BNSSG Health Community's Traffic Light System Shared Care Guidance

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Section 1: Heading

Trust(s)	**Avon and Wiltshire Mental Health Partnership NHS Trust**
	BNSSG Trusts
Speciality / Department:	Mental Health
Drug	**Naltrexone Hydrochloride 50mg film coated tablets for** **ALCOHOL DEPENDENCE** **Generic version (by Accord Healthcare Ltd):** For use as an additional therapy within a comprehensive treatment program including psychological guidance for detoxified patients who have been opioid-dependent & alcohol dependence to support abstinence. **Branded product Adepend®** : As part of a comprehensive programme of treatment against alcoholism to reduce the risk of relapse, as support treatment in abstinence and to reduce the craving for alcohol. Please note: The generic version should be used when the patient is abstinent from alcohol **as it is not licensed to be used if the patient is still drinking (unlike the branded product). It is also a lot more cost effective at £22.34 for 28 x 50mg tablets.** The branded version should only be used if the patient is still drinking. **It is also much more expensive at £47.42 for 28 x 50mg tablets.** (in the vast majority of cases, treatment with naltrexone is only initiated once the patient has stopped drinking so the generic should be used as first line where possible).

Date Approved
Date of Review

Section 2: Treatment Schedule

Please state the usual dosage range (the patient will have been stabilised, monitored on treatment and reviewed by the specialist). State also the formulation, frequency of administration and how long treatment should be continued and when the patient should be referred back to the specialist

Usual Dosage	50mg once a day. This is the dose given in the SPC although some specialists will titrate dose starting at 25 mg (half a 50mg tablet) per day for 2 days then 50 mg per day.
Frequency of administration	Once daily dosing.
Length of treatment	Up to 6 to 12 months but may be longer if service user is benefiting from the drug and wants to continue with it.
Referral back to specialist	• Pregnancy – there is no clinical data on naltrexone in pregnancy. Should only be given to pregnant women when potential benefits outweigh the possible risks. • Breastfeeding – There is no clinical data on naltrexone in breastfeeding. It is unknown whether naltrexone or 6-beta-naltrexol is excreted in human breast milk although it has been found to be present in milk in animal studies Breastfeeding whilst on naltrexone is not recommended. • Severe renal and hepatic impairment

Section 3: Monitoring

Please give details of any tests that are required, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care) and cause for adjustment and when it is required to refer back to the specialist.

Before treatment with naltrexone is started baseline urea and electrolytes, liver function tests and gamma glutamyl transferase 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 [(3)].

Special attention should be paid to patients with hepatic enzyme levels in serum exceeding three times the normal value and patients with renal impairment [(1)] .

Section 4: Side Effects

Please list the most common side effects and any management of them. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	**Very common (≥ 1/10):** Headache, sleeping disorders, restlessness, fatigue, nervousness and gastro-intestinal disorders such as abdominal pain, nausea and vomiting, joint and muscle pain, feebleness. **Common (≥1/100 to <1/10):** Thirst, sweating, shivering, dizziness, lacrimation, skin rashes, chest pain, diarrhoea, constipation, urine retention, lack of appetite, increased transpiration, delayed ejaculation, decreased potency, mood swings. **Rare (≥1/10,000 to <1/1,000):** Depression, hepatic disorders, vision disorders, speech disorders, tinnitus, exiguous increase in blood pressure, anxiety, suicide ideation\ attempted suicide, hepatic disorders (increased transaminases). **Very rare (<1/10,000),** Thrombocytopenia, tremor, agitation, euphoria, hallucinations, exanthema.
Referral back to specialist	• Report any serious, unacceptable or enduring adverse reactions to the specialist or the Primary Care Liaison Service. • Any relapse in patients condition to suggest emergence of alcohol or opiate dependence.

