DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Buprenorphine Sublingual Tablets for Substance Misuse

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 buprenorphine sublingual tablets sufficient for four weeks maintenance therapy. Buprenorphine should form part of a programme of psychosocial support from drug treatment services. For this reason it is only prescribed when a specialist drug service (SDS) worker is involved with the patient. These guidelines should be used in conjunction with Drug misuse and dependence UK guidelines on clinical management (DOH, 2017)). 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
GPSI should offer basic harm minimisation interventions for all drug users. This should include the following: **1.** Advice regarding safer injecting and avoidance of blood-borne virus transmission **2.** Advice of local needle exchange facilities **3.** Advice on safer sex **4.** Referral to specialist services if patient becomes pregnant **5.** Testing for hepatitis B and C and HIV with pre and post test discussion **6.** Vaccination for hepatitis A and B where appropriate **7.** Inquire about past drug use **8.** Assess for risk of overdose **9.** Give information avoiding overdose **10.** Inquire about other drug related problems **11.** Referral to infectious diseases services where necessary **12.** Referral to specialist drug treatment services where necessary / appropriate **13.** Referral to voluntary agencies offering supplementary services where necessary / appropriate The decision to prescribe will depend on: **1.** The overall treatment plan for the patient **2.** Discussion with members of the multidisciplinary team **3.** Advice where necessary from a specialist services prescriber in substance use **4.** Clinicians should prescribe within their competence and within agreed clinical governance frameworks **5.** Clinicians should be prepared to justify their clinical decisions, especially when operation outside these guidelines **6.** Clinicians should keep comprehensive notes to support their decisions Before deciding whether to prescribe the clinician should be clear as to the desired outcomes for the patient. These could be to: **7.** Reduce or prevent withdrawal symptoms **8.** Offer opportunity to stabilise drug intake and lifestyle	**1.** Prior to initiation of substitute medication the SDS worker should have done a full assessment of the patient, and arranged for a physical assessment to be carried out. **2.** Patients should be carefully selected as being able to change their drug use, and consideration of other treatment options will have been made. The SDS, GPSI and patient should agree treatment goals. These should be clearly recorded and may be given to the patient in writing. **3.** The SDS worker will be responsible for feeding back urine or mouth swab results to the GPSI, and for regular review of the patient. **4.** The SDS worker will be responsible for psychosocial counselling and help prior to initiation of substitute medication, during dose stabilisation, and at stages of change. **5.** Information about the substitute medication, and about possible risks to the patient and others, should be regularly discussed with the patient, and they should be provided with written information. **6.** Advice about risks of the substitute medication to the patient and others should be repeated where necessary especially when changes to dispensing

9. Promote a process of change in drug taking and risk behaviour **10.** Help maintain contact and offer an opportunity to work with the patient. A prescription for substitute medication should normally only be considered if: **1.** The patient is able to change some aspects of their drug use **2.** Opiates are being taken on a daily basis **3.** There is convincing evidence of signs of opiate withdrawal **4.** The assessment (including history, examination, toxicology and drug diary) clearly substantiates need for treatment **5.** The clinician is satisfied that the patient is able to comply with prescribing regimen **6.** The patient is not receiving a prescription from another clinician **7.** Before substitute prescribing a comprehensive assessment of the patient should be conducted Report any adverse effects to the referring specialist and the MHRA yellow card scheme www.mhra.gov.uk/yellowcard	occur e.g. moving to take home doses after a period of supervision. Report any adverse effects to the MHRA yellow card scheme

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 buprenorphine
- 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 (frequency of pharmacy attendance for medication, attendance for prescribing review)
- Information about the prescribed medication, the risks during induction, the dangers of mixing prescribed medication with other CNS depressants
- The risks to children and non tolerant adults of ingesting prescribed medication
- Responsibilities to inform the DVLA of medication and understand the Drug driving Testing Laws

Communication with community pharmacists

GPSIs should liaise with community pharmacists when prescribing substitute medication for a patient:

- To ensure the pharmacy has sufficient capacity to take on a new patient
- To introduce the pharmacist to a new patient
- To ensure the pharmacist is part of the locally agreed service for supervising the administration of medication
- To ensure that the pharmacist is able to confirm that the prescriber and prescription are genuine

It is important that pharmacists share relevant information with GPSIs and specialist drug services:

- When the pharmacist is aware the patient is not complying with their treatment
- The patient has missed three consecutive days of prescribed medication
- When there are concerns about the patient's health and wellbeing
- When the patient attends the pharmacy in a state of intoxication
- The pharmacist must follow locally agreed protocols when supervising the administration of medication
- When there are concerns for the safety and welfare of service user and others (notably with children in households)

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	Patients should be able access emergency help through out of hours GP services or NHS 111

