

Kent and Medway Policy Recommendation and Guidance Committee
Policy Recommendation

Policy:	PR 2015-22: Sodium oxybate for the treatment of narcolepsy with cataplexy in adults
Issue date:	December 2015
Review date:	December 2018
<p>The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, the baseline position, other CCGs' policies, evidence of safety, clinical- and cost-effectiveness and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account, the PRGC recommends that:</p> <ul style="list-style-type: none"> • Sodium oxybate¹ is not routinely funded for the treatment of adults with narcolepsy with cataplexy on the local NHS <p>This policy recommendation will be reviewed in light of new evidence or guidance from NICE. Clinical Commissioning Groups in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.</p>	

¹Sodium oxybate is listed as a High Cost Drug Exclusion (Payment by Results Exclusion).

Supporting documents

Health Care Intervention Appraisal and Guidance (HCiAG) team (2015) *Sodium oxybate for the treatment of narcolepsy with cataplexy in adults – Scoping report*

Equality Analysis Screening Tool – Sodium oxybate for the treatment of narcolepsy with cataplexy in adults (2015)

Key points and rationale

What is narcolepsy?

Narcolepsy is a chronic neurological condition producing disruption to the normal sleep pattern; excessive daytime sleepiness is the main symptom. Cataplexy is the second most common symptom of narcolepsy and the most specific one. Cataplexy is defined as a sudden loss of voluntary muscle tone with preserved consciousness triggered by emotion. The loss of muscle tone ranges from a just-perceptible weakening of the facial muscles through weakness at the knees, to total collapse on the floor. Cataplectic episodes can last just a few seconds or many minutes; frequency is extremely variable, from one or fewer per year to several per day.

What is sodium oxybate?

[Sodium oxybate](#) is a central nervous system depressant that is licensed for the treatment of narcolepsy with cataplexy in adults. It is the only licensed pharmacological treatment option considered to be effective in treating multiple symptoms of narcolepsy, including cataplexy.

What are the current treatment options?

There is currently no cure for narcolepsy with cataplexy; management relies upon lifestyle changes and symptomatic therapies. In addition to sodium oxybate, there are two pharmacological agents licensed for the treatment of patients with narcolepsy with cataplexy; clomipramine (a tricyclic antidepressant [TCA]) and modafinil (a central nervous system stimulant). However, these agents do not treat the whole condition, only single symptomatic aspects. Clomipramine is indicated for adjunctive treatment of cataplexy associated with narcolepsy. Modafinil is indicated in adults for the treatment of excessive sleepiness associated with narcolepsy with or without cataplexy. In addition, dexamfetamine is licensed for the treatment of narcolepsy but not cataplexy.

What does national and local guidance say?

There is no NICE guidance on the management of narcolepsy with cataplexy or on the use of sodium oxybate, and none is currently planned. The Scottish Medicines Consortium ([2007](#)) and the All Wales Medicines Strategy Group ([2008](#)) do not recommend the use of sodium oxybate within NHS Scotland or NHS Wales respectively, for the treatment of cataplexy in adults with narcolepsy.

There is currently no policy on the use of sodium oxybate in Kent and Medway. According to the summary of characteristics, sodium oxybate should be initiated by and remain under the guidance of a physician experienced in the treatment of sleep disorders.

What is the evidence base for sodium oxybate?

Randomised placebo-controlled trials have demonstrated that sodium oxybate reduces the symptoms of excessive daytime sleepiness and frequency of cataplexy attacks in patients with narcolepsy. There is a consistent dose-related trend with respect to the magnitude of effect, with higher doses generating greater responses than lower doses. The most commonly reported adverse reactions are dizziness, nausea and headache, all occurring in 10–20% of patients. There is no direct comparison between sodium oxybate and clomipramine, the only other licensed product for treatment of cataplexy in adults with narcolepsy. The impact of reported reductions in the frequency of cataplexy attacks on quality of life is unclear. No cost-effectiveness studies were identified but the Scottish Medicines Consortium concluded that the economic case has not been demonstrated.

What is the comparative cost of sodium oxybate?

Drug and dose	Cost per year
Sodium oxybate (9g nightly)	£13,149 excluding VAT
Sodium oxybate (6g nightly)	£8,766 excluding VAT
Clomipramine (10–75mg daily)	£20–£74 excluding VAT
Dexamfetamine (60mg daily)	£3,874 excluding VAT
Modafinil (200–400mg daily)	£1,281–£2,562 excluding VAT

Source: BNF on-line (accessed December 2015). These drugs do not have the same therapeutic effect as each other although they are used to treat symptomatic aspects of narcolepsy and cataplexy. Doses used do not imply therapeutic equivalence. Most participants (~80%) in clinical trials assessing sodium oxybate continued to take stimulant medications in addition to sodium oxybate.

What would be the cost impact of prescribing sodium oxybate across Kent and Medway?

The annual cost to Kent and Medway CCGs of formally commissioning sodium oxybate is estimated to range from £97,452 to £165,677, but could be higher as the precise size of the population suitable for treatment cannot be confidently predicted. The cost impact analysis considered local and epidemiological data as well as different doses of sodium oxybate.

Why is sodium oxybate not recommended for adults with narcolepsy with cataplexy on the local NHS?

There is no direct comparison between sodium oxybate and clomipramine, the only other licensed product for treatment of cataplexy in adults with narcolepsy, and the impact of reductions in cataplectic attacks on patient quality of life is unclear. It is unlikely that sodium oxybate at any dose would be considered cost effective versus standard treatment when assessed against conventional limits. Further, it is difficult to accurately estimate potential demand; commissioning this procedure may require considerable additional funding.