

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
<p><u>The population</u></p> <p>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?</p>	<p>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</p>	<p>The panel considered the application of adult evidence to post-pubescent children, weighing >40kg (the defined sub-group).</p>
<p><u>Population subgroups</u></p> <p>2. Are any population subgroups defined in the policy and if so do they match the subgroups considered by the evidence review?</p>	<p>The population subgroups defined in the policy are the same or similar as those for which there is evidence in the evidence review</p>	<p>Inclusion criteria specifically defined the sub-group.</p> <p>The panel noted that the criteria for commissioning are based on clinical consensus rather than available evidence base.</p>
<p><u>Outcomes - benefits</u></p> <p>3. Are the clinical benefits demonstrated in the</p>	<p>The clinical benefits demonstrated in the</p>	<p>The evidence identified shows benefits in reducing</p>

FOR PUBLIC CONSULTATION ONLY

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

FOR PUBLIC CONSULTATION ONLY

<p>comparators for patients in the English NHS and are they suitable for informing policy development.</p>	<p>patients in the English NHS and are not suitable for informing policy development.</p>	
<p><u>Advice</u> The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover:</p> <ul style="list-style-type: none"> • Uncertainty in the evidence base • Challenges in the clinical interpretation and applicability of policy in clinical practice • Challenges in ensuring policy is applied appropriately • Issues with regard to value for money • Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review. 		<p>The panel noted that the policy can proceed as a routinely commissioned policy proposition, provided that:</p> <ol style="list-style-type: none"> 1. Harms are clearly identified in the patient population; 2. That criteria for commissioning include psychological input; and 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