South West Yorkshire Area Prescribing Committee

Modafinil

- for use in the treatment of adults with excessive sleepiness associated with narcolepsy (with or without cataplexy), and excessive sleepiness (difficulty maintaining wakefulness and an increased likelihood of falling asleep in inappropriate situations)

Introduction	
General Statements	• That the responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and general practice notes. • Modafinil should be initiated in secondary care under specialist supervision. Once the patient's dose has been titrated to the optimum dose they may be considered suitable for shared care between the neurologist and the primary care prescriber. • Agreement of primary care prescriber must be sought before seeking patient agreement for shared care. • The primary care prescriber must reply in writing to the request for shared care within two weeks if unwilling to participate. • Patients receive supplies of drug from hospital until shared care is agreed. • That the agreement to consider the use of a shared care guideline is only undertaken when the patient's clinical condition is stable or predicatable, and there has been an effective response to therapy. • Be mindful of the abuse potential of this medicine. The full summary of product characteristics (SPC) should be read before prescribing.
Indication	• 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. • 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).
Criteria for prescribing	• Patients where fatigue is affecting their quality of life significantly, particularly those who work. • Patients who fail to respond to conservative measures like adjusting their activities in a way that will allow them to function within acceptable limits, i.e. patients will be advised to sleep early and well through the night if they are working in the morning, and obviously if they are doing evening shifts then they will be advised to sleep before they go to work etc. • If the more commonly used drug, amantadine, failed to make a difference to the patient's fatigue. • History of other medication which may be contributing to fatigue (subject to the indications above). • If the patient does not show a response to this medication in around 4 to 8 weeks it is unlikely that they will show much improvement after that and the drug can be discontinued. In some cases where the situation is not clear the drug can be continued for up to three months before withdrawal or continuation can be decided upon.

Modafinil

Individuals Responsibilities	
Hospital Specialist's Responsibilities	• Prescribing until treatment has been established and effective (usually 4-8 weeks). • Baseline monitoring of clinical parameters • Discussion of risks and benefits of medication with patients and carers • Sexually active women of child bearing potential should be established on a contraceptive programme • Communication to primary care prescriber of treatment regime, monitoring to be done and criteria for referral
Primary Care Prescriber's Responsibilities	• Continued discussion of risks and benefits with patients and carers as required • Prescribing once maintenance dose established • Continued monitoring as agreed with secondary care and referral back to secondary care if clinically indicated. • To respond to adverse drug reactions
Monitoring Required	No specific monitoring required, except that patients should periodically be assessed for clinical need to continue treatment
When and How to Discontinue Treatment	• Patients in whom the drug does not make a significant difference to their symptoms • Patients who develop any significant side-effects to the drug. • Patients in whom any medical condition or state occurs that will contra-indicate using this drug, i.e. pregnancy, high blood pressure, arrhythmia etc. • If the patient is on a high dose of the drug, around 400mg, this can be tailed off over a period of two to four weeks. People who have just started the treatment can stop it immediately if they develop early adverse reactions. Smaller doses can be stopped immediately.
Information given to the patient	• The patient will be involved in the choice of medication and verbal information given. • A patient information leaflet will be given to the patient with the medication.
Contact Details	To be included in specialist's letter

Product Information	
The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics	
Dosage	• The recommended daily dose is 200-400mg, commencing at 200mg and titrated according to clinical response. Modafinil may be taken as two divided doses in the morning and at noon, or as a single dose in the morning. • Elderly – initial dose should be 100mg daily. The maximum dose of 400mg daily should only be used in the absence of hepatic or renal impairment.
Adverse Effects	• Refer to the current BNF and www.medicines.org.uk/emc/
Precautions and Contra-indications	• Refer to the current BNF and www.medicines.org.uk/emc/
Clinically relevant Drug Interactions and their management	• Refer to the current BNF and www.medicines.org.uk/emc/