Title: Shared Care Guideline for Modafinil for the treatment of excessive sleepiness associated with narcolepsy	Salford Royal NHS NHS Foundation Trust University Teaching Trust safe • clean • personal
Authors Name: Emma Wilson, Clinical Pharmacist for Neurology.	
Contact Name: Emma Wilson	
Contact Phone No: 01612064209	
Authors Division: CSS & TM	
Departments/Groups This Document Applies to: Neurology, Pharmacy and Primary Care**.**	
Scope: Neurology and Primary Care	**Classification:** Shared Care Protocol
Keywords: Modafinil, Shared Care, Neurology	**Replaces Issue No:** New

To be read in conjunction with the following documents:

Current Summary of Product characteristics (http://www.medicines.org.uk)
BNF

Unique Identifier: TWCSC06(14)	**Review Date:** April 2016	
Issue Status: Approved	**Issue No:** 1	**Issue Date:** April 2014
Authorised by: SRFT Exec Medicines Management Group	**Authorisation Date:** Jan 2014	

Document for Public Display: Y

Required NHSLA Evidence **N**

If this policy is required for NHSLA evidence, then this document must have been checked against the current standards for compliance. If this is not known by the author, confirmation should be sought from the Risk and Health and Safety Department.

Contents

Shared Care Protocol for Modafinil

1. Introduction

Narcolepsy is a lifelong disorder of the central nervous system characterised by uncontrollable daytime sleepiness (also called 'excessive daytime sleepiness') and intermittent abnormal manifestations of rapid eye movement (REM) sleep during wake or sleep-wake transition, of which cataplexy is the most prominent.

The use of stimulant drugs to control excessive daytime sleepiness in narcolepsy has been proposed since 1931 and it is still the recommended first-line intervention. Stimulant drugs are classically divided into direct-acting sympathomimetic drugs, indirect-acting sympathomimetic drugs or stimulants with some other way of action and modafinil falls into this latter category. Modafinil is the drug of choice for patients with narcolepsy as it is associated with fewer side effects than other stimulants.

2. Purpose and Scope

Shared care is an agreement between the GP and the consultant.

This shared care document has been developed to facilitate the safe and appropriate prescribing, supply and monitoring of modafinil in primary and secondary care. It is aimed at all healthcare professionals involved in prescribing, dispensing and monitoring modafinil.

This document must be agreed by SRFT and the patients CCG.

3. Policy statement

This shared care protocol must be adhered to by all medical, nursing, pharmacy and other staff who are involved in the care of patients who are suitable for shared care, as agreed by both the GP and hospital specialist caring for the patient.

4. Monitoring and review

This shared care protocol will be reviewed on a two yearly basis or in the intervening period if new research is published, or changes to the drug license that means an update is required before the two years have passed.

Drug Name & Formulation:	
1. Licensed Indications	Modafinil is indicated in adults for the treatment of excessive sleepiness associated with narcolepsy with or without cataplexy. Excessive sleepiness is defined as difficulty maintaining wakefulness and an increased likelihood of falling asleep in inappropriate situations.
2. Therapeutic use & background	A review by the European Medicines Agency found that modafinil is strongly linked to a risk of serious, life-threatening skin reactions, psychiatric adverse reactions, such as suicidal thoughts, depression, psychotic episodes, and cardiovascular adverse reactions, such as hypertension (high blood pressure) and irregular heart beat. This review led to a restriction of the license to only cover narcolepsy and modafinil should no longer be used to treat: Obstructive sleep apnoea; Shift work sleep disorder and idiopathic hypersomnia.
3a. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	Hypersensitivity to the active substance or to any of the excipients. Uncontrolled moderate to severe hypertension and in patients with cardiac arrhythmias.
3b With caution:	Serious rash, including Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Rash with Eosinophilia and Systemic Symptoms Serious rash requiring hospitalisation and discontinuation of treatment has been reported with the use of modafinil occurring within 1 to 5 weeks after treatment initiation. Isolated cases have also been reported after prolonged treatment (e.g., 3 months) Modafinil should be discontinued at the first sign of rash and not re-started Multi-organ hypersensitivity reaction Multi-organ hypersensitivity reactions, including at least one fatality in post-marketing experience, have occurred in close temporal association to the initiation of modafinil. Although there have been a limited number of reports, multi-organ hypersensitivity reactions may result in hospitalization or be life-threatening. There are no factors that are known to predict the risk of occurrence or the severity of multi-organ hypersensitivity reactions associated with modafinil. Signs and symptoms of this disorder were diverse; however, patients typically, although not exclusively, presented with fever and rash associated with other organ system involvement. Other associated manifestations included myocarditis, hepatitis, liver function test abnormalities, haematological abnormalities (e.g., eosinophilia, leukopenia, thrombocytopenia), pruritus, and asthenia. Because multi-organ hypersensitivity is variable in its expression, other organ system symptoms and signs, not noted here, may occur. If a multi-organ hypersensitivity reaction is suspected, modafinil should be discontinued.

