

## Guidance on the Use of Antipsychotic Long-acting Injections in North of England

This guidance aims to inform and support prescribers within the three mental health service providers in the north of England in the cost-effective use of antipsychotic long-acting injections.

Long-acting or “depot” injections are a useful and well-established form of administering antipsychotics in the management of schizophrenia and other psychoses. The introduction of long-acting formulations of second-generation (atypical) antipsychotics has created an additional pressure on drug budgets in mental health services, which may be justified if their use results in reduced hospital admissions, shortened length of stay and improved quality of life compared with the first generation (typical) agents.

### Advantages of long-acting / depot injections

- Assured compliance with antipsychotic treatment
- Increased bioavailability (less first-pass metabolism)
- Steady plasma levels compared to oral medication
- Reduction in relapse rate, severity of relapse and rehospitalisation
- Stable therapeutic effects
- Better downward titration to minimise side-effects
- There is some evidence that long-acting injections cause less brain tissue loss and deterioration (CATIE study<sup>1</sup>)

### Disadvantages of long-acting / depot injections

- Treatment cannot be stopped quickly if severe side-effects develop (dystonia, EPSE, NMS)
- Perception by the patient of “being controlled”, losing control over their treatment, or possibly being punished.
- Pain at the site of injection, lasting possibly 10 days
- Tissue necrosis - over time hard plaques may form, which will reduce the ease of administration and the efficacy of the injection as well as causing discomfort.
- Loss of dignity with the gluteal route

Over and above these factors, NICE<sup>2</sup> recommend that consideration should be given to offering a depot / long-acting injectable antipsychotic to people with psychosis or schizophrenia who express a preference for such treatment after an acute episode.

### Prescribing second-generation long-acting injections

Due to their high cost, the long-acting injections of second generation antipsychotics (risperidone, paliperidone and aripiprazole) should be reserved for patients who have failed to respond to first generation antipsychotic depots or for whom these treatments are unsuitable (e.g. due to risk factors or adverse effects). Prospectively, it is recommended that Xeplion<sup>®</sup> (paliperidone) be used in preference to Risperdal Consta<sup>®</sup> (risperidone) because it has a number of practical advantages. The cost is slightly higher, but this is outweighed by increased concordance and decreased requirement for nursing input as well as easier storage requirements. Details are included in **appendix 1**.

These preparations are NOT recommended for treatment-resistant schizophrenia as they have been found to be ineffective for many of those patients.

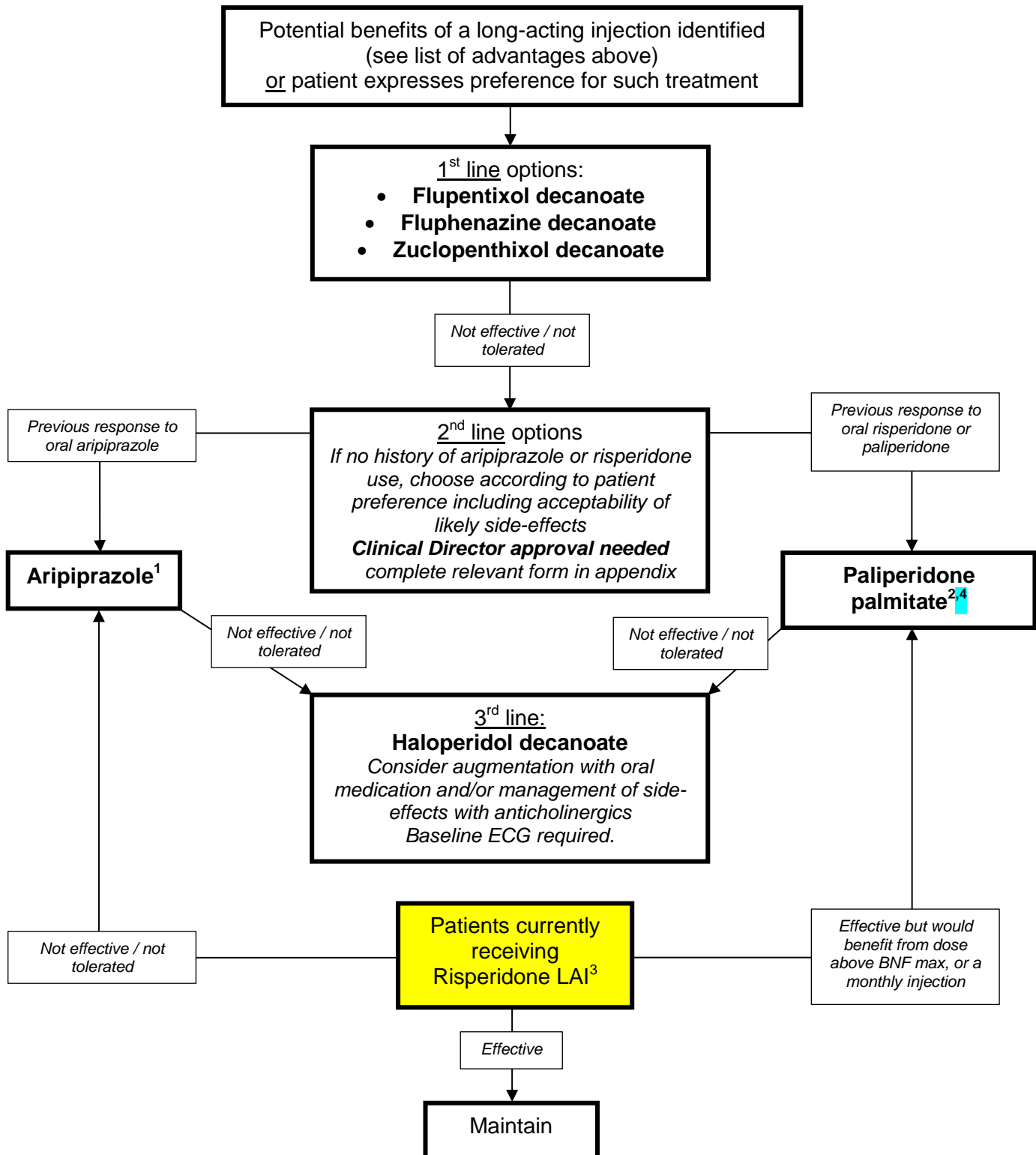
*N.B. this guidance does not apply to ZypAdhera<sup>®</sup> (olanzapine) long-acting injection for which existing policies covering non-formulary / restricted use in each Trust will remain.*

