Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

The 3T's Formulary
NHS Swindon, NHS Wiltshire
Great Western Hospitals NHS Foundation Trust
(In collaboration with Avon and Wiltshire Mental Health Partnership and Oxford Health NHS Foundation Trust)

Shared Care Agreement
Naltrexone Hydrochloride tablets for Opiate Dependence
(BNF 4.11)

Naltrexone should be initiated and stabilised by a specialist within AWP. Once the patients condition is clinically stable, it can be appropriate for a registered prescriber in primary care to resume prescribing with the guidance of a Shared Care Agreement.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of oral naltrexone can be shared between the specialist and general practitioner or Non medical prescriber. If the GP/NMP is not confident to undertake shared care, then s/he must let the specialist know within 3 weeks of receipt of this request. In such an event, the total clinical responsibility for the patient for the diagnosed condition will remain with the specialist.

Sharing of care assumes communication between the specialist, GP/NMP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients receiving naltrexone must be under regular follow-up, which provides opportunities to discuss drug therapy.

The doctor/NMP who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist (AWP)Team responsibilities
1 Assess patient, establish diagnosis and develop care plan. Ensure care plan contains contact details for care co-ordinator/ key worker and specialist.
2 To undertake physical health screen and assessment when patient is admitted to mental health services.
3 Ensure that arrangements for appropriate blood tests has been made. Blood tests may be taken at the GP surgery providing appropriate communication with the GP and the GP is in agreement with this. AWP is responsible for the interpretation and monitoring of these blood test results for the first 3 months of treatment.
4 Review results of any baseline tests – namely creatinine & electrolytes, and liver function including GGT, and relay any abnormal findings to the GP with appropriate advice.
5 To check patients use of opiates, including over the counter (OTC) preparations that may contain codeine. Advise patient to wait 5 to 7 days after stopping opiate / OTC product before starting naltrexone. Up to 10 days should be allowed for methadone.
6 Initiate therapy with naltrexone tablets, arrange prescription and assess patient.
7 Issue the patient with a Naltrexone warning card*.
8 Provide a patient information leaflet and discuss the benefits and side effects of treatment with the patient.
9 Ensure patient is fully informed about their treatment including any plans of pregnancy. Animal studies indicate a risk but there is no safety data on the use of naltrexone in pregnant women. Naltrexone should only be given to pregnant women when, in the judgement of the attending

physician the potential benefits outweigh the possible risk. The GP should be informed if it is known that the service user is pregnant prior to shared care being agreed.

10 Discuss the proposal of shared care agreement with the patient. If possible obtain consent (verbal is fine) and document in notes. If patient declines SCA, then please document this too.

11 Ask the GP/NMP whether s/he is willing to participate in shared care once patient has been stabilised on treatment. This must be done using the shared care agreement signature sheet for naltrexone for opiate dependence.

12 Ensure that the GP has a copy of the shared care agreement and a signed copy of the shared care agreement form.

13 To review the patient regularly for the first 3 months of treatment ensuring psycho-social needs are met.

14 Advise GP/NMP that there is no need to routinely monitor blood tests, although monitoring recovery of liver function may be useful as a motivational aid for patients. They may be useful for older people and for people with obesity.

15 Organise psychosocial support in conjunction with medication as an essential part of treatment, and for this to be continued following discharge by the specialist.

16 Forward copy of care plan to GP / NMP.

17 Prescribe the first 3 months of naltrexone treatment.

18 Advise GP/NMP that they may continue to prescribe naltrexone tablets for up to 6 to 12 months, or longer if benefit seen or patient wants to continue taking it. Advise GP/NMP that they may refer to specialist for re-assessment (at least every 6 months) as to whether there is a need for on-going therapy.

19 Discuss appropriate lifestyle issues with the patient as appropriate.

20 Monitor for response and adverse drug reactions; to report ADRs to MHRA and GP/NMP.

21 Communicate promptly with the GP when treatment is changed.

22 Inform GP/NMP of concurrent therapy (as this may interact with other medication patient gets from GP)

23 Advise the GP/NMP on when to adjust the dose, stop treatment (assuming no relapse in patients condition), or consult with the specialist.

24 To review patient / provide advice as requested via the GP or Primary Care Liaison Service as necessary

25 To review the patient and treatment at least once a year until the patient is discharged from the mental health service where this is possible

26 If GP/NMP has not agreed to resume prescribing, the specialist team must keep the GP informed of progress at least every 3 months or more frequently as needed and when the patient is discharged from mental health services.

27 Ensure that clear backup arrangements exist for GPs to obtain advice and support (See 'Back-up advice and support' for contact details).

