Specialised Medicine Service (SMS) Guideline ~

Solriamfetol for the treatment of excessive daytime sleepiness in adults with narcolepsy with or without cataplexy.

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

Specialist: Please complete letter at the end of this document and send together with a copy of this guideline to the GP.

GP: GPs are invited to participate. Please indicate whether you wish to share patient's care by completing letter at the end of this document 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 accept. In such an event, the total clinical responsibility for the patient with 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 will be 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 guideline covers the use of solriamfetol in adults as recommended by the National Institute for Health and Care Excellence (NICE) Technology appraisal guidance [TA758], 2022. Solriamfetol is recommended as an option for treating excessive daytime sleepiness in adults with narcolepsy with or without cataplexy. This is only if modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable.

Solriamfetol should be initiated by a healthcare professional experienced in the diagnosis and treatment of narcolepsy.

Solriamfetol is not licensed for use in children and adolescents less than 18 years old – management of this patient group falls outside the scope of this guideline. Solriamfetol is also licensed to improve wakefulness and reduce excessive daytime sleepiness in adult patients with **obstructive sleep apnoea** however this indication **is not recommended** by NICE Technology appraisal guidance [TA777], 2022 and use associated with this indication falls outside the scope of this guideline.

This guideline details the responsibilities for ongoing prescribing and monitoring to enable a shared care agreement to be arranged between the primary and secondary care interface. Refer to the online British National Formulary (BNF), individual summaries of product characteristics (SmPCs) or the Medicines and Healthcare products Regulatory Agency (MHRA) for up-to-date prescribing data.

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 narcolepsy (with or without cataplexy) after appropriate investigations and the need for treatment with solriamfetol. Ensure the patient and/ or the patient's carer is involved in making an informed choice about their treatment.
- Update patient records with list of existing drugs from available resources and ensure there are no drug interactions of clinical significance with current medication, recreational drugs or over the counter (OTC) 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, frequency of dosing, monitoring requirements of treatment and treatment reviews (timing and by whom). Links to patient information resources can be found in the Supporting Information section below.
- Ensure the patient and/or the patient's carer understands that treatment may be stopped if they do not attend for monitoring and 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, including consideration to cautions and contraindications, and required baseline monitoring (see monitoring requirements below) before initiating solriamfetol.
- Provide advice on the need for contraception, and the risks of pregnancy to individuals on initiation and at each review; the ongoing responsibility for providing this advice rests with both the specialist and the GP.
- **Prescribe solriamfetol and continue to monitor the patient for the first 2 months of treatment or until the patient's dose and condition is stabilised, whichever is longer, before sharing care with GP.**
- 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).
- Prescribing and monitoring will remain in secondary care until the GP agrees to share care.
- If the agreement is accepted, 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.
- If home blood pressure and pulse monitoring is considered appropriate on an individual patient basis whilst the specialist is overseeing the prescribing and monitoring of the patient, the specialist should agree the requirements and expectations directly with the patient and / or patient's carer. Specialist to advise the patient on suitable equipment to facilitate this and how to submit results for review.
- **Specify review dates at clinically relevant time intervals for both the GP and the specialist.**
- During the review consider and discuss clinical effectiveness and adverse effects with the patient and/ or the patient's carer; evaluate the long-term benefit and whether medication is still 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.
- Respond promptly to the GP and advise on action required when abnormal monitoring results are identified or adverse effects signs or symptoms are detected.
- Any individual who becomes pregnant or wishes to become pregnant will be referred back to the specialist for review, oversight of solriamfetol discontinuation, and discussion of alternative management plans. The shared care agreement will end. If the patient is restarted on solriamfetol in the future a new shared care agreement must be completed.

- Report suspected side effects to the MHRA via yellow card scheme.

General Practitioner responsibilities

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

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

If GP has agreed to share care:

- Continue to prescribe and monitor solriamfetol in accordance with these guidelines.
- Review monitoring results and take any necessary action (see monitoring requirements below).
- Be alert to the possibility of interactions when initiating new medicines or recommending over the counter (OTC) treatments, or interactions with recreational drugs.
- It is the responsibility of the specialist to provide advice on the need for contraception to individuals on initiation and at each review however the ongoing responsibility for providing this advice rests with both the specialist and the GP.
- 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.
- Any individual who becomes pregnant or wishes to become pregnant should be referred back to the specialist.
- 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 the specialist and the MHRA via yellow card scheme.