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	
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	Adjunct in the management and treatment of opiate users
ii. Therapeutic summary	Buprenorphine is a semi-synthetic opioid with a half-life of between 2-5 hours with a long terminal elimination phase of 20-25 hours. Buprenorphine, using flexible dosing regimens, is an effective, safe medication for use in the treatment of opiate users. Long-term prescribing of substitute medication achieves the following outcomes: 1. Improved mental / physical health (reduced risk of infectious disease) 2. Improved social functioning 3. Reduced or stopped injecting (reduced risk of infectious disease) 4. Reduced or stopped illicit drug use 5. Reduced criminal activity 6. Retention in treatment (reduced drug related deaths) Both buprenorphine and methadone are recommended by NICE for opiate substitute treatment. A number of factors should be taken into account when selecting an appropriate medication: 7. Level of opioid use 8. Safety (likelihood of diversion and overdose risk) 9. Patient experience with both illicit and prescribed medications, treatment history and response 10. Patient preference 11. Retention in treatment compliance Evidence suggests that methadone is more likely to retain patients in treatment but evidence for relative effectiveness of methadone and buprenorphine at preventing illicit opioid use is mixed. NICE recommends if both drugs are equally suitable, methadone should be prescribed as the first choice. The first two weeks of treatment are a particular risk to patients with regards overdose. Clinicians therefore need to balance the competing pressures of prescribing effective doses with the risk of overdose / precipitated withdrawal and rapidly responding to the needs of the patient with regards engaging and retaining in treatment.
iii. Dose & Route of administration	1. Buprenorphine sublingual tablets are available in 0.4mg, 2mg and 8mg strengths. The tablets are administered sublingually because it has poor oral bioavailability (inactivated by gastric acid and a high first pass metabolism) 2. The risks of prescribing buprenorphine include: toxicity when using other CNS depressants, toxicity in people with low opioid tolerance, risk of precipitated withdrawal and dropping out of treatment, risk of injecting or snorting prescribed medication 3. At the start of prescribing patients should be informed that they may experience withdrawal symptoms in the first two days after starting buprenorphine.

	4. If a patient is taking methadone then their dose should be 30mg or less before initiating buprenorphine. Patients on higher doses of methadone should be initiated in a specialist service. 5. The first dose of buprenorphine should be administered at least 8 hours after last use of heroin or 24 to 36 hours after last use of methadone. The patient should preferably be experiencing mild withdrawal symptoms to reduce the risk of precipitated withdrawal. 6. Precipitated withdrawal happens because of buprenorphine displacing other opiates at receptor sites. Symptoms typically occur 1-3 hours after the first buprenorphine dose and will subside after 4-6 hours. If this occurs, patients should be reassured and asked to take symptomatic medication if necessary. A further dose of buprenorphine should not be taken until the withdrawal symptoms have subsided. 7. A first dose of 4mg buprenorphine is generally recommended. Starting daily doses of between 4mg and 8mg can be used. 8. The dose can then be increased by 4-8mg daily until the patient is stable. 9. An adequate dose of buprenorphine should be prescribed (may average 12–16mg per day), with some people needing up to 32mg. 10. When comparing efficacy of maintenance dose 12 -16mg buprenorphine is approximately as effective as 50-80mg of methadone in reducing heroin use and retaining patients in treatment. 11. Daily dose of buprenorphine should not exceed 32mg 12. Patients may be seen at least weekly initially and then at least monthly when stable 13. Random urine or oral fluid tests may be helpful in monitoring prescribing – drug testing should be done every 3 months as a minimum for stable patients. It may be done more frequently if there are clinical concerns and the results used to improve clinical risk. 14. Supervising of consumption by an appropriate professional provides the best guarantee that a medication is being taken as directed 15. In most cases new patients should take their daily dose supervised for a period of time that may be around three months subject to assessment of patients compliance and individual circumstance 16. When a patient restarts buprenorphine after a break or receives a significant increase in dose daily dispensing with supervised consumption should be reinstated for a period of time agreed with the patient 17. In patients whose treatment is failing, a period of daily supervised consumption can improve observation of progress and increase interventions to improve outcomes 18. Supervised consumption and frequency of take home medication may have a role in contingency management. Relaxation of supervision being regarded as an incentive if progress such as drug free urine screens can be demonstrated. 19. Moving from one pick up frequency to another should be a graduated process as the patients and prescribers experience of treatment develops, taking into account compliance and individual patient circumstance 20. Prescribers will be informed by the dispensing pharmacist if the patient has not attended for buprenorphine for three consecutive days. In this situation the patient should be reassessed by the prescriber and, if necessary, buprenorphine may be restarted at the existing or lower dose. 21. If the patients has missed more than 5 days medication then their opioid use will have to be reassessed Lost prescriptions and or medication should not be replaced (except under exceptional circumstances) unless this is due to a fault on the part of the prescriber.
iv. Duration of treatment	1. While drug treatment has been shown to be effective in reducing illicit drug use patients may not cease illicit drug / alcohol use immediately, eliminating all drug / alcohol use may take months or years 2. Stability on substitute medication offers the opportunity to achieve and maintain health and social benefits while affecting wider lifestyle changes 3. If a patient is not benefiting from treatment clinicians should consider optimising treatment by increasing the intensity of programme rather than reducing it