#### References:

1. Lieberman JA et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. NEJM 2005; 353: 1209-23
2. NICE. Psychosis and schizophrenia in adults: treatment and management. CG178. February 2014.

## Choice of long-acting antipsychotic injection in new patients

(see summary on next page for prescribing details)



1. All patients should receive a trial of oral aripiprazole 10-20mg daily for a minimum of two weeks, assessing for efficacy and tolerability, before commencing the LAI
2. Patients with mild-moderate symptoms and previous response to oral risperidone / paliperidone do not require prior stabilisation with oral treatment; otherwise prior stabilisation with oral treatment is recommended
3. Do not initiate in new patients unless all other LAI options have been exhausted or are contra-indicate
4. Paliperidone 3 monthly injection (Trevicta) may be considered for patients clinically stable for at least 4 months on 1-monthly paliperidone palmitate injection.

## Requests for second generation long acting antipsychotic injections

A request form must be submitted for approval before a patient is prescribed a second generation long acting injection. This process will ensure that the treatment guidelines are followed. Sample request forms for paliperidone monthly, **paliperidone 3 monthly injection** and aripiprazole are available in Appendix 7.

### Monitoring

The baseline efficacy and tolerability of antipsychotic medication should be established by the use of objective and validated measures see appendix 2.

- **Side effects** - the LUNBERS or GASS scales can be used to assess tolerability
- **Physical Health monitoring** - see table for the appropriate clinical monitoring of physical parameters
- **Clinical response** - should be established using appropriate measures. Examples are the PANSS (positive and negative syndrome scale) in schizophrenia and the CGI (clinical global impressions) and GAF (global assessment of functioning) scales. Scores derived from the Mental Health Clustering Toolkit may also be useful if it is felt that people will be sensitive to clinical change over the course of their treatment.

### Review

Efficacy and tolerability measures should be repeated 4 weeks after initiating the LAI and six monthly thereafter. Where improved tolerability or response is not demonstrated, the LAI should not continue to be prescribed.

The on-going clinical need and patient preference for a LAI should be reviewed at least annually.

### Reduction of local reaction and necrosis

- Use the lowest practical volume
- Warm the injection before use, up to a maximum 37°C (body temperature). This lowers viscosity, making it easier to inject, and reduces shock to the muscle tissue.
- Use alternate buttocks or arms (rotate injection sites) to allow time to heal
- Use the Z-tracking technique to avoid extravasation or leakage of oily depots.
- Use a needle of the right size for the patient (longer for people with a higher BMI)
- Inject less frequently if possible to prevent hard plaques of tissue forming.
- See local medicines policies for guidance on injections

### Further advice and useful information

Manufacturer's patient information leaflet [www.medicines.org.uk](http://www.medicines.org.uk)

BNF (current) [www.bnf.org](http://www.bnf.org)

Royal College of Psychiatry [www.rcpsych.nhs.uk](http://www.rcpsych.nhs.uk)

