National shared care protocol:

Atomoxetine for patients within adult services

A logo with a blue and white logo

Description automatically generatedVersion 1.1

**SWL Local Adaptation**

**2023**

Please follow link to local amendment regarding[Locally agreed off-label use](#_3._Locally_agreed)

Please follow link to local addition to [appendix 1](#_Appendix_1:_Shared) and [appendix 2](#_Appendix_2:_Shared). This has been added to clearly define who will be responsible for completing the annual review specified in [Section 8](#_8._Baseline_investigations,) under ‘Ongoing Monitoring’ and [Section 9](#_9._Ongoing_monitoring). Work is being done to allow for the annual review to be conducted in primary care **only** where local arrangements allow for this. The specialist is responsible for ensuring local arrangements are in place prior to suggesting that the primary care prescriber could undertake the annual review.

**Version Control History**

Date: 15th February 2023, updated January 25

Version: 1.1

Type of change: Minor

Summary of change: Review date extended to February 26

Approved by: Integrated medicines committee (IMOC)

Approval date: 15th February 2023

Review Date: January 2025, as per NHS England. Extended to February 26, agreed by Integrated Medicines Optimisation Committee January 25

**The content of this shared care protocol was correct as of January 2022. As well these protocols, please ensure that**[**summaries of product characteristics**](https://www.medicines.org.uk/emc/)**(SPCs),**[**British national formulary**](https://bnf.nice.org.uk/?)**(BNF) or the**[**Medicines and Healthcare products Regulatory Agency**](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)**(MHRA) or**[**NICE**](https://www.nice.org.uk/)**websites are reviewed for up-to-date information on any medicine.**