	4. Continued use of illicit drugs / alcohol may indicate patient requires discrete treatment for these substances, eg relapse prevention, triggers to use 5. Prescribers have a responsibility to make individuals aware of the criteria they apply when deciding whether it is safe or not to continue to prescribe or when it is necessary to make a change to the prescription 6. It may be necessary on occasions on the basis of careful assessment of risk to the patient and staff that a prescription must be suspended or withdrawn. Such decisions must involve the prescriber and other members of the multidisciplinary team 7. Detoxification is thought of as being a clearly defined process supporting safe and effective discontinuation of opioids whilst minimising withdrawals 8. The assessment and review process can establish whether a patient is suitable for detoxification. The detoxification process should be an active process carried out following joint and informed decision between prescriber, patient and multidisciplinary team 9. It should be remembered that detoxification is rarely successful especially at the first attempt. Patients who do not successfully detoxify should be offered seamless access back into maintenance or other treatment 10. There is clear evidence that detoxification against the patients expressed will is likely to lead to lapse and increased wider risks such as overdose 11. The following factors can guide the clinician / patient about suitability for detoxification – patient is committed and informed about the process, patient aware of risk of lapse, patient is in a stable and supportive social situation, plans for continued support and treatment are in place 12. NICE guidelines suggest that methadone and buprenorphine are as effective as each other in achieving good outcomes. They concluded that detoxification should be carried out with the medicine on which the patient has stabilised 13. Some patients and prescribers agree to reduce doses slowly over many months. This is not really detoxification but can be a useful way of working towards detoxification. 14. The detoxification process should usually last about 28 days as an inpatient or up to 12 wks as an outpatient Buprenorphine doses can be reduced by about 2mg every 2 wks or so with final reductions being around 400mcg.
v. Adverse effects	The most common side effects include headaches, nausea, vomiting, constipation and sweating.
vi. Monitoring Requirements	**Buprenorphine and liver disease** Buprenorphine may have an effect on liver function especially in those with pre-existing liver disease, those who inject buprenorphine or those who take an overdose of buprenorphine. In practice it is recommended that: 1. LFTs checked at assessment. Buprenorphine may be started if patient is well 2. If LFTs normal, monitor 6 monthly. 3. If there is evidence of liver disease (HCV antibody positive, alcohol use), take LFTs before commencing buprenorphine (baseline) and monitor after 2-3 months. If there is marked deterioration in LFTs, refer to a liver specialist for advice.
vii. Clinically relevant drug interactions	The main drug interactions of buprenorphine are related to its opioid activity: **Other sedatives** There is an increased risk of overdose when buprenorphine is taken with other sedatives like, benzodiazepines, alcohol. **Opioid antagonists** Naltrexone can precipitate a delayed opioid withdrawal reaction in buprenorphine patients. In the event of buprenorphine overdose, higher doses of naloxone are required. **Opioid agonists** Buprenorphine reduces the effects of other opioids given for analgesia. **Other** The prescribing of ketoconazole will necessitate a buprenorphine dose reduction For up to date information on contra-indications, cautions, side effects and drug interactions please see current BNF

	All patients should be warned of the risks of taking buprenorphine, including risks around injecting. They should be told that buprenorphine and other prescribed drugs must be kept out of reach of children. They should be warned of the risks of concomitant use of other prescribed and illicit drugs and of the risk of overdose after a period of abstinence. Best practice would be to provide verbal and written information.
viii. Contraindication	**Contraindications:** Buprenorphine should not be used in the following population groups: - Allergy to buprenorphine - Non – opioid dependent - Severe respiratory insufficiency or hepatic insufficiency - Acute alcoholism or delirium tremens **Cautions:** 1. Pregnancy is not a contraindication under the UK licence; it is listed as a special warning. A pregnant patient on buprenorphine should be referred to a specialist service and advised to continue with buprenorphine, whilst being made aware of existing safety data. 2. Impaired liver / kidney function Buprenorphine is easily soluble and so easily injected. In France the use of the higher strength tablets showed suspected IV use in between 10-30% of patients. As with the use of heroin the potential injecting related harms (including acute toxic hepatitis) should be discussed with patients **Effects on ability to drive and use machines** Buprenorphine has minor to moderate influence on the ability to drive and use machine. Buprenorphine may cause drowsiness, particularly when taken together with alcohol or central nervous system depressants. Therefore, patients should be warned against driving or operating machinery, responsibilities to inform the DVLA of their medication and awareness of the Drug/driving testing laws. This medicine can impair cognitive function and can affect a patient's ability to drive safely. When prescribing this medicine, patients should be told: • The medicine is likely to affect your ability to drive • Do not drive until you know how the medicine affects you • It is an offence to drive while under the influence of this medicine • However, you would not be committing an offence (called “statutory defence”) if: 1. The medicine has been prescribed to treat a medical problem and 2. You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and It was not affecting your ability to drive safely
ix. Supply, storage and reconstitution instructions	Not applicable
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):

Buprenorphine Sunblingual Tablets for 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