Patient and / or carer responsibilities

- Understand the importance of monitoring treatment and attend specialist and 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, and in the case of home monitoring submit results in a timely manner.
- Ensure contact details are kept up to date with both the GP and the specialist.
- Read the solriamfetol patient information leaflet. Understand treatment, expected benefits and potential side effects. Request information in different format(s) if required to aid understanding. Links to patient information resources can be found in the Supporting Information section below.
- Take (or support administration of) medication as directed by the prescriber.
- Seek guidance from a pharmacist, GP or specialist on medication safety and potential interaction with solriamfetol if engaging in recreational drug use, or using over the counter (OTC) treatments.
- Individuals of childbearing potential or their sexual partners must use effective method of contraception while taking solriamfetol. Individuals should take a pregnancy test if they think there is a possibility they could be pregnant, and inform the GP or specialist immediately if they become pregnant or wish to become pregnant.
- Report any adverse events or newly presenting signs or symptoms to the GP or specialist regarding their treatment, including (but not limited to):
  - Palpitations, chest pain or syncope (fainting), shortness of breath
  - Mood changes, such as anxiety, agitation, irritability, insomnia
- Store their medicines safely and securely at home and dispose of any unused medication appropriately.
- Patients who hold a driving license must ensure the DVLA is aware of their narcolepsy diagnosis.
- Patients wishing to stop treatment should discuss with their specialist before doing so.
- Report suspected side effects to the GP or specialist, and the MHRA via yellow card scheme.

Monitoring requirements

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

- Medical history, and current medication
- Consideration of cautions and contraindications associated with solriamfetol
- Blood pressure and heart rate (measured with an appropriately sized cuff)
  - Pre-existing hypertension should be controlled before initiating treatment
- Exclude pregnancy in individuals of child-bearing potential prior to starting treatment.

Monitoring to be completed by the specialist service provider before initiation of shared care agreement:

- Prescribe solriamfetol and continue to monitor the patient for the first 2 months of treatment or until the patient's dose and condition is stabilised (whichever is longer) and ongoing 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 to be completed by the GP once shared care agreement in place:

Test	Frequency
Blood pressure and heart rate	Measure at 3 months (following treatment initiation) and then at 6 months. Measure every 6 months thereafter.
Adverse Effects	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 specialist for further support and guidance where required. **If monitoring results are forwarded to the specialist team, please include any supporting clinical information and the reason for sending, to inform action to be taken by secondary care.**

Test	Result prompting further action	Action to be taken by GP
Blood pressure	Systolic blood pressure greater than 140mmHg *Or* A clinically significant increase in blood pressure from baseline determined on an individual patient basis	Confirm raised blood pressure in line with good medical practice and NICE guideline [NG136]: Hypertension in adults. If raised blood pressure is confirmed, seek advice from initiating specialist to determine if dose reduction or discontinuation of solriamfetol required. Manage ongoing hypertension in accordance with local guidelines and NICE guideline [NG136]: Hypertension in adults.
Heart rate	Sustained resting tachycardia greater than 120bpm. (See table below for cardiovascular patient reported signs and symptoms)	Confirm increased heart rate in line with good medical practice. If tachycardia is confirmed, seek advice from initiating specialist to determine if dose reduction or discontinuation of solriamfetol required. Manage ongoing irregular pulse in accordance with local guidelines and specialist advice.

