Dorset HealthCare
University NHS Foundation Trust

REFERENCE NUMBER:

PALIPERIDONE LONG ACTING INJECTION PRESCRIBING GUIDELINE

AREA:	Trust-wide
NAME OF RESPONSIBLE COMMITTEE / INDIVIDUAL	Chief Pharmacist
NAME OF ORIGINATOR / AUTHOR	Chief Pharmacist
DATE ISSUED	May 2013
REVIEW DATE	
DUE FOR REVIEW:	September 2016

Date Ratified

RATIFIED BY

TARGET AUDIENCE / DISSEMINATED TO

Added to intranet by:
Directorate:

Date added:

PALIPERIDONE LONG ACTING INJECTION PRESCRIBING GUIDELINE

1.0 INTRODUCTION

1.1 Paliperidone Palmitate long-acting injection (LAI) is indicated for the maintenance treatment of adult patients with schizophrenia who have responded to oral risperidone or paliperidone but who are non-compliant. Oral paliperidone is non-formulary, however, patients do not need to take oral paliperidone prior to commencing the LAI.

1.2 Paliperidone Palmitate LAI is not indicated for treatment-resistant schizophrenia, unlicensed indications or for people intolerant of oral risperidone (or oral paliperidone).

1.3 Paliperidone Palmitate LAI has been recommended as 'RED' by the Bournemouth, Dorset and Poole Health Technologies Forum. This means that prescribing must remain with Secondary Care and cannot be transferred to Primary Care

1.4 The drug can only be prescribed within the following guidelines

2.0 SCOPE

2.1 This prescribing guideline applies to Mental Health services provided by Dorset HealthCare.

3.0 PURPOSE

3.1 To provide guidance on best practice in relation to prescribing paliperidone long acting injection and to encourage rational, safe and cost effective prescribing

4.0 GENERAL PRINCIPLES OF PRESCRIBING

4.1 Paliperidone LAI will only be approved for use if:

- The patient has responded to oral risperidone, but is not compliant
- The patient has had an appropriate trial of a typical (first generation) antipsychotic depot, but has experienced unacceptable side-effects.

4.2 Approval of a Senior Clinical Pharmacist is required before paliperidone LAI can be prescribed. A request must be made in writing detailing the reason for requesting paliperidone LAI. This should be accompanied by the application form (see Appendix A).

4.3 Paliperidone Palmitate LAI may only be initiated under the authority of a consultant psychiatrist to named patients.

4.4 Any suspected adverse drug reactions should be reported by the Yellow Card Scheme www.yellowcard.co.uk

5.0 REQUIREMENTS FOR PRESCRIBING AND MONITORING

5.1 For full details on these aspects, healthcare professionals are referred to the Summary of Product Characteristics and the British National Formulary.

5.2 A baseline eGFR should be carried out before commencing treatment.

5.3 Paliperidone LAI is intended for **once-monthly injection – i.e once per calendar month, not once every 4 weeks.** It should be given intramuscularly into the deltoid or gluteal muscle. Initial loading doses must be given into the deltoid muscle.

5.4 Paliperidone LAI requires the administration of two loading doses on day 1 and day 8, but does not require oral supplementation.

5.5 Switching from other antipsychotics to paliperidone LAI should normally only occur in response to inefficacy, intolerability or adherence issues. Switching well-stabilised patients should not generally occur as this will carry a risk of destabilisation, even where a change is made from risperidone LAI to paliperidone LAI.

5.6 Switching from oral antipsychotics - as described in Summary of Product Characteristics (SPC).

5.7 Switch from oral risperidone to paliperidone LAI by replacing the oral drug with an initiation dose of LAI on day 1. This should be followed with a second initiation dose on day 8 as described below:

Day 1	- 150mg into the deltoid muscle.
Day 8 (+/- 2 days)	- 100mg into the deltoid muscle.
Day 36 (+/- 7 days)	- Maintenance dose into deltoid or gluteal muscle

5.8 The oral drug would usually be discontinued at the time of starting paliperidone palmitate LAI.

5.9 Switching from risperidone LAI - as described in the SPC. Administer the equivalent dose of paliperidone LAI at the time the next scheduled date risperidone LAI is due. 50mg paliperidone replaces 25mg risperidone, 75mg replaces 37.5mg and 100mg replaces 50mg. Frequency changes from two weekly to once per calendar month.

5.10 Switching from traditional depot injections - There is no SPC guidance for this. From best practice, administer the paliperidone LAI dose at the time the next scheduled traditional depot injection is due. However, note that it is not possible to accurately determine 'dose equivalents' between paliperidone and traditional depot injections, therefore the choice of dose should be based on clinical experience and individual patient assessment. It is suggested that the dose does not initially exceed 75mg, and that the patient is very closely monitored, both for response and for adverse effects.

