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

URN: 1810
TITLE: Idebenone for treating visual impairment in adults and young people with Leber's hereditary optic neuropathy

CRG: Trauma
NPOC: Specialised Ophthalmology and Ear
[redacted]
Date: 17/10/18

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?	There is no other active treatment for this condition. The pivotal study 'RHODOS' compared the intervention with placebo.			
Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	No. Panel recognised that the drug has a license for the treatment of this disorder. However the primary end point in the pivotal study was visual acuity - logMAR between baseline and 24 week end-point for best recovery/least worsening of visual acuity – and the difference between the groups treated with idebenone and placebo was not statistically significant. There were some changes reported in visual acuity in sub groups with discordant visual acuity at baseline and some benefits in colour contrast sensitivity reported. There was no health-related quality of life benefit shown in the studies. Clinical Panel carefully considered the evidence of effectiveness and assessed the degree of benefit attributable to idebenone as modest at best with a high degree of uncertainty. Clinical Panel therefore did not			

	support a routine commissioning position.		
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?	There were no apparent serious adverse events attributable to idebenone.		
The Panel should provide advice on matters relating to the 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.	Panel recognised the serious nature of Leber's hereditary optic neuropathy and the potential serious impact on patients who are often young adults. Panel recognised the significant unmet need in this population and absence of any alternative active treatment. However, although ibedenone is licensed, the degree of benefit is uncertain and appeared small at best. As such, Panel could not recommend idebenone for routine commissioning. The not for routine commissioning policy proposition should return to Panel for consideration at a later date.		
Overall conclusion	This is a proposition for routine commissioning and	Should proceed for routine commissioning	
		Should be reversed and proceed as not for routine commissioning	X
	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