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Our Ref: SSC1684: sodium oxybate
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**EMAILED TO:
EAST MIDLANDS ACUTE PROVIDERS
CHIEF EXECUTIVES AND MEDICAL DIRECTORS**

Tel: 0116 206 0185

Dear Colleague

Re: Publication of a new clinical commissioning policy (16065/P) for sodium oxybate for symptom control of narcolepsy with cataplexy (children)

Following the outcome of the recent judicial review on HIV prevention (PrEP), NHS England announced on the 4th December 2016 the results of its annual process for deciding which new treatments and services it will make available to patients.

The associated press release can be found at:

<https://www.england.nhs.uk/2016/12/hiv-prevention-programme/>

The published policy can be found here:

<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e04/>

NHS England has approved the use of sodium oxybate for the symptom control of narcolepsy with cataplexy (children) in accordance with the criteria outlined in the published policy.

NHS England has reviewed the evidence to treat narcolepsy with cataplexy in children with sodium oxybate. It has concluded that there is enough evidence to consider making the treatment available for children who have reached puberty and until they are 19 years old following diagnosis confirmed by a specialist sleep centre (see Appendix for commissioned centres). Referrals to specialised sleep services can be made only from secondary care.

It can only be used in children who have not responded to currently commissioned 1st and 2nd line treatments, or children who cannot have those treatments.

Sodium oxybate will be prescribed for post-pubescent children (weighing >40kg and ≤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 three months. Specifically:

- i. Patients who present with narcolepsy with cataplexy according to International Classification of Sleep Disorders 3 (ICSD) criteria; AND
- ii. Adequately treated co-morbid sleep disorders (such as obstructive sleep apnoea and restless legs syndrome) as assessed by polysomnogram; AND
- iii. Show incomplete response to trial of more than one medication from each symptom group (Narcolepsy: methylphenidate, lisdexamphetamine, modafinil and atomoxetine. Cataplexy: venlafaxine, clomipramine and other SSRIs; OR
- iv. Have significant adverse effects as a result of second line medication in each symptom group; AND
- v. Are assessed as able to benefit from sodium oxybate by a properly constituted MDT.

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

Sodium oxybate treatment will be stopped if patients show evidence of incomplete response at three months as assessed by clinical examination.

Under the conditions set out in the policy, participating Trusts will be required to register all patients on Blueteq to demonstrate compliance with the decision to treat and evidence of effectiveness.

As outlined above, the clinical commissioning policy enables patients to access sodium oxybate up to their 19th birthday. Clinical Commissioning Groups are responsible for access to sodium oxybate for adults and Trusts will need to make arrangements with them to secure funding for continued access to treatment post a patient's 19th birthday.

Trusts should also be made aware that the drug company has agreed that access to sodium oxybate for patients aged 18 years and over is currently free for three months. This may therefore be pertinent to new patients presenting over the age of 18 but before their 19th birthday and therefore covered by this policy.

I would be grateful if you could cascade this letter to clinical and contracting teams

within the Trusts as appropriate to support the consistent adoption of the policy nationally.

Yours Sincerely



Mark Sheppard

Interim Assistant Director of Specialised Commissioning for East Midlands
NHS England – Midlands and East

Cc Provider Chief Pharmacist
Medical Director
Contracts lead

Appendix

Guy's and St Thomas's NHS Foundation Trust
Newcastle upon Tyne Hospitals NHS Foundation Trust
Alder Hey Children's NHS Foundation Trust
Birmingham Children's Hospital NHS Foundation Trust
Heart of England NHS Foundation Trust
Sheffield Children's NHS Foundation Trust
Oxford University Hospitals NHS Foundation Trust
South Tees Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Central Manchester University Hospitals NHS Foundation Trust