FOR PUBLIC CONSULTATION ONLY

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

URN: A11X04
TITLE: Selexipag in the treatment of Pulmonary Arterial Hypertension

CRG: Pulmonary Hypertension
NPOC: Internal Medicine
Lead: Ursula Peaple

Date: 20th January 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**
<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 is not the same or similar to the population(s) for which there is evidence of effectiveness that considered in the evidence review	*The studies only look at patients with PAH, but policy is written for three groups of patients. The study focuses on WHO groups II and III, but the policy focuses on III and IV.*
<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?	There is a difference between the population subgroups defined in the policy and the populations for there is evidence in the evidence review	*As above*
<u>Outcomes - benefits</u> 3. Are the clinical benefits	The clinical benefits demonstrated	*The benefits as described in the evidence did not*

demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?	in the evidence review do not support the eligible population and/or subgroups presented in the policy	*show any difference in mortality and reduction in symptoms between the two groups. The panel were concerned about the construction of the trial against placebo when other treatments are available and the lack of comparator studies.*
<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	
<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 are they suitable for informing policy development.	The comparator in the policy is not the same as that in the evidence review. The comparators in the evidence review do not include plausible comparators for patients in the English NHS and are not suitable for informing policy development.	*The comparator is placebo. The panel advised that in order for Selexipag to have a place in the treatment pathway, we would need to know its performance in relation to other treatment options.*

Advice 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.		*The panel requested that the policy proposition should be changed to a not routinely commissioned proposition, on the basis of the advice above.*

Overall conclusions of the panel

The evidence available is not sufficient to support the development of a policy and thus the intervention should be taken forward as not routinely commissioned.

Report approved by:

James Palmer
Chair
27 January 2016