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

URN: 1623 and 1696
TITLE: Cholic acid and chenodeoxycholic acid for inborn errors of bile acid synthesis/Cholic acid in combination with chenodeoxycholic acid for in born errors of bile synthesis

CRG: Metabolic Disorders
NPOC: Women & Children
Lead: [redacted]
Date: 18/10/18

This policy is being considered for:	For routine commissioning	X	Not for routine commissioning	
Is the population described in the policy similar to that in the evidence reviewed, including subgroups?	Yes.			
Is the intervention described in the policy similar to the intervention for which evidence is presented in the evidence review?	Yes.			
Are the comparators in the evidence reviewed plausible clinical alternatives within the NHS and are they suitable for informing policy development?	These disorders are rare and the research evidence is limited. The published research is limited to uncontrolled case series type studies. There are no studies that include a comparator arm. These drugs have been in use in the NHS for many years. There are very limited alternative treatments available with little evidence of effectiveness.			
Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	These drugs have been used for many years. Whilst the research evidence is limited, Clinical Panel were satisfied that treatment with these drugs may result in a significant clinical benefit, slowing or halting disease progression.			
Are the clinical harms described in the evidence review likely to apply to the eligible and /or ineligible population and/or subgroups in the policy?	These can be usually be managed by adjustments in dose.			
The Panel should provide advice on matters relating to the	The policy proposition should proceed to stakeholder testing.			

evidence base and policy development and prioritisation. Advice may cover: • Balance between benefits and harms • Quality and 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.			
Overall conclusion	This is a proposition for routine commissioning and	Should proceed for routine commissioning	X
		Should be 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	

Report approved by:

David Black
Deputy Medical Director, Specialised Services
14 November 2018