Section 5: Drug Interactions

Please list clinically significant drug interactions (see BNF appendix 1) and a reminder to ask the patients about particular problems

Significant Drug Interactions	• No studies for interactions have been performed. • Presently, experience about the effect of naltrexone hydrochloride on the pharmacokinetics of other substances is limited. Concomitant treatment with naltrexone and other medicinal products should be conducted with caution and should be followed carefully. • There has been one case of lethargy and somnolence reported after concomitant use of naltrexone and thioridazine. • It is unlikely that the pharmacokinetics of naltrexone is affected by cytochrome P450 enzyme inhibiting drugs. • Data from a safety and tolerability study of co-administration of naltrexone with acamprosate in non-

	treatment seeking, alcohol dependent individuals showed that naltrexone administration significantly increased acamprosate plasma level. Interaction with other psychopharmacological agents (e.g. disulfiram, amitryptiline, doxepine, lithium, clozapine, benzodiazepines) have not been investigated. • • If the patient needs opioid treatment, e.g. opioid analgesia or anesthesia in emergency situations, the dose needed may be higher than normal to reach the same therapeutic effect. In these cases, the respiratory depression and circulatory disturbance will be more profound and longer lasting. Symptoms related to release of histamine (diaphoresis, itching and other skin and mucocutaneous manifestations) can occur more easily. The patient requires specific attention and care in these situations. • During the treatment with naltrexone tablets, painful conditions should be treated with non-opioid analgesia only. • High dose opioid intake, concomitant with naltrexone treatment, can lead to life-threatening opioid poisoning from respiratory and circulatory impairment.
Reminder to ask patients about particular problems	• Advise the patient to avoid OTC products containing opioids and to report any side effects such as itching. • Advise the patient to tell their GP, specialist, community pharmacist that they are taking naltrexone.

Section 6: Cautions and Special Recommendations

Please indicate the need to give or avoid specific treatment

Contra-Indication:

- Hypersensitivity to naltrexone hydrochloride or to any of the excipients.
- Severe renal impairment
- Severe hepatic impairment
- Acute hepatitis
- Patients taking opioid-analgesics
- Opioid-addicted patients without successful withdrawal
- Patients with acute symptoms of opioid withdrawal
- Patients with symptoms of withdrawal after administration of naloxone hydrochloride
- Positive urine test for opioids

Section 7: Advice to the patient

Advice for GP/secondary care to pass onto the 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.
- To carry a 'Naltrexone warning card' with them at all times whilst on treatment with naltrexone.
- Patients might be more sensitive to opioid containing medicines after treatment with naltrexone.
- Patients should be told to inform their GP/specialist if they resume drinking alcohol.

Section 8: Responsibilities for Secondary Care

Please list the responsibilities of the secondary care team

1	Assess patient, establish diagnosis and develop care plan. Ensure care plan contains correct 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 the arrangements for the appropriate blood tests have 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. Secondary care is responsible for the interpretation and monitoring of these blood test results for the first month of treatment.
4	Review results of any baseline tests – namely urea & electrolytes, and liver function including GGT, and relay any abnormal findings to the GP with any 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	To follow the guidance as given in the treatment pathway for naltrexone 'Naltrexone (oral) for alcohol Shared Care Treatment Pathway'
9	Provide a Patient information leaflet on naltrexone tablets and discuss the benefits and side effects of treatment with the patient.
10	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 humans. Naltrexone should only be given to pregnant women when, in the judgement of the attending physician the potential benefits outweigh the possible risk.

