

FOR PUBLIC CONSULTATION ONLY

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

URN: A10X05

TITLE: Everolimus for immune suppression post cardiac transplant

CRG: Cardiac Surgery

NPOC: Internal Medicine

Lead: Ursula Peuple

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	<i>The clinical evidence focussed on use of everolimus versus cyclosporine, but the panel understands that the routine practice is to use tacrolimus which is less nephrotoxic. The evidence summary does not demonstrate any evidence that everolimus provides additional benefit to tacrolimus. The comparator was cyclosporine only</i>
<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	

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<p><u>Outcomes - benefits</u></p> <p>3. Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?</p>	<p>The clinical benefits demonstrated in the evidence review do not support the eligible population and/or subgroups presented in the policy</p>	<p><i>As above. There is no comparative evidence in the scenario of using tacrolimus with everolimus, or other treatment alternatives such as Sirolimus.</i></p>
<p><u>Outcomes – harms</u></p> <p>4. Are the clinical harms demonstrated in the evidence review reflected in the eligible population and/or subgroups presented in the policy?</p>	<p>The clinical harms demonstrated in the evidence review are reflected in the eligible population and/or subgroups presented in the policy</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 comparators for patients in the English NHS and are they suitable for informing</p>	<p>B: The comparator in the policy is not the same as that in the evidence review.</p> <p>B: The comparators in the evidence review do not include plausible comparators for patients in the English NHS and are not</p>	<p><i>There is no comparative evidence between tacrolimus and everolimus, or other alternatives such as Sirolimus.</i></p>

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policy development.	suitable for informing policy development.	
<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><i>The panel requested that this policy proposition be converted to a not routinely commissioned position, as the evidence does not support a proposal for routine commissioning.</i></p> <p><i>The panel requested that the Highly Specialised Team have a discussion with clinicians to identify whether evidence is being developed to support this in future. They note that international trials can be produced to provide Level 1 evidence in this area.</i></p>

Overall conclusions of the panel

The evidence presented is not sufficient to support the development of a policy and thus the proposal should be taken forward as a non-routinely commissioning.

Report approved by:

James Palmer
Chair
27 January 2016