

Specialised Medicines Service (SMS) Guideline ~

Oral aripiprazole for patients within adult mental health services (Devon wide)

Specialist: Please complete the shared care agreement letter at the end of this document and send together with the guideline to the GP.

GP: GPs are invited to participate. Please indicate whether you agree to share patient's care by completing the relevant letter at the end of this document and returning to the specialist.

Responsibilities remain with the specialist service until formally accepted by the GP. If a GP is not confident to undertake these roles, then they are 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 the GP agrees to share the care of the patient, the patient should not be discharged from the care of their specialist, but rather the care of the patient is shared between the patient, GP and specialist in accordance with the responsibilities outlined in this guideline.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

This guideline applies to the use of **oral aripiprazole in adults aged 18 years and over** and details the responsibilities for the ongoing prescribing and monitoring required to enable a shared care agreement to be arranged between the primary and secondary care interface. Refer to the online British National Formulary ([BNF](#)), Summary of Product Characteristics ([SmPCs](#)), Medicines and Healthcare products Regulatory Agency ([MHRA](#)) or the National Institute for Health and Care Excellence ([NICE](#)) website for up-to-date information on any medicine.

Introduction and aims of treatment

Aripiprazole is a second-generation atypical antipsychotic which should only be initiated by specialists who have a full understanding of the characteristics of the drug, its mode of action and risks of therapy.

The specialist must specify the indication for each patient when initiating shared care. It is the specialist's responsibility to determine the place of aripiprazole in the treatment pathway for the indication being managed, and its use alongside concomitant pharmacological treatments and psychological therapies.

Licensed indications vary between different medicines containing the same drug. The following **licensed** indications for aripiprazole are included within this guideline:

- Schizophrenia
- Treatment and recurrence prevention of mania

The following **unlicensed** indications for aripiprazole are well established and supported by local specialists and therefore included within this guideline:

- Adjunctive treatment in depression
- Obsessive compulsive disorder (OCD)
- Behaviour that challenges in autism spectrum disorder (ASD)
- Behaviour that challenges in adults with a learning disability
- Post traumatic stress disorder (PTSD)
- Adjunctive treatment to antipsychotic-induced hyperprolactinemia and/or metabolic side effects (i.e. weight gain)
- Tics
- Tourette syndrome

Use of aripiprazole for other indications, high dose antipsychotic prescribing* and instances whereby the GP has commenced aripiprazole in the absence of specialist oversight and a shared care agreement, falls outside the scope of this guideline.

***High Dose Antipsychotic Therapy** is defined as either:

- A total daily dose of a single antipsychotic which exceeds the upper limit stated in the BNF **or**
- A total daily dose of two or more antipsychotics which exceeds the BNF maximum as calculated by percentage. A cumulative dose of more than 100% is a high dose.

Stopping over medication of people with a learning disability and autistic people (STOMP)

STOMP is a national NHS England work programme to stop the inappropriate prescribing of psychotropic medications, an identified priority in the NHS Long Term Plan.

People should only be given psychotropic medication for the right reasons, in the lowest dose, for the shortest time.

Certain psychotropic medications can be prescribed for behaviour that is thought to be challenging. This is an unlicensed indication and the medication should be initiated, monitored, reviewed and stopped in line with NICE guidance. Specialist oversight is required, particularly for initiation.

The use of antipsychotics in the management of behaviour that challenges in adults with a learning disability should be reserved for use in exceptional cases only.

Service transition for young people currently receiving antipsychotics

- Refer also to: [NICE Guideline NG43 Transition from children's to adults' services for young people using health or social care services \(2016\)](#).
- Young people transferring from child/adolescent services to adult services should be offered a transition appointment jointly with the child/adolescent and adult specialist providers (contact details are provided later in the guideline).
- During the appointment drug treatment should be discussed with consideration of whether continuation into adulthood will continue to provide therapeutic benefit, or in some circumstances whether a change of medication is required. A treatment plan should be formulated collaboratively with the young person.
- Precise timing of transition arrangements may vary according to the needs and preferences of the individual patient but should usually be completed by the time the young person is 18 years old.

Specialist responsibilities

The specialist may decide to delegate some of these tasks to members of their team, however the responsibility for ensuring the following are undertaken remains with the named specialist overseeing the care of the individual patient:

- Assess the patient, establish diagnosis and the need for treatment with aripiprazole. Ensure the diagnosis is within scope of this SMS guideline.
- Assess the patient's capacity to make a decision regarding this treatment and their understanding of associated patient responsibilities.
 - **If patient has capacity:** Document their decision, consent and agreement to associated patient responsibilities (see below).
 - **If patient lacks capacity:** Follow Best Interest decision making processes, in line with the Mental Capacity Act (2005), taking into account the views of the patient, carers and significant others. Document the Best Interests discussion and decision
- Use a shared decision-making approach; provide appropriate counselling to ensure the patient and/ or the patient's carer is involved in making an informed choice about their treatment.
- Provide the patient and/ or the patient's carer with suitable written and verbal information about the medication prior to starting treatment, including benefits and risks, side effects, cautions, frequency of dosing, monitoring requirements and treatment reviews (timing and by whom). Resources may include use of the Choice and Medication website; refer to relevant provider: [Devon Partnership NHS Trust](#) / [Livewell](#)

[Southwest](#). It is acknowledged that it may not be possible to provide detailed written and verbal information prior to commencing treatment in people who are extremely distressed. In these circumstances clinical judgement should be used, and this should be provided at the earliest opportunity thereafter.

