Specialised Medicine Service (SMS) Guideline ~

Atomoxetine for attention deficit hyperactivity disorder in patients under the care of adult specialist services

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

Specialist: Please complete 'Specialist Request to GP Letter' and send together with a copy of this shared care guideline to the GP.

GP: GPs are invited to participate. Please indicate whether you wish to share patient's care by completing the appropriate 'GP Acceptance/Refusal Letter' and return to 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.

Introduction and aims of treatment

This Devon wide Specialised Medicines Service (SMS) Guideline covers the use of atomoxetine for the treatment of attention deficit hyperactivity disorder (ADHD) in patients under the care of adult ADHD services. It 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 BNF and individual summaries of product characteristics (SPCs) for full list of data.

Atomoxetine should only be initiated following assessment and diagnosis by a specialist with expertise in ADHD. A specialist includes all appropriately qualified healthcare professionals with training and expertise in the diagnosis and management of ADHD e.g. Psychiatrist and Non-Medical Prescriber (NMP). Treatment should be tailored effectively to the individual needs of the adult.

Service transition for young people with existing ADHD diagnosis

Young people transferring from child/adolescent services to adult services should be offered a transition appointment ideally 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 ADHD 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.

Where adult services are providing care for an individual below the age of 18 years, the specialist should provide the GP with age specific prescribing guidance (including dose) and confirm monitoring requirements. For some individuals, this may be as per the Devon-wide SMS guideline for atomoxetine for ADHD in children and young people.

Where patient care is transferred from one specialist service to another, and/or the patient is initiated on a different ADHD treatment (excluding brand / formulation / dose changes) with associated shared care prescribing guidelines, a new shared care agreement must be completed between the specialist, the GP and the patient.

Specialist responsibilities

Specialists 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 of ADHD, agree a management plan and the need for treatment with atomoxetine. Ensure the patient and/ or the patient's carer is involved in making an informed choice about their treatment.
- Update records with list of existing drugs from available resources and ensure there are no drug interactions of clinical significance with current medication or recreational drugs. Recommend the patient and/ or the patient's carer consults a pharmacist before using OTC treatments.
- Provide the patient and/ or the patient's carer with suitable written and verbal information about the medication prior to starting treatment, including benefits, side effects, cautions, frequency of dosing, monitoring requirements and treatment reviews (timing and by whom).
- Ensure the patient and/or the patient's carer understands that treatment may be stopped if they do not attend for monitoring & treatment review.
- Confirm patient and/or the patient's carer understands the treatment and record acceptance of associated patient responsibilities in the patient's medical records.
- Undertake pre-treatment screening and required baseline monitoring (see monitoring requirements below) and initiate atomoxetine for the management of ADHD.
- **In accordance with the SMS Guideline the transfer of monitoring and prescribing to the GP will take place once the patient's condition is stable and the dose is optimised (with no anticipated further changes expected in the immediate future).**
- Following the request to the patient's GP to initiate shared care, the specialist must 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 28 days.
- Ask the GP in writing whether they are willing to participate in shared care for a particular patient. Include all relevant test results (GPs may not have access to these results in primary care).
- **Review the patient at agreed specified clinically appropriate intervals.** NICE Guideline NG87 recommends that ADHD medication should be reviewed at least once a year. During the review, evaluate the long-term benefit and continuation of treatment; discuss trial periods off medication where indicated.
- 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.
- 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.
- Ensure that the GP is informed in writing of any changes to the patient's specialist or their contact details.
- Where patient care is transferred from one specialist service to another, and/or the patient is initiated on a different ADHD treatment (excluding brand / formulation / dose changes) with associated SMS guidelines, a new shared care agreement must be completed between the specialist, the GP and the patient.
- Respond promptly to the GP and advise on action required when abnormal monitoring results are identified or adverse effects signs or symptoms are detected.
- Report suspected side effects to MHRA via yellow card scheme when appropriate.

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 GP overseeing the care of the individual patient:

- Ensure a timely reply is sent to specialist in response to request for shared care.

If GP has agreed to share care:

- Be alert to the possibility of interactions when initiating new medicines or recommending over the counter (OTC) treatments, or interactions with recreational drugs.
- Continue to prescribe and monitor atomoxetine in accordance with these guidelines.
- Review monitoring results and take any necessary action (see monitoring requirements below).
- Be alert to the possibility of adverse effects at every contact. Ensure prompt action in the case of a severe adverse effect or signs or symptoms (see monitoring requirements below).
- 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, including pregnancy.
- 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 when appropriate.

