# FOR PUBLIC CONSULTATION ONLY

**SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION CRITERIA FOR A PROPOSITION FOR A CLINICAL COMMISSIONING POLICY FOR ROUTINE COMMISSIONING**

URN: E09X03
TITLE: Sodium oxybate for symptom control of narcolepsy with cataplexy (children)

CRG: Paediatric neurosciences
NPOC: Women and Children
Lead: Anthony Prudhoe

Date: 17th February 2016

The panel were presented a policy proposal for routine commissioning.

| **Question** | **Conclusion of the panel** | **If there is a difference between the evidence review and the policy please give a commentary** |
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| <u>The population</u><br>1. Are the eligible and ineligible populations defined in the policy consistent with the evidence of effectiveness, and evidence of lack of effectiveness; and where evidence is not available for the populations considered in the evidence review? | The eligible population(s) defined in the policy are the same or similar to the population(s) for which there is evidence of effectiveness considered in the evidence review | The panel considered the application of adult evidence to post-pubescent children, weighing >40kg (the defined sub-group). |
| <u>Population subgroups</u><br>2. Are any population subgroups defined in the policy and if so do they match the subgroups considered by the evidence review? | The population subgroups defined in the policy are the same or similar as those for which there is evidence in the evidence review | Inclusion criteria specifically defined the sub-group.<br><br>The panel noted that the criteria for commissioning are based on clinical consensus rather than available evidence base. |
| <u>Outcomes - benefits</u><br>3. Are the clinical benefits demonstrated in the | The clinical benefits demonstrated in the | The evidence identified shows benefits in reducing |

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| evidence review consistent with the eligible population and/or subgroups presented in the policy? | evidence review support the eligible population and/or subgroups presented in the policy | cataplexy attacks for adults.<br><br>Overall, the panel noted that the evidence in the adult population was strong.<br><br>The panel therefore agreed that the clinical benefits can be extrapolated to the eligible population. |
| <u>Outcomes – harms</u><br><br>4. Are the clinical harms demonstrated in the evidence review reflected in the eligible and / or ineligible population and/or subgroups presented in the policy? | The clinical harms demonstrated in the evidence review are not reflected in the eligible population and/or subgroups presented in the policy | The panel noted that there is evidence of harms included in the evidence base, including the risk of suicidal ideation.<br><br>The panel noted that the harms are not sufficiently reflected in the criteria for commissioning and requested that these be changed to include psychological input before drug is administered. |
| <u>The intervention</u><br>5. Is the intervention described in the policy the same or similar as the intervention for which evidence is presented in the evidence review? | The intervention described in the policy the same or similar as in the evidence review | |
| <u>The comparator</u><br><br>6. Is the comparator in the policy the same as that in the evidence review?<br><br>7. Are the comparators in the evidence review the most plausible | The comparator in the policy is not the same as that in the evidence review.<br><br>The comparators in the evidence review do not include plausible comparators for | The comparator in the evidence review is placebo. |

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| comparators for patients in the English NHS and are they suitable for informing policy development. | patients in the English NHS and are not suitable for informing policy development. | |
| Advice<br>The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover:<br>• Uncertainty in the evidence base<br>• Challenges in the clinical interpretation and applicability of policy in clinical practice<br>• Challenges in ensuring policy is applied appropriately<br>• Issues with regard to value for money<br>• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review. | | The panel noted that the policy can proceed as a routinely commissioned policy proposition, provided that:<br>1. Harms are clearly identified in the patient population;<br>2. That criteria for commissioning include psychological input; and<br>3. It is understood that Clinical Panel accepted the use of adult evidence can be extrapolated to post-pubescent children (the defined population). |

Overall conclusions of the panel

The policy can proceed as a routine commissioning policy.

Report approved by:
James Palmer
Clinical panel Chair
17/2/16

Post meeting note:
The following changes have been addressed:

- Changed age range to ≤ 18 years
- Clearly identified the risk of harms
- Clearly identified the role of psychologist, incl. CAHMS