BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Aripiprazole (oral)
Amber ***three months***	
Indication	The treatment of schizophrenia in adolescents aged 15 years and older. See NICE TA213 'Aripiprazole for schizophrenia in people aged 15-17 years.' (https://www.nice.org.uk/guidance/ta213).

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Usual range is 10mg to 30mg once daily depending on age and indication. Schizophrenia: Child 15 – 17 years. Gradual titration from 2mg to 10mg; increased if needed by 5mg increments to max 30mg daily.
Route and formulation	Oral Available for shared care as: Tablets – 5mg, 10mg, 15mg & 30mg Orodispersible tablets – 10mg, 15mg Liquid – 1mg / ml
Duration of treatment	Schizophrenia: Dependent upon response & tolerability. Long term (at least 3 years)

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
• Weight/ BMI • Waist circumference • BP & pulse • Lipids • HbA1c (for those with diabetes continue as per NICE) • U&Es • LFTs • FBC • Prolactin * • ECG** • Creatine phosphokinase (CK) • VTE risk assessment *** • Assessment of risk of pathological gambling****

* A baseline of >1000 mIU/L would require further investigation and possible referral to endocrinology.
** If personal cardiac history, family history of cardiovascular disease, high BP, admitted as an inpatient, taking other medication known to cause ECG or on high-dose antipsychotic therapy
*** MHRA: Antipsychotic use may be associated with an increased risk of VTE. At present there are insufficient data available to determine any difference in risk between atypical and conventional antipsychotics, or between individual drugs. All possible risk factors for VTE should be identified before and during antipsychotic treatment and preventative measures taken.
****MHRA: Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
Weight/ BMI	Baseline, weekly for first 6 weeks, at 3 months, at 12 months then annually.	AWP CAMHS	Weight and waist circumference to be plotted on a chart.
Waist circumference	Baseline, at 3 months, at 12 months then annually.	AWP CAMHS	Weight and waist circumference to be plotted on a chart.
BP& pulse	Baseline, at 3 months, at 12 months then annually.	AWP CAMHS	
Lipids	Baseline, at 3 months, at 12 months then annually. Lipids and HbA1c can be repeated again if there are concerns.	AWP CAMHS/ Primary Care	
HbA1C (for those with diabetes continue as per NICE)	Baseline, at 3 months, at 12 months then annually. Lipids and HbA1c can be repeated again if there are concerns. For patients with a higher baseline for developing diabetes, continue monitoring every 3-6 months.	AWP CAMHS/ Primary Care	
U&Es	Baseline, at 12 months then annually.	AWP CAMHS/ Primary Care	
LFTs	Baseline, at 12 months then annually.	AWP CAMHS/ Primary Care	

FBC	Baseline, at 12 months then annually.	AWP CAMHS/ Primary Care	
Prolactin	Baseline, 3 months then annually. Sooner in symptomatic individuals or where indicated.	AWP CAMHS/ Primary Care	A baseline of >1000 mIU/L would require further investigation and possible referral to endocrinology.
ECG	Baseline if personal cardiac history, family history of cardiovascular disease, high BP, admitted as an inpatient, taking other medication known to cause ECG or on high-dose antipsychotic therapy, and where clinically indicated.	AWP CAMHS/ Primary Care	
Creatine phosphokinase	Baseline, annually and where clinically indicated (i.e NMS suspected).	AWP CAMHS/ Primary Care	
Side effect monitoring	Weekly for first months, at each consultation,	AWP CAMHS/ Primary Care	Including (but not limited to): -Assessment of movement disorders -Enquiry about sexual side effects -Enquiry about menstrual changes where applicable

After initiation period, ongoing monitoring required at least every 6 months if high dose antipsychotic prescribing – AWP CAMHS to complete.

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Psychiatric disorders: restlessness, insomnia, anxiety	Common	Inform AWP specialist
Nervous system disorders: extrapyramidal disorder, akathisia, tremor, dizziness, somnolence,	Common	Inform AWP specialist

sedation, headache		
Eye disorders: Blurred vision	Common	Inform AWP specialist
Gastrointestinal disorders: Dyspepsia, vomiting, nausea, constipation, salivary hypersecretion	Common	More common during initiation, inform specialist if unmanageable for patient.
General Fatigue	Common	Inform AWP specialist
Weight gain	Not known	Antipsychotics are associated with weight gain especially in first 6 to 9 months of treatment (average 2 to 10lb or ~0.9Kg to 4.5Kg). This is less common with aripiprazole. Offer a combined healthy eating and physical activity programme.
Diabetes mellitus	Common	Signs / symptoms of hyperglycaemia e.g. polydipsia, polyuria, polyphagia and weakness, or worsening of glucose control; raised blood glucose or HbA1c from upper threshold -monitor closely / refer to AWP Consultant for advice.
Raised blood lipids/glucose	Not known	Inform AWP specialist
Abnormal ECG /Cardiac disorders, QTc prolongation and	Not known	Inform AWP specialist *
Raised prolactin	Uncommon	In those assigned female at birth, it can present as amenorrhoea, menstrual disorders, galactorrhoea and reduced libido. In those assigned male at birth: reduced libido, impotence & gynaecomastia. Inform AWP specialist.
Neuroleptic malignant syndrome	Not known	Raised creatinine phosphokinase/ development of symptoms such as fever, sweating, rigidity, confusion, fluctuating blood pressure, tachycardia (see special warnings in SPC https://www.medicines.org.uk/emc/product/7969/smpc): If NMS is suspected, stop aripiprazole and call for ambulance immediately. Inform AWP specialist.

If a person has rapid or excessive weight gain, abnormal lipid levels or problems with blood glucose management, offer interventions in line with relevant NICE guidance (see Obesity [NICE clinical guideline 43], Lipid modification [NICE clinical guideline 67] and Preventing type 2 diabetes [NICE public health guidance 38]).