Patient and/ or carer responsibilities

- Understand the importance of monitoring treatment and attend specialist appointments and/ or GP appointments to ensure timely monitoring can be completed in accordance with the prescribing guideline.
- Understand that treatment will be stopped if they do not attend for monitoring and treatment review.
- Read the patient information leaflet regarding atomoxetine. Request information in different format(s) if required to aid understanding. Understand treatment, expected benefits and potential side effects.
- Take medication as directed by the prescriber.
- Consult a pharmacist before using over the counter (OTC) treatments.
- Seek guidance from a pharmacist, GP or specialist on medication safety and potential interaction with atomoxetine if engaging in recreational drug use.
- Report any adverse effects or newly presenting signs or symptoms to the GP and/or specialist.
- Advise the GP and/or specialist immediately if pregnancy is suspected.
- Store medicines safely and securely and dispose of any unused medication appropriately.
- Tell DVLA if ADHD or ADHD medication affects their ability to drive safely.
- Report suspected side effects to the GP or specialist and to MHRA via yellow card scheme when appropriate.

Monitoring requirements

Baseline assessment to be completed by the specialist before initiating treatment in adults:

- Full history and physical examination to include:
  - Medical history and current medication
  - Social circumstances including a risk assessment for substance misuse and drug diversion
  - Pulse and blood pressure (measured with an appropriately sized cuff and compared with the normal range for age)
    - If blood pressure is over 140/90 mmHg, request GP carries out further assessment and readings. Possible treatment for hypertension may be required before ADHD medication can be initiated. Specialist to arrange follow-up.
  - Height and weight (measured and recorded against the normal range for age, height and gender)
    - If body mass index (BMI) is below 18.5kg/m^2, provide advice on weight gain before considering treatment with atomoxetine.
  - Cardiovascular assessment to include (but not limited to) the following considerations:
    - presence of cardiac disease, history of exercise syncope, undue breathlessness, signs of heart failure, chest pain suggesting cardiac origin, palpitations and heart murmur
    - family history of cardiovascular disease and consideration of major lifestyle risk factors such as smoking and obesity
  - An electrocardiogram (ECG) to be carried out if clinically indicated based on patient medical history, cardiovascular assessment or if the patient is being treated with a medicine that may pose an increased cardiac risk.
  - Specialist cardiac evaluation to be requested if the ECG shows abnormalities or if the cardiovascular assessment raises concerns.
    - The SPCs state that atomoxetine should be used with caution in patients with congenital or acquired long QT or a family history of QT prolongation.
  - Request Liver Function Tests (LFTs) if any indication of liver disease (or family history) and/or alcohol misuse.
- Before initiating treatment for women of child-bearing potential it is essential to consider and discuss contraception and/ or, where appropriate, the risks of pregnancy (including risk to the foetus and risks associated with stopping or changing medication). If there is any possibility that the individual may be pregnant it is important to exclude this prior to starting treatment. Refer also to supporting information below.

Monitoring to be completed by the specialist:

- Continue to monitor the patient until shared care agreement is accepted, and ongoing prescribing and monitoring responsibilities are transferred to the GP.
- Respond promptly with advice on action required if adverse effects signs or symptoms are reported by the patient, either directly or through their GP.

Monitoring during treatment to be completed by the GP:

Where adult services are providing care for an individual below the age of 18 years, the specialist should confirm monitoring requirements. For some individuals, this may be as per the Devon-wide SMS guideline for atomoxetine for ADHD in children and young people.

Compare results of monitoring against the normal range for age, height and gender:

Weight	Every 6 months
Pulse and blood pressure	Before and one week after each dose change, and every 6 months
Adverse events	Be alert to the possibility of adverse effects at every contact

Where abnormal results are identified during routine monitoring consider the actions in the table below, seeking advice from ADHD specialist for further support and guidance where required:

	Result prompting further action	**Action to be taken by GP**
Weight	Unintentional weight loss >5% total body weight over 6-12 months and other possible causes have been excluded	Continue treatment and contact ADHD specialist for advice
Pulse	Sustained resting tachycardia or arrhythmia measured on 2 occasions. See table below for cardiovascular patient reported signs and symptoms.	Consider reducing dose or stopping atomoxetine depending on clinical findings. Notify ADHD specialist. Manage irregular pulse in accordance with local guidelines referring patient to cardiologist as required. See supporting information below for potential interaction with antiarrhythmics.
Blood pressure	Systolic blood pressure greater than 140mmHg (or a clinically significant increase from baseline) measured on 2 occasions	Consider reducing dose or stopping atomoxetine depending on clinical findings. Notify ADHD specialist. If hypertension resolves, contact ADHD specialist for review of treatment. If hypertension persists, manage in accordance with local guidelines; once blood pressure stable re-instate atomoxetine (with appropriate monitoring), and contact ADHD specialist for review. See supporting information below for potential interaction with antihypertensives.

