NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Solriamfetol for treating excessive sleepiness caused by narcolepsy

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of solriamfetol within its marketing authorisation for treating excessive waketime sleepiness caused by narcolepsy.

Background

Excessive waketime sleepiness (also known as hypersomnia) means people struggle to stay awake and alert during the day (or equivalent waking hours), leading to an irrepressible need to sleep or unintended lapses into drowsiness or sleep. People with excessive sleepiness are likely to fall asleep during the day (often while eating or talking), regularly nap during the day but wake up feeling unrefreshed, and still sleep for long hours at night. One cause of excessive sleepiness is narcolepsy [1]. Excessive sleepiness caused by narcolepsy can affect many aspects of daily life, including education, employment, driving, relationships and emotional health and general health.

Narcolepsy is a rare, disabling long-term brain disorder that causes a person to fall asleep at inappropriate times. It is estimated to affect at least 25,000 people in the UK, and is usually diagnosed between 20 and 40 years of age, although the symptoms often begin during adolescence. In people with narcolepsy, the brain is unable to regulate sleep and waking patterns normally, which can result in excessive daytime sleepiness, sleep paralysis, excessive dreaming, disturbed nocturnal sleep, sleep attacks (falling asleep suddenly and without warning) and cataplexy (temporary loss of muscle control resulting in weakness and possible collapse)[2].

Medicines used to treat the symptoms of narcolepsy include stimulants such as modafinil, dexamfetamine or methylphenidate, and sodium oxybate. Pitolisant is another treatment option for people with narcolepsy (NICE evidence summary 8). Some of these medicines are not licensed for the treatment of narcolepsy and they vary in the evidence available for their effectiveness in treating narcolepsy.

The technology

Solriamfetol (Sunosi, Jazz Pharmaceuticals) is a phenylalanine-derived, second-generation wake-promoting agent. Solriamfetol prevents the reuptake of dopamine and noradrenaline, and indirectly enhances dopaminergic and noradrenergic neurotransmission. It is administered orally.

Solriamfetol does not currently have a marketing authorisation in the UK. It has been studied in clinical trials compared with placebo in adults with narcolepsy or with obstructive sleep apnoea.

Intervention(s)	Solriamfetol
Population(s)	Adults with excessive waketime sleepiness caused by narcolepsy
Comparators	• Modafinil • Dexamfetamine (does not have marketing authorisation in the UK for this indication) • Methylphenidate (does not have marketing authorisation in the UK for this indication) • Sodium oxybate • Pitolisant
Outcomes	The outcome measures to be considered include: • excessive waketime sleepiness • adverse effects of treatment • length of life • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	**Related Technology Appraisals:** Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008).

	NICE Technology Appraisal 139. Review date: TBC. **Appraisals in development (including suspended appraisals)** Solriamfetol for treating excessive sleepiness caused by obstructive sleep apnoea. NICE technology appraisals guidance [ID1499]. Publication date to be confirmed. **Guidelines in development:** 'Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s'. Expected publication date, August 2020. **Related Interventional Procedures:** Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. NICE interventional procedures guidance 598. Soft-palate implants for obstructive sleep apnoea. NICE interventional procedures guidance 241. **Related Evidence Summaries:** Narcolepsy with or without cataplexy in adults: pitolisant. NICE evidence summary 8. **Related NICE Pathways:** Neurological conditions (2014) NICE pathway Respiratory conditions (2015) NICE pathway
Related National Policy	NHS England (2017) Next steps on the five year forward view NHS England (2018) Manual for prescribed specialised services 2018/19 Chapter 128 NHS England (2014) NHS Five year forward view Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domain 2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

References

1 NHS (2017) Excessive daytime sleepiness (hypersomnia). Accessed September 2018.

2 NHS (2016) Narcolepsy: overview. Accessed September 2018.