Maudsley Guidelines ISBN-10: 0 415 42416 X

Psychotropic Directory Steve Bazire ISBN-10 0-9549193-8-6

Acknowledgement to Antipsychotic long-acting injections guidance - North Essex Partnership Foundation Trust March

Appendix 1

Guidance for the use of Antipsychotic long-acting injections

Injection	Route	Dose for adults under 65	Dose for adults 65+	Duration of action (weeks)	Peak (days)	Time to steady state (weeks)	Comments	Cost per dose	Rating
Aripiprazole	Gluteal	400mg 4-weekly Max. 100mg weekly	Safety and efficacy not established	4	at steady state 5-7 days	12	Patients must be stabilised on oral Aripiprazole first	400mg 4/52 - £204.98	2nd line - patients who have failed to respond to FGA depot or for whom they are contra-indicated
Flupentixol decanoate	Gluteal or Lateral thigh	Test 20mg Maintenance 50mg 4-weekly to 300mg 2-weekly Max. 400mg weekly	Reduce initial dose by 25-50%	3-4	7-10	10-12	May have activating affect (aggression/mood elevation) High maximum licenced dose.	50mg 4/52 - £2.56 300mg 2/52 - £23.42	1st line
Fluphenazine decanoate	Gluteal	Test 12.5mg Maintenance 12.5 - 100 mg 2-5-weekly Max. 50mg weekly	Halve Initial dose in patients over 60	1-3	6-48 hours	6-12	Less sedating and hypotensive Higher risk of EPS.	25mg 2/52 - £2.26 100mg 2/52 - £8.75	1st line
Haloperidol decanoate	Gluteal	50mg 4-weekly, increasing by 50mg increments to Max. 300mg.	Start with 12.5-25mg 4 weekly and increase slowly	6	3-9	10-12	High EPSE/Cardiac risk. Reserve for chronic relapsing patients who have responded well to Haloperidol.	330mg 4/52 - £13.26	3rd line - patients who have not responded to other depots or where these are contra-indicated
Paliperidone palmitate (Xeplion)	Deltoid initially, then deltoid or gluteal	Initial Dosing Regimen 150mg on day 1, 100mg on day 8. Maintenance 25-150mg monthly	Check renal function – if normal dose as per adults<65	Depends on route	13	8-12	Same active moiety as risperidone. Monthly injection may improve concordance.	50mg 4/52 - £183.92 100mg 4/52 - £314.07 150mg 4/52 - £392.59	2nd line - patients who have responded to oral risperidone but would benefit from a depot, and who are unsuitable for a FGA depot preparation.
Paliperidone palmitate (Trevicta)	Deltoid or gluteal	175mg – 525mg every 3 months depending on Xeplion dose.	Check renal function – if normal dose as per <65	12	30-33 days	(should already be on paliperidone )	Same active moiety as risperidone. 3 Monthly injection may improve concordance.	175mg 3/12 - £551.76 263mg - £734.70 350mg - £942.21 525mg - £1177.77	2 <sup>nd</sup> line – Patient’s who have been clinically stable on monthly paliperidone for at least 4 months.
Pipotiazine palmitate	Gluteal	Test 25mg Maintenance 50-100mg 4-weekly Max. 200mg 4-weekly	Reduce initial dose to 5-10mg	4-6	9-10	8-12 weeks	Has been discontinued by manufacturer	100mg 4/52 - £24.79	New patients should not be started on this

Risperidone	Deltoid or gluteal	Test 25-37.5mg 2-weekly. Maintenance 25-50mg 2-weekly. Maximum 50mg 2-weekly	Dose as per adults<65	2	4-6 weeks	6-8 weeks	Injection requires refrigeration and reconstitution. Initial 3 week lag period when oral or IM medication will need to be continued.	25mg 2/52 - £79.69 50mg 2/52 - £142.76	3rd line - patients who have failed to respond or who are unsuitable for a FGA depot. (New patients should be initiated onto paliperidone in preference to risperidone)
Zuclopenthixol decanoate	Gluteal or lateral thigh	Test dose 100mg 200-500mg every 1-4 weeks Max 600mg weekly	Reduce initial dose by 25-50%	2-4 weeks	4-9	10-12 weeks	More sedating than flupenthixol, therefore preferable in aggressive/agitated patients.	200mg 2/52 - £2.93 600mg 2/52 - £8.38	1st line
<b>Zuclopenthixol acetate injection. THIS IS ACUPHASE - NOT A DEPOT INJECTION. DO NOT USE AS A DEPOT. SEE RAPID TRANQUILLISATION PROCEDURE FOR MORE INFORMATION</b>									

