DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
(JAPC)
SHARED CARE AGREEMENT

NALTREXONE – for the maintenance of alcohol abstinence (for patients within services commissioned by appropriate body)

1. **REFERRAL CRITERIA**
   - Suitability for drug treatment with Naltrexone
   - Motivation to remain abstinent assessed
   - No contraindications to treatment
   - Appropriate support/supervisory network in place for Patient
   - Possess an agreed recovery plan
   - Condition is stable/predictable
   - Effective monitoring is established

2. **PRINCIPLES FOR THE SHARING OF CARE**
   - This shared care agreement outlines ways in which the responsibilities for managing the prescribing of Naltrexone are shared between the specialist services and General Practitioners (GP) where shared care provides an optimal solution for the patient.
   - GPs are invited to participate and if not confident to undertake these responsibilities, then he/she is under no obligation to accept shared care.
   - Where shared care is not accepted total clinical responsibility for the patient for the diagnosed condition and ongoing supply of medication remains with the specialist.
   - Sharing care assumes close communication between the specialist and GP, therefore a specialist asks the GP to prescribe this drug and the GP should reply to the request as soon as practicable.
   - Sharing care assumes communication between the Specialist, GP and Patient therefore the process should be explained to the patient by the specialist initiating treatment and they are in agreement.
   - The practitioner who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

3. **AREAS OF RESPONSIBILITY**

GP responsibilities	**Specialist responsibilities**
1. To reply to the request for shared care as soon as practical 2. To continue the prescribing following assessment, commencement and stabilisation by the specialist team, usually after 3 months of treatment. 3. Prescribe Naltrexone tablets at the dose recommended. 4. 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. 5. 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. 6. Adjust the dose / stop dose as advised by the specialist.	1. To carry out a full holistic review and assessment of the patient prior to prescribing 2. To arrange for a physical assessment, to discuss the results and record this in the patient's notes prior to prescribing 3. To ensure suitability for naltrexone and discuss the risk/benefits of treatment with the patient/carer. 4. To ensure the patient is abstinent from alcohol. This will usually have been achieved by a supervised alcohol detox or "drinkdown" with the Community Alcohol Team. 5. To perform baseline tests and where clinically appropriate routine tests. (LFTs at initiation and periodically as detailed in section 5(vi) below.) 6. To prescribe and monitor for the first 12 weeks of treatment with a view to continue or discontinue treatment. 7. To agree the recovery plan with the patient 8. To give the patient written information about the medication and a patient treatment card prior to commencement.

7. Inform specialist team of any change in the patient's medication that may interact with medication patient receives from secondary care. 8. Once the patient has been transferred to GP shared care from specialist services, advice may be sought on any aspect of the patient's recovery from alcohol dependence that is of concern to the GP/NMP. See 'Back-up advice and support for contact details. 9. Monitor patients overall health and compliance 10. To ensure there are no drug interactions with any other medicines initiated in primary care. 11. To transfer the patient to the specialist team where appropriate. For example: • Relapse to drinking • Concerns over patient compliance • Patient or GP is not comfortable to continue with existing regimen due to change in condition or side effects. 12. To discontinue treatment on the advice of the specialist team or immediately if urgent need to stop treatment arises. 13. Ensure patient awareness of recovery support services available from alcohol services and/or GP support during the prescribing period. 14. Report adverse events to the specialist and MHRA.	9. To consult GP whether he/she is willing to participate in prescribing/shared care. 10. To continue to prescribe until GP has agreed to take over prescribing, usually after 12 weeks of treatment. 11. On acceptance for shared care, to supply four weeks maintenance therapy to allow GP handover 12. To ensure local arrangements are made to support administration by a carer or relative 13. To provide the GP with a summary of information relating to the patient to support the GP in undertaking shared care. 14. To advise the GP of any dose adjustments required, monitoring required, when to transfer back and when and how to stop the treatment (if appropriate). 15. To stop naltrexone if the patient relapses into drinking which persists for 4-6 weeks after starting naltrexone. 16. To advise the GP when the patient will next be reviewed by the specialist team. 17. To keep the GP informed of the patient's progress 18. To ensure a mechanism is in place to receive rapid transfer of a patient from the GP if required if the patient deteriorates 19. To report any adverse events to the MHRA on the yellow card form and to inform the GP. 20. To ensure that clear communication and support is in place for the GPs to obtain if required
Patient responsibilities • To take medication as directed by the prescriber. • To report to the specialist prescriber or GP if he/she does not understand the treatment clearly. • To maintain contact and engagement with services, as per the recovery plan, to enable them to work towards their recovery goals and overcome alcohol dependence. • To attend GP and other follow up appointments as scheduled. • To share any concerns in relation to treatment. • To seek medical assistance if he/she experiences an adverse reaction or side effect. • To report any adverse effects or warning symptoms to the specialist prescriber or GP.	

