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

URN: 170101P
TITLE: Gemcitabine and capecitabine following pancreatic cancer

CRG: Chemotherapy
NPOC: Cancer
Lead: [redacted]
Date: 18/04/18

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?	The comparator is gemcitabine which is established therapy.			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?	There was debate about the relative benefits in patients with R0 status (clear resection margins) and patients with R1 status (positive resection margins). When taking the whole study group the survival confidence intervals showed overlap, but there was a statistically significant increase in overall survival. Pre-determined subgroup analysis showed with an increased median survival of 11 months in R0 status patients when compared to gemcitabine alone and a non-significant increase in median survival of 0.7 months in R1 status patients. Panel noted that the study was powered to assess overall survival in the whole group. Hence, caution is			

Are the clinical harms demonstrated in the evidence review reflected in the eligible and /or ineligible population and/or subgroups presented in the policy?	needed with regard to sub-group analysis. There were 730 participants in the trial, approximately 60% with R1 status and 40% with R0 status. The harms are identified.		
Rationale Is the rationale clearly linked to the evidence?	The Panel concluded that on balance the rationale for using the combination in R1 had not been adequately demonstrated.		
<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.	Proceed with the policy as a routine commissioning position for R0 status patients only. A referral will be made to the CDF for consideration as to whether the use of gemcitabine and capecitabine in combination for the R1 status population would be appropriate to be assessed through a CDF approach. However, given that the pivotal study is relatively large and had a control group it may be that a CDF approach would not be useful.		
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
4th May 2018

Post meeting note:
Following Stakeholder testing, and advice from the Chemotherapy CRG Chair and cancer drugs fund CDF lead, it was agreed that the policy should progress as routine commissioning for both the R0 and R1 patient cohorts. This decision was taken because the evidence presented supported a small improvement in median overall survival for both groups and is consistent with the pivotal trial protocol.