Shared Care Guideline: Prescribing Agreement Modafinil for Narcolepsy in adults

Section A: To be completed by the hospital consultant initiating the treatment

GP Practice Details:	**Patient Details:**
Name: ……	Name: ……
Address: ……	Address: ……
Tel no: ……	DOB: ……/……/……
Fax no: ……	Hospital number: ……
NHS.net e-mail: ……	NHS number (10 digits): ……

Consultant name: ……
Clinic name: ……
Contact details:
Address: .....
Tel no: …… Fax no: ……
NHS.net e-mail: ……

Diagnosis:	**Drug name & dose to be prescribed by GP:**
……	……

Next hospital appointment: ……/……/……..

Dear Dr. ……..,
Your patient was seen on …../…../……and I have started …….(insert drug name and dose) on (insert date) for the above diagnosis. I am requesting your agreement to sharing the care of this patient from …../…../…….. in accordance with the (attached) Shared Care Prescribing Guideline (approval date: …./…./……..). Please take particular note of Section 2 where the areas of responsibilities for the consultant, GP and patient for this shared care arrangement are detailed.

Patient information has been given outlining potential aims and side effects of this treatment and ……* supplied *(* insert any support materials issued such as patient held monitoring book etc where applicable).* The patient has given me consent to treatment possibly under a shared care prescribing agreement (with your agreement) and has agreed to comply with instructions and follow up requirements.

The following investigations have been performed on ……/……/…… and are acceptable for shared care.
Please monitor…….....every ……..

Test	**Result**	**Test**	**Result**
ECG			
Blood Pressure			
Heart Rate			

Other relevant information: ……..
……..

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above

Please sign and return your agreement to shared care within 14 days of receiving this request
Tick which applies:
□ I accept sharing care as per shared care prescribing guideline and above instructions
□ I would like further information. Please contact me on:…….
□ I am not willing to undertake shared care for this patient for the following reason:
……

GP name: ……

GP signature: ……Date: …/…/…..

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SHARED CARE PRESCRIBING GUIDELINE

MODAFINIL FOR NARCOLEPSY IN ADULTS

NOTES to the GP

The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing this drug.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your PCT pharmacist will assist you in making decisions about shared care.

It would not normally be expected that a GP would decline to share prescribing on the basis of cost.

The patient's best interests are always paramount

Date prepared: 30.04.2012	**Review date:** 06.07.2014
Approved by (date approved): Croydon Prescribing Committee 06 Jul 2012	

This shared care prescribing guideline has been signed off by the following individuals on behalf of their respective organisations:

Participating Primary Care Trusts	Participating Hospital Trusts
Croydon PCT **Eileen Callaghan, Chief Pharmacist**	**Croydon Healthcare Services** **Dr Bridget Macdonald, Consultant Neurologist** **Gideon Kotey, Acting Chief Pharmacist**

SHARED CARE PRESCRIBING GUIDELINE – MODAFINIL

MODAFINIL (Provigil®) For narcolepsy in adults

1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case and the hospital will continue to provide prescriptions until successful transfer of responsibilities as outlined below.
- The hospital will provide the patient with a minimum initial supply of 8 weeks therapy.

2. AREAS OF RESPONSIBILITY

Consultant

- Diagnosis, investigations and initiation of treatment
- Undertake ECG in all patients before treatment is initiated
- Dose adjustment according to response and stabilization of dose
- Prescribe Modafinil for at least 8 weeks and transfer prescribing when the GP formally agrees to shared care, ensuring that the patient has sufficient supply during the transfer period.
- Review to assess benefit at least yearly and make dosage adjustments where necessary
- Stop treatment if appropriate

GP

- Prescribing following stabilisation of the patient
- Make dosage adjustments on recommendation of the consultant
- Monitor blood pressure and heart rate
- Monitor patient's overall health and wellbeing
- Monitor adverse effects and potential drug interactions and report to the consultant where appropriate
- Refer back to consultant if concerned about the patient's condition

Patient

- Report any adverse effects to the specialist or GP
- Inform the specialist or GP if they do not have a clear understanding of their treatment
- Share any concerns they have in relation to Modafinil treatment

3. COMMUNICATION AND SUPPORT

Hospital contacts:
(the referral letter will indicate named consultant)

Croydon Healthcare Services
Neurology Department
Dr Fred Schon
Tel: Direct line (020) 8401 4003

Dr Bridget Macdonald
Tel: Direct line (020) 8401 3098
Fax: Direct Fax (020) 8401 3570
E-mail: bridget.macdonald@nhs.net

Out of hours contacts & procedures:

Switchboard
Tel: (020) 8401 3000
On call registrar

Specialist support/resources available to GP including patient information:

