

WORKING IN PARTNERSHIP WITH

Frimley Medicines Optimisation Board

| SHARED CARE Guideline – Amber Traffic Light Classification | | |
|--|--------------------------------|--|
| Name of medicine | | Paliperidone 3-monthly Long-Acting Injection (LAI) |
| Indication | | Schizophrenia |
| Author(s): Balazs Adam and Leena Nanavati Organisation(s): SABP and NHS Frimley ICB | | |
| Version: Final | Frimley MB date: March 2024 | Review date: March 2027 |

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.

This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.

An agreement notification form is included in annex A for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Circumstances when shared care is appropriate

Prescribing responsibility will only be transferred when both secondary and primary care teams in agreement that the patient's condition is stable or predictable, and the patient is:

- agreeable to care being transferred to primary care
- stable on medication for last 6 months
- compliant with treatment plan and no DNAs in last 6 months
- no or stable psychopathology
- stable mood
- aged 18+

Roles and Responsibilities

Patient, or where appropriate Relatives/Carers

- Receive Paliperidone 3 *monthly* long- acting injections as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist
- Tell anyone who prescribes them a medicine that they are taking Paliperidone 3 *monthly* long-acting injections
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of Paliperidone 3 *monthly* long- acting injection with their pharmacist before purchasing any OTC medicines
- Report any adverse effect or warning symptoms to GP
- Inform the GP and specialist if intending to become pregnant
- To report to the GP if pregnant or breastfeeding
- Inform the GP and CMHRS of any changes in address or telephone contacts

- Responsible for attending appointments as planned. If unable to attend, to contact the practice in a timely fashion to reschedule. Missed appointments may result in care being returned to CMHRS

Consultant / Specialist / CMHRS

- Assess the patient and provide diagnosis
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and provide the appropriate counselling to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet
- Assess for contraindications and cautions and interactions
- Supply treatment for at least 6 months
- Agree with the patient that further injections will be administered by their GP
- Complete the request for shared care form and send to the GP, and ensure the form is returned by the GP with agreement
- Ensure the dose, frequency and site of last injection is clearly stated on the transfer request form
- Inform the GP that the patient has been on Paliperidone *3 monthly* long- acting injection for at least 6 months
- Inform the GP of the results of baseline and subsequent tests including plasma glucose, plasma lipids, prolactin, ECG and weight
- Send copies of the My Recovery Care Plan, and the Crisis and Contingency plan to GP
- Complete and send the entire Shared Care Guideline by email to primary care and give a copy to the patient
- Provide timely advice and guidance when requested
- Provide a rapid review should the GP request it
- Undertake the actions required in the management of non-attendance described below

Primary Care Prescriber

- Ensure there is enough information to safely prescribe, administer and monitor treatment
- Complete and return the signed Shared Care Agreement (Annex A) by email to secondary care (whether or not accepted)
- Provide ongoing prescriptions for Paliperidone *3 monthly* long- acting injection
- Ensure that annual monitoring is undertaken of the persons physical and mental health wellbeing. See requirements set out in 'Monitoring' section below
- To identify any new side effects emerging since shared care commenced and to liaise with the Consultant/Specialist to seek advice on management, where necessary
- Refer the patient to the Consultant/Specialist if his/her condition deteriorates. The relapse indicators and early warning signs will be described in the crisis plan along with a recommended contingency plan. The GP will be sent a copy of this
- Undertake the actions required in the management of non-attendance described below
Refer and follow guidance in the Frimley ICB Standard Operating Procedure for the prescribing and administration of long-acting antipsychotic injections by Primary Care

Practice Nurse

- Ask whether the patient has noticed any mental health symptoms that have left them feeling concerned that they may be getting unwell and whether their (partner/family/friend) noticed any mental health symptoms that have left them feeling concerned the patient may be getting unwell

- Ask whether the patient has experienced any new side effects since the last injection
- Ask if patient is pregnant. Contact CMHRS on duty email as stated below if so
- Discuss any concerns with GP who can refer to care plan and contact CMHRS for advice if required
- Complete EMIS template at each appointment
- Provide the patient with the Patient Information Leaflet (PIL)
- Administer the injections and record as per template
- Ensure appointments are planned for regular injections and actively follow up any non-attendance
- Undertake the actions required in the management of non-attendance described below
- Refer and follow guidance in the Frimley ICB Standard Operating Procedure for the prescribing and administration of long-acting antipsychotic injections by Primary Care