Appendix 2

Monitoring requirements for antipsychotic long-acting injections

Test/ Measurement	Why is it important?	Baseline	3 months after initiation	Annually
<b>Weight</b> (Waist measurement and BMI where possible)	Antipsychotic drugs can cause weight gain and this can contribute to an ↑ risk of cardiovascular and metabolic problems	√ Then weekly for the first 6 weeks	√	√
<b>Urea and electrolytes</b> , (including creatinine or estimated GFR)	Patients with renal impairment may have reduced capacity to excrete drugs and dose reductions may be required. Hypokalaemia is linked to QTc lengthening and other ECG abnormalities	√		√
<b>Lipids</b> (Total cholesterol, HDL cholesterol, Total/ HDL-cholesterol ratio, Triglycerides - fasting sample if possible)	Some antipsychotics can cause small adverse changes in lipid profiles. Triglyceride levels can rise during periods of weight gain.	√	√	√
<b>Liver function</b> (Bilirubin, Alk Phos, ALT, Albumin, Total protein, Gamma-GT)	Patients with hepatic impairment may have reduced capacity to metabolise drugs and dose reductions may be required. Drug induced liver damage can be due to direct dose related hepatotoxicity or hypersensitivity reactions. Risk factors for drug induced hepatotoxicity include - ↑age, female gender, alcohol, prescribed enzyme inducing drugs, obesity	√		√
<b>Full Blood Count</b> (Hb, WBC, Platelets)	BNF advises caution when using antipsychotics in patients with blood dyscrasias Antipsychotics can cause blood dyscrasias including agranulocytosis and leucopenia	√		√
<b>Blood Glucose</b> FBG/HbA <sub>1c</sub>	Antipsychotics can increase the risk of developing diabetes.	√	√	√
<b>Blood Pressure (sitting / lying and standing) and pulse</b>	Hypotension is a side effect of many antipsychotics and it is important to monitor this during periods of initiation and stabilisation. Longer term it is important to monitor and manage factors that influence a patient's CV risk	√	Frequently during dose titration (determined by clinical situation) and also after 12 weeks	√
<b>Prolactin</b>	Antipsychotics can increase prolactin levels. This can inhibit sex hormones – oestrogen and testosterone and may ↑ risk of osteoporosis	√	√	√

Test/ Measurement	Why is it important?	Baseline	Annually
<p align="center"><b>ECG</b> (QTc Interval)</p>	<p>Many antipsychotics are associated with ECG changes and some are linked to prolongation of the QT interval. All new inpatients should have an ECG on admission. For long stay patients and those in the community. When clinically indicated ECGs should be performed at baseline and annually. Factors that may determine if ECG monitoring is clinically indicated include:</p> <ul style="list-style-type: none"> <li>• If there is a personal history of cardiovascular disease (e.g. - known ischaemic / structural heart disease QT prolongation),</li> <li>• If physical examination identifies cardiovascular risk factors</li> <li>• If patients on antipsychotics that require ECG monitoring e.g. - haloperidol or pimozide (check summary of product characteristics for more information)</li> <li>• If a patient is on high dose antipsychotic therapy (HDAT)</li> <li>• If patient is on other drugs known to cause ECG abnormalities (e.g. Tricyclic antidepressants, erythromycin, anti-arrhythmics – see BNF for further information)</li> <li>• If the patient has Factors which may predispose to arrhythmias including:               <ul style="list-style-type: none"> <li>○ Electrolyte abnormalities – hypokalaemia, hypocalcaemia, hypomagnesaemia</li> <li>○ Systemic disease – liver disease, renal disease, hypothyroidism</li> </ul> </li> </ul>		
<p><b>Pregnancy test</b></p>		<p>If there is any uncertainty about the possibility of pregnancy, a urine pregnancy test should be carried out</p>	
<p><b>Smoking status</b></p>	<p align="center">Linked to CV risk</p>	<p align="center">√</p>	<p align="center">√</p>
<p><b>Drug screening</b></p>		<p align="center">If indicated by history or clinical picture</p>	
<p><b>Review of the side effects of drug treatment, efficacy and adherence</b></p>	<p>Before treatment the side effects the patient is least willing to tolerate should be assessed. On review the treatment efficacy patient adherence and side effects experienced should be assessed. Including :</p> <ul style="list-style-type: none"> <li>• Extrapyramidal symptoms, akathisia, dystonia and tardive dyskinesia</li> <li>• Common side effects e.g. – sedation</li> <li>• Less common but serious adverse effects e.g. palpitations.</li> </ul> <p>An appropriate rating scale may be useful (e.g. GASS)</p>	<p align="center">√</p>	<p align="center">√</p>
<p><b>References</b></p>	<p align="center">Maudsley Prescribing Guidelines 11<sup>th</sup> edition (2013) SPC of individual medicines, available at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> BNF 68, September 2014 Royal College of Psychiatrists Consensus Statement on high dose antipsychotic prescribing May 2006 Lester UK Adaptation Positive Cardiometabolic Health Resource June 2014 - <a href="http://www.rcpsych.ac.uk/quality/NAS/resources">www.rcpsych.ac.uk/quality/NAS/resources</a></p>		

