Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	8th December 2020
Appraisal & Details	**Solriamfetol for obstructive sleep apnoea in adults.** The Northern (NHS) Treatment Advisory Group considered an appraisal of Solrimafetol for obstructive sleep apnoea (OSA) in adults.
Recommendation	**The Northern (NHS) Treatment Advisory Group <u>does not</u> currently recommend the use of Solriamfetol for obstructive sleep apnoea adults.** This recommendation was made taking into account the views of local clinicians because: • NTAG felt Solriamfetol offered no clinical or cost advantage over current treatment options for obstructive sleep apnoea to use ahead of a NICE technology appraisal being issued. • Concerns around safety (in particular cardiovascular safety) in this patient group. The group noted that NICE is due to issue a technology appraisal for Solriamfetol for obstructive sleep apnoea which when issued will supersede this NTAG recommendation.
Clinical evidence summary	Solriamfetol is a dopamine and noradrenaline reuptake inhibitor, but the mechanism of effect in OSA is not fully known. It is licensed at a dose of 37.5 mg, 75 mg or 150 mg daily to improve wakefulness and reduce EDS in adult patients with (OSA) whose sleepiness has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP). Solriamfetol was assessed in two phase III efficacy trials and one safety trial. TONES-3 found that solriamfetol treatment resulted in significant improvements in mean sleep latency time (MSLT) and Epworth sleepiness scale (ESS) scores compared to placebo. No minimum clinically important difference (MCID) has been established for the MSLT. Patients in all groups exceeded the MCID for the ESS, including those who received placebo. The pivotal trial was reasonably large (n=459) but due to testing of multiple doses some groups were small (e.g. n=58 in the 37.5 mg arm). The study was also short, with primary outcome assessment at 12 weeks. However, the longer safety study suggests that improvements in ESS scores are maintained over 40-52 weeks. The safety study had an open label design and used a subjective measure (the ESS) to assess efficacy. There are no other licensed pharmacological options for sleepiness associated with OSA, so there are no comparisons available. Solriamfetol appears to result in significant improvements in EDS symptom scores, but these do not always translate to improvements in quality of life.

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Safety	Across all clinical trials to date adverse effects (AEs) were more common with solriamfetol than placebo. The most commonly reported AEs were headache, nausea, decreased appetite, and anxiety. Cardiovascular events were more common with solriamfetol than placebo in people with OSA.
Patient Perspective	Solriamfetol is a dopamine and noradrenaline reuptake inhibitor, but the mechanism of effect in OSA is not fully known Current treatment includes lifestyle modification (e.g. weight loss, smoking cessation, reduced alcohol intake) and continuous positive airway pressure (CPAP) devices.
Cost analysis summary	The international prevalence of obstructive sleep apnoea syndrome is around 1-2%. People of any age can be affected but, in the UK, prevalence is around 2% in middle-aged women and 4% in middle aged men. An estimated 5% of people in the UK (over 2.5 million people) have undiagnosed obstructive sleep apnoea/hypopnoea.
Financial impact PbR: Tariff excluded	Solriamfetol is a CCG-commissioned a specified High Cost Drug (PBR-excluded). Solriamfetol costs £2,300-£3,200 per patient per year (based on NHS List price), depending on dose. The cost will be additive to current spend on CPAP.