Northern Treatment Advisory Group

Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults - Appeal

This document should be read in conjunction with the NICE ESNM on pitolisant for a summary of the clinical evidence

Backgound

NTAG agreed at November 2017 meeting that there were grounds for appeal on the NTAG recommendation from June 2017 not recommending the use of Pitolisant on the following basis:

- Additional information had been presented suggesting a pathway for use which was not available previously.
- Costings considered by NTAG may not reflect proposed place in therapy in the North East & Cumbria, and give a true reflection of potential patient numbers.

The group agreed to seek further information from the specialists at James Cook and the RVI, and seek a regional consensus on the use of pitolisant to come back to the February 2018 NTAG meeting for the appeal to be discussed in full.

Proposed Pathway

Both the RVI and James Cook clinicians are in agreement with the pathway suggested by James Cook in their appeal letter:

- 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.
- 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 and Royal Victoria Infirmary.
- 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.

Prior to the NTAG recommendation of June 2017 both the North of Tyne & Gateshead APC (April 2016) and the South Tees Hospitals NHS Foundation Trust D&T (July 2015) had approved the addition of Pitolisant to their respective formularies as a RED drug for use in patients with narcolepsy who experience psychomotor side effects with modafinil and dexamfetamine.

Cost analysis

The revised estimated cost impact based on the number of patients currently treated in the NE&C is £431k pa.

Pitolisant is not a tariff excluded drug or NHSE commissioned drug.

Cost analysis – summary
The original NTAG cost analysis appears to have over-estimated the potential cost impact in the NE&C since it did not account for patients discontinuing treatment after an initial trial.

Current prescribing data shows that there is very little prescribing of pitolisant in primary care and gives assurance that current RED status on South Tees and Newcastle Hospital formularies is being followed and complied with by specialists.