DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Shared Care Agreement for Naltrexone 50mg tablets for Opioids in Substance

This shared care agreement is aimed at General Practitioners with a special interest (GPSI) in drug misuse within the Local Enhanced Service (LES) working alongside specialist services to manage the care of drug users.
The shared care is between
GPSI prescribers: managing the prescription management of substitute medication and
Specialist drug services: providing assessment and psychosocial interventions.

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case, subject to receiving the relevant clinical information.
- The patient will be given a supply of naltrexone 50mg tablets sufficient for four weeks maintenance therapy.
- Naltrexone should form part of a programme of psychosocial support and relapse prevention. For these reasons Naltrexone is normally prescribed when a Specialist Drug Service (SDS) worker is involved with the patient.Treatment may be initiated in a number of settings, including Primary Care, prison before release, or SDS clinics.
  These guidelines should be used in conjunction with Drug misuse and dependence UK guidelines on clinical management (DOH, 2017) and NICE technology appraisal.
  https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management

2. AREAS OF RESPONSIBILITY

GP responsibilities (for GPSI in Local Enhanced Service)	Consultant (SDS) responsibilities
1. Naltrexone should only be prescribed following screening of the patient by the SDS. **2.** Liver function tests (LFTs) should be taken, and results known, before the administration of Naltrexone – the SDS will arrange this for the first month and share the results with the GP. Do not prescribe if ALT or GGT is greater than twice the upper limit of normal. LFTs should be repeated after three weeks of treatment. If normal, further monitoring should be as clinically indicated. If there is clinical evidence of severe chronic liver disease, or if ALT is greater than twice the upper limit of normal, then Naltrexone should not be started without advice of a Specialist in Hepatology or Infectious Diseases. Naltrexone should be discontinued if ALT rises to greater than three times normal, unless some other cause is found. **3.** The GPSI should be satisfied that patients will be reviewed by themselves or by the SDS seven days after initiation, then after a further fourteen days, and thereafter monthly. Repeat prescription should not be issued without this review. It is unusual for patients to take Naltrexone for more than six months, but this can occasionally be indicated. **4.** If there is uncertainty about the possibility of pregnancy, Naltrexone should be withheld until a negative pregnancy test is obtained. The GP should be alert to, and monitor any drug interactions, and any adverse effects of Naltrexone.	**1.** Prior to initiation of Naltrexone the SDS Worker should have done a full review and assessment of the patient, and arranged for liver function tests (LFTs) to be carried out. The SDS will arrange the necessary LFTs for the first month and inform the GPSI of the results. **2.** Counselling the patient regarding Naltrexone is essential. This should be supplemented by written information. Specific areas of importance include: a. The importance of being opiate free, and the risk of acute withdrawal, if the patient is not opiate free. b. The risk of attempting to overcome the antagonist effect of naltrexone (overdose) c. The loss of tolerance that occurs after a period of abstinence and the risk of overdose, if the person lapses to opioid use. **3.** A urine sample should be obtained and must test negative for opiates immediately prior to initiation of Naltrexone. A test dose of Naltrexone 25mgs should be administered, and the patient observed for one hour for signs of withdrawal. Subsequently 50mgs daily should be prescribed. **4.** Patients should be reviewed seven days after initiation, and then after a further fourteen days when LFTs should be repeated. Thereafter, the GPSI or SDS Worker should review patients monthly.

5. The GPSI will monitor the patient's general health, and seek specialist advice, if uncertain about continuing to prescribe Naltrexone. Report any adverse effects to the referring specialist and the MHRA yellow card scheme. www.mhra.gov.uk/yellowcard	**5.** Where there is significant other/third party involvement, with the patient's consent, it may be useful to enlist their support in the administration of Naltrexone. Report any adverse effects to the MHRA yellow card scheme and GP.

Patient responsibilities Patients should understand the rationale for treatment and confirm this with SDS:

- To attend appointments and undergo the recommended monitoring.
- Share any concerns they have in relation to treatment with naltrexone.
- Inform the SDS or GPSI of any other medication being taken, including herbal or over-the-counter preparations. Seek advice before self-medicating with herbal or over-the-counter preparations.
- The expectations placed on them (cooperate with blood and urine testing.)
- Information about the prescribed medication, to be fully aware of the benefits, and the potential risks of the Naltrexone antagonist effect

3. COMMUNICATION AND SUPPORT

i. Specialist Drug Service Contacts:	**ii. Out of hours contacts and procedures:**
Derbyshire Recovery Partnership, (DRP) **Specialist Substance Misuse Service** Name: Dr Deepak J Sirur Consultant Psychiatrist in Substance Misuse Services Name: Dr Sugato Sarkar Consultant Psychiatrist Substance Misuse Services Southern Derbyshire Specialist Services Division Derbyshire Healthcare NHS Foundation Trust 42, St. Marys Gate, Chesterfield, Derbyshire S41 7TH Tel. 0300 123 1201 Fax 01246 216512	Patients should be able access emergency help through out of hours GP services or NHS 111