### Appendix 3: Risperidone

# RISPERDAL CONSTA®

Unlike oily injections, this injection will not begin to work until **at least** three weeks after the first injection (usually three injections), with peak concentrations at 5-6 weeks. This means that the first few weeks must be covered with another preparation if necessary, the effect of dose changes are 3-6 weeks after the event, and discontinuation will need planned alternative medication several weeks **after** the last dose, not immediately. It will take about 10 weeks for blood levels to return to zero after discontinuation.

#### Indications for use

- Patients who are not compliant with oral antipsychotic therapy
- Patients who are experiencing or have experienced significant side effects from oily depot injections.
- Patients who are having or have had side-effects from typical antipsychotics, and who would prefer to have a long-acting injection instead of oral atypicals

#### Side effects

Commonly: weight gain, depression, fatigue, EPSE, slowed reaction times, sexual dysfunction, hyperprolactinaemia, reduction in bone density, incontinence.

Uncommonly: weight loss, nervousness, sleep disorder, apathy, impaired concentration, abnormal vision, syncope, rash, pruritis, peripheral oedema, injection site reactions.

Others: See full Summary of Product Characteristics (SPC) or the BNF.

#### Withdrawal recommended

- If patient has persistent orthostatic hypotension
- Neuroleptic Malignant Syndrome (NMS) which will not commence until 3-4 weeks after the injection was administered. Observation required until at least 4 weeks after the last dose.
- If significant extra pyramidal side effects occur.
- If there are other significant side effects
- If the injection is ineffective
- 

N.B. withdraw gradually from higher doses or taper in alternative therapy after four to six weeks.

#### Contra-indicated

- Known hypersensitivity to product or diluent
- For patients with dementia or at risk of stroke
- For patients who are breastfeeding
- Intolerance to oral risperidone

#### Use with caution

- Elderly, frail or debilitated patients
- Orthostatic hypotension
- Hepatic or renal impairment
- Cardiovascular disease
- Parkinson's disease
- Epilepsy
- Care with weight gain & risk of coronary heart disease
- In pregnancy. Notify the manufacturers

#### Not recommended

- For patients who are willing and able to take oral therapy
- **For patients who are treatment-resistant and/or severely ill**
- Patients with a long history of illness, or whose current medication is above 50% BNF maximum
- Patients under 18 years old



# RISPERDAL CONSTA®

## Initiation of treatment

- By consultant or senior medical staff, with inpatient support or adequate support from appropriate community team. This may be facilitated by a non-medical prescriber.
- Oral risperidone must be tried before initiating the injection to ensure the patient will tolerate the drug. The long-acting injection will not release significant amounts of medication for at least 3 weeks after the dose, so adequate antipsychotic cover, preferably risperidone, **MUST** be provided in the first three weeks.
- NEPFT will prescribe and supply until stability is re established.

## Storage

Store complete pack in refrigerator at 2-8°C. Can be stored at room temperature below 25°C for up to 7 days before use. Once reconstituted, can be kept at room temperature for up to 6 hours.

## Use/Dose for initiation

*No previous history of oral risperidone:* Pre-treatment with oral risperidone for at least 3 days to assess tolerability

*Documented exposure to, and toleration of, oral risperidone in last year, but not stabilized:* Start risperidone injection 25mg/2weeks. Oral risperidone may also be needed during the first few weeks, at the minimum effective dose, tapering after 4 weeks. Review after 3 doses.

*Patient stabilized on oral risperidone 4mg or less:* Start risperidone injection as above

*Patient stabilized for at least 1 month on dose above 4mg:* Start risperidone injection 25mg or 37.5mg. Review after 3 doses

*Patient aged over 65 years, or frail or debilitated:* Maximum dose 25mg/2 weeks. No smaller strengths available. Fractions of the vial must not be used.

## Switching from other treatments

**1. From oral risperidone.** Prescribe 3 weeks oral risperidone at therapeutic dose following first injection. Review and adjust at 3 weeks if necessary. Taper off from 4 weeks, over the next week, if appropriate. If oral medication continues, review 2-weekly and taper off.

**2. From other oral antipsychotic.** Try a test dose of oral risperidone for at least 3 days for tolerability. Prescribe 3 weeks of oral antipsychotic following first dose. Taper from 4 weeks as above.

