Northern (NHS) Treatment Advisory Group

Pitolisant for Narcolepsy Treatment Pathway

- Patients diagnosed with narcolepsy (aged 18 and over) will normally receive Modafinil as a first line treatment for excessive sleepiness, provided there are no contraindications.
- When Modafinil is not effective or tolerated, dexamfetamine/methylphenidate will be considered as the main second line option, provided there are no contraindications.
- If dexamfetamine/methylphenidate treatment is not effective or tolerated, Pitolisant will be considered as a third line option, provided there are no contraindications.
- Nacroleptic patients with residual severe daytime sleepiness who have an Epworth score of 14 or over should be eligible to Pitolisant if they have already tried modafinil and dexamfetamine or methylphenidate, and where therapy will make a substantial difference to their quality life.
- Patients with resistant narcolepsy are often unable to study effectively or work in sedentary occupation that involves typing or computer work, for example, and use of pitolisant would be expected to significantly improve or even allow this type of activity. Improvement in social activities, such as being able to watch a film all the way through, is also something that is reviewed in clinic.
- Ineffective or non-tolerated treatments should be stopped prior to the commencement of pitolisant.
- Clinician experience suggests that patients may also benefit from/need an additional low dose amphetamine taken flexibly as a “rescue” therapy i.e. Pitolisant would give them background improved alertness through the day but for a drive or a meeting, for example, many would normally take an amphetamine dose to give them an hour or two of increased wakefulness/alertness.
- Patients with significant pre-existing medical conditions such as uncontrolled hypertension, history of stroke, TIA, myocardial infarction, coronary artery disease or severe depression, bipolar disorder, treatment resistant epilepsy for whom Modafinil, dexamphetamine, methylphenidate are contraindicated, will be offered Pitolisant.
- Patients who developed severe allergic reaction or other significant adverse effects to Modafinil, dexamfetamine, methylphenidate or Sodium Oxybate, will be offered Pitolisant.
- Pregnant and breastfeeding women, women of childbearing age who are actively trying to become pregnant and not using adequate contraception will not be offered Pitolisant.
- Children under age 16 will not be offered Pitolisant since the medication is not licenced for use in children.
- Prescription of this medication will be limited to Sleep Centres with adequate expertise in managing narcolepsy and using this medication : The James Cook University Hospital, Department of Sleep Medicine (Dr Paul Reading and Dr Adrienn Petreczky) and Royal Victoria Infirmary (Dr Kirstie Anderson)
- Eligible patients will be given a month’s trial of Pitolisant at 18mg a day with a view to increasing to 36mg a day for a further month if there has been a partial response as assessed

by a reduction in Epworth score. After a two month trial of Pitolisant patients will be reviewed and Pitolisant will only be continued with there has been an improvement in quality of life and the patient has an Epworth score less than 10.

- In the absence of clear and objective improvement in narcolepsy then pitolisant should be discontinued.
- Prospective data will be collected about the use of this medication in each centre over the period of the following 12 months as a part of the audit cycle and submitted to NTAG to provide evidence for safety and potential cost efficacy. It will also monitor adherence to prescription guidelines.