Where an individual presents with any of the following adverse effects, signs or symptoms which may be associated with atomoxetine specialist advice must be sought:

Adverse effects, signs and symptoms	**Action to be taken by GP**
Worsening behaviour	Continue treatment and contact ADHD specialist for review
Change in sleep pattern	Continue treatment, advise patient to record sleep diary and if problem persists and other possible causes have been excluded, contact ADHD specialist for review
Sexual dysfunction (erectile and ejaculatory dysfunction)	Continue treatment and contact ADHD specialist for review
Onset or exacerbation of motor and verbal tics	Continue treatment and contact ADHD specialist for advice
Development of symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other symptoms suggestive of cardiac disease. See table above for tachycardia or arrythmia detected during routine monitoring	Stop atomoxetine. Manage patient in accordance with local guidelines. Refer for prompt cardiology review if indicated. Notify ADHD specialist.
Development or worsening of psychiatric disorders e.g. suicidal tendency or ideation, anxiety, irritability, agitation, tension, aggression, hostility, emotional lability, depression, psychotic or manic symptoms	If there is an urgent crisis consider whether atomoxetine may have caused or worsened it; if in doubt stop treatment. Follow local guidelines for treatment and/or referral to mental health services. Notify the ADHD specialist.
Onset or exacerbation of seizures	Stop atomoxetine and refer for urgent neurology review in accordance with local referral guidance. Notify ADHD specialist
Hepatic impairment: symptoms may include abdominal pain, unexplained nausea, malaise, darkening of the urine, or jaundice	Stop atomoxetine in patients with jaundice or laboratory evidence of liver injury and refer for urgent gastroenterology review in accordance with local referral guidance. Notify ADHD specialist

Supporting Information

This section provides additional information regarding atomoxetine. Refer to the online BNF and SPCs for full prescribing data.

Where adult services are providing care for an individual below the age of 18 years, the specialist should provide the GP with age specific prescribing guidance (including dose). For some individuals, this may be as per the Devon-wide SMS guideline for atomoxetine for ADHD in children and young people.

Refer to NICE Guideline NG87 Attention deficit hyperactivity disorder: diagnosis and management (2018) for guidance on the management of ADHD.

Dosage and administration (to be determined by specialist)

Refer to Devon formulary for list of preparations approved for use locally.

Atomoxetine can be administered as a single daily dose in the morning. Patients who do not achieve a satisfactory response (tolerability [e.g., nausea or somnolence] or efficacy) when taking 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.

Adults aged 18 years or over: Initially 40 mg/day for 7 days, dose is increased according to response; maintenance 80-100 mg/day. The maximum recommended total daily dose is 100 mg. The safety of single doses over 120 mg and total daily doses above 150 mg have not been systematically evaluated.

The SPCs do not provide altered dosing based on adult weight however the online BNF recommends the following for body-weight up to 70 kg: Initially 500 micrograms/kg/day for 7 days, dose is increased according to response; maintenance 1.2 mg/kg/day; maximum 1.8 mg/kg/day; maximum 120 mg/day.

Atomoxetine is metabolised via the CYP2D6 pathway in the liver. For individuals who lack CYP2D6 activity the half-life of atomoxetine will be prolonged, increasing the rate of side effects and reducing tolerance. It is difficult to identify these individuals, but a history of previous intolerance to other medications metabolised by this pathway should prompt slower titration of atomoxetine, in case the patient is a poor metaboliser.

Moderate hepatic insufficiency (Child-Pugh Class B): Reduce initial and target doses to 50% of the usual

Severe hepatic insufficiency (Child-Pugh Class C): Reduce initial dose and target doses to 25% of usual

Treatment review and discontinuation

It is important to ensure that sufficient time (at least 12 weeks) on the therapeutic dose of atomoxetine has passed before drawing conclusions on the clinical response in individual cases. Other circumstances surrounding treatment, such as adherence to medication schedule, side effects and motivation should be considered. If paradoxical aggravation of symptoms or other intolerable adverse effects occur, the dosage should be reduced or treatment discontinued. In cases of significant adverse effects, atomoxetine may be stopped abruptly; otherwise the drug may be tapered off over a suitable time period.