|  |  |  |
| --- | --- | --- |
| Specialist responsibilities  * Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care. * Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet. * Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review * Assess for contraindications and cautions (see section 4) and interactions (see section 7). * Conduct required baseline investigations and initial monitoring (see section 8). * Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised. * Once treatment is optimised, complete the shared care documentation and send to patient’s GP detailing the diagnosis, current and ongoing dose, any relevant test results, and when the next monitoring is required. Include contact information (section 13). * Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care. * Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements. * Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations should be managed by the specialist. * Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant. * Provide advice to primary care on the management of adverse effects if required.  Primary care responsibilities  * Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible. * If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per [section 5](#Five_dosing), taking into any account potential drug interactions in [section 7](#Seven_interactions). * Adjust the dose of atomoxetine prescribed as advised by the specialist. * Conduct the required monitoring as outlined in [section 9](#Nine_primary_care_monitoring). Communicate any abnormal results to the specialist. * Manage adverse effects as detailed in [section 10](#Ten_ADRs_and_Management) and discuss with specialist team when required. * Stop atomoxetine and make an urgent referral for appropriate care if cerebral ischaemia or new or worsening seizures occur. * Refer the management back to the specialist if the patient becomes or plans to become pregnant. * Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.  Patient and/or carer responsibilities  * Take atomoxetine as prescribed and avoid abrupt withdrawal unless advised by their prescriber. * Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend. * Report adverse effects to their primary care prescriber and consider recording adverse effects by using checklist. Seek immediate medical attention if they develop any symptoms as detailed in section 11. * Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of atomoxetine with their pharmacist before purchasing any OTC medicines. * Not to drive or operate heavy machinery if atomoxetine affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11). * Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant. | | |
| 1. Background [Back to top](#Responsibilities) | | |
| Atomoxetine is a sympathomimetic drug indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It is an alternative treatment option in patients who cannot tolerate lisdexamfetamine or methylphenidate, or whose symptoms have not responded to separate 6-week trials of lisdexamfetamine or methylphenidate (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.  Atomoxetine is licensed for use in adults with ADHD of at least moderate severity. Adults should have ADHD symptoms pre-existing from childhood, which should ideally be confirmed by a third party.  Atomoxetine should be used as part of a comprehensive treatment programme, typically including psychological, educational, and social measures.  Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children’s to adults’ services for young people using health or social care services should be followed.  Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. | | |
| 2. Indications [Back to top](#Responsibilities) | | |
| Licensed indication: attention deficit hyperactivity disorder (ADHD) | | |
| 3. Locally agreed off-label use [Back to top](#Responsibilities) | | |
| The South West London Integrated Medicines Optimisation Committee recommended the use of this document for the indications as outlined above.  The following information should be provided in correspondence to support prescribing in line with this shared care.   * Dosing specific to the indication * Relevant interaction information * Any additional monitoring requirements over and above the shared care. * Duration of treatment * Frequency of review. * Specific features of adverse effects or deterioration pertinent to the specific indication for which it is used | | |
| 4. Contraindications and cautions [Back to top](#Responsibilities) This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drugs/) & [SPC](https://www.medicines.org.uk/emc/) for comprehensive information. | | |
| **Contraindications:**   * Hypersensitivity to the active substance or to any of the excipients * During treatment with monoamine oxidase inhibitors (MAOI), or within 14 days of discontinuing those drugs, due to the risk of hypertensive crisis * Narrow angle glaucoma * Severe cardiovascular or cerebrovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, cerebral aneurysm, or stroke * History of phaeochromocytoma   **Cautions:**   * Psychiatric and neuropsychiatric symptoms or disorders, including psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, and mania * Known serious structural cardiac abnormalities; consultation with a cardiac specialist required before treatment * Underlying medical conditions which could be worsened by increases in blood pressure and heart rate, including hypertension, tachycardia, or cardiovascular or cerebrovascular disease * Prolonged QT interval (congenital or acquired, e.g. drug-induced) or family history of QT prolongation * Any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes (risk of orthostatic hypotension) * Concomitant medications that elevate blood pressure: assess for neurological signs and symptoms at every monitoring visit * Other conditions that may precipitate or otherwise induce cerebrovascular conditions: assess for neurological signs and symptoms at every monitoring visit * Hepatic insufficiency; dose adjustments required, see [section 5](#Five_dosing). * History of seizures * Susceptibility to angle-closure glaucoma * Age over 65 years; safety and efficacy has not been systematically evaluated * Known CYP2D6 poor metaboliser genotype. Dose reduction required, see [section 5](#Five_dosing). | | |
| 5. Initiation and ongoing dose regimen [Back to top](#Responsibilities)  * Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 4 weeks. * The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. * All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. * Termination of treatment will bethe responsibility of the specialist. | | |
| **Initial stabilisation:**   * Adults weighing 70 kg or above: 40 mg daily for at least 7 days, * Adults weighing up to 70 kg: 500 micrograms/kilogram daily for at least 7 days   Then titrated according to clinical response and tolerability. Total daily dose may be given as a single dose in the morning or in two equally divided doses, with the last dose no later than the early evening.  **The initial stabilisation period** **must be prescribed by the initiating specialist.**  **Maintenance dose (following initial stabilisation):**   * Adults weighing 70 kg or above: 80 mg to 100 mg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 100 mg. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist. * Adults weighing up to 70 kg: up to 1.2 mg/kg daily in a single dose, or in two equally divided doses, as above. Usual maximum total daily dose is 1.8 mg/kg daily. Higher doses, up to a maximum of 120 mg, are off-label and must be given under the direction of a specialist.   **The initial maintenance dose must be prescribed by the initiating specialist.**  **Conditions requiring dose adjustment:**  Hepatic insufficiency:   * moderate hepatic insufficiency ([Child-Pugh](https://www.sps.nhs.uk/articles/what-is-the-child-pugh-score/) Class B) reduce starting and target doses to 50% of usual (reduce dose by half, i.e. starting dose should be 20mg daily, and total daily dose should not exceed 50mg daily) * severe hepatic insufficiency ([Child-Pugh](https://www.sps.nhs.uk/articles/what-is-the-child-pugh-score/) Class C) reduce starting and target doses to 25% of usual (reduce dose by three quarters, i.e. starting dose should be 10mg daily, and total daily dose should not exceed 25mg daily)   Renal insufficiency:  No adjustment is necessary, but be aware that atomoxetine may exacerbate hypertension in patients with end stage renal disease.  Known CYP2D6 poor metaboliser genotype:   * Due to several-fold increase in atomoxetine exposure, consider a lower starting dose and slower up-titration. | | |
| 6. Pharmaceutical aspects [Back to top](#Responsibilities) | | |
| Route of administration: | Oral | |
| Formulation: | Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg  Atomoxetine hydrochloride 4 mg/mL oral solution | |
| Administration details: | Atomoxetine can be taken with or without food.  Capsules should not be opened for administration: risk of irritation.  Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste.  If a dose is missed then take it as soon as possible, but no later than the early evening. Do not take more than the usual total daily dose in any 24 hour period. A double dose should not be taken to make up for a missed dose. | |
| Other important information: | The initiating specialist will decide the formulation on an individual basis as this will depend on the needs and preferences of the patient. | |
| 7. Significant medicine interactions [Back to top](#Responsibilities) The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drugs/) or [SPC](https://www.medicines.org.uk/emc/) for comprehensive information and recommended management. | | |
