

Sodium oxybate for narcolepsy with cataplexy

The routine commissioning of sodium oxybate is accepted in NHS Kernow Clinical Commissioning Group (NHS Kernow) for the treatment of narcolepsy with cataplexy in adults aged 19 years and over as follows:

- to allow continuation of treatment in individuals reaching 19 years old who had previously been successfully treated with sodium oxybate under the NHS England commissioning policy criteria (see below)
- in patients aged 19 years and older who meet equivalent criteria

The NHS England commissioning policy criteria for commissioning are as follows:

Inclusion criteria

Sodium oxybate will be prescribed for post-pubescent children (weighing greater than 40kg and less than or equal to 18 years old) where attempts to control symptoms of narcolepsy with cataplexy have failed despite a trial of first and second line medications from each symptom group for at least 3 months.

Specific inclusion criteria

- Patients who present with narcolepsy with cataplexy according to International Classification of Sleep Disorders 3 (ICSD) criteria; and
- Adequately treated co-morbid sleep disorders (such as obstructive sleep apnoea and restless legs syndrome) as assessed by polysomnogram; and
- Show incomplete response to trial of more than 1 medication from each symptom group:
 - Narcolepsy. First line: methylphenidate. Second line: dexamfetamine, lisdexamfetamine, modafinil and atomoxetine.
 - Cataplexy. First line: venlafaxine. Second line: clomipramine and other selective serotonin reuptake inhibitors (SSRIs); or
- Have significant adverse effects as a result of second line medication in each symptom group; and
- Are assessed as able to benefit from sodium oxybate by a properly constituted multidisciplinary team

Exclusion criteria

Patients who do not fit the above criteria and for whom this treatment is contraindicated, including exclusion as advised by manufacturer.

Stopping criteria

- Serious adverse effects including signs of respiratory depression; or

- Show evidence of incomplete response at 3 months as assessed by clinical examination according to:
 - For cataplexy: the severity and frequency criteria below; and
 - For narcolepsy: the Epworth or paediatric sleepiness scale below.

At least 1 of the cataplexy scores (either severity or frequency) should improve after 3 months of treatment*.

Severity of cataplexy

- 1 = moderate weakness
- 2 = can maintain posture with external support
- 3 = loses posture and falls to the ground

Frequency of cataplexy

- 0 = less than 1 episode per year
- 1 = greater than or equal to 1 attack per year
- 2 = more than one attack per month
- 3 = greater than 1 attack per week
- 4 = greater than 1 per day

Improvements in narcolepsy should be monitored by using either the Epworth sleepiness scale or the paediatric sleepiness scale.

*It is noted that patients with both a severity score of 1 and a frequency score of 0 or 1 are by definition unable to demonstrate the required improvement after 3 months, since their severity score cannot improve, and 3 months is inadequate to demonstrate the required reduction from baseline in frequency score. These patients are therefore not suitable for a trial of sodium oxybate.

Arrangements for the prescribing and supply of sodium oxybate for adults according to this NHS Kernow policy will have to be made with the relevant provider.

Review by: May 2024