REPORT FROM CLINICAL PANEL

Title: **E09X04/01**
Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex

CRG: Paediatric Neurosciences
NPOC: Women and Children
Lead: Anthony Prudhoe

Date: 16 December 2015

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 population(s) defined in the policy is the same or similar to the population(s) for which there is evidence of effectiveness considered in the evidence review.	The panel were satisfied that the populations were sufficiently similar to support the routine commissioning policy proposition. The panel determined that the evidence of tumour size reduction would apply to the population defined in the policy.
<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.	Subject to clarification of criteria within the policy proposition. In particular, the first criteria need to clearly state that the intervention is only available to those patients who have disease that is not amenable to surgery. Stopping criteria need to be clarified regarding the time interval for continued tumour growth on MRI.

Outcomes - benefits		
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.	
Outcomes – harms		
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 populations in the policy.	
The intervention		
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.	
The comparator		
1. Is the comparator in the policy the same as that in the evidence review?	Not applicable	The panel noted that there was no licenced comparator.
2. 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?	Not applicable	As above.

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Overall conclusions of the panel

The Clinical Panel supported the policy proposition for routine commissioning subject to minor amendments and clarifications, specifically:

- The criteria should be reordered, with the first criteria being patients who are not amenable to surgery.
- The stopping criteria to be refined.

Report approved by:

David Black
Chair
04 January 2016