BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Atomoxetine for adults with ADHD
Amber ***three months***	
Indication	Treatment of ADHD in Adults

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	**This Shared Care Guidance only covers adult ADHD patients with no other serious mental health co-morbidities who are stabilised on an Atomoxetine prescription.** Atomoxetine is a non-stimulant, indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Atomoxetine should be initiated as follows: Up to 70kg body weight: 0.5 mg / kg daily, increased after 7 days according to response to approximately 1.2 mg / kg daily Over 70kg body weight: 40 mg daily or less, increased after 7 days according to response. The recommended maintenance daily dose is 80mg to 100mg. The maximum recommended total daily dose is 120 mg. The safety of single doses over 120mg and total daily doses above 150mg have not been systematically evaluated. Atomoxetine can be administered as a single daily dose in the morning, with or without food. Patients who do not achieve a satisfactory clinical response (tolerability [e.g. nausea or somnolence] or efficacy) when taking Atomoxetine as a single daily dose might benefit from taking it as twice daily evenly divided doses in the morning and late afternoon or early evening. In adults, the presence of symptoms of ADHD that were pre-existing in childhood should be confirmed. Third-party corroboration is desirable and Atomoxetine should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis cannot be made solely on the presence of one or more symptoms of ADHD. Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in 2 or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an

	individual's life. The NICE Guideline NG87 recommends to offer atomoxetine if a patient cannot tolerate lisdexamfetamine or methylphenidate or their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative formulations and doses. However Atomoxetine may be the preferred first line medication with certain conditions co-morbid with ADHD, e.g. psychosis.
Route and formulation	Oral, capsules, brand Strattera available in 10mg, 18mg, 25mg, 40mg, 60mg, 80 mg or 100 mg hard capsules. In case of swallowing difficulties or aversion to tablets/capsules, an oral solution (Atomoxetine 4mg/ml) is available.
Duration of treatment	Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist clinic if desired. Reduce the dose at weekly increments and discontinue over a four week period. If desired and clinically appropriate, Atomoxetine can be restarted by the GP, referral back into the ADHD service is not necessary.

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

1. The GP practice to check BP, pulse and weight at referral, as per Referral form.
2. GP to carry out cardiac exam/ ECG if clinically indicated (e.g. family history of early CHD etc) prior to referral.
3. ADHD clinic to check BP, pulse and weight at the first appointment after starting treatment.

If any physical abnormality is found or suspected at baseline, investigate and treat as appropriate for that abnormality

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

Test	Frequency	Who by	Action/management
BP, Pulse, Weight, height	First appointment	ADHD clinic	To prepare for medication titration
BP	After each dose increase and every 6 months and at annual review.	ADHD clinic if titration taking place in clinic At 6 monthly intervals: Patients can self-monitor and report to primary care or can be done by Primary Care At annual review: To be done by primary care.	If there is a clinically significant increase in blood pressure, monitor and treat as per usual unless it is felt that ADHD treatment benefits don't outweigh antihypertensive treatment requirement; discuss with ADHD clinic to consider dose adjustment or alternative ADHD treatment
Pulse			NICE guidance suggest to investigate a resting tachycardia of > 120pbm; we suggest to monitor and possibly investigate a sustained resting

			tachycardia >100bpm; consider ECG; discuss with ADHD clinic.
Weight			If there is evidence of significant weight loss, measure BMI and discuss with patient as appropriate. Strategies to manage weight loss include: -Taking medication with or after food. -Additional meals/snacks early morning or late evening when stimulant effects have worn off. -Choosing high calorie foods of good nutritional value. -Taking a planned break from treatment or changing medication.

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
GI effects: abdominal pain, nausea and vomiting, decreased appetite, constipation, dyspepsia.	Very common/common	Often transient. Take medication after breakfast/food; Maximise food intake at times of least appetite suppression; increase snacking, introduce liquid calories (smoothies etc.) Consult specialist clinic if this persists.
Headache, somnolence	Very common	Split dose to BD regime; take medication at night; reduce dose
Dry Mouth	Common	sugar free sweets and water to counteract dry mouth
Urinary retention/hesitancy	Common	Split dose; reduce dose. Seek expert advice.
Sleep disturbances: Early wakening,	Common	Split dose; change timing of medication
Decreased libido/Erectile disorder	Common	Reduce dose; seek expert advice.
Menstrual irregularities	Common	Reduce dose; seek expert advice.
Hot flushes	Common	Split dose; reduce dose
Rash	Common	Stop medication; seek expert advice
Cardiac effects: pulse and BP increase	Common	Monitor and treat accordingly or reduce Atomoxetine in discussion with expert
Irritability, dizziness, fatigue	Uncommon	Reduce dose; stop iif necessary; discuss with expert
Hepatic disorders	Rare	Advise to stop medication immediately and seek medical input without delay
Suicidal ideation	Uncommon	Stop medication and seek medical review/input. See section 5 for information.