Management of Non-attendance and Concerns / Escalation Protocol

- If the patient does not attend the planned appointment, then the practice nurse will call patient and establish reason and rebook if agreeable within 7 days
- Ensure repeat LAI administered within 7 days
- If the person is refusing treatment or shows signs of relapse or DNA'd without successful follow up then escalate to the CMHRS (see under Rapid Response below).
 - a. Prescribing and administration in primary care is to be paused until further notice by CMHRS
 - b. The injection due will then be administered by CMHRS
 - c. CMHRS will complete assessment and communicate outcome to primary care. Outcome will either be:
 - a. Continue with shared care with primary care, or
 - b. The person needs to be reallocated a care coordinator and prescribing and administration responsibility to return to SABP, and share care agreement to be terminated

Rapid Response and Advice for Primary Care

Please refer to the Crisis plan for relapse indicators and early warning signs and contingency plans.

| Team | Duty Inbox |
|--------------------------------------|---|
| CMHRS North East Hampshire & Farnham | nehcmhrs@sabp.nhs.uk The CMHRS NEHF team is contactable by email. The duty inbox is monitored multiple times a day Monday to Friday and an acknowledgment email will be sent to the practices on the day of receipt; actions will be taken following an MDT discussion depending on the nature and urgency of each case. |
| CMHRS Surrey Heath | surreyheathadmin@sabp.nhs.uk |

Background to condition and use of medicine for the given indication

Indication

There is established evidence for the use of antipsychotics in psychosis and schizophrenia as well as in bipolar disorder. First and second generation LAIs are generally considered to be equally effective, however there is considerable variation in the adverse effect profiles.

Together with other factors such as patient preference, response and adherence to treatment with oral antipsychotics, medical and drug history often determine the choice of LAIs.

According to NICE Clinical Guideline [CG178] entitled *Psychosis and schizophrenia in adults: prevention and management*, LAI antipsychotics should be offered to patients:

- who would prefer such treatment after an acute episode
- where avoiding covert non-adherence (either intentional or unintentional) to antipsychotic medication is a clinical priority within the treatment plan.

Dosage and Administration

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance

Practical Considerations

The maintenance dose can be administered once every 3 months. Dose range is 175–525 mg every 3 months, dose to be adjusted according to response.

If necessary, the dose may be administered up to 14 days before or after the maintenance dose is due.

The suspension should be injected slowly as a single injection, deep into the deltoid or gluteal muscle. A switch from gluteal to deltoid (and *vice versa*) should be considered for future injection in the event of injection site discomfort.

The median apparent half-life of paliperidone following administration over the dose range of 175-525 mg ranged from 84-95 days following deltoid injections and 118-139 days following gluteal injections.

Bibliography

1. Bazire Stephen, Psychotropic Drug Directory. 2018 ed Lloyd-Reinhold Publications;216-225
2. Taylor, David et al. The Maudsley Prescribing Guidelines in Psychiatry.13th ed Wiley Blackwell;66-77
3. Summary of Product Characteristics. www.Medicines.org.uk
4. Janssen-Cilag Ltd, medinfo@janssen-cilag.co.uk

Monitoring

| Tests & Measurements (based on NICE Guidance for Psychosis & Schizophrenia CG178) | Responsible clinician |
|---|-----------------------|
| Baseline Monitoring <ul style="list-style-type: none"> • HbA1C (or fasting glucose, if appropriate) • Lipids • FBC • LFTs • U&Es including eGFR • Creatine Phosphokinase (CPK) • Prolactin • ECG - Recommended if: <ul style="list-style-type: none"> ○ Specified in SPC ○ Physical examination shows specific cardiovascular risk ○ Personal history of CVD ○ Admitted as inpatient • BP & Pulse • Weight & BMI • Waist Circumference | Specialist |
| Weekly for first 6 weeks <ul style="list-style-type: none"> • Weight & BMI | Specialist |
| At first 3 months of treatment <ul style="list-style-type: none"> • HbA1C (or fasting glucose, if appropriate) • Lipids • BP & Pulse • Weight & BMI | Specialist |
| Tests & Measurements (based on NICE Guidance for Psychosis & Schizophrenia CG178) | Responsible clinician |
| Annually <ul style="list-style-type: none"> • HbA1C (or fasting glucose, if appropriate) • Lipids • Prolactin • ECG - Recommended if: <ul style="list-style-type: none"> ○ Specified in SPC ○ Physical examination shows specific cardiovascular risk ○ Personal history of CVD • BP & Pulse • Weight & BMI • Waist Circumference | GP |

