if the patient does not attend appointment Provide GP with advice on when to stop this drug. Provide patient with relevant drug information to enable Informed consent to therapy Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action .
----------	Initiate treatment as directed by the specialist
14. Responsibilities of the GP	To monitor and prescribe in collaboration with the specialist according to this protocol To ensure that the monitoring and dosage record is kept up to date To discontinue medication if lack of efficacy, full relapse or side effects. Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary.
----------	To take medication as directed by the prescriber, or to contact the GP if not taking medication
15. Responsibilities of the patient	To attend hospital, CAT and GP clinic appointments To report adverse effects to their Specialist or GP.

16.Additional Responsibilities	**List any special considerations**	**Action required**	**By whom**	**Date**
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet.			
19. Shared care agreement form	Attached below			

Shared Care Agreement Form

Specialist request

***IMPORTANT: ACTION NEEDED**

Dear Dr *[insert Doctors name here]*

Patient name: *[insert Patients name here]*
Date of birth: *[insert date of birth]*

Diagnosis: *[insert diagnosis here]*

This patient is suitable for treatment with *[insert drug name]* for the treatment of *[insert indication]*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust / LHB / AWMSG). I am therefore requesting your agreement to share the care of this patient.

Treatment was started on [insert date started] [insert dose].

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

Baseline tests: *[insert information]*

Next review with this department: *[insert date]*
You will be sent a written summary within 14 days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *[insert text here]*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

[insert Specialist name]

Shared Care Agreement Form

GP Response

Dear Dr *[insert Doctors name]*

Patient *[insert Patients name]*

Identifier *[insert patient date of birth/address]*

I have received your request for shared care of this patient who has been advised to start *[insert text here]*

A I am willing to undertake shared care for this patient as set out in the protocol

B I wish to discuss this request with you

C I am unable to undertake shared care of this patient.

GP signature Date

GP address/practice stamp