Referral back to specialist	Contact specialist for advice if: • The patient finds the medication intolerable for any given reason • If there is concern about observed mental or physical side effects (e.g. depression or hypertension)

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** • MAOIs • Due to potential for additive pharmacological effects, caution is advised in patients on concomitant treatment with: - High dose nebulised or systemically administered salbutamol (or other beta2 agonists) - Pressor agents (eg. the decongestants pseudoephedrine or phenylephrine) - Drugs that affect noradrenaline (eg. antidepressants such as imipramine, venlafaxine and mirtazapine) - Drugs which inhibit CYP2D6 isoenzyme (eg. fluoxetine, paroxetine) – slower titration may be necessary. • Concurrent use of atomoxetine and methylphenidate does not cause increased side effects of either drug. There is no interaction between atomoxetine and alcohol. **Contraindications** • Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. • Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOIs). • Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with a MAOI. Treatment with a MAOI should not be initiated within 2 weeks after discontinuing atomoxetine. • Atomoxetine should not be used in patients with narrow-angle glaucoma, as in clinical trials the use of atomoxetine was associated with an increased incidence of mydriasis. • Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders. Severe cardiovascular disorders may include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels). Severe cerebrovascular disorders may include cerebral aneurysm or stroke. • Atomoxetine should not be used in patients with phaeochromocytoma or a history of phaeochromocytoma. **Cautions** *Suicide-related behaviour:* Suicide-related behaviour (suicide attempts and suicidal ideation) has been reported in patients treated with atomoxetine. Patients who are being treated for ADHD should be carefully monitored for the appearance or worsening of suicide related behaviour. *Sudden death and pre-existing cardiac abnormalities*: Sudden death has been

	reported in patients with structural cardiac abnormalities who were taking atomoxetine at usual doses. Although some serious structural cardiac abnormalities alone carry an increased risk of sudden death, atomoxetine should only be used with caution in patients with known serious structural cardiac abnormalities and in consultation with a cardiac specialist. *Cardiovascular effects:* Atomoxetine can affect heart rate and blood pressure. Most patients taking atomoxetine experience a modest increase in heart rate (mean <10 bpm) and/or increase in blood pressure (mean <5 mm Hg). Long-term sustained changes in blood pressure may potentially contribute to clinical consequences such as myocardial hypertrophy. As a result of these findings, patients who are being considered for treatment with atomoxetine should have a careful history and physical exam to assess for the presence of cardiac disease, and should receive further specialist cardiac evaluation if initial findings suggest such history or disease. It is recommended that heart rate and blood pressure be measured and recorded before treatment is started and, during treatment, after each adjustment of dose and then at least every 6 months to detect possible clinically important increases. For adults, current reference guidelines for hypertension should be followed. Patients who develop symptoms suggestive of cardiac disease during atomoxetine treatment should undergo a prompt specialist cardiac evaluation. In addition, atomoxetine should be used with caution in patients with congenital or acquired long QT or a family history of QT prolongation *Hepatic effects:* Very rarely, spontaneous reports of liver injury, manifested by elevated hepatic enzymes and bilirubin with jaundice, have been reported. Also very rarely, severe liver injury, including acute liver failure, have been reported. Atomoxetine should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted. *Psychotic or manic symptoms:* Treatment-emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, mania or agitation in patients without a prior history of psychotic illness or mania can be caused by atomoxetine at usual doses. If such symptoms occur, consideration should be given to a possible causal role of atomoxetine, and discontinuation of treatment should be considered. The possibility that Atomoxetine will cause the exacerbation of pre-existing psychotic or manic symptoms cannot be excluded. *Aggressive behaviour, hostility or emotional lability:* Hostility (predominantly aggression, oppositional behaviour and anger) was more frequently observed in clinical trials of adults treated with Atomoxetine compared to those treated with placebo. Patients should be closely monitored for the appearance or worsening of aggressive behaviour, hostility or emotional lability. Possible allergic events: Although uncommon, allergic reactions, including anaphylactic reactions, rash, angioneurotic oedema, and urticaria, have been reported in patients taking atomoxetine. *Seizures:* Seizures are a potential risk with atomoxetine. Atomoxetine should be introduced with caution in patients with a history of seizure. Discontinuation of atomoxetine should be considered in any patient developing a seizure or if there is an increase in seizure frequency where no other cause is identified. Patients who are being treated for ADHD with Atomoxetine should be monitored for seizure frequency and severity? **Dose reduction and discontinuation** If the symptoms of ADHD do not improve after appropriate dosage adjustment treatment must be stopped by the clinic. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued – advice should be sought from and managed by the clinic.