	Psychiatric disorders Patients should be monitored for the development of de novo or exacerbation of pre-existing psychiatric disorders at every adjustment of dose and then regularly during treatment. If psychiatric symptoms develop in association with modafinil treatment, modafinil should be discontinued and not restarted. Caution should be exercised in giving modafinil to patients with a history of psychiatric disorders including psychosis, depression , mania, major anxiety, agitation, insomnia or substance abuse. Suicide-related behaviour Suicide-related behaviour (including suicide attempts and suicidal ideation) has been reported in patients treated with modafinil. Patients treated with modafinil should be carefully monitored for the appearance or worsening of suicide-related behaviour. If suicide-related symptoms develop in association with modafinil, treatment should be discontinued. Cardiovascular risks Modafinil tablets are not recommended in patients with a history of left ventricular hypertrophy or cor pulmonale and in patients with mitral valve prolapse who have experienced the mitral valve prolapse syndrome when previously receiving CNS stimulants. This syndrome may present with ischaemic ECG changes, chest pain or arrhythmia. Lactose intolerance Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
4. Prescribing in pregnancy and lactation	Modafinil is not recommended for use during pregnancy or in women of childbearing potential unless they are using effective contraception. As modafinil may reduce the effectiveness of oral contraception alternative additional methods of contraception are required. Modafinil should not be used during breast feeding.
5. Dosage regimen for continuing care	Route of administration: For oral use. Tablets should be swallowed whole.
	Is titration required? — Yes for some patients
	Titration guidance: The recommended starting daily dose is 200 mg. The total daily dose may be taken as a single dose in the morning or as two doses in the morning and at noon, according to physician assessment of the patient and the patient's response. Doses of up to 400mg in one or two divided doses can be used in patients with insufficient response to the initial 200mg modafinil dose.
	Adjunctive treatment regimen: Not applicable
	Conditions which might require dose reduction depending on clinical

	judgment: In view of the potential for lower clearance and increased systemic exposure, it is recommended that patients over 65 years of age commence therapy at 100 mg daily. The dosage of modafinil should be reduced by half in patients with severe hepatic impairment. There is inadequate information to determine safety and efficacy of dosing in patients with renal impairment.
	Usual response time: Quick response
	Duration of treatment: Modafinil therapy is a treatment for a chronic disease and therefore course length can be long term. Patient monitoring and clinical assessment of the need for treatment should be performed on a periodic basis.
	Treatment to be terminated by: Specialist Consultant
6.Drug Interactions **For a comprehensive list consult the BNF or Summary of Product Characteristics**	The following drugs must not be prescribed without consultation with the specialist: Not applicable
	The following drugs may be prescribed with caution: Anticonvulsants: The makers advise vigilance if anticonvulsants, particularly phenytoin, are used with modafinil. Steroidal contraceptives: The effectiveness of steroidal contraceptives may be impaired. Alternative or concomitant methods of contraception are recommended for patients treated with modafinil. Adequate contraception will require continuation of these methods for two months after stopping modafinil. Antidepressants: Lower doses of some antidepressants may be required in some patients whilst on modafinil. Anticoagulants: The clearance of warfarin may be decreased when modafinil is administered concomitantly. Prothrombin times should be monitored regularly during the first 2 months of modafinil use and after changes in modafinil dosage. Other medicinal products: Substances that are largely eliminated via CYP2C19 metabolism, such as diazepam, propranolol and omeprazole may have reduced clearance upon co-administration of modafinil and may thus require dosage reduction. Modafinil reduces plasma concentration of ciclosporin and may require review.

<table>
<tr><td>7. Adverse drug reactions

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF</td><td colspan="5">Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.

<table><tr><th>Adverse Event</th><th>Action to be taken</th><th>By whom</th></tr><tr><td>Rash</td><td>As above- discuss with Consultant</td><td>GP</td></tr><tr><td>Psychiatric disorders</td><td>As above- discuss with Consultant</td><td>GP</td></tr><tr><td>Cardiovascular disorders</td><td>As above- discuss with Consultant</td><td>GP</td></tr><tr><td>Headache (common affecting ~21% of patients)</td><td>Treat symptomatically- disappears within days</td><td>Patient/GP</td></tr><tr><td>Decreased appetite, abdominal pain, nausea, dry mouth, diarrhoea, dyspepsia, constipation</td><td>Treat symptomatically</td><td>Patient/GP</td></tr></table>Additional guidance / warnings:
Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the “Yellow Card” scheme.</td></tr>
<tr><td>8.Baseline investigations</td><td colspan="5">An ECG is recommended in all patients before Modafinil treatment is initiated. Patients with abnormal findings should receive further specialist evaluation and treatment before Modafinil treatment is considered.</td></tr>
<tr><td>9. Ongoing monitoring requirements to be undertaken by GP</td><td colspan="5"><table><tr><td>Is monitoring required?</td><td>Yes</td></tr></table><table><tr><th>Monitoring</th><th>Frequency</th><th>Results</th><th>Action</th><th>By whom</th></tr><tr><td>Blood pressure and heart rate</td><td>Six monthly</td><td>Communicated to Consultant</td><td>Modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension</td><td>GP</td></tr></table></td></tr>
</table>

