SHARED CARE PRESCRIBING GUIDELINE

Aripiprazole long-acting injection for the treatment of schizophrenia in adults

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| **NOTES to the GP** |
| The information in the shared care guideline has been developed in consultation with South East London CCG and it has been agreed that it is suitable for shared care.This document should provide sufficient information to enable you to make an informed decision regarding the clinical and legal responsibility for prescribing **aripiprazole long-acting injection** for the treatment of **schizophrenia in adults.**The questions below will help you confirm this: * Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
* Have you been provided with relevant clinical details including monitoring data?

**If you can answer YES to all these questions** (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.**If the answer is NO to any of these questions** you should contact the requesting consultant or your local Borough Medicines Management Team. There may be implications for the patient where the invitation to share care is declined. For example, the patient may need to be changed to an alternative treatment regimen. It would not normally be expected that shared care prescribing would be declined on the basis of cost. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **It is important that patients are consulted about treatment and are in agreement with it**. Prescribing should follow requirements in the South East London Interface Prescribing Policy. **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient’s best interests are always paramount.** |

**Once you have read the shared care guideline and considered the information above, please complete the GP decision form on the next page and email back to the requesting clinician if you are in agreement to participate in shared care.**

 **If you are not in agreement please include reasons for this.**

**GP DECISION FORM**

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of **aripiprazole long-acting injection for the treatment of schizophrenia in adults** can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

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| **AGREEMENT TO PARTICIPATE IN SHARED CARE****Aripiprazole long-acting injection for the treatment of schizophrenia in adults** |
| **Consultant/Specialist Name:** | **Patient name:** |
| **Consultant/Specialist signature:** | **Patient Hospital Number:****Patient NHS Number:**  |
| **Date completed:** | **Patient/carer Agreement:**Patient / carer agrees to shared care □Patient /carer does not agree to shared care □ |
| **Hospital/specialist requesting shared care:** |
| **GP Name:** |
| **This is to confirm that I agree to participate in shared care for Aripiprazole long-acting injection for the treatment of schizophrenia for this patient as outlined in this shared care document** |
| **GP Signature:** |
| **Date signed:**  |
| **ACTION**1. **HOSPITAL / COMMUNITY CONSULTANT Tick to confirm**
* Explain shared care to patient/ carer and obtain agreement Date agreement obtained:\_\_\_\_\_\_\_\_\_ 🞏
* Indicate requesting hospital /clinic 🞏
* Complete and sign agreement 🞏
* Email full shared care guideline (including signed agreement to GP) 🞏
* Place original in patient’s notes 🞏
1. **GP PRACTICE**
* If **in agreement** to participate in shared care, sign and email (via secure NHS.net) this sheet back **within 2 weeks** of receipt **of request from specialist** to either:

Email address (via secure nhs.net):……………………………………. [TRUST to ADD email address] * If **you do not agree** to participate in shared care, contact consultant and local Primary Care Borough Medicines Management Team within 2 weeks of receipt to discuss. If after discussion it is agreed not to undertake shared care for this patient, both the consultant and the local Primary Care Borough Medicines Management team should be informed.
* Once decision reached file a copy in the Patient’s medical notes.
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 **Aripiprazole long-acting injection for the treatment of schizophrenia**

# **CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE**

* Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient’s condition is stable or predictable.
* The hospital will administer the injection each month until the GP agrees to shared care.
1. **Areas of responsibility**

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| **Consultant / Specialist team responsibilities** |
| * To initiate aripiprazole long-acting injection and assess its effects (clinical benefit and side effects)
* To supply treatment and administer injections for the first **12 months**
* To inform patients that further injections will be administered at their GP practice.
* To inform the GP of the results of baseline and routine treatment tests, including plasma glucose, plasma lipids and ECG.
* To inform the GP of how often the patient will be reviewed by the psychiatric team
* To review patient at the request of GP should any problems arise (side-effects / lack of efficacy).
* To inform the GP within 2 weeks of any changes to treatment
* To report any suspected adverse effects to the MHRA: <http://www.yellowcard.gov.uk>
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| **General Practitioner responsibilities**  |
| ***Before agreement to shared care:**** To consider shared care proposal within 2 weeks of receipt. If agree to request to continue prescribing as detailed in shared care guideline. Confirmation to the requesting consultant is required within 2 weeks of receipt of this guideline by completing and returning the agreement on page 3
* If do not agree to shared care discuss with requesting consultant or local primary care medicines management team within 2 weeks of receipt of shared care request

