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

URN: 1679
TITLE: Lomitapide for familial homozygous hypercholesterolaemia

CRG: Specialised Endocrinology
NPOC: Internal Medicine
Lead: Ursula Peaple
Date: 18/11/17

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.			
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 Panel noted that some of the studies proceed availability of newer therapeutic agents Panel would like clarification on the place of evolucumab in the pathway and that this is consistent between the text and the flow chart			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy? Are the clinical harms demonstrated in the evidence review reflected in the eligible	Yes. The benefits are expressed in LDL cholesterol reduction and not in outcomes meaningful to patients; in this case cardiovascular disease events and mortality. Clinical Panel are aware that CPAG will need to understand potential benefits in terms of meaningful reduction in CVD risk for patients. The PWG are asked to clarify likely benefits in terms of CVD event and mortality reduction to patients who are already receiving maximal therapy for who addition of this drug would be indicated. The Panel felt that the policy itself and the CPAG Summary Report did not fully describe the health risks of this population in terms of early cardiovascular event risk			

and /or ineligible population and/or subgroups presented in the policy?	and early death. This needs to be more explicitly described so that the magnitude and significance of this condition is clear. The Panel noted that there were significant side effects particularly affecting the liver. This is referenced in the stopping criteria section. In addition to the narrative and reference to the SPC a bullet should be added to say 'modify or discontinue where liver damage may be occurring as guided by the SPC'. The stopping criteria should also include inability to adhere to a low fat, which should be monitored throughout treatment and treatment discontinued where SPC requirements are not met.		
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.	Although the studies are phase 2, the degree of reduction in LDL cholesterol was significant and consistent across studies. The panel were therefore convinced that the intervention has an acceptable level of evidence regarding its effectiveness. The Panel noted that the pathway should be clear regarding other agents and treatments. Please can the PWG amend the policy to remove references in section 8, as these must have been described in the evidence review and do not need to be repeated. The reference to Heart UK and the European Atherosclerosis Society may remain in the text. A brief mention of the MDT should be added with a comment that this must include a dietician. It is expected that the NICE Clinical Guideline is followed with regards to the treatment of familial hypercholesterolemia. The policy should be cross checked with the NICE guideline to ensure it is consistent.		
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	

Overall conclusions of the panel
Report approved by:
David Black
Clinical Panel Co-Chair
28/11/17