- Inform the patient and/or the patient's carer if the indication being treated is unlicensed.
- Update records with list of existing drugs from available resources and ensure there are no drug interactions of clinical significance with current medication.
- Discuss the use of alcohol, tobacco, recreational drugs, over the counter (OTC) drugs, herbal remedies and other complementary therapies; discuss the safety, efficacy and possible interaction with prescribed medication. Recommend the patient and/ or the patient's carer consults a pharmacist before using any new over the counter (OTC) drugs or herbal remedies.
- Provide advice on the need for contraception, and the risks of pregnancy to individuals on initiation and at each review; the ongoing responsibility for providing this advice rests with both the specialist and the GP.
- Ensure the patient and/ or the patient's carer understands that treatment may be stopped if they do not attend for monitoring & treatment review.
- Undertake pre-treatment screening and required baseline monitoring before initiating aripiprazole.
- Initiate, prescribe and optimise aripiprazole. Continue to prescribe and monitor the patient for at least the first 12 months or until the patient's condition has stabilised whichever is longer. Monitoring during this period will include drug specific monitoring and physical health monitoring as defined within this guideline. Review the patient regularly during this period in line with relevant NICE guidelines.
 - Any deviation from this timeframe, e.g. in exceptional clinical circumstances, must only occur where the GP has agreed to take on shared care in advance of any change of arrangements.
- The condition should be stable with satisfactory monitoring results (see below) for at least 4 weeks and the dose optimised with no anticipated further changes expected in the immediate future, before the responsibility for prescribing and monitoring may be transferred to primary care under shared-care arrangements.
- It will remain the specialist's ongoing responsibility to monitor the continued efficacy of aripiprazole.
- After this time ask the GP in writing whether they are willing to participate in shared care for a particular patient using the shared care agreement letter below. Include all relevant test results (GPs may not have access to these results in primary care). Prescribing and monitoring will remain in secondary care until the GP agrees to share care.
- Ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued by the specialist if, for unforeseen reasons, arrangements for shared care are not in place at the end of this period.
- Continue to review the patient at GP and specialist mutually agreed and clinically appropriate intervals. Specialist review should assess response to antipsychotic treatment and the need to continue therapy. For most patients NICE recommends that a review of antipsychotic medication should take place annually.
 - **Behaviour that challenges in adults with a learning disability:** NICE recommends a review at least every 6 months.
- Ensure prompt written summary is sent to the GP whenever the patient is reviewed including any changes in treatment or monitoring requirements, results of monitoring undertaken, assessment of adverse events, or guidance on when to stop treatment if indicated. Confirm ongoing dose.
- Urgent changes to treatment should be communicated electronically and directly to the GP surgery (and followed up by telephone as required) to ensure prompt and immediate update.
- Provide the GP with relevant contact information and clear arrangements for back-up advice and support.
- Where the named specialist overseeing the care of the individual patient within the same service provider changes the GP should be notified in writing and updated contact details provided.
- Where patient care is transferred from one mental health service provider to another, and/or the patient is initiated on a different antipsychotic with associated SMS guidelines a new shared care agreement must be completed between the specialist, the GP and the patient (this excludes brand / formulation / dose changes for the same drug).
- Respond promptly to GP or patient queries and advise on action required when abnormal monitoring results are identified or adverse effects signs or symptoms are detected and flagged.
- If the patient wishes to become pregnant, where appropriate seek advice from perinatal mental health team (see contact details in supporting information below). Notify GP.

- If the patient becomes pregnant the specialist will reassume prescribing responsibility, ending the shared care agreement.
- Report suspected side effects to [MHRA via yellow card scheme](#).

General practitioner responsibilities

GPs may decide to delegate some of these tasks to members of their team; however, the responsibility for ensuring the following are undertaken remains with the named GP overseeing the care of the individual patient:

- Ensure a timely reply is sent to the specialist in response to the request for shared care using the shared care agreement letters below. Where possible this should be undertaken within 14 days of the request being made.

If GP has agreed to share care:

- Continue to prescribe aripiprazole as requested by the specialist.
- Continue to monitor treatment in accordance with these guidelines. Review monitoring results and take any necessary action, communicating any results of concern to the specialist (see monitoring requirements below).
- Be alert to the possibility of interactions when initiating new medicines, recommending over the counter (OTC) treatments or herbal remedies, or disclosure of the use of recreational drugs.
- Provide ongoing advice on the need for contraception where clinically appropriate.
- Be alert to the possibility of adverse effects at every contact. Manage patient in accordance with guidance below. Ensure prompt action in the case of a severe adverse effect or signs or symptoms.
- Contact the specialist urgently if any of the following are suspected:
 - Suspected relapse in medical condition being treated
 - Significant increase in the use of alcohol or substance misuse
 - Non-adherence to medication
- Ensure advice sought promptly from the specialist if there is a change in the patient's physical or mental health status which is of concern to the GP and may affect treatment.
- If the patient wishes to become pregnant, seek advice from perinatal mental health team (see contact details in supporting information below). The perinatal mental health team will be responsible for ensuring the initiating specialist and GP are notified of the outcome.
- If the patient becomes pregnant the specialist will reassume prescribing responsibility, ending the shared care agreement.
- Respond promptly to advice from specialist regarding any changes in treatment or monitoring requirements.
- Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.
- Where patient care is transferred from one GP practice to another a new shared care agreement must be completed.
- Report suspected side effects to specialist and to [MHRA via yellow card scheme](#).