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

Summary of Product Characteristics, BNF
Patient information available from the DRP

4. CLINICAL INFORMATION

i. Prescribed indications	Naltrexone is an opioid antagonist licensed in oral form as an adjunct to prevent relapse in detoxified formerly opioid dependent patients who have remained opioid free. Naltrexone should only be administered under adequate supervision to people who have been fully informed of potential adverse effects of treatment. It should be given as part of a programme of supportive care.
ii. Therapeutic summary	Naltrexone is a opioid antagonist capable of blocking the effects of heroin and other opioid drugs (including codeine based medications). It does not block the effects of other drugs (e.g. cocaine, amphetamines). Depending on the dose Naltrexone blocks the effect of opiates for 24-72 hours. If a person on Naltrexone uses Heroin they experience no opioid effect. Specifically, unlike alcohol and Antabuse, there are no negative effects.

iii.	**Dose & Route of administration**	It is available as 50mgs tablets. A test dose (25mgs) is recommended at the initiation of treatment. The initial dose, therefore, is 25mgs, and then 50mgs daily, which can be taken three times a week (e.g. 100mgs on Monday and Wednesday, 150mgs on Friday), if needed for supervision purposes. Naltrexone treatment must begin only when the opioid has been discontinued for a sufficiently long period (about 5 to 7 days for heroin and at least 10 days for methadone). A urine test is necessary to confirm abstinence from opioids before initiation of treatment.
iv.	**Duration of treatment**	It is unusual for patients to take Naltrexone for more than 6 months. Initially patients should be reviewed weekly and after that every 28 days or at a frequency based on clinical judgement.
v.	**Adverse effects**	Common or very common: joint and muscle pain, abdominal pain, anxiety, chest pain, chills, constipation, decreased potency, delayed ejaculation, diarrhoea, dizziness, headache, increased- energy, lacrimation, sweating, thirst, irritability, mood swings, nausea, rash, reduced appetite, sleep disorders, urinary retention, vomiting.
vi.	**Monitoring Requirements**	Liver function tests (LFTs) should be taken, and results known, before the administration of Naltrexone LFTs should be repeated after three weeks of treatment. If normal, further monitoring should be as clinically indicated. A drug test should be performed at each review to confirm abstinence from opioids. It is available as 50mgs tablets. A test dose (25mgs) is recommended at the initiation of treatment. Initially patients should be reviewed weekly and after that every 28 days or at a frequency based on clinical judgement.
vii.	**Clinically relevant drug interactions**	Concomitant administration of naltrexone with an opioid-containing medication should be avoided.
viii.	**Contraindication**	Hypersensitivity to the active substances or excipients. Naltrexone must not be given to patients currently dependent on opioids, as acute withdrawal will result. Naltrexone is potentially hepatotoxic and is contraindicated in acute liver failure or acute hepatitis. Naltrexone has not been established as safe in pregnancy or breast-feeding. If a user tries to overcome the block by taking increasing doses of heroin there is the danger of respiratory depression occurring before euphoria with risk of death.
ix.	**Supply, storage**	Store below 25°C
x.	**Prepared by**	Mrs CM Jones Specialist Pharmacist Substance Misuse Drug and Alcohol Advisory Group DHCFT **Approved by DHCFT Medicine Management Committee**

This does not replace the SPC, which should be read in conjunction with it.

Date JAPC Agreed: October 2018 **Review Date:** September 2020 (Extended to September 2021)

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)**	

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

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 and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions 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).

REGARDS EIRA: Assessing Equality Relevance (Stage 1)

1. Name of the service / policy / project or proposal (give a brief description):

Naltrexone 50mg Tablets for Opioids in Substance Misuse

2. Answer the questions in the table below to determine equality relevance:

	Yes	No	Insufficient data / info to determine
Does the project / proposal affect service users, employees or the wider community, and potentially have a significant effect in terms of equality?		✔	
Is it a major project / proposal, significantly affecting how functions are delivered in terms of equality?		✔	
Will the project / proposal have a significant effect on how other organisations operate in terms of equality?		✔	
Does the decision/ proposal relate to functions that previous engagement has identified as being important to particular protected groups?		✔	
Does or could the decision / proposal affect different protected groups differently?		✔	
Does it relate to an area with known inequalities?		✔	
Does it relate to an area where equality objectives have been set by our organisation?		✔	

3. On a scale of high, medium or low assess the policy in terms of equality relevance.

	Tick below:	Notes:
High		If ticked all 'Yes' or 'Insufficient data'
Medium		If ticked some 'Yes' and / or 'Insufficient data' and some 'No'
Low	✔	If ticked all 'No'

EIRA completed by: Caroline Jones
Date: 06.06.2018