28 Any verbal communication between primary and AWP should be confirmed in writing.

Primary Care responsibilities

1 Reply to the request for shared care within 3 weeks of receipt of request.

2 If the GP decides **not** to prescribe naltrexone tablets it should still be added to the patients repeat list as a "non issued item" for information and safety purposes and 'Hospital prescribing only. Do not prescribe' on the dose line. This should also be done during the stabilisation period before the GP/NMP takes over the prescribing.

3 If GP/NMP is **not** happy to prescribe naltrexone but will do LFTs if clinically warranted for any reason.

4 To take over prescribing after 3 months of treatment.

5 Remind patient that some OTC preparations may contain codeine and hence they should not take or buy such products. Please also see 'Advice to patient' on page 5.

6 GP to be aware that patient needs to wait 5 to 7 days if being taking opiates (including OTC products) before starting or re-starting naltrexone. Up to 10 days should be allowed for methadone.

7 To check patient has a '*Naltrexone warning card'

8 Prescribe Naltrexone tablets at the dose recommended by the specialist.

9 GP/NMP may continue prescribing naltrexone tablets for up to 6 to 12 months, or longer if benefit seen or patient wants to continue taking it. If required, may refer to specialist for re-assessment (at least every 6 months) as to whether there is a need for ongoing therapy.

10 Adjust the dose / stop dose as advised by the specialist.
11 Review patient as agreed per shared care agreement and care plan.
12 Inform specialist team of any change in the patient's medication that may interact with medication patient receives from secondary care.
13 To request specialist review or seek specialist advice when necessary. See ' Back-up advice and support' for contact details.
14 Once the patient has been discharged from specialist services, advice may be sought from the Primary Care Liaison Service on any aspect of the patient's mental health that is of concern to the GP/NMP. See ' Back-up advice and support' for contact details.
15 Monitor patients overall health and compliance
16 Report adverse events to the specialist and MHRA.

Primary Care Liaison Service (PCLS) responsibilities
1. Accept referrals by registered GPs in line with DoH guidance.
2. To advise the GP on appropriate action regarding any issues they may have on the patient's management regarding shared care.
3. To try and resolve the issue(s) raised by the GP or to refer to the specialist team as appropriate.
4. Provide rapid & prioritised specialist mental health assessment with recommendation/s for care & treatment within multiple care pathways.
5. Determine the nature & severity of mental health needs with consequent sign posting and pathway facilitation.
6. Provide rapid and accessible ongoing support & advice to the non-specialist workforce.

Patient's role
1 Report to the specialist or GP if he/she does not have a clear understanding of the treatment.
2 Share any concerns in relation to treatment with naltrexone tablets.
3 Inform specialist or GP of any other medication being taken, including over-the-counter products.
4 Report any adverse effects or warning symptoms to the specialist or GP whilst taking naltrexone tablets.
5 Carry a 'Naltrexone Warning Card' at all times, in case of involvement in accident, where strong (opioid) analgesia is required.
6 Report to the specialist or GP if he/she does not have a clear understanding of the treatment.

*Naltrexone warning cards for opiates are only available for the branded product 'Nalorex'. Warning cards for the generic version are not available; please explain this to the service user when the generic is prescribed to avoid any confusion with the drug name. The card may also be obtained by emailing bethan.shepherd@awp,nhs.uk

MONITORING REQUIREMENTS

Prescriber responsibilities:

Before treatment with naltrexone is started baseline urea and electrolytes, liver function tests and gamma glutamyl transferase (GGT) should be done. Blood tests do not need to be done routinely, but be considered for older people, for those with obesity, for monitoring of liver function and as a motivational aid for service users to show improvement.

Special attention should be paid to patients with hepatic enzyme levels in serum exceeding three times the normal value and patients with renal impairment.

MEDICATION DETAILS

Supporting information - Please also refer to the Summary of Products Characteristics (SPC) for full prescribing information on naltrexone tablets www.medicines.org.uk.