Contraindications

- Hypersensitivity to atomoxetine or any product excipients
- Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOI). Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with MAOI. Treatment with MAOI should not be initiated within 2 weeks after discontinuing atomoxetine.
- Atomoxetine should not be used in patients with narrow-angle glaucoma; 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.
- Atomoxetine should not be used in patients with pheochromocytoma or a history of pheochromocytoma.

Precautions

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

- 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.
- Atomoxetine should be used with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure and heart rate, such as patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.
- The SPCs state that atomoxetine should be used with caution in patients with congenital or acquired long QT or a family history of QT prolongation.
- Atomoxetine should be used with caution in any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes.
- Co-morbidity of psychiatric disorders should be taken into account when prescribing.
- Atomoxetine should be introduced with caution in patients with a history of seizure.
- 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.

Adverse effects

Only very common (greater than 1 in 10), common (1 in 100 to 1 in 10) and uncommon (1 in 1000 to 1 in 100) side effects are listed below as detailed in the online BNF. Refer to the online BNF and SPCs for further information and less frequent adverse effects.

Common or very common: Anxiety; appetite decreased; arrhythmias; asthenia; chills; constipation; depression; dizziness; drowsiness; dry mouth; feeling jittery; flatulence; gastrointestinal discomfort; genital pain; headaches; hyperhidrosis; menstrual cycle irregularities; mood altered; nausea; palpitations; prostatitis; sensation abnormal; sexual dysfunction; skin reactions; sleep disorders; taste altered; thirst; tremor; urinary disorders; vasodilation; vomiting; weight decreased

Uncommon: Behaviour abnormal; chest pain; dyspnoea; feeling cold; hypersensitivity; muscle spasms; peripheral coldness; QT interval prolongation; suicidal behaviour; syncope; tic; vision blurred

Interactions

This list is not exhaustive. Refer to the online BNF and SPCs 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 drug interactions are classified in the online BNF as **severe** (the result may be a life-threatening event or have a permanent detrimental effect):

- **Bupropion** and **cinacalcet** are predicted to markedly increase the exposure to atomoxetine. Manufacturer advises adjust dose.
- **Dacomitinib** is predicted to markedly increase the exposure to atomoxetine. Manufacturer advises avoid or adjust dose.
- **Dexamfetamine** and **lisdexamfetamine** are predicted to increase the risk of adverse effects when given with atomoxetine. Manufacturer advises caution.
- **Selective serotonin reuptake inhibitors (SSRIs)** and **terbinafine (CYP2D6 inhibitors)** are predicted to markedly increase the exposure to atomoxetine. Manufacturer advises slower titration and final lower dosage of atomoxetine may be necessary in patients who are already taking CYP2D6 inhibitor medicinal products. If a CYP2D6 inhibitor is prescribed or discontinued after titration to the appropriate atomoxetine dose has occurred, the clinical response and tolerability should be re-evaluated for that patient to determine if dose adjustment is needed. The SPCs also list **quinidine** as a CYP2D6 inhibitor.

- **Monoamine oxidase inhibitors** (**MAOIs) (isocarboxazid**, **phenelzine** and **tranylcypromine)** are predicted to increase the risk of adverse effects when given with atomoxetine. Manufacturer advises avoid and for 2 weeks after stopping the MAOI.
- **Panobinostat** is predicted to increase the exposure to atomoxetine. Manufacturer advises monitor and adjust dose.

The following interactions in the online BNF are noted 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):

- **High-dose beta$_2$ agonists:** Atomoxetine is predicted to increase the risk of cardiovascular adverse effects. Manufacturer advises caution. Manufacturer advises that attention should be paid to monitoring heart rate and blood pressure, and dose adjustments may be justified in the event of significant increases during coadministration.
- **Berotralstat, eliglustat, fedratinib:** Predicted to increase the exposure to Atomoxetine. Monitor and manufacturer advises adjust dose.
- **Ropeginterferon alfa:** Predicted to increase the exposure to Atomoxetine. Manufacturer advises caution.

