Shared Care Guideline: Prescribing Agreement Modafinil for Narcolepsy in Adults

Section A: To be completed by the hospital Consultant initiating the treatment. All sections must be completed in full.

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 and 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: …/…/…..

Kingston Hospital NHS
NHS Trust

SHARED CARE PRESCRIBING GUIDELINE

MODAFINIL FOR NARCOLEPSY IN ADULTS

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: 14th January 2013	Review date: 14th January 2015
Approved by (date approved): Drug and Therapeutics Committee, Kingston Hospital NHS Trust (22nd Jan 2013) NHS Kingston Medicines Management Committee (7th Feb 2013)	

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
NHS Kingston: Seema Buckley, Chief Pharmacist Dr Jonathan Edwards, GP on behalf of Kingston Medicines Management Committee	Kingston Hospital NHS Trust: Derek Cock, Chief Pharmacist Dr Al-Memar, Consultant Neurologist

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 *(include follow up and monitoring arrangements, details to provide to GP, communication with GP, provision of patient information etc)* 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 *(include monitoring arrangements and indicate when and how to refer back to consultant etc.)* Prescribing following stabilization of the patient Make dosage adjustments on recommendation of the consultant Monitor blood pressure and heart rate 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 *(include attendance for follow up appointment, any tests, keeping record books and showing this to relevant HCP etc)* 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) **Kingston Hospital Switchboard Tel 0208 546 7711** Dr Ali Al-Memar Dr Saleh Omer Dr Jeremy Isaacs Dr Dora Lozsadi Tel: Ext 3690	**Out of hours contacts & procedures:** **Please contact Kingston Hospital Switchboard**

Specialist support / resources available to GP including patient information:

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 hypertension, history of left ventricular hypertrophy, cor pulmonale, chest pain, arrhythmia or other manifestations of mitral valve prolapse in association with CNS stimulant use 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: *(for using drug locally in relation to other treatment options, e.g. 2nd line)*	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: *(Brief description of drug's effects)*	Modafinil promotes wakefulness in patients with narcolepsy. The precise mechanism is unknown
Dose & route of administration:	**Adults over 18**: initiate at 200 mg daily. The total daily dose may be taken as a single dose in the morning or as two divided 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 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

Summary of adverse effects: *(See summary of product characteristics (SPC) for full list)* *(include incidence, identification, importance and management)*	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		

Monitoring Requirements	<u>Consultant Monitoring</u> 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. <u>GP Monitoring</u> Blood pressure and heart rate should be regularly monitored in patients receiving Modafinil (as outlined in the patient specific prescribing agreement). 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. <u>Consultant and GP Monitoring</u> • 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. • 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. <u>Investigations</u> 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
Clinically relevant drug interactions: *(include management of drug interactions)*	Modafinil accelerates the metabolism of oral contraceptives leading to reduced contraceptive effectiveness. Change to an alternative method unaffected by enzyme-inducing drugs. Alternatively if used, a product containing 50mcg or more of ethinyloestradiol should be taken. An extended or tricycling regimen and pill-free interval of 4 days is also recommended. Co-administration of potent inducers of CYP activity, such as carbamazepine and phenobarbital, could reduce the plasma levels of modafinil. Clearance of phenytoin may be decreased when modafinil is administered concomitantly. Patients should be monitored for signs of phenytoin toxicity, and repeated measurements of phenytoin plasma levels may be appropriate upon initiation or discontinuation of treatment with modafinil. 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: *(e.g. storage and reconstitution instructions if applicable)*	
Key references:	These guidelines have been adapted from joint Croydon University Hospital and NHS

	Croydon shared care guidelines produced on 30.04.2012 SPC Modafinil (Provigil® 100mg/200mg) (last updated on September 2012) SPC Modafinil 100mg tablets (last updated on October 2012) MHRA Drug Safety Update Volume 4, Issue 8 March 2011 Modafinil (Provigil): information to support safer use; now restricted to narcolepsy BNF 64 September 2012 Faculty of Sexual and Reproductive Healthcare Guidance. Drug interactions with hormonal contraception: Clinical effectiveness Unit, January 2011.