SHARED CARE GUIDELINE FOR MODAFINIL

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of modafinil.

2. The Guidance

2.1. See below for the Shared Care Guideline.

MODAFINIL

This shared care guideline sets out details for sharing care of adult patients prescribed Modafinil. These guidelines provide limited information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with the BNF, ABPI summary of product characteristics and do not replace them.

BACKGROUND / INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE:

Modafinil is licensed for 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

A diagnosis of narcolepsy should be made according to the International Classification of Sleep Disorders guideline. Such an evaluation usually consists, in addition to the patient's history, sleep measurements testing in a laboratory setting and exclusion of other possible causes of the observed hypersomnia.

Modafinil, in similar dosages to those below, is also used off-license for:

- the hypersomnia that may occasionally be seen in chronic fatigue syndrome (CFS/ME),
- sleepiness and fatigue associated with multiple sclerosis,
- excessive daytime sleepiness in people with Parkinson's disease
- sleepiness associated with myotonic dystrophy (a common form of adult muscular dystrophy). and
- sleepiness associated with idiopathic hypersomnolence (debilitating sleepiness throughout the day without a diagnosed medical reason).

Note that modafinil is no longer indicated for shift-worker sleep disorder and obstructive sleep apnoea.

Narcolepsy is a rare (1: 50,000) disorder of sleep. It is neurological disorder marked by uncontrollable attacks of daytime sleepiness and also quite often characterised by cataplexy (sudden loss of muscle power triggered by emotion).

The sleep pattern typically seen in CFS/ME is of poor quality, disrupted and unrefreshing night-time sleep, which may lead to compensatory day time sleeping; usual approaches to improving night-time sleep (sleep hygiene; low-dose tricyclics or related agents) are indicated, and modafinil is not appropriate in this setting. However, a very few CFS/ME patients have disabling hypersomnia, despite good night-time sleep; it is for these patients that modafinil may be considered, as it has proved helpful and well tolerated in clinical experience. A starting dose of 100mg in the morning is appropriate, as some CFS/ME patients may be more sensitive to the effects of medication.

DOSAGE

Treatment should be initiated by or under the supervision of a physician with appropriate knowledge of indicated disorders.

The recommended starting dose is 200mg a day, or 100mg a day for CFS/ME patients. 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 modafinil dose.

Doses should be halved in patients with severe hepatic or renal failure (100 – 200mg / day).

INITIATION & MONITORING

A baseline electrocardiogram should be done before treatment initiation. Patients with abnormal findings should be further evaluated by specialists before modafinil treatment can be initiated.

Cardiovascular function—especially blood pressure and heart rate—should be monitored after one to two months of treatment, and then regularly annually, or more frequently if there are significant risk factors. Modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension, and should not be restarted until the condition has been adequately evaluated and treated.

CONTRAINDICATIONS

Pregnancy and breast feeding; use in children; uncontrolled moderate to severe hypertension and in patients with cardiac arrhythmias; 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.

PRECAUTIONS - caution is advised as follows:

Patients with major anxiety should only receive treatment in a specialist unit.

Modafinil should be used with caution in patients with a history of:

- Psychosis, depression, or mania
- Abuse of alcohol, drugs, or illicit substances

Such patients should be monitored closely and advised to report any suspected adverse behaviours or thoughts. These patients should be assessed immediately and treatment stopped if appropriate.

Modafinil should be discontinued and not restarted in cases of psychiatric disorders such as suicidal ideation.

Sexually active women of childbearing potential should be established on a contraceptive programme before taking modafinil.

Whilst studies with modafinil have demonstrated a low potential for dependence, the possibility of dependence with long-term use cannot be entirely excluded.
Serious rash, including Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Rash with Eosinophilia and Systemic Symptoms: Serious skin rashes requiring hospitalization and discontinuation of treatment have been reported in adults and children in association with the use of modafinil occurring within 1 to 5 weeks after treatment initiation [isolated cases have been reported after prolonged treatment (e.g. 3 months)]. Modafinil should be discontinued at the first sign of rash and not restarted unless the rash is clearly not drug – related

SIDE EFFECTS
Below are some of the more common side effects. Please note that this list is NOT exhaustive and that it is recommended that the SPC and BNF should be consulted for a more comprehensive list : - decreased appetite, nervousness, insomnia, anxiety, depression, abnormal thinking, confusion, headache, dizziness, somnolence, paraesthesia, blurred vision, tachycardia, palpitation, vasodilatation, abdominal pain, nausea, dry mouth, diarrhoea, dyspepsia, constipation, asthenia. Patients with excessive sleepiness, including those taking modafinil should be frequently reassessed for their degree of sleepiness and, if appropriate, advised to avoid driving or any other potentially dangerous activity.