Patient and/ or carer responsibilities

- Take aripiprazole as directed by the prescriber. Patients wishing to reduce their dose or stop aripiprazole should discuss with their specialist before doing so. Avoid abrupt withdrawal unless advised by the GP or specialist.
- Understand the importance of monitoring treatment and attend specialist and GP appointments to ensure timely monitoring and reviews can be completed in accordance with the guideline. Understand that treatment will be stopped if they do not attend.
- Ensure contact details are kept up to date with both the GP and the specialist.
- Read the aripiprazole patient information leaflet and any other resources which the specialist may recommend. Request information in different format(s) if required to aid understanding. Understand treatment, expected benefits and potential side effects.
- Tell anyone who prescribes them a medicine that they are taking aripiprazole.
- Seek guidance from a pharmacist, GP or specialist on medication safety and potential interaction with aripiprazole if engaging in over the counter (OTC) treatments, recreational drug use, or herbal remedies. Report the use of any regular items to the GP.

- Report any adverse effects or newly presenting signs or symptoms to the GP and/or specialist in a timely way for assessment.
- Ensure adequate hydration and continued mobility where possible to reduce the risk of certain side effects
- Avoid direct sunlight exposure; take appropriate precautions when outside (photosensitisation may occur with higher dosages).
- Report to the GP and/or specialist any developing urges or cravings to behave in ways that are unusual for you, including behaviours such as addictive gambling, excessive eating or spending, or an abnormally high sex drive.
- The patient should take a pregnancy test if they think there is a possibility they may be pregnant, and inform the specialist and GP immediately if they become pregnant or wish to become pregnant.
- Store medicines safely and securely; it must not be shared with anyone else. Dispose of any unused medication appropriately.
- Report suspected side effects to the GP or specialist and the [MHRA via yellow card scheme](#).

Monitoring requirements

Baseline assessment to be undertaken and recorded by the specialist prior to commencing antipsychotic treatment:

- Weight (plotted on a chart) and BMI
- Waist circumference
- Pulse and blood pressure
- Fasting blood glucose or HbA1c
- Blood lipid profile
- LFTs
- ECG
- Assessment of any movement disorders
- Assessment of nutritional status, diet and level of physical activity

Consideration should also be given to baseline measurement of prolactin levels, U&Es (including creatinine and eGFR), FBC, and creatinine phosphokinase.

Any baseline measurement results outside of the reference range should be managed accordingly prior to commencing treatment. Alternative antipsychotic may be required in some cases.

Specialist should copy all results to GP.

Ongoing drug monitoring requirements once stable:

Local specialists have determined that there is no ongoing drug safety monitoring required for aripiprazole.

Given the observed risk for worsening metabolic profile (weight gain, hyperglycaemia, dyslipidaemia) in patients with severe mental illness (SMI), changes in metabolic parameters in this patient group should be regularly monitored. Annual physical health monitoring for patients with an SMI is the subject of a separately commissioned local enhanced service (LES).

Risk of sudden death is increased with most antipsychotics. Aripiprazole has a very low/zero incidence and severity of QT prolongation. Ongoing annual ECG is not mandatory for aripiprazole. In situations where the patient has co-morbidities or concomitant medication which may warrant cardiac monitoring the specialist will advise on the necessity (and frequency) on an individual patient basis.

Healthcare providers should be alert to the possibility of side effects at every contact. Refer to table below and contact specialist for advice as required.

Important safety information**[MHRA Drug Safety Update \(December 2014\): Atypical \(second-generation\) antipsychotics](#)**

Reminder to monitor and manage weight, glucose, and lipid levels. **See above for local monitoring requirements.**

Presentation of the following adverse effects, signs or symptoms and associated actions should be noted. Any serious adverse reactions should be reported to the [MHRA via the Yellow Card scheme](#). See also adverse effects in supporting information below.

Adverse effects, signs and symptoms	Action to be taken by GP
Risk to self or others; suicidal behaviour or thoughts; unusual changes in behaviour	Refer to appropriate mental health team according to severity. Contact initiating specialist who will determine whether aripiprazole should be withdrawn.
Increased weight Aripiprazole is associated with a low risk of weight gain.	If BMI >25 and/or weight gain >5kg from baseline provide exercise & dietary advice. Consider referral to dietician. Seek further advice from initiating specialist as required.
Hyperglycaemia Symptoms include polydipsia, polyuria, polyphagia and weakness	Investigate for hyperglycaemia. <u>Prediabetes:</u> HbA1c: 42-47mmol/mol (6.0% - 6.4%), fasting: 5.5 - 6.9mmol/l. <u>Diabetes:</u> HbA1c: ≥48 mmol/mol (≥6.5%), fasting ≥7.0mmol/l, random ≥11.1mmol/l. Follow Devon Formulary Guidance on the management of T2DM (see here N&E / S&W). Seek further advice from initiating specialist as required.
Extrapyramidal side effects (EPSEs)	Contact initiating specialist for advice as required.
Somnolence and related symptoms, such as sedation	Advise patients not to drive/operate machinery if affected. If symptoms are judged to be clinically concerning or persistent, a dose decrease or treatment discontinuation should be considered; seek specialist advice.

