Full SHARED CARE AGREEMENT FOR

MODAFINIL

for use in

Daytime Sleepiness associated with Narcolepsy

Prepared by:
Dr Andrew Hall, Consultant in Sleep Disorders Medicine
Helen Knight, Acting Directorate Lead Pharmacist, ACCP

Updated by:
Dr Andrew Hall, Consultant in Sleep Disorders Medicine
Helen Hardman, Leicestershire Health Community Interface Pharmacist

On behalf of:
East Leicestershire and Rutland Clinical Commissioning Group
Leicester City Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
Leicestershire Partnership NHS Trust
University Hospitals of Leicester NHS Trust

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Additional medicines information is available from:
Trent Medicines Information Centre
Victoria Building, Leicester Royal Infirmary, LE1 5WW
Tel: 0116 255 5779 / 0116 258 6491
Fax: 0116 258 5680 e-mail: medicines.info@uhl-tr.nhs.uk
Full Shared Care Agreement for the prescribing of Modafinil in the treatment of daytime sleepiness associated with narcolepsy

Introduction and purpose
This shared care agreement has been produced following classification of Modafinil in the Leicestershire drug traffic light scheme.

Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out these responsibilities from initial diagnosis to ongoing support.

Drug indications covered by the agreement
Modafinil is not a typical stimulant. It is often described as a “wakefulness promoting agent” and has been classed as a memory-improving and mood-brightening psychostimulant.

Modafinil is licensed for the treatment of daytime sleepiness associated with narcolepsy.

Modafinil should not be used in patients with uncontrolled hypertension, cardiac arrhythmias or in women who are pregnant or breastfeeding.

Modafinil should be discontinued and not restarted in cases of: serious skin or hypersensitivity reactions or psychiatric disorders such as suicidal ideation.

The licensed dose is 200mg, taken shortly after waking, which may be increased up to 400mg per day if necessary. In exceptional circumstances, doses more than 400mgs per day are used. The total daily dose can be divided over two doses throughout the day. This can maintain effectiveness and reduce the incidence of side effects. However, the second dose should not be taken so late that it impacts upon normal planned sleep.

Disease Background

Narcolepsy is a rare (1: 50,000) disorder of sleep. It is neurological disorder marked by uncontrolable attacks of daytime sleepiness and also quite often characterised by cataplexy (sudden loss of muscle power triggered by emotion). Modafinil is the drug of choice used to treat sleepiness and cataplexy is usually treated with clomipramine, an SSRI or an SNRI e.g. venlafaxine (unlicensed indication). Some patients with more marked narcolepsy benefit from treatment with Sodium Oxybate (Xyrem®, which should only be prescribed following specialist advice)
Secondary Care Clinician Responsibilities

- Diagnosis of the cause of hypersomnia (idiopathic hypersomnia, narcolepsy or narcolepsy with cataplexy based on a timely and comprehensive assessment and potentially an investigation including PSG and MSLT).
- 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.
- Modafinil is first line treatment in narcolepsy.
- Initiation of prescription of modafinil for a one-month trial.
- Titration of modafinil dose to the optimum level for control of symptoms jointly with the General Practitioner involving discussion with the patient if necessary.
- Monitoring for response and adverse drug reactions (ADRs) during the initiation period.
- Ask the general practitioner (GP), using the Shared Care Request Form, to share the patient’s care when a stable dose has been achieved and proven benefit has been established.
- Propose an annual review by a Consultant Sleep Specialist, after GP has taken over the prescribing, to monitor progress.
- Evaluating ADRs raised by the GP and evaluating any concerns arising from physical checks and reviews undertaken by GP.
- Advising GP on related issues such as drug interactions and use in pregnancy.

GP Responsibilities

- Consider request to share patient’s care as soon as possible, and contact the specialist in cases of concern. Return the agreement form if the shared care request is declined.
- Blood pressure and heart rate should be monitored every six months 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.
- Observing the patient for evidence of ADRs or any abnormalities and raising with the secondary care clinician if necessary.
- Providing prescriptions of modafinil to maintain the optimum level for control of symptoms after establishment by secondary care and liaising where necessary.
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status.
- Reducing and stopping treatment in line with secondary care clinician’s request.

Contact for support and advice

Consultant Sleep Specialists:

Dr Andrew Hall (andrew.p.hall@uhl-tr.nhs.uk)

Dr Philippa Graff-Baker (philippa.graffbaker@uhl-tr.nhs.uk)

LGH Phone number: 0116 258 4659

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### Supporting Information: Modafinil **Summary of Product Characteristics**

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<td>Brand name removed as generic available</td>
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<td>BP and HR monitoring clarified as required every six months</td>
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