Acute Services Division
Diagnostics Directorate

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Clinical Lead: Dr Rosemarie Davidson

Please quote this reference in all correspondence
Our ref: CHI: XXXXXXXXXXXX

Dear Doctor,

Re: <Patient Name>; CHI XXXXXXXXXXXXXXX

If you would have no objections, I would be very grateful if you might prescribe modafinil 200mg mane for this patient.

During the recent attendance of your patient <Patient name> at our Myotonic Dystrophy Management Clinic, it was noted that symptoms of excessive daytime sleepiness (EDS) are having a significant impact on their daily functioning. <Patient name> appears to meet our eligibility criteria to trial the drug modafinil to treat this symptom, and I am therefore writing to ask for your co-operation in initiating this.

As you may be aware, the causes of excessive in myotonic dystrophy are complex. Peripheral muscle weakness, leading to sleep disordered breathing and apnoeas, can be a contributory factor. However, it is also recognised that a primary effect of the disease on the brain results in a central component to sleepiness symptoms. Treatment options for 'central' sleepiness are extremely limited, although the wakefulness-promoting drug modafinil has been utilised for many years, with patients frequently reporting considerable symptomatic improvement (Hilton-Jones *et al. Neuromuscular Disorders* 2012;**22**:597-603).

In the UK, modafinil is licensed only for the treatment of narcolepsy with or without catalepsy. The lack of large, randomised control trial data to support its use in myotonic dystrophy mean that prescription in this context is thus considered "off-label".

We have discussed the "off label" status of this drug with the patient. While our local experience is of the drug generally being very well tolerated, there is some evidence to suggest that it may have a stimulatory effect on heart rate and blood pressure. Given that myotonic dystrophy itself can predispose to cardiac conducting system disease, we would plan to monitor the patient intermittently during the initiation period with ECG and blood pressure monitoring as outlined in the guideline enclosed.

We will take responsibility through the Myotonic Dystrophy Management Clinic for monitoring of ECG and blood pressure during the initiation period. We will also co-ordinate the longer term monitoring through cardiology and respiratory services as outlined in the guideline. Your patient is aware that, should they fail to engage with the monitoring and follow up process, we would contact you to recommend that prescription of modafinil be discontinued.

If you wish to discuss any aspect of this letter please do not hesitate to contact me. Many thanks for your support in sharing the care of <patient name>.

Yours sincerely,

Addendum:

Further information regarding modafinil can be found at:
https://www.medicines.org.uk/emc/medicine/27040

Further information regarding the European Medicine Agency's Recommendations can be found at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Modafinil/human_referral_000236.jsp