***After agreement to shared care:**** To provide ongoing prescriptions for aripiprazole long-acting injection. To adjust the dose as advised by the specialist.
* To administer injections
* To agree monitoring requirements with specialist
* To report and seek advice regarding any concerns, for example: side-effects, co-morbidities, pregnancy, or lack of efficacy to the specialist team
* To advise the specialist psychiatric team if the patient does not attend appointment for the injection.
* To advise the specialist psychiatric team if the patient refuses injection.
* Agree between the specialist psychiatric team and GP who will contact the patient if he/she misses their appointment.
* To refer back to specialist if the patient's condition deteriorates.
* To stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
* To report any suspected adverse effects to the MHRA via the Yellow Card scheme: <http://www.yellowcard.gov.uk>
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| **Patient's / Carer’s responsibilities** |
| * To contact the specialist or GP if he or she does not have a clear understanding of any aspect of the treatment.
* To inform prescribing specialist, GP and other healthcare professionals of any other medication being taken, including over the counter products, alternative therapies or recreational drugs.
* To inform community pharmacists that they are prescribed aripiprazole long-acting injection before purchasing medication over-the-counter
* To attend all hospital and GP appointments
* To take medicines as agreed and take steps to ensure that no doses are missed and not to share medicines with others
* To read the patient information leaflet included with the medication.
* To inform GP or hospital specialist of any concerns about treatment.
* To report any adverse effects or warning symptoms to GP or hospital specialist
* Inform GP and specialist if intending to become pregnant.
* To report to GP if pregnant or breastfeeding.
* To inform GP and specialist psychiatric team of any changes in addresses or telephone contact numbers.
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1. **CLINICAL INFORMATION**

**NOTE:** The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPC) before prescribing for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via [www.medicines.org.uk](http://www.medicines.org.uk))

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| **Licensed indication(s)** |
| Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole. |
| **Place in Therapy (as approved by SEL APC)** |
| Aripiprazole long-acting injection is approved for use in South East London in line with its licensed indication  |
| **Dose & route of administration** |
| Aripiprazole long-acting injection is for intramuscular administration into the gluteal or deltoid muscle. One of two regimens may be followed for administering the starting dose: **Note:** Starting doses will usually be administered by the specialist psychiatric team. The loading dose information is provided here for information only. The shared care covers the maintenance dosing only. **For missed doses please contact medicines information for advice (see below for details).** One injection startOn the day of initiation, administer one injection of 400 mg aripiprazole long-acting injection and continue treatment with oral aripiprazole for 14 consecutive days. **Or**Two injection start: On the day of initiation, administer two separate injections of 400 mg aripiprazole long-acting injection at separate injection sites in two different muscles (see [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/)), along with one 20 mg dose of oral aripiprazole. **Maintenance dose*** 300–400mg each month.
* The starting dose is 400mg. The dose may be reduced to 300mg a month if 400mg is poorly tolerated. However, GPs should contact the psychiatrist before making any dose adjustments. No other doses may be used except in those patients receiving potent hepatic enzyme inhibiting drugs (e.g., ketoconazole and quinidine). Aripiprazole long-acting injection is not recommended for patients taking concomitant CYP3A4 inducers (e.g., carbamazepine). See [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) for further details or contact medicines information.
* Dose adjustments are necessary in patients taking CYP2D6 and CYP3A4 inhibitors. See [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) for details or contact medicines information when introducing a new drug for long-term use.
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| **Duration of treatment**  |
| Indefinite. Long-term  |
| **Criteria for stopping treatment** |
| * Significant adverse reaction
* Intolerable side effects
* Lack of efficacy
* At request of patient/family. Patient must discuss any decision to stop or change medication with the specialist team.
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| **Monitoring Requirements including frequency** |
| **Consultant:** Baseline plasma lipids, plasma glucose, weight/BMI, U&Es, FBC, LFTs, BP, CPK and ECG**GP:** Annual plasma lipids, plasma glucose, weight/BMI, U&Es, FBC, LFTs and BP, ECG ***Note:*** *Aripiprazole is not clearly associated with weight gain, dyslipidaemia or glucose dysregulation. However, prevalence of these is high in* *this patient group. Aripiprazole may have a minor effect on cardiac QTc interval. However, patients with schizophrenia have a higher risk of sudden cardiac death than general population. Thus the recommendation for annual ECG.* |
| **Follow up arrangements** |
| * The patient should be seen by the specialist psychiatric team at least once a year.
* Where there are local CCG commissioned mental health in primary care services in place and there is agreement, the annual review may be carried out by the primary care service.
* In addition, the patient may be referred for a review by the specialist psychiatric team if there are concerns about the patient’s mental state or their long-acting injection treatment.
* The patient should be referred to A&E for out of hours specialist psychiatric care.
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| **Practical issues including other relevant advice/information****Reminder: this list is not exhaustive - for full details of adverse effects and all potential drug interactions refer to latest Summary of Product Characteristics (SPC) for the drug, available via** [**www.medicines.org.uk**](http://www.medicines.org.uk)**.** |
| * Aripiprazole long-acting injection is not recommended for patients taking concomitant CYP3A4 inducers (e.g., carbamazepine). See [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) for further details or contact medicines information.
* The safety and efficacy of aripiprazole long-acting injection has not yet been established in children, adolescents and older adults (aged 65 and over).
* There are limited data on the safety of aripiprazole in pregnancy and breastfeeding. GPs should contact the medicines information service if pregnancy is planned or suspected.
* Side effects commonly and uncommonly reported at the start of treatment usually wear off within the first few weeks. If side effects persist or emerge contact the specialist psychiatric team or medicines information.