11 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.
12 Ask the GP/Non Medical Prescriber whether s/he is willing to participate in shared care.
13 Ensure that the GP has a copy of the shared care agreement.
14 To review the patient regularly for the first month of treatment ensuring psycho-social needs are met.
15 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. However consider them for older people and for people with obesity.
16 Organise psychosocial support in conjunction with medication as an essential part of treatment, and for this to be continued following discharge by the specialist.
17 Forward copy of care plan to GP / NMP.
18 Prescribe the first month of naltrexone treatment.
19 Advise GP/NMP to continue naltrexone for 4 to 6 weeks if relapse to alcohol, but to stop after this time if full relapse has occurred.
20 Advise GP/NMP that s/he 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.
21 Discuss appropriate lifestyle issues with the patient as appropriate.
22 Monitor for response and adverse drug reactions; to report ADRs to MHRA and GP/NMP.
23 Communicate promptly with the GP when treatment is changed.
24 Inform GP/NMP of concurrent therapy (as this may interact with other medication patient gets from GP)
25 Advise the GP/NMP on when to adjust the dose, stop treatment (assuming no relapse in patients condition), or consult with the specialist.
26 To review patient / provide advice as requested via the GP or Primary Care Liaison Service as necessary
27 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
28 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.
29 Ensure that clear backup arrangements exist for GPs to obtain advice and support (See 'Back-up advice and support' for contact details.
30 Any verbal communication between primary and secondary care should be confirmed in writing.

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Section 9: Responsibilities for Primary Care

Please list the responsibilities of the GP

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/GGT if clinically warranted for any reason.
4	To follow the guidance as given in the treatment pathway for naltrexone 'Naltrexone (oral) for alcohol Shared Care Treatment Pathway'
5	To take over prescribing after 1 month of treatment.
6	Remind patient that some OTC preparations may contain codeine.
7	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.
8	To check patient has a 'Naltrexone warning card*'
9	Prescribe Naltrexone tablets at the dose recommended.
10	GP/NMP to continue prescribing naltrexone tablets for up to 6 to 12 months, or longer if benefit 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 on-going therapy.
11	Adjust the dose / stop dose as advised by the specialist.
12	Review patient as agreed in the SCA & care plan.
13	Inform specialist team of any change in the patient's medication that may interact with medication patient receives from secondary care.
14	To request specialist review or seek specialist advice when necessary. See ' Back-up advice and support' for contact details.
15	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.
16	Monitor patients overall health and compliance
17	Report adverse events to the specialist and MHRA.

***Naltrexone warning cards for alcohol (only available from Orphan Pharmaceuticals) can be obtained by email to bethan.shepherd@awp,nhs.uk or 07775562391.

Section 10: Responsibilities of the Primary Care Liaison Service

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.
7. Accept referrals by registered GPs in line with DoH guidance.

Section 11: Patients role

1	Report to the specialist or GP if he or 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 or she does not have a clear understanding of the treatment.

Section 12: Contact Details

Name	Organisation	Telephone Number	E mail address / Fax
Dr Fergus Law Consultant Psychiatrist in Substance Misuse	AWP Mental Health NHS Trust, Blackberry Centre, Blackberry Hill Hospital, Manor Rd. Fishponds, Bristol, BS16 2EW	0117 378 4500	fergus.law@awp.nhs.uk 0117 9021174
Care co-ordinator	AWP Mental Health NHS Trust,		
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	01179195625
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 and at Fountain Way	**North Wiltshire** (Green Lane Hospital): 01380 7311341 **South Wiltshire** (Fountain Way): 01722 820372	01380 731295 01722 820376
Bethan Shepherd	AWP NHS Mental Health Trust	07775562391 (Tues 9am-2.30pm; Wed & Thurs 9am-4pm)	Bethan.shepherd@awp.nhs.uk

Section 11: Document Details

Date prepared	23rd August 2012. Amended18th September; & 6th November 2012 to reflect feedback from Formulary meetings and AWP MMG group. Minor update July 2024 - removed link to agreement form as no longer in use.
Prepared by	Bethan Shepherd. Formulary Pharmacist
Date of review	2 years or earlier if guidance changes.
Document Identification	SCA Naltrexone for alcohol BNSSG V3.1 Nov 2012

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

Contribution by Specialist Psychiatrist in substance misuse.

Section 13: 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 CG 115
4. British National Formulary 63 March 2012
5. NHS Bristol Primary Care Policy for Initiation of Naltrexone Summary (2009)
6. Patient Information Leaflet (Adepend®)
7. http://www.choiceandmedication.org/nsft/medications/143/