GUIDELINES FOR THE USE OF PALIPERIDONE PALMITATE THREE MONTHLY INJECTION (Trevicta)

Summary

Trevicta® long-acting injection (LAI) is indicated for the maintenance treatment of adult patients with schizophrenia (licensed use) or bipolar prophylaxis (unlicensed use) who:

- Have taken Paliperidone Palmitate One Monthly Injection (Xeplion) for **at least 4 months**
- The last 2 doses of Xeplion® must have been the same dosage strength

Trevicta® LAI is **not indicated** for treatment-resistant schizophrenia, other unlicensed indications or for people intolerant of oral risperidone (or oral paliperidone).

Trevicta® LAI will only be supplied for named individuals using the Named Patient Request Form appended to this document. It should be prescribed as Trevicta®, to avoid confusion.

Trevicta® LAI may only be initiated by Consultant Psychiatrist.

Trevicta® LAI is intended for administration **every three months – i.e. four times a year.** It should be given intramuscularly into the deltoid or gluteal muscle.

Trevicta® LAI is **extremely expensive** compared with typical antipsychotic depots and is also more expensive than risperidone LAI. It is the same cost per year as Paliperidone Palmitate One Monthly LAI.(Xeplion®)

1. Prescribing

1.1 Patients must have taken Xeplion® for at least 4 months

1.2 The last two doses of Xeplion® must have been the same dosage strength

1.3 Trevicta® Lai should be initiated in place of the next scheduled dose of Xeplion® (+/-7 days)

1.4 The recommended maintenance dose is:

Trevicta® dose for adults adequately treated with Xeplion®	
If the last Xeplion® dose was:	Initiate Trevicta® at the following dose:
50mg	175mg
75mg	263mg
100mg	350mg
150mg	525mg

1.5 If needed, dose adjustments of Trevicta® can be made every 3 months in increments within the range of 175-525mg based on tolerability and efficacy in individual patients.

2. Other considerations

2.1 In general, recommended dosing of Trevicta® for elderly patients with normal renal function is the same as for younger adult patients with normal renal function. Efficacy and safety in elderly patients > 65 years have not been established. For elderly patients with reduced renal function, see below dosing recommendations for patients with renal impairment.

2.2 Paliperidone LAI is not licensed for use in patients under 18 years – no safety or efficacy data are available.

2.3 No dosage adjustment is required in mild or moderate hepatic impairment. However, paliperidone has not been studied in severe hepatic impairment; therefore caution is recommended in such cases.

2.4 For patients with mild renal impairment (creatinine clearance 50mL/min – 80mL/min), dose should be adjusted and the patient stabilized using Xeplion® and then transitioned to Trevicta®

2.5 In patients with moderate or severe renal impairment (creatinine <50mL/min) Trevicta® is not recommended

3. Administration

3.1 Trevicta® should be initiated in place of the next scheduled dose of Xeplion®. (+/- 7 days).

3.2 Trevicta® is administered intramuscularly into either the deltoid or gluteal muscle using only the thin wall needles provided with the Trevicta® pack. Needles from Xeplion® pack or other commercially available needles must not be used when administering Trevicta®.

Needle information		
	Deltoid administration	Gluteal administration
Trevicta®	≥90Kg: 22G 1 1/2 inch <90Kg: 22G 1 inch	22G 1 1/2 inch (regardless of weight)

3.3 **Trevicta® must be administered once every three calendar months – i.e. 4 injections per year.** If required, to avoid a missed dose, Trevicta® may be administered up to 2 weeks before or after the 3-month time point. If a dose is missed the following recommendations apply:

If scheduled dose is missed and time since last administration is:	**Action**
3 1/2 to 4 months	Trevicta® should be administered as soon as possible and then resume the 3-month administration schedule
4 to 9 months	Use the recommended re-initiation regimen shown in the table below
>9 months	Re-initiate treatment with Xeplion® as described in the manufacturers' prescribing information. Trevicta® can be resumed after the patient has been adequately treated with Xeplion® for 4 months or more

Recommended re-initiation regimen after missing 4 to 9 months of Trevicta®			
If last dose of Trevicta® was:	Administer 2 Xeplion® doses 1 week apart (into deltoid)		Then administer Trevicta® (into deltoid or gluteal)
	Day 1	Day 8	1 month after Day 8
175mg	50mg	50mg	175mg
263mg	75mg	75mg	263mg
350mg	100mg	100mg	350mg
525mg	100mg	100mg	525mg

3.4 There is no requirement for specific post injection monitoring over and above that which applies to other depot injections.

3.5 Action if patient misses a dose of Trevicta®

4. Storage

4.1 Trevicta® should be stored in a locked medicine cupboard. There is no requirement for refrigeration

4.2 Trevicta® is supplied in pre-filled syringes. There is no requirement for reconstitution or dilution

5. Cost comparison of long-acting antipsychotic injections

Drug	Dose	Cost per year
Trevicta® LAI	175mg 3-monthly (x4) 263mg 3 monthly (x4) 350mg 3-monthly (x4) 525mg 3-monthly (x4)	£2207 £2939 £3769 £4711
Xeplion® LAI	50mg monthly (x12) 75mg monthly (x12) 100mg monthly (x12) 150mg monthly (x12)	£2207 £2939 £3769 £4711
Risperidone LAI	25mg every 2 weeks (x26) 37.5mg every 2 weeks (x26) 50mg every 2 weeks	£2072 £2894 £3712
Flupentixol decanoate	200mg every 2 weeks (x26)	£364
Fluphenazine decanoate	100mg every 2 weeks (x26)	£234
Haloperidol decanoate	200mg every 4 weeks (x13)	£130
Pipotiazine palmitate	200mg every 4 weeks (x13)	£689
Zuclopenthixol decanoate	500mg every 2 weeks (x26)	£130

TREVICTA® LONG ACTING INJECTION NAMED PATIENT REQUEST FORM

This form must be completed for each patient being switched to 3-monthly paliperidone palmitate LAI

Patient Name			
Date of Birth			
Name of Ward/Team			
Name of Initiating Consultant		Consultant Signature	
Date of Request			
Name of Care Coordinator			
Telephone Number for Care Coordinator			
Current Monthly Dose of Paliperidone			

- I confirm that arrangements are in place for the administration of paliperidone palmitate LAI to take place on a 3-**monthly** basis
- I confirm that the patient will be closely monitored for efficacy and tolerability, using Glasgow Antipsychotic Rating Scale (GASS) 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
- I confirm that the patient is non-compliant with oral antipsychotic
- I confirm that the patient has been taking Xeplion® for at least 4 months
- I confirm that the last 2 doses of Xeplion® have been the same

Please scan and email completed form to: kmpt.lai-authorisation@nhs.net

LAI Approval

Pharmacist 1	Signature	Date
Pharmacist 2	Signature	Date

If the prescribing of Trevicta LAI is being continued from another Trust please email the clinical lead pharmacist in your locality for approval and this form will not need to be completed.