**3. From other depot injection.** Try at least 3 days of oral risperidone for tolerability.

Option1. Overlapping injections. Administer risperidone injection 1 week before the depot is due. Give depot on due date. Administer risperidone injection 1 week later. Stop the depot. Continue with 2-weekly risperidone injections.

Option2. Replacing the depot. Administer the risperidone injection instead of the depot on the day it is due. Give oral risperidone for the first 3 weeks, as in method 1.

## Appendix 4: Aripiprazole

**ABILIFY  
MAINTENA®**

### Switching from other treatments

Patients should be switched to oral aripiprazole prior to initiation on depot treatment.

Treatment should be initiated by a consultant with inpatient support or adequate support from community team.

### Initiation and Dose

Patients must be stabilised on oral aripiprazole prior to starting depot treatment with aripiprazole.

Recommended dose for initiation and maintenance is 400mg monthly. No dose titration is required.

After the first injection oral treatment should be continued for 14days to retain therapeutic concentrations during initiation of therapy.

If there are adverse reactions with the 400mg dosage, reduction of the dose to 300mg monthly should be considered.

### Interactions

Dosage adjustments should be done in patients taking concomitant strong CYP3A4 inhibitors or strong CYP2D6 inhibitors for more than 14 days. If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the dosage may need to be increased to the previous dose.

- Reduce dose to 300mg in patients taking Strong CYP2D6 and strong CYP3A4 inhibitors
- Reduce dose to 200mg in patients taking strong CYP2D6 and strong CYP3A4 inhibitors

Avoid use in patients prescribed CYP3A4 inducers.

For full list of interactions see Summary of Product Characteristics (SPC) or the BNF.

### Storage

Abilify Maintena can be stored at room temperature (15-25°C)

### Side effects

Generally associated with fewer side effects than other antipsychotics.

Common: weight changes, diabetes, agitation, anxiety, insomnia, akathisia, tremor, headache, EPSE.

Less common: depression, dry mouth; erectile dysfunction, sedation.

Others: See full Summary of Product Characteristics (SPC) or the BNF.

### Contra-indicated

- Known hypersensitivity to product or diluent
- Patients prescribed CYP3A4 inducers

### Use with caution

- Suicidal behaviour
- Cardiovascular disorders
- Elderly or frail patients
- In pregnancy and breast feeding

### Not recommended

- For patients willing and able to take oral medication
- Patients under 18
- Patients acutely unwell or treatment resistant

**Appendix 5: Paliperidone**

**XEPLION®**

XEPLION (Paliperidone LAI) is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone

- Patients who are not compliant with oral antipsychotic therapy
- Patients who are experiencing or have experienced significant side effects from oily depot injections.
- Patients who are having or have had side-effects from typical antipsychotics, and who would prefer to have a long-acting injection instead of oral atypicals
- Patients stabilised on Risperdal Consta but may benefit from doses above licenced maximum dose

**Initiation and Dose**

Recommended initiation of XEPLION is with a dose of 150 mg on treatment day 1 and 100 mg one week later (day 8), both administered in the deltoid muscle in order to attain therapeutic concentrations rapidly.

Following the second dose, monthly maintenance doses can be administered in either the deltoid or gluteal muscle.

Dose range 50-150mg monthly.

Recommended starting dose when transferred from Risperdal Consta

Risperdal Consta dose	Xeplion dose
25mg 2/52 →	50mg monthly
37.5mg 2/52 →	75mg monthly
50mg 2/52 →	100mg monthly

Secondary care will prescribe and supply until stability is re established.

**Switching from oral risperidone**

Unlike with Risperdal Consta, previous oral paliperidone or oral risperidone can be discontinued at the time of initiation of treatment with XEPLION.

**Switching from Risperdal consta**

Switching from Risperdal Consta – start Xeplion when next depot would have been due and go straight to monthly injections.

**From other depot injection.**

Try at least 3 days of oral risperidone for tolerability. Start Xeplion when next depot would have been due and go straight to monthly injections.

**Storage**

Xeplion can be stored at room temperature (15-25°C)

**Side effects**

Commonly: weight gain, depression, fatigue, EPSE, slowed reaction times, sexual dysfunction hyperprolactinaemia, reduction in bone density, incontinence.

Uncommonly: weight loss, nervousness, sleep disorder, apathy, impaired concentration, abnormal vision, syncope, rash, pruritis, peripheral oedema, injection site reactions.

Others: See full Summary of Product Characteristics (SPC) or the BNF.

**Contra-indicated**

- Known hypersensitivity to product or diluent

**Use with caution**

- Elderly or frail patients
- Hepatic or Renal impairment
- Cardiovascular disorders
- In pregnancy and breast feeding

**Not recommended**

- For patients willing and able to take oral medication
- Patients under 18
- Patients acutely unwell or treatment resistant

**Appendix 6: Paliperidone 3 monthly inj**

TREVICTA®

**Initiation and Dose**

Patients who are adequately treated with 1-monthly paliperidone palmitate injectable (preferably for four months or more) and do not require dose adjustment may be switched to TREVICTA.