10. Pharmaceutical aspects	This medicinal product does not require any special storage conditions.
11. Secondary care contact information	Further information and support is available from the following contacts: Acute Neurology Ward, Hope Hospital Phone: 0161 206 4586 Open seven days a week. Pharmacy Medicines Information Phone: 0161 206 5223 Between 9am and 5pm Monday to Friday Outside these hours the neurology registrar on call may be contacted through switchboard for advice.
12. Criteria for shared care	This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of modafinil can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is 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 a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.
13. Responsibilities of initiating specialist: Consultant	Assessing the need for treatment • Confirming with GP the use of the Shared Care Protocol • Check baseline ECG and repeat on an annual basis as indicated. • Prescribing medication until maintenance regimen established • Evaluating any adverse events noted by GP or patient • Advising GP on change of, or discontinuation, of therapy • Overall monitoring of disease status and efficacy of treatment
14. Responsibilities of the GP	Reply to the request for shared care as soon as practicable • Prescribe modafinil once treatment regimen has been stabilised. • Monitor patient's response to treatment; make dosage adjustments if agreed with specialist. • Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment. • Refer back to specialist if condition deteriorates. • Report adverse events to specialist and CSM • Stop treatment on advice of specialist

15.Responsibilities of District Nurses	Not applicable
16. Responsibilities of the patient	• Attend GP and out-patient appointments • Attend appointments for monitoring purposes • Report any concerns to GP or Consultant
17. Supporting documentation	Not applicable
18. Patient monitoring booklet	Not applicable
19. Shared care agreement form	Attached below

Appendix 1- PLEASE ADAPT LETTERS AS APPROPRIATE TO DRUG

Shared Care Agreement Letter

Shared care is an agreement between the GP and the hospital consultant. This form is a request by the consultant to share the suggested pathway of your patient. If you are unable to agree to the sharing of care and continued prescription of the suggested medication, please make this known to the Consultant within 14 days, stating the nature of your concern.

Please contact the consultant within 14 days if you have any concerns or implied consent applies.

(Insert patients name and identifier such as DOB) is being considered for treatment with modafinil.
If this treatment should prove to be successful, the modafinil would need to be prescribed by yourself when your patient is discharged.
If you have any queries regarding this medication and its administration or if there is any reason why you do not wish this treatment to be undertaken, could you please contact myself, Dr ([insert Dr's Name) or Dr (insert Dr's name)'s secretary within the next fourteen days.
I will be happy to respond to any of your questions at any time.

Please find enclosed the Salford Royal NHS Foundation Trust Shared Care Protocol.

Kind regards

Yours sincerely,

(Insert Consultant's signature) (Insert signature of specialist nurse)

Dr (insert Dr's Name) (Insert name of specialist nurse)
Consultant (Insert Dr's role) (Print role of specilised nurse)

Appendix 2- PLEASE ADAPT LETTERS AS APPROPRIATE TO DRUG

Patient Information Letter

Dear (Insert patients name & hospital number),

As you are aware Dr (insert Dr's name) wants you to commence on treatment with (insert name of drug).

Your GP has agreed to prescribe this treatment and so your prescriptions will come from your GP surgery in the usual way.

If you have any queries please contact (insert contact name and details),

Kind regards

Yours sincerely

(Insert Consultant's signature)	(Insert signature of specialist nurse)
Dr (insert Dr's Name) Consultant (Insert Dr's role)	(Insert name of specialist nurse) (Print role of specilised nurse)

Appendix 2- PLEASE ADAPT LETTERS AS APPROPRIATE TO DRUG

Discharge Form for GP
Copy to be given to patient

Dear Dr [insert Doctors name here]

Patient name:[insert Patients name here]
Date of birth: [insert date of birth]
Diagnosis: [insert diagnosis here]

This patient is suitable for treatment with (insert name of drug) for the treatment of (insert name of indication)

This drug has been accepted for Shared Care.

Treatment was started on [insert date started] at a dose of [insert dose]

Further dosing instructions are listed below (include if appropriate, delete sentence if not).

