

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	8 th December 2020
Appraisal & Details	<p>Solriamfetol for the treatment of narcolepsy with or without cataplexy in adults.</p> <p>The Northern (NHS) Treatment Advisory Group considered an appraisal of Solriamfetol for the treatment of narcolepsy with or without cataplexy in adults.</p>
Recommendation	<p>The Northern (NHS) Treatment Advisory Group recommends the use of Solriamfetol for the treatment of narcolepsy with or without cataplexy in adults as an alternative to Pitolisant in those who would have otherwise received Pitolisant.</p> <p>Solrimafetol or Pitolisant only to be considered as an option in narcoleptic patients with residual severe daytime sleepiness who have an Epworth score of 14 or over, if they have already tried modafinil and dexamfetamine or methylphenidate, and where therapy will make a substantial difference to their quality life.</p> <p>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. And to be used in line with an agreed regional pathway for the management of narcolepsy.</p> <p>This recommendation does not support the use of solrimafetol in combination regimens.</p> <p>In the absence of clear and objective improvement in narcolepsy then solrimafetol should be discontinued.</p> <p>The group noted that NICE is due to issue a technology appraisal for Solriamfetol for the treatment of narcolepsy which when issued will supersede this NTAG recommendation.</p>
Clinical evidence summary	<p>In a phase III trial, solriamfetol produced significant improvements in excessive daytime sleepiness and sleep latency times compared to placebo. There were no significant improvements in quality of life at the licensed doses, as measured by the Functional Outcomes of Sleep Questionnaire 10 item version. The trial was small, with less than 60 participants per arm, and short (12 weeks).</p> <p>An open label safety study enrolled participants who had previously completed a clinical trial of solriamfetol for narcolepsy or obstructive sleep apnoea. The study suggested that improvements in excessive daytime sleepiness were largely maintained over the 40-52 week treatment period.</p>
Safety	<p>Across all clinical trials 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, but this effect appears to be restricted to patients with OSA. There was one cardiovascular event leading to</p>

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

	<p>discontinuation in a patient with narcolepsy (palpitations). There were no serious events or adjudicated cardiovascular events in patients with narcolepsy.</p> <p>The safety and efficacy of solriamfetol in children and adolescents (<18 years old) have not yet been established.</p>
Patient Perspective	<p>Narcolepsy is a disabling sleep disorder characterised by excessive daytime sleepiness. Patients are often unable to stay awake or asleep for long periods of time. Around 70% of people with narcolepsy also have cataplexy, which is a sudden loss of muscle tone triggered by strong emotions. Episodes can last from seconds to minutes and occur with varying frequency.</p> <p>Patients will be pleased that there is another treatment option available for a difficult to treat condition. However they will also want to know that solriamfetol will be of benefit in the long term and that there are no long term adverse effects; there is currently insufficient published information available to confirm this.</p>
Cost analysis summary	<p>There are an estimated 500-1,700 patients with narcolepsy in the NTAG region, many of whom will be undiagnosed.</p> <p>Solriamfetol costs £2,300-£3,200 per patient per year, depending on dose. The cost impact of introducing solriamfetol will depend on the proposed place in therapy.</p>
Financial impact PbR: Tariff excluded Based on NHS List Price	<p>Solriamfetol is a CCG-commissioned a specified High Cost Drug (PBR-excluded).</p> <p>Each pack of 28 solriamfetol tablets costs £177.52 (75 mg) or £248.64 (150 mg), exclusive of VAT. The cost per patient varies with the required dose, ranging from £178 to £249 per 28 days (£2,308 to £3,232 per year) based on a daily dose of 75 mg to 150 mg.</p> <p>For comparison Pitolisant costs between £3761 to £7523 per patient per year depending on the dose.</p>