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

URN: 1745
TITLE: Telotristat for treating carcinoid syndrome

CRG: Specialised Endocrinology
NPOC: Internal Medicine
[redacted]
Date: 15/08/18

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			
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	The clinical benefits are very limited and there is no significant impact on overall measures of quality of life in the main randomised controlled study. Yes.			

and /or ineligible 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.	Clinical Panel recognised the potentially serious nature of the symptoms that patients experience with this disorder. Panel recognised that existing treatments did not offer all patients satisfactory outcomes. We recognise the work that has been done by the Policy Working Group to ensure that the case of clinical needs is well made and to ensure that the research concerning this intervention is clearly explained. . Clinical Panel noted that the 'TELESTAR' study is a high quality randomised control study. The evidence demonstrated only a small statistically significant reduction in the mean number of bowel movement per day (0.8) compared with placebo. Clinical Panel noted that the improvement in quality of life measures specific to a diarrhoea subscale score demonstrated in the research appeared to be small and overall quality of life was not statistically significantly improved. Clinical Panel noted that symptoms of importance to patients include; abnormal pain, diarrhoea and urgency. These were measured in the TELESTAR study, which did not find a statistically significant difference in these symptoms experienced by patients receiving telotristat and placebo. Panel noted that rescue treatments may have been used differently between the control and treatment arm in the Telstar study. Patients in the studies were also on varying doses of somatostatin analogue (SSA) in the placebo and telotristat arms of study, which may disguise the true treatment effect of telotristat. However, Panel was unable to draw firm conclusions regarding the impact on the reported outcomes of the study. Panel noted the biochemical efficacy of telotristat, based on urinary 5- hydroxyindoleacetic acid (u5-HIAA) levels, which were reduced by treatment. It is disappointing that these biochemical changes were not matched by the degree of symptom improvement. Clinical Panel therefore determined that the research evidence included good quality research that demonstrated clinical benefit that was so limited that a routine commissioning position could not be justified. Therefore, a not for routine commissioning policy proposition would be completed and progressed to stakeholder testing and public consultation.

	The Panel also noted that the list of available treatments listed in the draft policy document includes interventions that are not routinely available in the NHS in England. This list should therefore be removed or amended so as to avoid the possibility of suggesting that these treatments are commissioned.		
Overall conclusion	This is a proposition for routine commissioning and	Should proceed for routine commissioning	
		Should 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	

Overall conclusions of the panel

Report approved by:
David Black
Clinical Panel Chair
28/08/18