| * **MAOIs**: avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of adverse effects. * **CYP2D6 inhibitors**: increased atomoxetine exposure. E.g. selective serotonin reuptake inhibitors (SSRIs), quinidine, terbinafine, bupropion, cinacalcet, dacomitinib, and panobinostat. Slower dose titration and lower final dose may be necessary. Clinical response and tolerability should be re-evaluated if a CYP2D6 inhibitor is started or stopped. * **Potent inhibitors of other cytochrome P450 isoforms** in patients who are poor CYP2D6 metabolisers. It is not clear whether there is a clinically significant increase in atomoxetine exposure in this patient group. * **Beta-2 agonists, including salbutamol**: high dose beta-2 agonists, such as salbutamol, may potentiate cardiovascular effects. * **Drugs which prolong the QT interval**: risk of QT interval prolongation. E.g. antipsychotics, class IA and III anti arrhythmics, some antibiotics such as ciprofloxacin or erythromycin, methadone, mefloquine, tricyclic, antidepressants, lithium, and some selective serotonin reuptake inhibitors (SSRIs) such as citalopram. * **Drugs which cause electrolyte imbalance:** risk of QT interval prolongation. E.g. thiazide diuretics. * **Drugs which lower the seizure threshold:** risk of seizures. E.g.tricyclic antidepressants, SSRIs, antipsychotics, phenothiazines, mefloquine, chloroquine, bupropion, and tramadol. Use caution when stopping medications that may induce seizures on withdrawal, such as benzodiazepines. * **Anti-hypertensive drugs:** effectiveness of anti-hypertensives may be decreased, monitoring is required. * **Drugs that increase blood pressure:** possible additive effects, monitoring is required. * **Drugs that affect noradrenaline:** possible additive or synergistic pharmacological effects. E.g. dexamfetamine, lisdexamfetamine, imipramine, venlafaxine, mirtazapine, pseudoephedrine, phenylephrine. | | |
| 8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist [Back to top](#Responsibilities) Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care. | | |
| **Baseline investigations:**   * A full assessment, as recommended by [NICE guidance for ADHD](https://www.nice.org.uk/guidance/ng87/chapter/Recommendations#medication). This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for atomoxetine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required * Risk assessment for substance misuse and drug diversion * Height, weight, and body mass index (BMI) * Appetite * Blood pressure (BP) and heart rate * Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:   + history of congenital heart disease or previous cardiac surgery   + sudden death in a first-degree relative under 40 years suggesting a cardiac disease   + shortness of breath on exertion compared with peers   + fainting on exertion or in response to fright or noise   + palpitations   + chest pain suggestive of cardiac origin   + signs of heart failure, heart murmur or hypertension   + current treatment with a medicine that may increase cardiac risk   **Initial monitoring:**   * Before every change of dose: assess heart rate, blood pressure, and weight. * After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring. * including development or worsening of tic and movement disorders * Assessment of symptom improvement. Discontinue if no improvement is observed after 4-8 weeks.   **Ongoing monitoring:**  Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.  Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. | | |
| 9. Ongoing monitoring requirements to be undertaken  by primary care [Back to top](#Responsibilities) See [section 10](#Ten_ADRs_and_Management) for further guidance on management of adverse effects/responding to monitoring results. | | |
| **Monitoring** | | **Frequency** |
| * Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms * Weight and appetite * Assessment for new or worsening psychiatric and neurological signs or symptoms | | At least every 6 months |
| * Assessment of adherence, and for any indication of atomoxetine abuse, misuse, or diversion | | As required, based on the patient’s needs and individual circumstances |
| * Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD | | Annually |
| **(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.** | | |
| 10. Adverse effects and other management [Back to top](#Responsibilities) **Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  For information on incidence of ADRs see relevant summaries of product characteristics | | |
|  | | |
| **Result** | | **Action for primary care** |
| **As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.** | | |
| **Cardiovascular** | | Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP |
| Hypertension | | Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see [section 7](#Seven_interactions)).  If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice. |
| **Gastrointestinal disorders**  Including abdominal pain, vomiting, nausea, constipation, dyspepsia | | Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally resolves. |
| **Weight or BMI outside healthy range**, including anorexia or weight loss | | Recommend small, frequent meals and/or snacks, and high calorie foods of good nutritional value. Recommend taking atomoxetine with or after meals, and not before. Obtain dietary advice if required.  Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medicine may be required. |
| **Psychiatric disorders**  New or worsening psychiatric symptoms, e.g. suicide related behaviour, psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette’s syndrome), anxiety, agitation or tension, bipolar disorder, or depression | | Contact specialist team and refer for psychiatric assessment if appropriate. Refer for urgent psychiatric assessment if suicide related behaviour or ideation occurs.  Discuss ongoing benefit of treatment with specialist team. |
| **Hepatic effects**  Signs or symptoms of liver injury, e.g. abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine | | Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team.  Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist). |
| **Nervous system disorders**  Somnolence or sedation | | Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in late afternoon or early evening). Generally resolves. |
| New onset of seizures, or increased seizure frequency | | Discuss with specialist team. Discontinuation of atomoxetine should be considered. |
| 11. Advice to patients and carers [Back to top](#Responsibilities) The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines. | | |
| **The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**   * Abnormally sustained or frequent and painful erections. **If an erection persists for more than 2 hours go to A&E**; this is an emergency. * Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of **angle closure glaucoma**, seek immediate medical attention, ideally from an eye casualty unit or A&E. * Symptoms suggestive of cardiac disease (e.g. palpitations, exertional chest pain, unexplained syncope, or dyspnoea). * New or worsening psychiatric symptoms (e.g. psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania). * Report **suicidal thoughts or behaviour**, and development or worsening of irritability, agitation, and depression. * New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory). * Risk of **hepatic injury**: report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistentabdominal pain. * Symptoms of allergic or anaphylactic reactions (e.g. rash, angioedema, or urticaria). * If they suspect they may be pregnant or are planning a pregnancy.   **The patient should be advised:**   * Not to drive or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or fatigue, and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/adhd-and-driving>. * Not to stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.   Patient information:   * Royal College of Psychiatrists – ADHD in adults. <https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults> * NHS – Attention deficit hyperactivity disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/>   Patient information leaflets are also available from <https://www.medicines.org.uk/emc/search?q=atomoxetine> | | |
| 12. Pregnancy, paternal exposure and breast feeding [Back to top](#Responsibilities) It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist. | | |
| **Pregnancy:**  Atomoxetine is not recommended for use during pregnancy unless a clinical decision is made that the potential benefit outweighs the risk to the fetus.  Evidence on exposure to atomoxetine during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks, and additional monitoring should be considered on a case-by-case basis.  Patients who become pregnant while taking atomoxetine, or who plan a pregnancy, should be referred to the specialist team for review.  **Breastfeeding:**  There is no published evidence on the safety of atomoxetine in breastfeeding. Decisions to use atomoxetine while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and the benefits of therapy. Long half-life in slow metabolisers increases risk of accumulation in some breastfed infants. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite or slow weight gain, sleep disturbances, gastrointestinal symptoms), although these may be difficult to detect.  Information for healthcare professionals: <https://www.sps.nhs.uk/medicines/atomoxetine/>  **Paternal exposure**:  No evidence regarding adverse outcomes following paternal exposure was identified. | | |