SHARED CARE PRESCRIBING GUIDELINE – MODAFINIL

4. CLINICAL INFORMATION

Indication(s):	Excessive sleepiness in adults 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 Contra-indicated in pregnancy & breast feeding, in children, moderate to severe uncontrolled hypertension, history of left ventricular hypertrophy, chest pain, arrhythmia or other manifestations of mitral valve prolapse in association with CNS stimulant use (including ischaemic ECG changes, chest pain and arrythmias) Patients with major anxiety should receive treatment in a specialist unit Sexually active women of child bearing potential should be established on a contraceptive programme before taking modafinil. Modafinil should be used with caution in patients with a history of: Psychosis, depression, or mania Abuse of alcohol, drugs or illicit substances.
Place in Therapy:	Treatment should be initiated by or under the supervision of a physician with appropriate knowledge of indicated disorders A diagnosis of narcolepsy should be made according to the International Classification of Sleep Disorders (ICSD2) 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. Patient monitoring and clinical assessment of the need for treatment should be performed on a periodic basis. Physicians prescribing modafinil for an extended time should periodically re-evaluate the long-term use for the individual patients as the long-term efficacy of modafinil has not been evaluated (> 9 weeks).
Therapeutic summary:	Modafinil promotes wakefulness in patients with narcolepsy. The precise mechanism is unknown
Dose & route of administration:	Adults over 18 years: initially 200mg daily either in two divided doses or as a single dose in the morning. Dose adjusted according to response to 200-400mg daily in 2 divided doses or as a single dose. Elderly: Initiate at 100mg daily Doses should be halved in patients with severe hepatic failure (100-200mg daily). Inadequate information to determine safety and efficacy of dosing in patients with renal impairment Not licensed for use in children. **Modafinil should not be used in children aged less than 18 years old because of safety and efficacy concerns**
Duration of treatment:	Long-term

SHARED CARE PRESCRIBING GUIDELINE – MODAFINIL

Summary of adverse effects: *(See summary of product characteristics (SPC) for full list)*	**Adverse effect**	**Frequency**	**Management**
	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).	0.8% in paediatric patients (age <17 years). No serious skin rashes have been reported in adult clinical trials. Rare report in post marketing surveillance	Modafinil should be discontinued at the first sign of rash and not re-started. Immediate referral back to hospital. Do not restart treatment.
	Multi-organ hypersensitivity reaction 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.	Rare	Modafinil should be discontinued and not restarted. Immediate referral back to hospital
	Psychiatric disorders Patients should be monitored for the development of *de novo* or exacerbation of pre-existing psychiatric at every adjustment of dose and then regularly during treatment.	Rare	If psychiatric symptoms develop in association with modafinil treatment, modafinil should be discontinued and not restarted. Refer to hospital
	Arrhythmia or moderate to severe hypertension	Uncommon	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.
Other Common adverse Effects:	Headache Dizziness, somnolence, paraesthesia Decreased appetite Nervousness, insomnia, anxiety, depression, abnormal thinking, confusion Blurred vision Tachycardia, palpitation Vasodilatation Abdominal pain, nausea, dry mouth, diarrhoea, dyspepsia, constipation Rash, pruritis		
Investigations to note:	Common: abnormal liver function tests, dose related increases in alkaline phosphatase and gamma glutamyl transferase have been observed. Uncommon: abnormal ECG, weight increase, weight decrease		

SHARED CARE PRESCRIBING GUIDELINE – MODAFINIL

Monitoring Requirements:	Consultant Monitoring An ECG is recommended in all patients before modafinil treatment is initiated. ECG will be carried out by the initiating hospital and the results assessed by the hospital specialist before treatment with modafinil is initiated. Patients with abnormal findings should receive further specialist evaluation and treatment before modafinil treatment is considered. Consultant will review to assess benefit at least yearly. GP Monitoring Blood pressure and heart rate should be regularly monitored in patients receiving modafinil. 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. Consultant and GP Monitoring o Patients should be monitored for the development of *de novo* or exacerbation of pre-existing psychiatric at every adjustment of dose and then regularly during treatment. o Patients with abnormal levels of sleepiness who take modafinil should be advised that their level of wakefulness may not return to normal. 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. Undesirable effects such as blurred vision or dizziness might also affect ability to drive.
Clinically relevant drug interactions:	Modafinil accelerates the metabolism of oral contraceptives leading to reduced contraceptive effectiveness. If used, a product containing 50mcg or more of ethinyloestradiol should be taken. 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 – prothrombin time should be monitored regularly during the first 2 months and after changes in modafinil dosage Blood levels of ciclosporin may be reduced.
Practical issues:	
Key references:	SPC Modafinil June 2011 MHRA Drug Safety Update Volume 4, Issue 8 March 2011 Modafinil (Provigil): information to support safer use; now restricted to narcolepsy