

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	6 th June 2017
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered a re-appraisal of Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients.
Recommendation	<p>The Northern (NHS) Treatment Advisory Group only recommends the use of sodium oxybate in adult patients who have received and benefited from treatment with sodium oxybate as commissioned by NHS England. i.e. continuing treatment for those >19 years old.</p> <p>The strict NHS England criteria for starting and stopping must continue to be followed.</p> <p>The use of sodium oxybate in new adult patients is not recommended.</p> <p>NETAG reviewed sodium oxybate in 2009 and did not recommend use, since it was considered unlikely to be cost effective. There is limited new evidence since that time.</p>
Clinical evidence summary	A meta-analysis and systematic review published in 2012 summarises all of the available randomised controlled trial evidence. The analysis demonstrates significant improvements in number of cataplexy attacks, wakefulness, number of sleep attacks and global clinician global impression of change associated with sodium oxybate against placebo. However, sample sizes for some comparisons were very small, and confidence intervals were wide in several cases, limiting the precision of these estimates of treatment effect.
Safety	<p>Adverse effects including gastrointestinal effects, dizziness and enuresis were more common with sodium oxybate than placebo.</p> <p>Discontinuation due to adverse effects occurred in 7-9% of patients</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>This recommendation means that children and young people who have shown benefit from sodium oxybate therapy will be able to continue this treatment into adulthood.</p>



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Cost analysis summary	<p>The cost of sodium oxybate varies with the dose, which ranges from 4.5 g to 9g daily. This results in an estimated cost per patient of £6,500 to £13,100 per year. Mean doses used in practice are likely to be in the middle of that range.</p> <p>No cost-effectiveness studies were found. The number of patients eligible for treatment with sodium oxybate is expected to be low. NHS England estimates that there are currently 10 children treated with sodium oxybate nationally.</p>
Financial impact PbR: Excluded.	<p>Sodium oxybate is currently protected by several active patents; however generics are expected to enter the market in Europe starting in January 2020 which may alter costs.</p>