The patient was discharged with [insert number of days of medication] supply of (insert name of drug)

[Insert any monitoring details]

Next review with this department: [insert date]

You will be sent a written summary within 14 days. The medical staff of the department are available at all times to give you advice.

The patient will not be discharged from out-patient follow-up while taking (insert name of drug).

Ongoing prescribing will depend on attendance at clinics as requested by the clinicians.

The Consultant or Specialist Nurse Prescriber is responsible for any dose adjustment.

Thank you.

Yours sincerely,

[insert Specialist signature]

[insert Specialist name and role]

Explanation of Terms Used
NOT APPLICABLE

Appendices
Add appendices as appropriate, if not delete this section

References

No references used

Endorsed by:		
Name of Lead Clinician/Manager or Committee Chair	**Position of Endorser or Name of Endorsing Committee**	**Date**
Dr Paul Cooper	Consultant Neurologist	March 2014
Dr Chris Murphy	Consultant Neurologist	March 2014
Dr Richard Hackett	Consultant Neuropsychiatrist	March 2104
Dr John MacDonald	Medicines Management Group Chairman	Jan 2014
Lindsay Harper	Director of Pharmacy	Jan 2014
Claire Vaughan	Head of Medicines Management NHS Salford Clinical Commissioning Group	Jan 2014

Record of Changes to Document - Issue number:				
Changes approved in this document by - Corporate Governance and Risk Management			Date: Jan 2014	
Section Number	Amendment (***shown in bold italics)***	Deletion	Addition	Reason
	The whole document has been re written and transferred to the new template.			

Screening Equality Analysis Outcomes (Policies/Procedures)

The Trust is required to ensure that all our policies/procedures meet the requirements of its service users, that it is accessible to all relevant groups and **furthers the aims of the Equality Duty for all protected groups by age, religion/belief, race, disability, sex, sexual orientation, marital status/civil partnership, pregnancy/maternity, gender re-assignment. Due consideration may also be given to carers & socio/economic.**

Have you been trained to carryout this assessment? YES **If 'no' contact Equality Team 62598 for details.**	
Name of policy or document : Shared Care Guideline for Modafinil for the treatment of excessive sleepiness associated with narcolepsy **Key aims/objectives of policy/document (impact on both staff & service users):** To support the safe prescribing and monitoring of modafinil in patients with Narcolepsy. The guidelines are intended for use by the Neurology team at Salford Royal NHS Foundation Trust, and any GP who has responsibility for the care of such patients.	
1) a) Whom is this document or policy aimed at?	1a) The Neurology team at Salford Royal NHS Foundation Trust, and any GP who has responsibility for the care of such patients.
2) a) Is there any evidence to suggest that your 'end users' have different <u>needs</u> in relation to this policy or document; (e.g.health/employment inequality outcomes) (**NB If you do not have any evidence you should put in section 8 how you will start to review this data)**	2a)No
3) a) Does the document require any decision to be made which could result in some individuals receiving different treatment, care, outcomes to other groups/individuals?	3a) No
b) If yes, on what basis would this decision be made? **(It must be objectively justified)**	3b)
4) a) Have you included where you may need to make reasonable adjustments for disabled users or staff to ensure they receive the same outcomes to other groups ?	4a) Yes

5) a) Have you undertaken any consultation/involvement with service users or other groups in relation to this document?	5a) NHS Salford
b) If yes, what format did this take? face/face or questionnaire? (please provide details of this)	5b) Face to face meeting (MMG)
c)Has any amendments been made as a result?	5c) No
6) a) Are you aware of any complaints from service users in relation to this policy?	6a) No
b) If yes, how was the issue resolved? Has this policy been amended as a result?	6b)

7) a) To summarise; is there any evidence to indicate that any groups listed below receive different outcomes in relation to this document?

	Yes		No	unsure
	Positive	Negative*		
Age			No	
Disability			No	
Sex			No	
Race			No	
Religion & Belief			No	
Sexual orientation			No	
Pregnancy & Maternity			No	
Marital status/civil partnership			No	
Gender Reassignment			No	
Carers *1			No	
Socio/economic2**			No	

1: That these two categories are not classed as protected groups under the Equality Act.

2: Care must be taken when giving due consideration to socio/economic group that we do not inadvertently discriminate against groups with protected characteristics

Negative Impacts

*If any negative impacts have been identified you must either a) state below how you have eliminated these within the policy or b) conduct a full impact assessment:

8) How will the future outcomes of this policy be monitored?
By discussion of feedback at Exec MMG or MMG

9) **If any negative impact has been highlighted by this assessment, you will need to undertake a full equality impact assessment:**

Will this policy require a full impact assessment? No
(if yes please Contact Equality Officer on 206 7204, for further guidance)

High/Medium/Low Type/signEmma Wilson
date: 13.12.13