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

URN: 1716
TITLE: Human coagulation factor X for hereditary factor X deficiency (all ages)

CRG: Specialised Blood Disorders
NPOC: Blood & Infection
[redacted]
Date: 19/12/17

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?	Yes. The policy population is restricted to long-term prophylaxis rather than acute administration. The evidence base covers a broader population but clinical advice is recommending restriction to the longer term use.			
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?	Yes. The comparator is placebo.			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?	Yes. There are clinical benefits which are theoretical and those in the evidence review relate to higher volume administration in the paediatric population.			
Are the clinical harms demonstrated in the evidence review reflected in the eligible and /or ineligible	No specific harms were identified in the evidence review. The trials included were small and it was noted that therefore, the harms may not be fully understood. The complications that have been identified were headache and infection site reactions.			

population and/or subgroups presented in the policy?			
Rationale Is the rationale clearly linked to the evidence?	Yes.		
<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 • Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.	The Panel were advised that there were elements in the policy proposition and evidence review that were academic in confidence so the papers cannot be progressed at this stage. The documents can however progress to stakeholder testing with academic in confidence elements redacted. All relevant information should be published prior to consultation taking place.		
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 by:

James Palmer
Clinical Panel Chair
20/12/17

Post meeting note:
The policy working group have recommended Factor X for adult and paediatric patients with hereditary factor X deficiency only for prophylactic treatment rather than acute administration.

The documents progressed to stakeholder testing with no academic in confidence elements included. The PWG had access to the unpublished studies and took this into account when drafting the policy proposition. The evidence review has been refreshed to include the published studies and this refreshed version is included in the CPAG papers. All relevant information has now been published and all redactions have been removed from the final papers.