Reminder to ask patient about specific problems	Ask about emergence of any possible side effects/compliance to treatment issues.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. It is not advisable to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Atomoxetine.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the GP.
3. Failure to attend annual reviews when called for by the GP, could result in the medication being stopped.
4. Patients can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Information on drug prescribed including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found at: http://www.choiceandmedication.org/awp/

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 10: Contact Details

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Section 11: Document Details

Date prepared	6th December 2019
Prepared by	Emily Knight/Dietmar Hank
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Section 12: 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

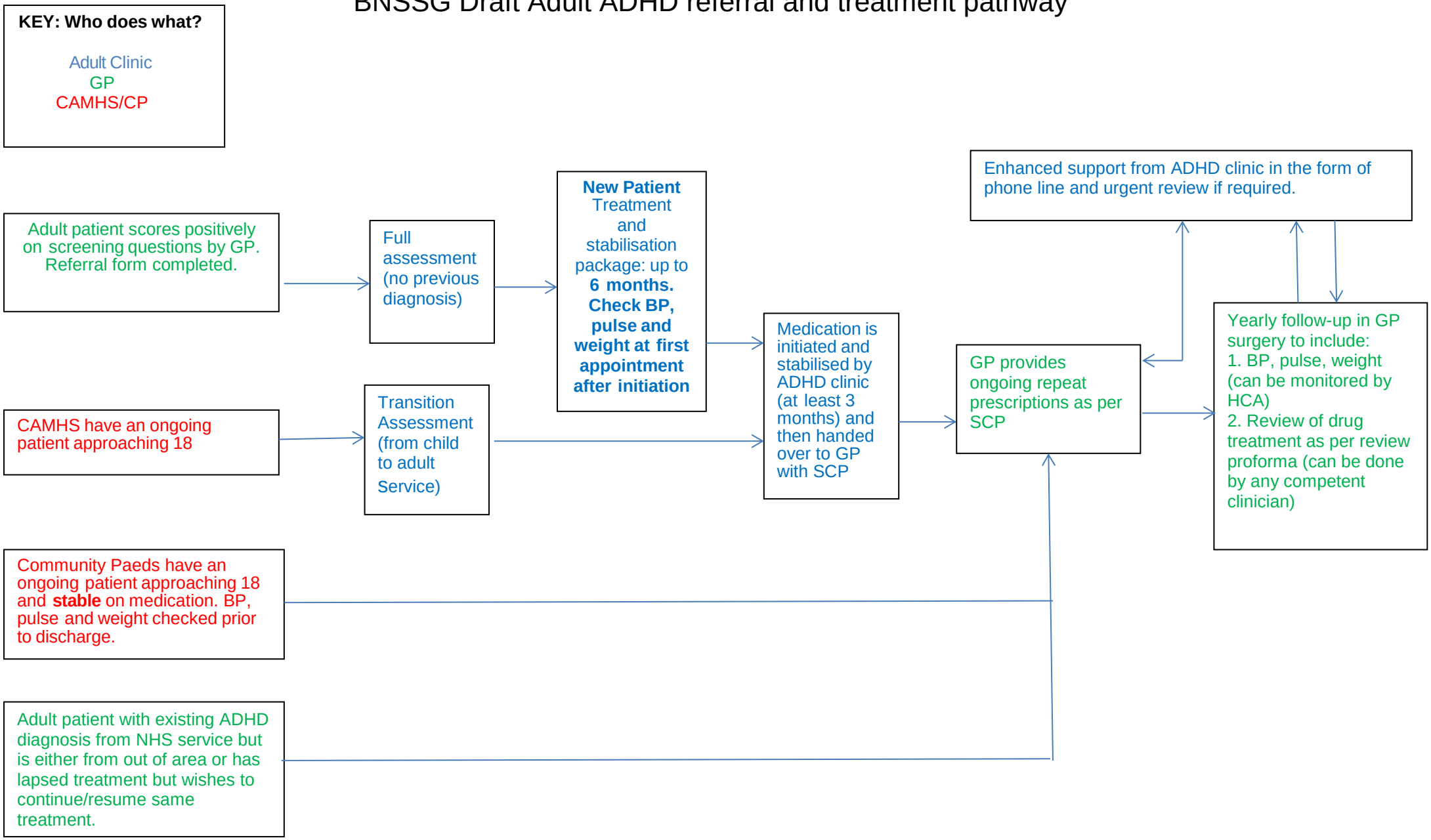
1. Click here to enter details

Section 13: References

Please list references

1. BNF online [accessed Jan 2020]
2. EMC SPC for Atomoxetine https://www.medicines.org.uk/emc/product/10507/smpc

BNSSG Draft Adult ADHD referral and treatment pathway



Patients under CAMHs will generally be more complex and may be more likely to require Adult specialist input at transition. Patients under Community Paediatrics will generally be defined as more stable and able to be moved to care of the GP at transition.