TREVICTA should be initiated in place of the next scheduled dose of 1-monthly paliperidone palmitate injectable ( $\pm 7$  days). The TREVICTA dose should be based on the previous 1-monthly paliperidone palmitate injectable dose using a 3.5-fold higher dose shown below :

Xeplion dose	Trevicta dose
50mg	175mg
75mg	263mg
100mg	350mg
150mg	525mg

Secondary care will prescribe and supply until stability is re-established

TREVICTA, a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product

Switching directly from other depots is not recommended.

**Storage**

Trevicta ® can be stored at room temperature (15-25°C)

**Side effects**

Commonly: weight gain, depression, fatigue, EPSE, slowed reaction times, sexual dysfunction hyperprolactinaemia, reduction in bone density, incontinence.

Uncommonly: weight loss, nervousness, sleep disorder, apathy, impaired concentration, abnormal vision, syncope, rash, pruritis, peripheral oedema, injection site reactions.

Others: See full Summary of Product Characteristics (SPC) or the BNF.

**Contra-indicated**

Known hypersensitivity to product or diluent

**Use with caution**

Elderly or frail patients  
Hepatic or Renal impairment  
Cardiovascular disorders  
In pregnancy and breast feeding

**Not recommended**

For patients willing and able to take oral medication  
Patients under 18  
Patients acutely unwell or treatment resistant

## Appendix 6

### Aripiprazole Long Acting Injection - prescribing management

#### Restricted use

Aripiprazole LA injection will be issued solely for those patients who have been agreed to receive it. The pharmacy will only issue a supply for a new patient following the agreement of the Clinical Director.

Requests to prescribe aripiprazole LA injection should be made by the consultant psychiatrist using an agreed form (attached). If the indications for prescribing meet the agreed criteria the medicine will be supplied usually within 1 week.

If the request is for circumstances outside the agreed criteria the agreement may be delayed. It may be necessary to follow the non-formulary process.

#### Resolving Disagreements

From time to time disagreements will arise as to whether a particular patient meets the criteria indicated for aripiprazole LA injection. In such circumstances the case is referred to the Group Medical Director for a second opinion. The decision of that second opinion will be final.

#### Criteria For Prescribing Aripiprazole LA Injection

<b>Aripiprazole</b> <i>LA Injection</i> Request form required	Diagnosis of Schizophrenia <b>and</b> Good clinical response and tolerability to oral aripiprazole <b>and</b> Partial or complete non-adherence to oral antipsychotic therapy associated with poor clinical outcome, or patient preference for a long acting injection <b>and</b> Proven intolerance (suffered significant and untreatable neurological or other adverse effects) to any first generation antipsychotic drug
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## Request for the Prescribing of Aripiprazole Long-Acting Injection

Name of Patient	Date of Birth	NHS number
Location of Patient (Ward, Community Team etc.)	Current Diagnosis	
<b>Response/tolerance to oral aripiprazole</b>		
Has the patient been treated with oral aripiprazole? Yes or No If yes, please give details of dose, duration, clinical response and tolerability:  If no, please explain why this has not been attempted:		
<b>Adherence</b>		
Is there an established history of non-adherence to oral antipsychotic medication? Yes or No      Details:  Have attempts been made to achieve adherence e.g. by structured psycho-education or concordance therapies? Yes or No      Details:  Has the supervision of oral medicines been tried and failed? Yes or No      Details:		
For this patient non-adherence has resulted in poor clinical outcome: Hospital admission Yes or No      Self-harm Yes or No Harm to others Yes or No Other (please state):		
<b>Patient preference</b>		
Has the patient expressed a preference for a long acting injection rather than oral therapy? Yes or No		
<b>Response/tolerance to first generation antipsychotics</b>		
Is the patient unable to tolerate first generation antipsychotic drugs? Yes or No State the nature of the intolerance and why it is untreatable:		
Has the patient received Clozapine in the past or been classified as treatment resistant? Yes or No Comments:		
Has the patient remained compliant with depot medicines in the past? Yes or No or N/A      Details:		
Name of Consultant	Signature	Date
I support this request to prescribe long acting Aripiprazole Injection		
Agreement of Clinical Director / Associate Clinical Director	Signature	Date
Send form to relevant Pharmacy	Date	
For pharmacy use: Initial supply dispensed	Date	

## Paliperidone Long Acting Injection - prescribing management

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If the request is for circumstances outside the agreed criteria the agreement may be delayed. It may be necessary to follow the non-formulary process.