Table continued overleaf

Adverse effects, signs and symptoms	Action to be taken by GP
Orthostatic (postural) hypotension: usually defined as $\geq 20\text{mmHg}$ fall in systolic blood pressure and/or a $\geq 10\text{mmHg}$ fall in diastolic blood pressure within 3 minutes of standing. Symptoms include dizziness, light-headedness, asthenia, headache and visual disturbance	Check blood pressure in suspected cases. Offer practical advice to patient and contact initiating specialist for further advice where required.
Neuroleptic malignant syndrome Clinical manifestations include hyperthermia, altered mental status, muscular rigidity, autonomic instability, and increased creatine phosphokinase.	This is a medical emergency where early recognition and treatment is essential. In an emergency call 999. Hyperthermia is often an early sign of this syndrome. Antipsychotic treatment must be withdrawn immediately and appropriate supportive therapy and careful monitoring instituted. Inform initiating specialist who will follow up patient directly.
Serotonin syndrome Symptoms may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.	Stop aripiprazole. Inform initiating specialist who will follow up patient directly. Management depends on severity; use clinical judgement and seek advice from specialist.
Hepatic impairment Symptoms may include: fatigue, pain in the upper right abdomen, jaundice, swelling, and confusion	Measure LFTs. Refer to table above for threshold for action and action to be taken by GP.
Neutropenia or agranulocytosis Signs/symptoms include infection, fever, weakness, lethargy, sore throat, mouth ulcers	Exclude other causes, including adjunctive treatments; in the case of concomitant chemotherapy a multidisciplinary review of medication must be undertaken. Measure white blood cell (WBC) count and an absolute neutrophil count (ANC) promptly. If Neutrophils $< 1.5 \times 10^9/\text{L}$ *: • Stop aripiprazole. Inform initiating specialist who will follow up patient directly. • Repeat FBC in one week (48 hours if neutrophils $< 1 \times 10^9/\text{L}$) • Advise patient to seek urgent medical attention if they become unwell or febrile Arrange urgent medical assessment if: • patient is unwell or febrile, or • neutrophils $< 0.5 \times 10^9/\text{L}$ <i>* If the patient has benign ethnic neutropenia (BEN), use a threshold of $< 1 \times 10^9/\text{L}$.</i>

Table continued overleaf

Adverse effects, signs and symptoms	Action to be taken by GP
Severe cutaneous adverse reactions (SCARs) such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) SCARs commonly present with one or more of the following symptoms: extensive cutaneous rash which may be pruritic or associated with pustules, exfoliative dermatitis, fever, lymphadenopathy and possible eosinophilia or neutrophilia.	Stop aripiprazole. Urgent referral to dermatology. Inform initiating specialist who will follow up patient directly.
Pathological gambling and other impulse control disorders New or increased urges to gamble and other impulse control symptoms, such as excessive eating or spending, or an abnormally high sex drive	Contact initiating specialist for advice.
Hyperprolactinemia Symptoms may include: unexplained headaches or visual impairment, breast enlargement, galactorrhoea, reduced libido, erectile dysfunction, amenorrhoea, anorgasmia, delusions of pregnancy. Long term adverse consequences may include reduced fertility in women, reductions in bone mineral density and a possible increase in the risk of breast cancer.	If hyperprolactinaemia is suspected obtain prolactin level. Early morning sample should be obtained and stress during venepuncture minimised. If elevated compared to handover baseline (with / without symptoms), consider other causes e.g. stress (physical or psychological, including venepuncture), exercise, pregnancy, lactation, seizures, renal impairment, hypothyroidism, prolactinoma and other medical conditions or medicines. This is particularly important if the patient has been taking a stable dose of aripiprazole for a long time without prolactin level changes. Consider taking a repeat measurement; if exercise is the cause, repeat test after rested for 2-3 days.

Important safety information

[MHRA Drug Safety Update \(December 2023\): Aripiprazole \(Abilify and generic brands\): risk of pathological gambling](#)

Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders. Healthcare professionals should advise patients, their families and friends to be alert to the development of new or increased urges to gamble and other impulse control symptoms, such as excessive eating or spending, or an abnormally high sex drive.

Gambling is recognised as a common risk factor linked to suicide and is included within the [suicide prevention in England: 5-year cross sector strategy](#).

MHRA Drug Safety Update (August 2020): Clozapine and other antipsychotics: monitoring blood concentrations for toxicity

This update reminds healthcare professionals that following fatal cases involving toxicity of clozapine and other antipsychotic medicines, the MHRA advises that monitoring blood concentration of aripiprazole may be helpful in certain circumstances.