* GPs should also be aware of non-psychotropic drugs which are associated with QT prolongation. Some examples include: erythromycin, clarithromycin, ampicillin, co-trimoxazole, quinidine, amiodarone, sotalol, chloroquine, mefloquine, quinine, methadone, tamoxifen, diphenhydramine.

Referral back to specialist	Persistent side effects which are intolerable to the service user or are of concern.

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	**Significant Drug Interactions** • Due to its α1-adrenergic receptor antagonism, aripiprazole has the potential to enhance the effect of some antihypertensive agents. • Enhanced sedation likely when taken with other centrally acting drugs e.g. alcohol. • Potent inhibitors of CYP2D6 e.g. fluoxetine, paroxetine (and quinidine) may increase levels of aripiprazole so dose reductions of aripiprazole are advised. Potent inhibitors of CYP3A4 e.g. itraconazole & ketoconazole can also increase aripiprazole levels, requiring dose reduction of aripiprazole. Upon discontinuation of the CYP2D6 or 3A4 inhibitor, the dosage of aripiprazole should be increased to the level prior to the initiation of the concomitant therapy. • Potent inducers of CYP3A4 e.g. carbamazepine likely to reduce levels of aripiprazole; dose of Aripiprazole should be doubled when taken concomitantly with carbamazepine. Same applies with other potent inducers CYP3A4 e.g. rifampicin, rifabutin, phenytoin, phenobarbital, primidone, efavirenz, nevirapine and St John's Wort. Upon discontinuation of potent CYP3A4 inducers, the dosage of aripiprazole should be reduced to the level prior to the initiation of the concomitant therapy. **Contra-indication** – Hypersensitivity to aripiprazole or to any of the excipients. **Special warnings and precautions for use:** 1. Suicidal behaviour: The occurrence of suicidal behaviour is inherent in psychotic illnesses and in some cases has been reported early after initiation or switch of antipsychotic therapy. Close supervision of high-risk patients should accompany antipsychotic therapy. 2. Cardiovascular disorders: Aripiprazole should be used with caution in patients with known cardiovascular disease (history of myocardial infarction or ischaemic heart disease, heart failure, or conduction abnormalities), cerebrovascular disease, conditions which would predispose patients to hypertension (dehydration, hypovolemia, and treatment with antihypertensive medicinal products) or hypertension, including accelerated or malignant. 3. Tardive dyskinesia: in clinical trials of one year or less duration, there were uncommon reports of treatment emergent dyskinesia during treatment with aripiprazole. If signs and symptoms of tardive dyskinesia appear in a patient on aripiprazole, dose reduction or discontinuation should be considered. These symptoms can temporarily deteriorate or can even arise after discontinuation of treatment. 4. Neuroleptic Malignant Syndrome (NMS): NMS has been associated with antipsychotic treatment. Clinical manifestations include hyperpyrexia, muscle rigidity, altered mental status, evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia) and

	elevated creatinine phosphokinase. If a patient develops signs and symptoms indicative of NMS, or has unexplained high fever, all antipsychotic medicinal products must be discontinued. 5. Seizure: in clinical trials, uncommon cases of seizure were reported during treatment with aripiprazole. Therefore, aripiprazole should be used with caution in patients who have a history of seizure disorder or have conditions associated with seizures. 6. Hyperglycaemia and diabetes mellitus: Hyperglycaemia has been reported during treatment with aripiprazole. Patients with diabetes mellitus or with risk factors for diabetes mellitus (e.g. obesity or family history of diabetes) should be monitored regularly for signs and symptoms (e.g. polydipsia, polyuria, polyphagia and weakness) for hyperglycaemia or worsening of glucose control). Weight gain: Weight gain has been reported post-marketing among patients prescribed aripiprazole; usually in those with significant risk factors such as history of diabetes, thyroid disorder or pituitary adenoma. In clinical trials aripiprazole has not been shown to induce clinically relevant weight gain in adults. 7. Venous thromboembolism: Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with aripiprazole and preventative measures undertaken.
Reminder to ask patient about specific problems	Discuss any non-prescribed therapies patient wishes to use in terms of efficacy, safety and interactions.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Agitation, insomnia and restlessness may be present when treatment is started. This usually improves after a few weeks.
2. Inform your doctor if you or your family or friends notice that you are 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

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
CAMHS Specialist	AWP Mental Health NHS Trust	As per referral details	As per referral details
CAMHS Pharmacist	AWP Mental Health NHS Trust	Via locality team contact	Via locality team contact

Section 10: Document Details

Date prepared	13.06.2024
Prepared by	Sarah Steel
Date approved by JFG	03/09/2024
Date of review	September 2027
Document Identification: Version	V1

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. This Shared Care Agreement has been developed by the lead pharmacist for CAMHS with feedback from CAMHS specialist prescribers and the AWP medicines optimisation group– includes consultants, senior nursing staff and pharmacists.

Section 12: References

1. Summary of product characteristics for aripiprazole https://www.medicines.org.uk/emc/product/7969/smpc (accessed 13.06.2024)
2. NICE Clinical Guideline CG155: Psychosis and Schizophrenia in children and young people : recognition and management – updated October 2016.
3. D Taylor et al. Maudsley Prescribing Guidelines 14th Edition (latest edition).
4. MHRA PUBLIC ASSESMENT REPORT. The risk of venous thromboembolism associated with antipsychotics. June 2009.
5. MHRA. Aripiprazole (Abilify and generic brands): risk of pathological gambling Aripiprazole (Abilify and generic brands): risk of pathological gambling - GOV.UK (www.gov.uk) (accessed 13.06.2024)