### Resolving Disagreements

From time to time disagreements will arise as to whether a particular patient meets the criteria indicated for paliperidone LA injection. In such circumstances the case is referred to the Group Medical Director for a second opinion. The decision of that second opinion will be final.

### Criteria For Prescribing Paliperidone LA Injection

<p><b>Paliperidone</b> <i>LA Injection</i></p> <p>Request form required</p>	<p>Diagnosis of Schizophrenia <b>and</b> Previously responsive to paliperidone or risperidone <b>and</b> Partial or complete non-adherence to oral antipsychotic therapy associated with poor clinical outcome, or patient preference for a long acting injection <b>and</b> Proven intolerance (suffered significant and untreatable neurological or other adverse effects) to any first generation antipsychotic drug <b>or</b> Stabilised on Risperdal Consta but may benefit from doses above licenced maximum dose or a monthly injection</p>
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## Request for the Prescribing of Paliperidone (Monthly) Long-Acting Injection

Name of Patient	Date of Birth	NHS number
Location of Patient (Ward, Community Team etc.)	Current Diagnosis	
<b>Response/tolerance to oral risperidone or oral paliperidone</b>		
Has the patient been treated with oral risperidone or oral paliperidone? Yes or No If yes, please give details of dose, duration, clinical response and tolerability:  If no, please explain why this has not been attempted:		
<b>Adherence</b>		
Is there an established history of non-adherence to oral antipsychotic medication? Yes or No      Details:		
Have attempts been made to achieve adherence e.g. by structured psycho-education or concordance therapies? Yes or No      Details:		
Has the supervision of oral medicines been tried and failed? Yes or No      Details:		
For this patient non-adherence has resulted in poor clinical outcome: Hospital admission Yes or No      Self-harm Yes or No Harm to others Yes or No Other (please state):		
<b>Patient preference</b>		
Has the patient expressed a preference for a long acting injection rather than oral therapy? Yes or No		
<b>Response/tolerance to first generation antipsychotics</b>		
Is the patient unable to tolerate first generation antipsychotic drugs? Yes or No State the nature of the intolerance and why it is untreatable:		
Has the patient received Clozapine in the past or been classified as treatment resistant? Yes or No      Comments:		
Has the patient remained compliant with depot medicines in the past? Yes or No or N/A      Details:		
<b>For patients stabilised on Risperdal Consta</b>		
Would the patient benefit from doses above the licensed maximum dose or a monthly injection? Yes or No		
Name of Consultant	Signature	Date
I support this request to prescribe long acting Paliperidone Injection		
Agreement of Clinical Director / Associate Clinical Director	Signature	Date
Send form to relevant Pharmacy		Date
For pharmacy use: Initial supply dispensed		Date



## Paliperidone 3 monthly Injection - prescribing management

### Restricted use

Paliperidone 3 monthly injection (Trevicta) will be issued solely for those patients who have been agreed to receive paliperidone monthly Long Acting injection. When switching from the monthly to the 3 monthly injection no further approvals are required but the patient should have been clinically stable for at least 4 months on the monthly injection.

If the request is for circumstances outside the agreed criteria the agreement may be delayed. It may be necessary to follow the non-formulary process.

### Resolving Disagreements

From time to time disagreements will arise as to whether a particular patient meets the criteria indicated for paliperidone 3 monthly injection. In such circumstances the case is referred to the Group Medical Director for a second opinion. The decision of that second opinion will be final.

### Criteria for Prescribing Paliperidone 3 monthly injection

<p><b>Paliperidone</b></p> <p><i>3 monthly Injection</i></p> <p>Request form to pharmacy required but no clinical director approval needed.</p>	<p>Stabilised on Paliperidone monthly injection for at least 4 months.</p>
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## Request for the Prescribing of Paliperidone 3 monthly Injection

Name of Patient	Date of Birth	NHS number
Location of Patient (Ward, Community Team etc.)	Current Diagnosis	
<b>Is the patient currently prescribed Paliperidone palmitate monthly injection ?</b>		
<b>Yes or No</b>		
If yes, please give details of <b>dose, duration</b> , clinical response and tolerability:		
If no, please explain why this has not been attempted:		
Has the patient been clinically stable for 4 months or more on Paliperidone LA monthly injection?		
<b>Yes / No</b>		
Give details on how patient will be monitored.		
<b>Patient preference</b>		
Has the patient expressed a preference for a 3 monthly injection rather than a monthly one?		
<b>Yes or No</b>		
Name of Consultant	Signature	Date
Clinical Director approval not required if initial support for paliperidone monthly long acting injection gained. Please send form direct to pharmacy <enter pharmacy email>		
Send form to relevant Pharmacy		Date
For pharmacy use: Initial supply		Date