COMMON / SIGNIFICANT DRUG INTERACTIONS
There is a low potential for drug-drug interactions. The SPC and BNF should be consulted for a more comprehensive list of potential drug interactions.
Modafinil accelerates the metabolism of oral contraceptives leading to reduced contraceptive effectiveness hence alternative or concomitant methods of contraception are recommended. Adequate contraception will require continuation of these methods for two months after stopping modafinil
In view of the enzyme inducing potential of modafinil, care should be taken when co-administering with anti-convulsants.
The clearance of warfarin may be decreased – prothombin times should be monitored regularly during the first two months and after changes in modafinil dosage.
Blood levels of ciclosporin may be reduced.

PRODUCT INFORMATION
Modafinil is available as a generic 100mg and 200mg tablet.

REFERENCES

- Summary of Product Characteristics http://emc.medicines.org.uk/
- British National Formulary www.bnf.org.uk

CONTACTS **(in hours)**
- RCHT medicine information: 01872 252587

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AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of patients who are prescribed modafinil can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Specialist:

- To assess the patient and establish/confirm the diagnosis of hypersomnia, ensuring the suitability of the patient for modafinil.
- To undertake or arrange a baseline electrocardiogram before treatment initiation. Patients with abnormal findings should be further evaluated by specialists before modafinil treatment can be initiated.
- Prescribe modafinil until GP formally agrees to shared care, then transfer prescribing ensuring patient has 4 weeks supply.
- Review of treatment to assess benefit e.g. an annual review by a Consultant Sleep Specialist, after GP has taken over the prescribing.
- At least every 12 months, a healthcare professional with specialist expertise in Parkinson's disease should review people with Parkinson's disease who are taking modafinil
- Stop treatment at any appropriate time.
- Ensure clear arrangements for back-up advice and support.
- Reporting adverse events to the MHRA.

General Practitioner:

- Reply to request for shared care as soon as practical.
- Prescribing following stabilisation of patient
- Blood pressure and heart rate should be monitored after one to two months of treatment, and then regularly annually, or more frequently if there are significant risk factors. Modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension and not restarted until the condition has been adequately evaluated and treated.
- Consider discontinuing if psychiatric symptoms develop in association with modafinil treatment and not restarting OR consider discussing with Neurology Team / Psychiatry.
- Discontinue at the first sign of serious drug related rash and not restart.
- Monitoring adverse effects and potential drug interactions and reporting to specialist as appropriate.
- Reporting adverse events to MHRA.
- Stopping treatment in the case of a severe adverse event or as per shared care guideline.

Patient:

- Patients should be advised that modafinil is not a replacement for sleep and good sleep hygiene should be maintained.
- Report any adverse effects to their GP and/or specialist whilst being treated with modafinil.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM

3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	No specific tool
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Medicines Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Relevant Clinical Staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Shared Care Guideline for Modafinil					
Date Issued/Approved:	September 2017					
Date Valid From:	September 2017					
Date Valid To:	11 November 2020					
Directorate / Department responsible (author/owner):	Neurology Team M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT					
Contact details:	01872 253548					
Brief summary of contents	Some clinical issues and details of prescribing responsibilities for GP and specialists					
Suggested Keywords:	Shared care					
	RCHT	✓	CFT		KCCG	✓
Executive Director responsible for Policy:	Medical Director					
Date revised:	September 2017					
This document replaces (exact title of previous version):	Shared care guideline for modafinil					
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee					
Divisional Manager confirming approval processes	Not required					
Name and Post Title of additional signatories						
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			
Document Library Folder/Sub Folder	Clinical / Pharmacy					
Links to key external standards	None					
Related Documents:	None					
Training Need Identified?	No					

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
Sept'14	V2.0	Updated to comply with latest RCHT format	M Wilcock
Sept'17	V2.1	Slight text alteration	M Wilcock

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This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

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Appendix 2.Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as *policy)* to be assessed: Shared care guideline for modafinil	
Directorate and service area: Pharmacy	Is this a new or existing Procedure? Existing
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow	Telephone:01726 627953

1. Policy Aim*	To provide information on prescribing of modafinil to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives*	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. Policy – intended Outcomes*	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
5. How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
5. Who is intended to benefit from the Policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.
6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b. If yes, have these groups been consulted? c. Please list any groups who have been consulted about this procedure.	No Cornwall & IoS Area Prescribing Committee

7. The Impact
Please complete the following table.

Are there concerns that the policy **could** have differential impact on:

Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	
Sex (male, female, trans-gender / gender reassignment)		✓	
Race / Ethnic communities /groups		✓	

Disability - learning disability, physical disability, sensory impairment and mental health problems		✓	
Religion / other beliefs		✓	
Marriage and civil partnership		✓	
Pregnancy and maternity		✓	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**	**No** ✓

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director	Date of completion and submission

Names and signatures of members carrying out the Screening Assessment	1. Dan Thomas 2. Mike Wilcock	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____ Dan Thomas and Mike Wilcock _____

Date _____ Sept 2014 _____