DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Shared Care Agreement for Methadone 1mg/ml Sugar Oral Solution and Methadone 1mg/ml Sugar-free Oral Solution in Substance Misuse Services

This shared care agreement is aimed at General Practitioners with Extended Roles (GPwER) 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
GPwER 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 methadone 1mg/ml sugar oral solution **or** methadone 1mg/ml sugar-free oral solution sufficient for four weeks maintenance therapy by DHCFT Drug Recovery partnership, in a supply format appropriate for the individual.
- Methadone 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 GPwER in Local Enhanced Service)	Consultant (SDS) responsibilities
GPwERs 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 **7.** Clinicians are responsible for monitoring the risk of QT prolongation as recommended in the SPC and Drug Misuse and	**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, GPwER 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 GPwER, 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

Dependence: UK Guidelines on Clinical Management (see clinical information) Before deciding whether to prescribe the clinician should be clear as to the desired outcomes for the patient. These could be to: **8.** Reduce or prevent withdrawal symptoms **9.** Offer opportunity to stabilise drug intake and lifestyle **10.** Promote a process of change in drug taking and risk behaviour **11.** 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. **7.** 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 methadone.
- Inform the SDS or GPwER 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

GPwERs 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 prescribers 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 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.Local arrangements for referral

Specialist drug services: providing assessment and psychosocial interventions will coordinate/facilitate the transfer between Specialist drug services prescriber and GPwER in primary care and vice versa

iv. 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	Methadone is a synthetic opioid with a half-life of between 24-36 hours. Methadone, 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 methadone and buprenorphine are recommended by NICE TA114 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 TA114 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. Methadone is available as methadone 1mg/1ml sugar oral solution and as methadone 1mg/ml sugar-free oral solution. It is taken orally. Aside from sugar content there is no pharmaceutical difference between the sugar and sugar-free oral solutions. 2. The risks of prescribing methadone include: toxicity when using other CNS depressants, toxicity in people with low opioid tolerance, too high an initial dose, increases in dose that are too rapid, slow methadone clearance 3. These risks can be minimised by: careful initial assessment, identification of high risk patients, avoiding too high starting doses, avoiding too rapid dose increases, frequent monitoring during induction, supervised consumption and alerting patients and carers to early signs of overdose 4. In general an initial dose will be in the range of 10-30mg 5. If tolerance is low or uncertain then 10-20mg is more appropriate 6. With longer term users who are tolerant and where the clinician is experienced or competent, a first dose can be up to 40mg The process of dose induction requires clinical judgement from the prescriber and a facility to be able to monitor the patient regularly 7. Where doses need to be increased in the first week increments should be no more than 5mg to 10mg on one day and a maximum of 30mg in the first week 8. Following the first week doses can continue to be increased incrementally up to a total of between 60mg to 120mg or at which the patient reports to feeling comfortable 9. Daily dose of Methadone should not normally exceed 120mgs – in such cases a specialist opinion may be required 10. Caution needs to be exercised and it may take several weeks to reach the desired dose 11. Patients may be seen at least weekly initially and then at least monthly when stable 12. Random urine or oral fluid tests may be helpful in monitoring prescribing – drug testing should be done 3-4 monthly randomly and as a minimum 6 monthly for stable patients. Drug testing may be done more frequently if there are clinical concerns and the results used to manage clinical risk 13. Supervising of consumption by an appropriate professional provides the best guarantee that a medication is being taken as directed 14. 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 15. When a patient restarts methadone 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 16. In patients whose treatment is failing, a period of daily supervised consumption can improve observation of progress and increase interventions to improve outcomes 17. 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. 18. 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 19. Prescribers will be informed by the dispensing Pharmacist if the patient has not attended for methadone for three consecutive days. In this situation the patient should be reassessed by the prescriber and, if necessary, methadone may be restarted at the existing or lower dose. 20. If the patients has missed more than 5 days medication then their opioid use will have to be reassessed 21. 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. Pregnancy, paternal exposure and breastfeeding	<u>Pregnancy: Referral back to Specialist drug Prescribing</u> <u>Breastfeeding: Referral back to Specialist drug Prescribing</u> Pregnancy and breastfeeding cases are reviewed by Specialist services and retained appropriately. However there may be exceptions where cases are best

	placed with the GPwER (SC) in the primary care practice, where all parties are in agreement : Consultant, GPwER (SC), specialist key worker and the patient.
v. 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, e.g. 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 TA114 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 Methadone doses can be reduced by about 5mg at a rate which will result in zero in about 12 weeks. There is no evidence to suggest superiority of any regimen Patient preference is important.
vi. Adverse effects	The most common side effects include headaches, nausea, vomiting, constipation and sweating. Further information is available in the SPC and BNF.
vii. Monitoring Requirements	Methadone may prolong QTc interval and induce torsade de pointes. (dose dependent) The MHRA recommends monitoring for patients on high dose methadone (>100mg) and with other QT prolongation risk factors such as heart or liver disease, electrolyte abnormalities, concomitant treatment with CYP 3A4 inhibitors, or other medicines with the potential to cause QT interval prolongation. Refer to the link 4.4.2.2 page 91 for further information https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management Screening before commencing methadone is not currently advocated but may be considered. Any QT prolongation needs full investigation and consideration of specialist referral.

		If the patient becomes pregnant, they should be referred to a specialist service and advised to continue with prescribed methadone
viii.	**Clinically relevant drug interactions**	Co-administration of the following enzyme inducers will reduce plasma methadone levels: • Phenytion • Carbamazepine • Rifampicin • Phenobarbitone Co-administration of the following drugs with methadone may cause adverse (though transient) effects in some susceptible patients: • Protease inhibitors used in the treatment of HIV - Ritanover, Zidovudine • Antibiotics – erythromycin, ciprofloxacin • Histamine H2 Antagonists – cimetidine The use of methadone in along with, alcohol, benzodiazepines, sedative antidepressants, antipsychotics, other opiates lead to an increased risk of respiratory depression and overdose. 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 Methadone, including the risk to non-addicted persons especially children. They should be told that Methadone 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.**
ix.	**Contraindication**	**Contraindications** Allergy to methadone, non – opioid dependent, acute respiratory depression **Cautions** Respiratory depression, severe hepatic and renal disease, recent head injury. **Effects on ability to drive and use machines** Methadone may produce drowsiness and patients should be advised not to drive or operate machinery if affected. 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
x.	**Additional information**	Where patient care is transferred from one specialist service or GPwER practice to another, a new shared care agreement must be completed.
xi.	**Supply, storage and reconstitution instructions**	Store below 25°C, protect from light
xii.	**To be read in conjunction with the following documents**	• NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care • NICE TA114.Methadone and buprenorphine for the management of opioid dependence. 2007 • DoH. Drug misuse and dependence UK guidelines on clinical management. 2017
xiii.	**Prepared by**	Mr Martin Smith Recovery Lead Substance Misuse Drug and Alcohol Advisory Group DHCFT

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

Date JAPC Agreed: February 2025 **Review Date:** January 2028

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	*AS PER CARE PLAN*

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*)
* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

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 ANONYMISED 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).