For antipsychotics other than clozapine, drug level monitoring for toxicity is not routine practice. This service is not provided by local trust laboratories. **Local advice is that clinicians who have concerns about a patient receiving an antipsychotic should in the first instance contact the mental health specialist team for advice. This applies to patients with symptoms suggestive of toxicity, or when concomitant medicines may interact to increase antipsychotic drug levels, and also when non-adherence or poor response to treatment is suspected.**

MHRA Drug Safety Update (December 2014): Antipsychotics: risk of venous thromboembolic events (VTE)

Use of Antipsychotic may be associated with an **increased risk of venous thromboembolic events**.

Supporting Information

This section provides additional information regarding aripiprazole. Refer to the online [BNF](#), [SmPCs](#), the [MHRA](#) or [NICE](#) websites for up-to-date information on any medicine.

Formulation

Refer to [Devon formulary](#) for list of preparations approved for use locally.

Dosage and administration

Dosing titration schedules and maintenance doses vary depending on indication and individual patient factors including concomitant medication, co-morbidities, and response to treatment. Patients must receive clear information on the appropriate dose for their condition.

The specialist retains responsibility for initiating aripiprazole and optimising the dose in accordance with tolerability and efficacy; the maximum daily dose should not exceed 30mg. For further information, refer to the [BNF](#), [SmPC](#), and specialist advice.

High dose antipsychotic prescribing falls outside the scope of this guideline.

Elderly

Lower starting dose and slower / smaller titration steps may be required.

Hepatic impairment

Manufacturer advises caution in patients with severe impairment (see [BNF](#) and [SmPC](#)).

Treatment withdrawal

Treatment duration will be determined by the specialist. Termination of treatment will be the responsibility of the specialist with exceptions due to adverse effects detailed in the table above. The specialist will determine the rate of withdrawal and continue to oversee the patient during this time to avoid the risk of acute withdrawal syndromes or rapid relapse. Antipsychotic withdrawal effects can be delayed in onset for weeks and sometimes months.

Shared care prescribing arrangements can continue during the treatment withdrawal period if felt to be clinically appropriate.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients (some formulations may contain lactose)

Precautions and special warnings

As aripiprazole has several indications, the safety profile should be considered in the context of the individual patient's diagnosis and the dose being administered.

In addition to the points listed below, refer to the monitoring section above for further cautions to be noted during and/ or prior to treatment depending on patient medical history, and actions to take in the case of a severe adverse effect or patient reported signs or symptoms.

Blood dyscrasias; cardiovascular disease; cerebrovascular disease; conditions predisposing to hypotension (dehydration, hypovolemia, treatment with antihypertensives) or hypertension, including accelerated or malignant; conditions predisposing to seizures / history of seizures; depression; diabetes or associated risk factors for diabetes (may raise blood glucose); elderly (reduce initial dose); epilepsy; family history of QT prolongation; history of jaundice; Lewy Body disease, myasthenia gravis; parkinsonism, Parkinson's disease (may be exacerbated); patients prone to falls (may cause gait dyspraxia, parkinsonism), photosensitisation (may occur with higher dosages); prostatic hypertrophy; risk of aspiration pneumonia; severe respiratory disease; suicidality; susceptibility to angle-closure glaucoma; VTE risk factors

Adverse effects

The data below has been taken from the online [BNF](#). **The list is not exhaustive.** Refer to the online [BNF](#) and [SmPCs](#) for full prescribing data. Seek specialist advice where necessary. See also adverse effects, signs and symptoms in monitoring requirements section above.

Very common ($\geq 1/10$) or common ($\geq 1/100$ to $< 1/10$): Agitation; amenorrhoea; anxiety; appetite abnormal; arrhythmias; constipation; diabetes mellitus; dizziness; drowsiness; dry mouth; erectile dysfunction; fatigue; galactorrhoea; gastrointestinal discomfort; gynaecomastia; headache; hyperglycaemia; hyperprolactinaemia; hypersalivation; hypotension (dose-related); insomnia; leucopenia; movement disorders; muscle rigidity; musculoskeletal stiffness; nausea; neutropenia; parkinsonism; postural hypotension (dose-related); QT interval prolongation; rash; seizure; tremor; urinary retention; vision disorders; vomiting; weight decreased; weight increased

Uncommon ($\geq 1/1000$ to $< 1/100$): Agranulocytosis; alopecia; confusion; depression; diarrhoea; hiccups; hypertension; neuroleptic malignant syndrome (discontinue—potentially fatal); sexual dysfunction; suicidal behaviours; thrombocytopenia

Rare ($\geq 1/10,000$ to $< 1/1,000$) or very rare ($< 1/10,000$): Sudden death; withdrawal syndrome neonatal

Frequency not known: Aggression, cardiac arrest; chest pain; diabetic hyperosmolar coma; diabetic ketoacidosis; dysphagia; embolism and thrombosis; generalised tonic-clonic seizure; hepatic disorders; hyperhidrosis; hyponatraemia; laryngospasm; myalgia; oropharyngeal spasm; pancreatitis; pathological gambling; peripheral oedema; photosensitivity reaction; pneumonia aspiration; rhabdomyolysis; serotonin syndrome; speech disorder; syncope; temperature regulation disorder; urinary incontinence

Interactions

The following list is not exhaustive; where an extensive list of interacting medicines exists those more commonly prescribed in primary care are highlighted as examples below. The lists are intended to alert the reader and prompt further consideration before prescribing. Refer to the online [BNF](#) and [SmPCs](#) for full prescribing data. Seek specialist advice where necessary and / or refer to specialist Medicines Information services for additional support (and reference to Stockley's Drug Interactions where paid subscription available) if concomitant administration of interacting medicines clinically indicated.