What is it?	Naltrexone is a specific opioid antagonist shown to reduce euphoria, alcohol intake, and relapse risk by alcohol dependent, or misusing individuals. These actions seem to be mediated by its property to block

	opiate receptors mainly located in the central and peripheral nervous system. This antagonism appears to inhibit the actions of endogenous opioids released, because of alcohol intake, upon the mesolimbic pathway which would otherwise produce a rise in dopamine in the accumbens nuclei.
Licensed indication	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.
Formulations available	50mg strength tablets
Administration & dose titration	Once daily administration. 25mg (half a tablet) daily for 2 days then 50mg daily
Contraindications	Hypersensitivity to naltrexone hydrochloride or to any of the excipients. Severe renal impairment Severe hepatic impairment Acute hepatitis Opioid addicted patients with a current use of any opioids since an acute withdrawal syndrome may ensue. Positive screening result for opioids or after failure of the naloxone provocation test.
Special warnings and precautions for use	During treatment with naltrexone, painful conditions should be treated with non-opioid analgesia only.
Side effects	**Very common (≥ 1/10):** Headache, sleeping disorders, restlessness, fatigue, anxiety and gastro-intestinal disorders such as abdominal pain, nausea and vomiting, joint and muscle pain. **Common (≥1/100 to <1/10):** Increased thirst, sweating, shivering, dizziness, lacrimation, skin rashes, chest pain, diarrhoea, constipation, urine retention, lack of appetite, delayed ejaculation, mood swings. **Rare (≥1/10,000 to <1/1,000):** Depression, hallucinations, hepatic disorders **Very rare (<1/10,000),** Thrombocytopenia, tremor, agitation, euphoria, hallucination.
Drug interactions	No interaction studies have been performed; One case of lethargy and somnolence has been reported after concomitant use of naltrexone and thioridazine. Opioids taken during naltrexone treatment may cause an acute withdrawal syndrome.
Monitoring	Please see Monitoring section.
Advice to patient	Patients should be warned that large doses of opioids to overcome the blockade may after the cessation of the naltrexone, result in an acute opioid overdose, with possible fatal outcome. Naltrexone should not be started if the patient has used opiates in the last

	5-10 days depending on opiate used. They may be given a "Naloxone Challenge", with an injection of naloxone to make sure they don't get sudden withdrawal symptoms. The tablets should be swallowed with at least half a glass of water whilst sitting or standing. Patients must be warned against the concomitant use of opioids (e.g. in cough medication, symptomatic medication for the treatment of common colds, or opioids contained in anti diarrhoeal agents, etc.) during naltrexone treatment as the opioid wont be as effective as its effects will be blocked by the naltrexone. Patients might be more sensitive to opioid containing medicines after stopping treatment with naltrexone. To carry a 'Naltrexone warning card' with them at all times whilst on treatment with naltrexone. Patients should be told to inform their GP/Specialist if they resume drinking alcohol.

BACK-UP ADVICE AND SUPPORT

CONTACT DETAILS

Name	Tile / Role	Telephone	Email	Fax
Dr Fergus Law, **Blackberry Centre,** Blackberry Hill Hospital, Manor Rd. Fishponds, Bristol, BS16 2EW	Consultant Psychiatrist in Substance Misuse	T:(0117) 378 4500	fergus.law@awp.nhs.uk	0117 9021174
Bethan Shepherd	Formulary Pharmacist	07775562391	bethan.shepherd@awp.nhs.uk	01225 362795
	Care co-ordinator			
Primary Care Liaison Service: **BaNES**	Intensive and Primary Care Liaison – Hillview Lodge	01225 371480		01225362799
Primary Care Liaison Service: **Bristol**	Intensive and Primary Care Liaison – interim to Speedwell then to Callington Road	0117 9195670		0117 9195625
Primary Care Liaison Service: **North Somerset**	Intensive and Primary Care Liaison – Long Fox Unit	01934 836406		01934 836405

Primary Care Liaison Service: **South Gloucestershire:**	Intensive and Primary Care Liaison – Bybrook Lodge, Blackberry Hill Hospital	01173 787960		0117 3787941
Primary Care Liaison Service: **Swindon**	Intensive and Primary Care Liaison – Sandalwood Court	01793 835787		01793 836817
Primary Care Liaison Service: **Wiltshire**	Intensive and Primary Care Liaison – Green Lane (GLH) and at Fountain Way (FW)	**North Wiltshire** (GLH): 01380 7311341 **South Wiltshire** (FW): 01722 820372		01380 731295 01722 820376

REFERENCES:

1. Summary of product characteristics Naltrexone hydrochloride 50mg film coated tablets (Accord Healthcare Ltd)
2. Summary of product characteristics Naltrexone hydrochloride (Adepend®)50mg film coated tablets (A Orphan Pharmaceutical)
3. NICE Clinical Guideline 115 Alcohol-use disorders: Diagnosis, assessment and management of harmful drinking and alcohol dependence.
4. NHS Bristol Primary Care Policy for Initiation of Naltrexone Summary (2009)
5. Patient Information Leaflet (Adepend®)
6. http://www.choiceandmedication.org/nsft/medications/143/

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