MTRAC
Midlands Therapeutics Review and Advisory Committee

Commissioning Support

Pitolisant *(Wakix®▼)*

For the treatment of narcolepsy with or without cataplexy (Type 1 and type 2 narcolepsy)

Commissioning guidance:

Commissioners may wish to bear the following in mind when considering the commissioning of pitolisant:

- That the Summary of Product Characteristics (SPC) advises that treatment should be initiated by a physician experienced in the treatment of sleep disorders.
- Specialist advice was that the initial diagnosis of narcolepsy should be confirmed at a tertiary sleep clinic. They were also of the opinion that pitolisant was a suitable option following treatment with methylphenidate or modafinil.
- Once the patient's condition and drug dose are stable a RICaD (Rationale for Initiation, Continuation and Discontinuation) or other locally agreed transfer of care protocol may be appropriate on discharge of the patient from the tertiary care clinic. The Summary of Product Characteristics (SPC) for pitolisant advises that, as long-term efficacy data are limited, the continued efficacy of treatment should be regularly evaluated by the physician.

Strength of the evidence for efficacy

The evidence for the efficacy of pitolisant was considered to be relatively weak. Pitolisant was shown to lower excessive daytime sleepiness more than placebo, but non-inferiority to modafinil, another standard treatment for this condition, was not proven. The rate of cataplexy attacks was also shown to be significantly lower with pitolisant treatment compared with placebo over seven weeks of treatment. The outcomes used in the trials were appropriate and patient-centred, but the duration of treatment in the trials (7 or 8 weeks) was short for a chronic condition. According to the European licensing report, longer term data were available up to 12 months from an uncontrolled open label study that suggested that efficacy (less daytime sleepiness) was maintained over this period.

MTRAC considered pitolisant because it was a new licensed product that primary care prescribers may be asked to prescribe.

References

1. Wakix 4.5 mg / 18mg film-coated tablets. EMC 2016 www.medicines.org.uk/emc/medicine/32397
2. Thorpy MJ, Dauvilliers Y. Clinical and practical considerations in the pharmacologic management of narcolepsy. Sleep Medicine 2015; 16:9-18.
3. Narcolepsy. NHS Choices 2016 http://www.nhs.uk/Conditions/Narcolepsy
4. Strambi LF. A need for new treatments in narcolepsy. Lancet Neurol 2013; 12(11):1039-1040.
5. Narcolepsy with or without cataplexy in adults: pitolisant. NICE 2017 www.nice.org.uk/advice/es8
6. Dauvilliers Y et al. Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. Lancet Neurol 2013; 12(11):1068-1075.
7. Szakacs Z et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomised, double-blind, placebo-controlled trial. Lancet Neurol 2017; 16(3):200-207.