The following interactions are classified in the online [BNF](#) as **severe** (the result may be a life-threatening event or have a permanent detrimental effect):

- **Medicines which prolong the QT interval / increase the risk of QT prolongation (e.g. amiodarone and other anti-arrhythmics, antipsychotics, citalopram, domperidone, erythromycin, escitalopram, fluconazole, hydroxychloroquine, hydroxyzine, methadone, ondansetron, quinine, tramadol*):** Most manufacturers advise avoiding the use of two or more drugs that are associated with QT prolongation.

Increasing age, female sex, cardiac disease, and some metabolic disturbances (notably hypokalaemia) predispose to QT prolongation. The following resources can identify medicines which can affect the QT interval: [CredibleMeds](#) (access is free but users must be registered); [BNF](#); [SmPCs](#); [MHRA](#); [Stockley's Drug Interactions](#) (subscription required); [Specialist Pharmacy Service \(SPS\)](#)

**Tramadol not listed in the BNF or SmPC for this side effect but noted as a potential interaction by local specialists and cited by CredibleMeds as being associated with QT prolongation when taken at clinically recommended doses*

- **Medicines which may cause hypokalaemia (e.g. antibiotics, diuretics, corticosteroids and mineralocorticoids, beta₂-agonists (e.g. salbutamol), xanthines (e.g. theophylline), chemotherapy agents** – refer to BNF / product literature for full list): potentially increasing the risk of torsade de pointes. Consideration should be given to other medicines which cause hypokalaemia but not listed in the BNF as a severe interaction such as insulin, laxatives and enemas.
- **Foslevodopa** - aripiprazole might decrease the effects of the active metabolite of foslevodopa (monitor)
- **Ivabradine** - predicted to increase the risk of torsade de pointes (avoid)
- **Levodopa** - aripiprazole is predicted to decrease the effects

The following interactions are classified in the online [BNF](#) as **moderate** (the result could cause considerable distress or partially incapacitate a patient; they are unlikely to be life-threatening or result in long-term effects.):

- **Dopamine receptor agonists (e.g. amantadine, apomorphine, cabergoline, pramipexole, rotigotine)** - aripiprazole is predicted to decrease the effects
- **Medicines predicted to decrease exposure to aripiprazole (e.g. carbamazepine, phenytoin, rifampicin, St John's wort** – refer to BNF / product literature for full list): avoid or adjust dose.
- **Medicines predicted to increase exposure to aripiprazole (e.g. bupropion, cinacalcet, clarithromycin, diltiazem, escitalopram, fluoxetine, HIV protease inhibitors and cobicistat, itraconazole, ketoconazole, paroxetine, posaconazole, terbinafine** – refer to BNF / product literature for full list): avoid or adjust dose.
- **Nirmatrelvir boosted with ritonavir**: predicted to increase the concentration of aripiprazole (adjust dose).

The [BNF](#) and [SmPCs](#) also highlight the following interactions:

- **Medicines which increase the risk of hypotension or hyponatraemia**
- **Medicines which effect the CNS and cause sedation.** Use of two or more drugs that have effects on the CNS might also increase the risk of CNS depressant effects (e.g. sedation, unconsciousness, coma, respiratory depression, and/or cardiovascular depression).
- **Serotonin syndrome:** Cases of serotonin syndrome have been reported in patients taking concomitant serotonergic medicinal products, such as SSRI/SNRI, or with medicinal products that are known to increase aripiprazole concentrations

[Pregnancy and lactation](#)

No psychotropic medication has a UK marketing authorisation specifically for women who are pregnant or breastfeeding.

If the patient becomes pregnant, the specialist will reassume prescribing responsibility, ending the shared care agreement.

Before prescribing in this area seek specialist advice and check up-to-date sources of information.

Pregnancy (Maternal exposure)

The [UK Teratology Information Service \(UKTIS\)](#) provides a national service on all aspects of the toxicity of drugs and chemicals in pregnancy (Tel: 0344 892 0909), and provides the '[best use of medicines in pregnancy](#)' ([bumps](#)) website for supportive patient information relating to individual treatments.

A summary of the UKTIS monograph for aripiprazole can be accessed [here](#) and the bumps patient information leaflet can be accessed [here](#).

Aripiprazole should only be used in pregnancy if potential benefit outweighs risk.

The [BNF](#) and [SmPCs](#) report that all antipsychotics that extrapyramidal effects and withdrawal syndrome have been reported occasionally in the neonate when antipsychotic drugs are taken during the third trimester of

pregnancy. Following maternal use of antipsychotic drugs in the third trimester, neonates should be monitored for symptoms including agitation, hypertonia, hypotonia, tremor, drowsiness, feeding problems, and respiratory distress.