Presentation of the following adverse effects, signs or symptoms and associated actions should be noted:

Adverse effects, signs and symptoms	**Action to be taken by GP**
Concerns about misuse or abuse of medication	Contact initiating specialist for advice
Development or worsening of psychiatric disorders including anxiety, insomnia, irritability, agitation	Anxiety, insomnia, irritability, agitation are commonly observed adverse reactions during treatment initiation but tend to resolve with continued treatment. Discuss with the initiating specialist if these symptoms persist or worsen, as dose reduction or discontinuation of solriamfetol may be required. Follow local guidelines for treatment and/or referral to mental health services.
Palpitations, chest pain, unexplained syncope, dyspnoea or other symptoms suggestive of cardiac disease or arrhythmia	Seek advice from initiating specialist to determine if dose reduction or discontinuation of solriamfetol is required. Following discussion with specialist manage ongoing irregular heart rate in accordance with local guidelines referring patient to cardiologist as required.
Hypersensitivity reactions including rash erythematous, rash, urticaria	Discontinue solriamfetol and contact initiating specialist for advice

Supporting Information

This section provides additional information regarding solriamfetol. Refer to the online BNF, SmPCs, MHRA or NICE websites for up-to-date information on any medicine.

Dosage and administration

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

The licensed starting dose is 75mg once daily, upon awakening. Patients with more severe levels of sleepiness, may require a starting dose of 150mg. Depending on response, the dose can be increased by doubling the dose after at least 3 days. Recommended maximum daily dose of 150mg once daily.

Limited data are available in elderly patients. Consideration should be given to the use of lower doses and close monitoring in this population. Solriamfetol is predominantly eliminated by the kidney and since elderly patients are more likely to have decreased renal function, dosing may need to be adjusted based on creatinine clearance in these patients (see below).

Solriamfetol can be taken with or without food; avoid taking less than 9 hours before bedtime as it may affect night time sleep.

The need for continued treatment and the appropriate dose should be periodically assessed by the specialist during extended treatment.

Renal impairment:

Patients with moderate or severe renal impairment may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of solriamfetol.

- Mild impairment (creatinine clearance of 60-89 mL/min): No dose adjustment required.
- Moderate impairment (creatinine clearance of 30-59 mL/min): Recommended starting dose is 37.5 mg once daily. Dose may be increased to a maximum of 75 mg once daily after 5 days.
- Severe impairment (creatinine clearance of 15-29 mL/min): Recommended dose is 37.5 mg once daily.
- End stage disease (creatinine clearance <15 mL/min): Solriamfetol is not recommended

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Myocardial infarction within the past year, unstable angina pectoris, uncontrolled hypertension, serious cardiac arrhythmias and other serious heart problems.
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days after MAOI treatment has been discontinued

Cautions in the following patient groups

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.

- History of, or concurrent psychosis or bipolar disorders; psychiatric adverse reactions could exacerbate pre-existing disorders.
- Moderate or severe renal impairment; patients may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of solriamfetol.
- Pre-existing hypertension, known cardiovascular or cerebrovascular disease, elderly and any other patient at higher risk of major adverse cardiovascular event (MACE).
- Elderly; limited information available and reduced renal function. Consider lower doses and close monitoring
- History of stimulant or alcohol abuse; patients should be monitored for signs of misuse or abuse.
- Increased ocular pressure or at risk of angle closure glaucoma; risk of mydriasis
- Individuals of childbearing potential or sexual partners to individuals of child bearing potential - effective methods of contraception required.

Adverse effects

This list is not exhaustive. Refer to the online BNF and SmPCs for full prescribing data. Seek specialist advice where necessary.

Very common (≥1/10) or Common (≥1/100 to <1/10): Abdominal pain; anxiety; appetite decreased; bruxism; chest discomfort; constipation; cough; diarrhoea; dizziness; dry mouth; feeling jittery; headache; hyperhidrosis; insomnia; irritability; nausea; palpitations; teeth grinding; vomiting

Uncommon (≥1/1,000 to <1/100): Agitation; concentration impaired; chest pain; dyspnoea; hypertension; restlessness; tachycardia; thirst; tremor; weight decreased

Not known: Mydriasis

The SmPCs also report that in post-marketing experience, there have been reports of hypersensitivity reactions which have occurred with one or more of the following: rash erythematous, rash, urticaria.

Interactions

The following lists are not exhaustive. Consider interaction with prescription and recreational drugs. Refer to the online BNF and SmPCs for full prescribing data. Seek specialist advice where necessary and / or refer to specialist Medicines Information services for additional support (and reference to Stockley's Drug Interactions where paid subscription available) if concomitant administration of interacting medicines clinically indicated.