The SPCs also document the following interactions:

- Caution is advised when combining atomoxetine with potent inhibitors of cytochrome P450 enzymes other than CYP2D6 in patients who are poor CYP2D6 metabolisers as the risk of clinically relevant increases in atomoxetine exposure in vivo is unknown.
- There is the potential for an increased risk of QT interval prolongation when atomoxetine is administered with other **QT prolonging drugs (such as neuroleptics, class IA and III anti-arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants, lithium, or cisapride), drugs that cause electrolyte imbalance (such as thiazide diuretics),** and **drugs that inhibit CYP2D6**.
- Caution is advised with concomitant use of medicinal drugs which are known to lower the seizure threshold such as **tricyclic antidepressants** or **SSRIs**, **neuroleptics**, **phenothiazines** or **butyrophenone**, **mefloquine**, **chloroquine**, **bupropion** or **tramadol**. In addition, caution is advised when stopping concomitant treatment with **benzodiazepines** due to potential withdrawal seizures.
- Atomoxetine should be used cautiously with **anti-hypertensive drugs** - atomoxetine may decrease their effectiveness. Atomoxetine should also be used cautiously with **pressor agents** or **medications that may increase blood pressure** (such as salbutamol). Attention should be paid to monitoring of blood pressure and review of treatments may be justified in the case of significant changes of blood pressure.
- **Drugs that affect noradrenaline** should be used cautiously when co-administered with atomoxetine because of the potential for additive or synergistic pharmacological effects. Examples include **antidepressants**, such as **imipramine**, **venlafaxine**, and **mirtazapine**, or the **decongestants pseudoephedrine** or **phenylephrine**.

Pregnancy and lactation

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

The SPCs advise that atomoxetine should not be used during pregnancy unless potential benefit outweighs risk and to avoid atomoxetine use during breast-feeding (atomoxetine and/or its metabolites were excreted in milk in animal studies).

Devon Partnership NHS Trust have produced a Prescribing Guideline for the Pharmacological Management of Perinatal Mental Health Conditions which can be accessed here. Contact details for perinatal mental health services can be found below.

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. UKTIS information on the use of atomoxetine in pregnancy can be accessed here.

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. Information relating to atomoxetine can be accessed here.

Support

Local adult ADHD service providers	
Devon Adult Autism & ADHD Service (DAANA); Devon Partnership NHS Trust Email: dpt.adhd@nhs.net Telephone: 01392 674250	**Livewell Southwest** Email: livewell.adultadhdassessment@nhs.net Telephone: 01752 434034

Local child and adolescent ADHD service providers	
Children and Family Health Devon https://childrenandfamilyhealthdevon.nhs.uk Email: CFHD.DevonSPA@nhs.net Telephone: 0330 0245 321	**University Hospitals Plymouth NHS Trust** Email: plh-tr.cdcplymouth@nhs.net Telephone 01752 439400
RD&E Foundation Trust Email: rde-tr.exeterchildhealth@nhs.net	**Livewell Southwest** https://www.livewellsouthwest.co.uk/childrens-services/camhs Telephone: 01752 434476
Torbay and South Devon NHS Foundation Trust www.torbayandsouthdevon.nhs.uk/services/camhs/ Telephone: 01803 655692	

Additional ADHD service providers with an NHS Devon ICB Contract
Refer to the DRSS ADHD and Autism FAQ for a list of additional providers with an NHS Devon contract (and Devon shared care agreements): North & East Devon | South & West Devon

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

Date ratified: 23rd June 2021 (Link to DRSS ADHD and Autism FAQ added Dec 25)

Shared Care Agreement Letter - Specialist Request to GP

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."

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

Atomoxetine *(state formulation, dose, frequency)*

……

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients under the care of adult ADHD services.

Treatment was started on ……..

The patient has been on the optimised dose stated for ……..

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 for atomoxetine.

In accordance with the SMS Guideline the transfer of monitoring and prescribing to the GP will take place once the patient's condition is stable and the dose is optimised (with no anticipated further changes expected in the immediate future).

I have provided the patient with sufficient medication to last until …….

Please undertake prescribing and monitoring from …… in line with the SMS Guideline.

The next monitoring is due on ……

I have arranged a follow up with this patient in ……

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete (YES / NO)
Baseline investigation and monitoring as set out in the SMS Guideline have been completed and were satisfactory	
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	
The risks and benefits of treatment have been explained to the patient	
The roles of the Specialist / GP / Patient have been explained and agreed	
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	
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, early monitoring and any additional supportive information are included below and/or attached:

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:

Medicine	Formulation	Route	Dose and frequency
Atomoxetine		Oral	

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 for atomoxetine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients under the care of adult ADHD services.

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 atomoxetine as a "shared care" drug which requires 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 applicable box**
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 for atomoxetine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this condition is identified locally as requiring shared care with atomoxetine 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 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. 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.