Important Safety Information

[MHRA Drug Safety Update \(December 2014\): Antipsychotics: risk of extrapyramidal effects or withdrawal symptoms in newborns](#)

Risk of extrapyramidal effects or withdrawal symptoms (or both) in newborns after maternal use of antipsychotics during the third trimester of pregnancy.

Lactation

[UK Drugs in Lactation Advisory Service \(UKDILAS\)](#) provides evidence-based information on the use of drugs during the breastfeeding period to all UK healthcare professionals.

The Specialist Pharmacy Service (SPS) also has guidance on the use of antipsychotics during breastfeeding produced by the UKDILAS [here](#).

The [BNF](#) reports for all antipsychotics that there is limited information available on the short- and long-term effects of antipsychotic drugs on the breast-fed infant. Chronic treatment with antipsychotic drugs whilst breastfeeding should be avoided unless absolutely necessary.

The [SmPC](#) states that aripiprazole/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from aripiprazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

The [SPS](#) offers practical guidance which is endorsed by local specialists. The guidance states that oral aripiprazole can be used with caution during breastfeeding and with infant monitoring, but other antipsychotics are preferred. Further detail is available [here](#).

Further resources

National Institute for Health and Care Excellence (NICE)

- Clinical Guideline 31: Obsessive-compulsive disorder and body dysmorphic disorder: treatment, 2005
- Clinical Guideline 142: Autism spectrum disorder in adults: diagnosis and management, 2012
- Clinical Guideline 178: Psychosis and schizophrenia in adults: prevention and management, 2014
- Clinical Guideline 185: Bipolar disorder: assessment and management, 2014
- NICE Guideline 11: Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges, 2015
- NICE Guideline 54: Mental health problems in people with learning disabilities: prevention, assessment and management, 2016
- NICE Guideline 116: Post-traumatic stress disorder, 2018
- NICE Guideline 222: Depression in adults: treatment and management, 2022

Support

Adult mental health service providers

Devon Partnership Trust

See website for community teams contact details: <https://www.dpt.nhs.uk/locations>

Trust HQ (Wonford House reception): 01392 208866

Medicines Helpline: 01392 674900

Email: dpt.medsquery@nhs.net

(Available 10am - 4pm, Monday to Friday, excluding Bank Holidays)

Livewell Southwest

Email: livewell.antipsychoticadviceguidance@nhs.net

(Available 10:00am – 4:00pm, Monday to Friday, excluding Bank Holidays. Response within 2 working days)

Urgent advice / support requiring a same day response

Please contact switchboard: 01752-435502 and ask to be directed to the relevant team / specialist (Mon-Fri 9am-5pm) or the on-call consultant psychiatrist after-hours.

Non-urgent enquiries

Please email the relevant medical secretary team:

- Avon House
livewell.cmhsmedsecs.avon@nhs.net
- Cumberland Centre
livewell.cmhsmedsecs.cumberland@nhs.net
- OPMH
livewell.OPMHSMedicalSecretaries@nhs.net

Learning disabilities and autism service providers

Devon Partnership Trust

See website for learning difficulties service contact details: <https://www.dpt.nhs.uk/service-details/service/learning-disability-intensive-assessment-and-treatment-service-75/>

See website for autism service contact details (various depending on support required):

<https://www.dpt.nhs.uk/services>

Livewell Southwest

Community Learning Disability Team:

livewell.cldreferrals@nhs.net

Autism queries to be emailed to the Community Mental Health Teams (Avon House and Cumberland Centre – see above).

Perinatal mental health teams

Exeter

Email: dpn-tr.PerinatalTeamExeter@nhs.net

Telephone: 01392 674964

North Devon

Email: dpn-tr.perinatalNorth@nhs.net

Telephone: 01271 322772

Plymouth

Email: livewell.perinatalmht@nhs.net

Telephone: 01752 431607

South Hams and West Devon

Email: dpt.perinatalteamwestdevon@nhs.net

Telephone: 01822 813 070

Torbay

Email: dpn-tr.PerinatalTeamTorbay@nhs.net

Telephone: 01803 396590

For further support and information in relation to individual shared care agreements please contact your practice pharmacist or alternatively please contact the Medicines Optimisation Team.

Email: D-ICB.medicinesoptimisation@nhs.net

Version 1

Date ratified: 28th January 2026

This guideline has been reviewed by stakeholders across Devon and is intended for use in accordance with locally commissioned services.

Shared Care Agreement Letter - Specialist Request to GP (New initiations)

To	GP name	
	Practice address	
Patient name		
Hospital number		
NHS number		
Date of birth		
Address		

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

This patient is now suitable for prescribing to move to primary care. The patient fulfils criteria for shared care therefore I am writing to request your agreement to continue the care of this patient according to the Specialised Medicines Service (SMS) Guideline.

In accordance with the SMS Guideline the transfer of monitoring and prescribing to the GP is normally after the patient has been treated for 12 months or until the patient's condition has stabilised whichever is longer. The condition should be stable with satisfactory blood results for at least 4 weeks and the dose optimised with no anticipated further changes expected in the immediate future, before the responsibility for prescribing and monitoring may be transferred to primary care under shared-care arrangements.