4. COMMUNICATION AND SUPPORT

i. Contacts:	ii. Out of hours contacts and procedures:
DHCFT Derbyshire Recovery Partnership **Derbyshire Recovery Partnership** www.derbyshirerecoverypartnership.co.uk 42 St Mary's Gate, Chesterfield S41 7TH tel: 0300 123 1201 The Mews 7 Church Street Ripley DE5 3BU tel: 01773 744597	Patients should be able access emergency help through out of hours GP services or NHS 111

Erewash House Station Rd. Ilkeston tel: 01159 309442 Bankgate Unit 13-15 Rinkway Ind Estate Rink Drive Swadlincote DE11 8JU tel: 0300 790 0263	

iii. **Specialist support/resources available to GP including patient information**:

Patient leaflets and treatment cards are available from the manufacturer.
Downloadable patient information: http://www.medicines.org.uk

5. CLINICAL INFORMATION

i. Prescribed indications	Naltrexone is licensed for use as part of a comprehensive programme of treatment, including psychosocial guidance, for detoxified patients who have been alcohol-dependent or opiate-dependent to support abstinence
ii. Cautions	• Naltrexone is extensively metabolised by the liver and excreted predominantly in the urine. Therefore, caution should be observed in administering the medicinal product to patients with impaired hepatic or renal function. Liver function tests should be carried out both before and during treatment. • During treatment with naltrexone, painful conditions should be treated with non-opioid analgesia only. If opioids cannot be avoided i.e. opioid analgesia or anaesthesia in emergency situations, the dose needed may be higher than normal. In these cases, the respiratory depression and circulatory effects will be more profound and longer lasting. The patient requires monitoring carefully in these situations for signs of opioid toxicity. High dose opioid intake, concomitant with Naltrexone treatment, can lead to life-threatening opioid poisoning from respiratory and circulatory impairment. • Patients must be warned against the concomitant use of opioids (e.g. opioids in cough medication, opioids in symptomatic medication for the treatment of common colds, or opioids contained in anti-diarrhoeal agents, etc.) during naltrexone treatment
iii. Dose and route of administration	In accordance to national guidance the therapy should be initiated and supervised by a specialist prescriber experienced in treatment of alcohol-dependent patients. NICE guidance recommends starting at a dose of 25mg daily and aim for a maintenance dose of 50mg daily. Unlicensed for use in children under 18 years of age. Safe use in children has not been established. Not recommended in elderly patients due to insufficient data on the safety and efficacy of naltrexone for this indication
iv. Duration of treatment	Up to six months, or longer if service user is benefitting from the drug and wants to continue with it
v. Adverse effect	Common or Very common: Joint and muscle pain, abdominal pain, anxiety, chest pain, chills, constipation, decreased potency, delayed ejaculation, diarrhoea, dizziness, headache, increased energy, increased lacrimation, increased sweating, increased thirst, irritability, mood swings, nausea, rash, reduced appetite, sleep disorders, urinary retention, vomiting.
vi. Monitoring requirements	LFTs: Always before treatment and during treatment only where considered clinically appropriate. NICE guidelines state 'Do not use blood tests routinely, but consider them for older people, for people with obesity, for monitoring recovery of liver function and as a motivational aid for service users to show improvement'.

	NICE recommends that patients should be supervised at least monthly for the first 6 months of treatment. After 6 months this can be reduced in frequency but must still be regular. (NICE 2011)
vii. Clinically relevant drug interactions	Clinical experience and experimental data on the effect of naltrexone on the pharmacokinetics of other substances are limited. No interaction studies have been performed, thus concomitant treatment with naltrexone and other medicinal products should be conducted with caution and should be followed carefully. **Concomitant administration of naltrexone with an opioid-containing medication should be avoided.** There are no known interactions between naltrexone and alcohol.
viii. Supply of ancillary equipment	Not applicable
ix. Contraindications	Hypersensitivity to the active substances or excipients. Severe renal impairment or severe hepatic impairment including acute hepatitis Opioid addicted patients with current abuse of opioids. Positive urine screen for opioids or failure of the naloxone provocation test. Use in conjunction with an opioid – containing medication
x. Prepared by	Stephen Miller, Specialist Nurse Practitioner

This does not replace the SPC, which should be read in conjunction with it.
Date prepared: January 2018 **Reviewed** November 2019 **Next review date**: October 2022

6. REFERENCES

Summary of Product Characteristics Naltrexone (Accord): Accessed Jan 2018. Available from: https://www.medicines.org.uk/emc/medicine/25878.

NICE Clinical Guideline 115 (2011) Alcohol Use Disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. Available from: https://www.nice.org.uk/guidance/cg115.

British National Formulary: Accessed Jan 2018. Available from: http://dx.doi.org/10.18578/BNF.269764922

Sample Transfer Letter

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_ADDRESS_4»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3» «CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable): **See overleaf for initiation criteria.**		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*

I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to:

1. The specialist/consultant requesting shared care
2. **AN <u>ANONYMISED</u> COPY OF THIS FORM ONLY** to the Medicines Management Clinical Effectiveness Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: sderccg.derbyshiremedicinesmanagement@nhs.net

(Sending a copy of this form to the Clinical Effectiveness Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).