6. ADMINISTRATION

6.1 There is no specific training required in order to administer paliperidone LAI. However, nurses must be competent in administering long acting injection via the deltoid route.

7 STORAGE AND RECONSTITUTION

7.1 Paliperidone LAI is a prefilled syringe. The drug must be stored below 25^0C. Please see the Summary of Product Characteristics for full information

9.0 DISSEMINATION AND IMPLEMENTATION

9.1 This guideline will be distributed to all prescribers, all pharmacy/medicines management staff and all healthcare professionals involved in the administration of medicines in the Trust.

10.0 MONITORING COMPLIANCE

10.1 The Medicines Management Group will be responsible for monitoring prescribing in line with this guideline.

11 APPENDIX

11.1 ***Appendix A –*** Application for the Use of Paliperidone Long Acting Injection

APPENDIX A

Application for the Use of Paliperidone Long Acting Injection

Patient Name	NHS No.	DOB
ADDRESSOGRAPH		
Requesting Consultant	Date	
Does this patient have treatment resistant Schizophrenia?		
Current medication		
Previous response to oral risperidone and maximum dose used		
Previous depot medication and outcomes, including side effects		
Proposed Paliperidone LAI initiation dose		

- I confirm that arrangements are in place for the administration of paliperidone palmitate LAI to take place on a **monthly** basis (i.e once per calendar month, not 4-weekly), after initial loading doses have been administered at day 1 and day 8
- I confirm that the patient will be closely monitored for efficacy and tolerability, using appropriate rating scales and that a full assessment will be carried out at 3 months, 6 months and regularly thereafter
- I understand that the Trust will remain responsible for prescribing and that referral cannot be made to Primary Care for continuation of prescribing

Consultant Signature	Date

Appendix B

Equality Analysis

1. Policy/Practice/Service development	Directorate	New or existing?	Date of Assessment

2. Briefly provide an overview of the policy/practice/service development and describe the aims, objectives and purpose of the Policy/Service:

3. Who will be affected? E.g. staff, patients, service users etc

3. Please demonstrate below the potential impacts on people or equality groups with protected characteristics. List the main sources of data, research and other sources of evidence reviewed to determine the impact or potential impact on each equality group (protected characteristic)

Equality target group (protected characteristic)	Is the policy/ practice/ service development relevant to this equality area? Yes/No. If No what evidence did you rely on to reach this conclusion.	Assessment of Potential Impact: High/ Medium/ Low/ Not Known		Required Actions or Action Plans	
		Positive (+)	Negative (-)		
Gender reassignment					
Race					
Sex					
Disability					
Age					

Religion or Belief					
Sexual orientation					
Marriage and Civil Partnership					
Pregnancy and Maternity					

4. Engagement and Involvement. How have you engaged stakeholders in gathering evidence, testing the available evidence and what stakeholders/groups both internal and external were consulted and when? What was the outcome of that engagement and involvement?

5. Summary of Analysis: In considering the evidence and engagement activity listed above, summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether this is adverse or positive and for which groups. Detail how any negative impacts will be mitigated. Are there any alternative measures that could be taken which could achieve the desired aim without the adverse impact identified? Can the adverse impact or indirect discrimination be objectively justified? Specify how certain protected groups will be included in services or how their participation in public life will be expanded.

6. Consider and detail below how the proposals impact on and have due regard to the need to eliminate discrimination, harassment and victimisation, advance equality of opportunity between people who share a protected characteristic and those who do not and foster good relations between people who share a protected characteristic and those who do not**.**

6.1 Eliminate discrimination, harassment and victimisation. Where there is evidence address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation, marriage and civil partnership).

6.2 Advance equality of opportunity. Where there is evidence address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).

6.3 Promote good relations between groups. Where there is evidence address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).

7. What is the overall impact? Consider whether there are different levels of access experienced, needs or experiences, whether there are any barriers to engagement and what is the combined impact?
8. Addressing the impact on equalities. Provide an outline of what broad action should be considered by you or any other body to address any inequalities identified through the evidence and consultation. Outline what changes will be made to the policy, practice or service as a result, when and by whom.
9. Action planning for improvement and implementation. Provide an outline of the key actions based on any gaps, challenges and opportunities identified. Actions to improve the policy, practice or service development need to be summarised including any general action to address specific equality issues and data gaps that need to be addressed through further research or consultation. Use the attached Action Improvement Plan.
10. Monitoring and review. Detail the processes for monitoring, how this will be measured and when and how the policy, practice, service development will be reviewed.
11. Publication. Outline how and where this assessment will be published

Review Date			
Name of responsible Director			
Assessment Completed By		**Date signed**	