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

- Solriamfetol is predicted to increase the risk of a hypertensive crisis when given with **isocarboxazid**, **phenelzine**, **rasagiline**, **safinamide**, **selegiline** and **tranylcypromine**. Manufacturer advises avoid and for 14 days after stopping mono-amine oxidase inhibitors (MAOIs).

The SmPCs confirm that there have been no interaction studies to evaluate the interactions of solriamfetol with other medicinal products. Concomitant use of medicinal products that increase blood pressure and heart rate should be used with caution.

The SmPCs also state that medicinal products that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with solriamfetol. Concomitant use of such medicinal products should be used with caution.

Pregnancy and lactation

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

Pregnancy: Any individual who becomes pregnant or wishes to become pregnant should be referred back to the specialist for review, oversight of solriamfetol discontinuation, and discussion of alternative management plans. The shared care agreement will end. If the patient is restarted on solriamfetol in the future a new shared care agreement must be completed.

The SmPCs state that there are no or limited amount of data from the use of solriamfetol in pregnant women. Animal studies have shown reproductive toxicity. Solriamfetol is not recommended during pregnancy and in women of childbearing potential (or their male partners) not using contraception.

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.

Lactation: The SmPCs state that it is unknown whether solriamfetol is excreted into human milk. Animal studies have shown excretion of solriamfetol in milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the women. The online BNF recommends that breast-fed infants should be monitored for adverse reactions such as agitation, insomnia, poor feeding, and reduced weight gain.

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 safety in lactation for drugs used to treat sleeping disorders is available here.

Patient Resources

Narcolepsy UK – solriamfetol	https://www.narcolepsy.org.uk/resources/solriamfetol
NHS – Narcolepsy	https://www.nhs.uk/conditions/narcolepsy/

Support

Narcolepsy specialist contact details
Contact initiating specialist for guidance and support via hospital switchboard. **Christopher Price – regional specialist** Contact by email or via the secretary who may be telephoned through the Royal Devon University Healthcare NHS Foundation Trust switchboard Email: c.price@nhs.net Telephone: 01392 411611
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: May 2023

Shared Care Agreement Letter - Specialist Request to GP

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

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:

Solriamfetol tablets for the management of excessive daytime sleepiness in adults with narcolepsy with or without cataplexy in accordance with the recommendation made by NICE TA758.

I can confirm that modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable.

Treatment was started on *Insert date*

The current dose is *Insert dose and frequency*

The patient has been initiated on this therapy and has been on an optimised dose for *Insert duration*

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 solriamfetol.

In accordance with the SMS Guideline the transfer of monitoring and prescribing to the GP is after the first 2 months of treatment or until the patient's dose and condition is stabilised, whichever is longer, before sharing care with GP.

I have provided the patient with sufficient medication to last until *Insert date*

Please undertake prescribing and monitoring from *Insert date* in line with the SMS Guideline.

The next monitoring is due on *Insert date*

I have arranged a follow up with this patient in *State timescale for review*

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

	Specialist to complete
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:

Insert text

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

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

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	*Insert text*
Patient name	*Insert text*
Hospital number	*Insert text*
NHS number	*Insert text*
Date of birth	*Insert text*
Address	*Insert text*

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	**Route**	**Dose and frequency**
Solriamfetol tablets	Oral	*Insert dose and frequency*

I can confirm that **I am willing to take on this responsibility** from *Insert date* and will maintain the prescribing and monitoring responsibilities as set out in the Specialised Medicines Service (SMS) Guideline for solriamfetol for excessive daytime sleepiness in adults with narcolepsy with or without cataplexy in accordance with the recommendation made by NICE TA758.

GP signature		**Date**	*Insert date*
GP name	*Insert text*		
Practice address	*Insert text*		
Telephone number	*Insert text*		
Email address	*Insery text*		

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**	*Insert text*
Patient name	*Insert text*
Hospital number	*Insert text*
NHS number	*Insert text*
Date of birth	*Insert text*
Address	*Insert text*

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 solriamfetol 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:	**Check 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.** *Insert text*	☐

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 solriamfetol 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 solriamfetol 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): *State reason*	☐

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**	*Insert date*
GP name	*Insert text*		
Practice address	*Insert text*		
Telephone number	*Insert text*		
Email address	*Insert text*		

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