**Administration** * The injection is available as a pre-filled syringe (containing a powder and solvent) and as a vial with powder (and solvent for reconstitution). The needles are provided with the vials. For instructions on reconstitution and administration see [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) and the package inserts. There are some specific requirements for reconstitution and administration that nursing staff should familiarise themselves with. For doses other than 400mg the vial must be used.
* The suspension should be injected immediately after reconstitution.
* The suspension should be administered slowly as a single injection into either the gluteal or the deltoid muscle. The injection sites should be rotated between the two gluteal or deltoid muscles. Care should be taken to avoid inadvertent injection into a blood vessel.
* The recommended needle for gluteal administration is a 38 mm (1.5 inch), 22 gauge hypodermic safety needle. For obese patients (Body mass index > 28 kg/m2), a 51 mm (2 inch), 21 gauge hypodermic safety needle should be used. See [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) for further details
* The recommended needle for deltoid administration is a 25 mm (1 inch), 23 gauge hypodermic safety needle. For obese patients, a 38 mm (1.5 inch), 22 gauge hypodermic safety needle should be used. See [SPC](http://www.medicines.org.uk/emc/medicine/28494/SPC/ABILIFY%2BMAINTENA%2B400%2Bmg%2Bpowder%2Band%2Bsolvent%2Bfor%2Bprolonged-release%2Bsuspension%2Bfor%2Binjection/) for further details.
* The powder and solvent vials are for single-use only.

**Missed dose*** Contact medicines information for guidance on administration when a dose is missed. See page 6 for contact details.
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| **Information provided to the patient** |
| Patients should be asked to contact their GP if:* They have concerns about their medication
* They are considering stopping medication.
* Are considering becoming pregnant
* Suspect they are pregnant
* Wish to breastfeed
* Have been prescribed medication by another specialist service, so that drug interactions can be checked
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# **COMMUNICATION AND SUPPORT - Please also refer to patient’s clinic letters for specific clinic contact details if required.**

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| **South London and Maudsley (SLAM): switchboard 020 3228 6000** |
| **Medication – Prescribing advice, interactions, availability of medicines**Medicines Information | SLAM Tel: 020 3228 2317  |
| **Oxleas NHS Trust switchboard : 01322 625700** |
| **Medication – Prescribing advice, interactions, availability of medicines**Medicines information  | Tel: 01322 625002Email: oxl-tr.medicinesinfo@nhs.net  |

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| **Evidence Base for treatment and key references** |
| 1. Otsuka Pharmaceuticals (UK) Ltd. Abilify Maintena 400 mg powder and solvent for prolonged-release suspension for injection. SPC (date of revision of the text 11 Nov 2020)

<https://www.medicines.org.uk/emc/product/7965/smpc>1. Scottish Medicines Consortium. Aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®): SMC No. (962/14) issued 04 April 2014. <http://www.scottishmedicines.org.uk/SMC_Advice/Advice/962_14_aripiprazole_Abilify_Maintena/aripiprazole_Abilify>
2. NICE. Schizophrenia: aripiprazole prolonged-release suspension for injection, ESNM39: published 26 March 2014. <https://www.nice.org.uk/advice/esnm39/resources/schizophrenia-aripiprazole-prolongedrelease-suspension-for-injection-pdf-1502680932221893>
3. Anon. Second-generation long-acting injectable antipsychotic agents: an overview. DTB 2012 50: 102-105
4. NICE. Psychosis and schizophrenia in adults: treatment and management. Clinical guideline 178 (issued: February 2014, last checked March 2019): <https://www.nice.org.uk/guidance/cg178>
5. Hanna P, Suo T, Komossa K, Ma H, Rummel-Kluge C, El-Sayeh HG, Leucht S, Xia J. Aripiprazole versus other atypical antipsychotics for schizophrenia. Cochrane Database of Systematic Reviews 2014, Issue 1. Art. No.: CD006569. DOI: 10.1002/14651858.CD006569.pub5. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006569.pub5/abstract>
6. Kirson N.Y., Weiden P.J., Yermakov S., et al. Efficacy and effectiveness of depot versus oral antipsychotics in schizophrenia: Synthesizing results across different research designs. J Clin Psychiatry,2013; 74: 568-575
7. Belmonte C et al. Evaluation of the relationship between pharmacokinetics and the safety of aripiprazole and its cardiovascular effects in healthy volunteers. J Clin Psychopharmacol 2016; **36**:608–614.
8. Taylor D et al. The Maudsley Prescribing Guidelines in Psychiatry. **13th Edition May 2018**
9. UKMI patents database accessed 09 June 2014
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