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Warning: Neuroleptic Malignant Syndrome, although very rare, is a medical emergency – signs and symptoms include hyperthermia, fever, sweating, muscle rigidity, autonomic instability, altered consciousness, confusion, fluctuating blood pressure, tachycardia, raised creatinine kinase.

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

ANNEX A: Shared Care Agreement for Amber Drugs
For the attention of the Practice Manager and Primary Care Prescriber

Agreement between Secondary Care, Primary Care and Patient

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|-----------------|--|-----------------------------|------------------|--|--|--|--------------------|--|-------------|-----------------------------|-----------|--|--|--|--------------------------------|--|--|--|------------------------------|--|--|--|---------------------|-----------------------------|--|--|
| SECONDARY CARE TO COMPLETE | AGREEMENT DETAILS | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | SECONDARY CARE DETAILS | | PRIMARY CARE DETAILS | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Trust | SABP | Primary care prescriber name | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Team | Choose an item. | Practice name | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Team SABP email | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Team telephone number | Choose an item. | Practice nhs.net email | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Specialist name | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Signature of specialist | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <table border="1"> <tr> <td>Patient name</td> <td colspan="3"></td> </tr> <tr> <td>Patient NHS number</td> <td></td> <td>Patient DOB</td> <td>Click here to enter a date.</td> </tr> </table> | | | | Patient name | | | | Patient NHS number | | Patient DOB | Click here to enter a date. | | | | | | | | | | | | | | | | |
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| | Dose | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Frequency | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Indication / Working diagnosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site of last administration* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Injection Next Due* | Click here to enter a date. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *Ensure these are kept up-to-date while agreement is being finalised with primary care | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ELIGIBILITY CRITERIA (ALL MUST BE TICKED) | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Agreeable to care being transferred to primary care Stable on medication for last 6 months Compliant with treatment plan and no DNAs in last 6 months No or stable psychopathology Stable mood Age 18+ | | | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | | |
| DOCUMENTATION ATTACHED (ALL MUST BE TICKED) | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Final clinic / transfer of care letter Baseline and subsequent test results My Recovery Care Plan Crisis and Contingency Plan | | | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | | |

| | |
|---|-----------------------------|
| Agreement to undertake shared care (Yes/No) | Choose an item. |
| If NO, please state why | |
| Primary care prescriber name | |
| Signature of primary care prescriber | |
| Date of Acceptance of Agreement | Click here to enter a date. |



Please note this shared care agreement may be terminated by any of the parties involved (secondary care, primary care and patient) at any time. Any such decision must be communicated to all parties.

Secondary care opinion must always be sought before an LAI is stopped in primary care.

Email to send shared care agreement:

For CMHRS North East Hampshire & Farnham: nehcmhrs@sabp.nhs.uk

CMHRS Surrey Heath: surreyheathadmin@sabp.nhs.uk

How to Complete this Agreement

1. Secondary care to complete the relevant sections above and email the entire shared care guideline to the primary care prescriber. Please note that the shared care agreement is not valid until finalised and returned by primary care.
2. Primary care to read the associated shared care document for this drug prior to acceptance of the agreement.
3. Primary care to complete the relevant section above and email this form back to secondary care. The agreement is then to be saved in the patient's notes.
4. Upon receipt of the signed agreement (if accepted), secondary care to save the agreement to the electronic patient record and move patient to the virtual caseload (shared care with primary care) or have an alert system on the patients record to highlight that they are on shared care with GP