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

URN: 1735
TITLE: Selexipag for pulmonary arterial hypertension (adults)

CRG: Specialised Respiratory
NPOC: Internal Medicine
Lead: [redacted]
Date: 19/12/17

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|---|---|---|---|---|
| This policy is being considered for: | For routine commissioning | X | Not for routine commissioning | |
| Is the population described in the policy the same as that in the evidence review including subgroups? | The evidence review describes the main study of Sitbon which was in class 2 & 3. The policy proposition has restricted to functional class 3 on the basis of being the population most likely to benefit from the drug at that point in the pathway. | | | |
| Is the intervention described in the policy the same or similar as the intervention for which evidence is presented in the evidence review? | Yes. | | | |
| Is the comparator in the policy the same as that in the evidence review? 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 research is placebo we do not have evidence of comparators of other treatments at a similar stage in the pathway of care. | | | |
| Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?<br><br>Are the clinical harms demonstrated in the evidence review reflected in the eligible | The panel heard that the main benefit of the large study was a composite outcome measure that includes mortality, hospitalisation, progression, oxygen requirements and measures such as forced vital capacity. These were agreed to be consistent measures for this particular patient population (as had been confirmed by the EPAR).<br><br>Yes. There remains uncertainty about potential severity about some of the side effects. | | | |

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| and /or ineligible population and/or subgroups presented in the policy? | | | |
| Rationale<br>Is the rationale clearly linked to the evidence? | The rationale in the criteria for commissioning was not clear. The narrative was not as detailed as the previous policy for riociguat which lies in similar place in the pathway. | | |
| <u>Advice</u><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>• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review. | The Panel requests that the section on commissioning criteria should be rewritten to align with the riociguat policy so it can be used side by side.<br><br>The Panel did raise concerns regarding the issue that a comparator of alternative treatments has not been undertaken. It will be important for the benefits included in the composite outcome to be clearly described in the CPAG Summary report.<br><br>The group noted that there was some uncertainty in the improvement of quality of life from a patient perspective and potential benefits. | | |
| Overall conclusion | This is a proposition for routine commissioning and | Should proceed for routine commissioning | X |
| | | Should reversed and proceed as not for routine commissioning | |
| | This is a proposition for not routine commissioning and | Should proceed for not routine commissioning | |
| | | Should be reconsidered by the PWG | |

<u>Overall conclusions of the panel</u>
Report approved

James Palmer
Clinical Panel Chair
20/12/17

Post-meeting note:

The policy working group supported by NICE CSP made revisions to resolve the Clinical Panels comments including:

1. Used the riociguat policy as a guide to presenting the narrative on the pathway
2. Used the riociguat policy to aid revision of the criteria for commissioning
3. NICE CSP supported review of the information on patient benefit to be included in the CPAG coversheet