|  |
| --- |
| 13. Specialist contact information [Back to top](#Responsibilities) |
| Name: insert name  Role and specialty: insert role and speciality  Daytime telephone number: insert daytime telephone number  Email address: insert email address  Alternative contact: insert contact information, e.g. for clinic or specialist nurse  Out of hours contact details: insert contact information, e.g. for duty doctor |
| 14. Additional information [Back to top](#Responsibilities) |
| Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. |
| 15. References [Back to top](#Responsibilities) |
| * eBNF. Atomoxetine. Accessed via <https://bnf.nice.org.uk/drug/atomoxetine.html> on 01/09/2021 * Atomoxetine hydrochloride 10 mg hard capsules (Strattera®). Date of revision of the text 26/01/2021. Accessed via <https://www.medicines.org.uk/emc/product/5531> * NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <https://www.nice.org.uk/guidance/ng87/> on 14/04/21 * NICE NG43: Transition from children’s to adults’ services for young people using health or social care services. Last updated February 2016. Accessed via <https://www.nice.org.uk/guidance/ng43/> on 01/09/21 * UKTIS. Use of atomoxetine in pregnancy. Last updated December 2017. Accessed via <https://www.toxbase.org/poisons-index-a-z/a-products/atomoxetine-in-pregnancy/> on 26/05/2021 * Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via <https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/> on 26/05/2021 * Specialist Pharmacy Service. Atomoxetine Lactation Safety Information. Last updated January 2018. Accessed via <https://www.sps.nhs.uk/medicines/atomoxetine/> on 26/05/2021 * NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Atomoxetine. Last updated January 2021. Accessed via <https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/atomoxetine/> on 09/06/21. * MHRA. Drug Safety Update: Atomoxetine (Strattera▼): increases in blood pressure and heart rate. January 2021. Accessed via <https://www.gov.uk/drug-safety-update/atomoxetine-strattera-increases-in-blood-pressure-and-heart-rate> on 09/06/21. |
| 16. Other relevant national guidance [Back to top](#Responsibilities) |
| * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/> * NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/> * General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care> * NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/> |
| 17. Local arrangements for referral [Back to top](#Responsibilities) Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. |
| Follow Place based processes |

# Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *insert Primary Care Prescriber's name*

Patient name: *insert patient's name*

Date of birth: *insert date of birth*

NHS Number*: insert NHS Number*

Diagnosis: *insert diagnosis*

As per the agreed SWL shared care protocol for *insert medicine name* for the treatment of *insert indication,* this patient is now suitable for prescribing to move to primary care

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

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

|  |  |
| --- | --- |
|  | **Specialist to complete** |
| *The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:* |  |
| *Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory* | *Yes / No* |
| *The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care* | *Yes / No* |
| *The risks and benefits of treatment have been explained to the patient* | *Yes / No* |
| *The roles of the specialist/specialist team/* *Primary Care Prescriber / Patient and pharmacist have been explained and agreed* | *Yes / No* |
| *The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments* | *Yes / No* |
| *I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)* | *Yes / No* |
| *I have included with the letter copies of the information the patient has received* | *Yes / No* |
| *I have provided the patient with sufficient medication to last until* |  |
| *I have arranged a follow up with this patient in the following timescale* |  |

**Annual review to be completed by**:

|  |  |
| --- | --- |
| Specialist | Yes / No |
| Primary care clinician  *Only where local arrangements allow for this and if the primary care clinician is happy to do this* | Yes / No |

Treatment was started on *insert date started* and the current dose is *insert dose and frequency*

If you are in agreement, please undertake monitoring and treatment from *insert date* NB: date must be at least 3 months from initiation of treatment.

The next blood monitoring is due on *insert date* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

# Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

**Primary Care Prescriber Response**

Dear *insert Doctor's name*

Patient: *insert Patient's name*

NHS Number : *insert NHS Number*

Identifier: *insert patient's date of birth and/or address*

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 | Route | Dose & frequency |
|  |  |  |

**Annual review to be completed by**:

|  |  |
| --- | --- |
| Specialist | Yes / No |
| Primary care clinician  *Only where local arrangements allow for this and if the primary care clinician is happy to do this* | Yes / No |

I can confirm that I am willing to take on this responsibility from *insert date* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_

Primary Care Prescriber address/practice stamp

# Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

**Re*:***

Patient: *insert Patient's name*

NHS Number : *insert NHS Number*

Identifier: *insert patient's date of birth and/or address*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS SWL ICB, in conjunction with local acute trusts have classified *insert medicine name* as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care

**I regret to inform you that in this instance I am unable to take on responsibility due to the following:**

|  |  |  |
| --- | --- | --- |
|  |  | **Tick which apply** |
| **1.** | **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 primary care prescriber I do not feel clinically confident to manage this patient’s condition because *insert reason.* I have consulted with other primary care prescribers 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 above.** |  |
| **2.** | **The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement**  As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.  **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you** |  |
| **3.** | **A minimum duration of supply by the initiating clinician**  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.*** |  |
| **4.** | **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.*** |  |
| **5.** | **Shared Care Protocol not received**  As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.***  For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.  ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.*** |  |
| **6.** | **Other (Primary Care Prescriber 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.

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 this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

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

Yours sincerely

**Primary Care Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

**Primary Care Prescriber address/practice stamp**