I have discussed and agreed the following treatment with the patient:

	Specialist to complete
ORAL ANTIPSYCHOTIC <i>(Specify formulation and dose to be administered)</i>	
Indication <i>(Indicate licensing status)</i>	
Treatment start date	
Patient has been on the optimised dose stated for	
Sufficient medication has been provided to last until	
GP to undertake prescribing and monitoring in line with the SMS Guideline from	
Next monitoring due date	
Next medication review planned for <i>(Expected timeframe if exact date not known)</i>	

I can confirm that the following have occurred with regard to this treatment:

	Specialist to complete (YES/NO)
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	
The roles of the Specialist / GP / Patient have been explained and agreed	
The risks and benefits of treatment have been explained to the patient	
Baseline investigation and monitoring as set out in the SMS Guideline have been completed and were satisfactory	
I have enclosed a copy of the SMS Guideline which covers this treatment. The guideline can also be found here	
I have included with this letter copies of the information the patient has received	

The results of baseline tests or monitoring performed by the specialist, and any additional supportive information is included below and/or attached.

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GP please sign response letter and return promptly (where possible this should be within 14 days of the request being made).

Specialist signature		Date	
Specialist name, role, speciality			
Daytime telephone number			
Email address			
Alternative contact e.g. clinic or specialist nurse			
Out of hours contact details e.g. duty doctor			

Remember to keep a copy of this letter for the patient's records.

Shared Care Agreement Letter - Specialist Request to GP (Patients in primary care, already established on treatment)

To	GP name	
	Practice address	
Patient name		
Hospital number		
NHS number		
Date of birth		
Address		

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to continue prescribing this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

This patient is already established on oral antipsychotic treatment and fulfils criteria for shared care therefore I am writing to request your agreement to continue the care of this patient according to the Specialised Medicines Service (SMS) Guideline.

Please continue to prescribe and perform ongoing drug safety monitoring in accordance with the SMS Guideline.

	Specialist to complete
ORAL ANTIPSYCHOTIC (Specify formulation and dose to be administered)	
Indication (Indicate licensing status)	
Next medication review planned for (Expected timeframe if exact date not known)	

I can confirm that the following have occurred with regard to this treatment:

	Specialist to complete (YES/NO)
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	
The roles of the Specialist / GP / Patient have been explained and agreed	
The risks and benefits of treatment have been explained to the patient	
Patient is optimised on treatment with no anticipated further changes expected in the immediate future	
I have enclosed a copy of the SMS Guideline which covers this treatment. The guideline can also be found here	

The results of any recent monitoring performed by the specialist and any additional supportive information are included below and/or attached.

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GP please sign response letter and return promptly (where possible this should be within 14 days of the request being made).

Specialist signature		Date	
Specialist name, role, speciality			
Daytime telephone number			
Email address			
Alternative contact e.g. clinic or specialist nurse			
Out of hours contact details e.g. duty doctor			

Remember to keep a copy of this letter for the patient's records.

Shared Care Agreement Letter – GP Acceptance Letter to Specialist

To	Specialist name
Patient name	
Hospital number	
NHS number	
Date of birth	
Address	

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment:

<State oral antipsychotic, formulation and dose to be administered>

.....

I can confirm that **I am willing to take on this responsibility** from and will maintain the prescribing and monitoring responsibilities as set out in the Specialised Medicines Service (SMS) Guideline.

GP signature		Date	
GP name			
Practice address			
Telephone number			
Email address			

Remember to keep a copy of this letter for the patient's records. If this letter is not returned sharing of the care for this patient will not commence.

Shared Care Agreement Letter – GP Refusal Letter to Specialist

To	Specialist name
Patient name	
Hospital number	
NHS number	
Date of birth	
Address	

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

In the interest of patient safety NHS Devon, in conjunction with local acute trusts have classified a number of oral antipsychotics as "shared care" drugs which require a number of conditions to be met before transfer can be made to primary care.

Thank you for your request for me to accept prescribing responsibility for this patient. I regret to inform you that in this instance I am unable to take on responsibility due to the following:	Tick all applicable
The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care. As the patients GP I do not feel clinically confident to manage this patient's condition. I have consulted with other GPs in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given below.	

The condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement. As the condition requested to be treated is not included on the locally recognised list of indications for shared care I am unable to accept clinical responsibility for prescribing this medication at this time. Until this condition is identified locally as requiring shared care the responsibility for providing this patient with their medication remains with you.	
A minimum duration of supply by the initiating specialist. As the patient has not had the minimum supply of medication to be provided by the initiating specialist (28 days) I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.	
Initiation and optimisation by the initiating specialist. The transfer of monitoring and prescribing to the GP is normally after the patient has been treated for 12 months or until the patient's condition has stabilised whichever is longer. The condition should be stable with satisfactory blood results for at least 4 weeks and the dose optimised with no anticipated further changes expected in the immediate future, before the responsibility for prescribing and monitoring may be transferred to primary care under shared-care arrangements. As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.	
Other (GP to complete if there are other reasons why shared care cannot be accepted):	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

GP signature		Date	
GP name			
Practice address			
Telephone number			
Email address			

Remember to keep a copy of this letter for the patient's records.