SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION CRITERIA FOR CLINICAL COMMISSIONING POLICY DEVELOPMENT

URN: A03X02
TITLE: Tolvaptan for hyponatraemia secondary to the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) in patients requiring cancer chemotherapy

CRG: Specialised Endocrinology
NPOC: Internal Medicine
Lead: Debbie Hart

Date: 20th of January

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**
<u>The population</u> 1. What are the eligible and ineligible populations defined in the policy and are these consistent with populations for which evidence of effectiveness is presented 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	
<u>Population subgroups</u> 2. Are any population subgroups defined in the policy and if so do they match the subgroups for which there is evidence presented in 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	Sub-population in the evidence review only mentioned in the cost effectiveness section.

<u>Outcomes - benefits</u> 3. Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?	The clinical benefits demonstrated in the evidence review support the eligible population and/or subgroups presented in the policy	Unclear what level of **sodium needs to be achieved to commence** chemotherapy. **Although outcomes do reference that the required level was obtained in some reports.**
<u>Outcomes – harms</u> 4. Are the clinical harms demonstrated in the evidence review reflected in the eligible population and/or subgroups presented in the policy?	The clinical harms demonstrated in the evidence review are reflected in the eligible population and/or subgroups presented in the policy	
<u>The intervention</u> 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	Policy suggests a maximum use for 10 days, though RCT evidence goes to 30 days
<u>The comparator</u> 6. Is the comparator in the policy the same as that in the evidence review? 7. Are the comparators in the evidence review the most plausible comparators for patients in the English NHS and	The comparator in the policy is the same as that in the evidence review. The comparators in the evidence review include plausible comparators for patients in the English NHS and are	Comparator was placebo.

are they suitable for informing policy development.	suitable for informing policy development.	
<u>Advice</u> The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover: • 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.		Change name: Add '…for patients who require cancer chemotherapy' Define level of hyponatraemia: >120 or 125-135 Further comments: PLS: Clarify an important cause of hyponatraemia is SIADH (rather than most common) Section 2, p.5, last sentence in paragraph – replace with: Tolvaptan is proposed in patients with malignant disease where chemotherapy is delayed due to hyponatraemia. Section 5, p. 7, first sentence in last paragraph – remove: 'One of the largest cancer centres in the UK estimates that…' and provide a named source in brackets at the end of the sentence. Section 7, p.11, 3rd inclusion criteria – change: 'patients' to 'patient' AND, add at the end of sentence: ', caused by SIADH'

		Section 8, p.12; Remove box referring to exceptional use

Overall conclusions of the panel

The policy reflects the findings of the clinical evidence review. It should progress as a routinely commissioned policy following suggested updates.

Report approved by:

Jeremy Glyde
Clinical Effectiveness Team
10 February 2016