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

URN: 1748
TITLE: Addition of rituximab to standard chemotherapy for newly diagnosed CD20 positive-B-cell precursor acute lymphoblastic leukaemia

CRG: Chemotherapy
NPOC: Cancer
Date: 21 November 2018

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, note the Policy Working Group were not able to identity a particular sub group of adults most likely to benefit. Clinical Panel noted the removal or children from routine commissioning recommendation as had been advised. Panel noted that treatment protocols appear to differ for older adults compared to younger adults and that rituximab may offer greater benefit in younger compared to older adults but accepted the limitation of the evidence base.			
Is the intervention described in the policy similar to the intervention for which evidence is presented in the evidence review?	Yes, the addition of rituximab to first line treatment.			
Are the comparators in the evidence reviewed plausible clinical alternatives within the NHS and are they suitable for informing policy development?	Appropriate.			
Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	Panel noted that no overall survival benefit was shown although there appeared to be some increase in event free survival. The main studies were one randomised controlled open-label phase III trial (GRAALL-2005R; n = 209), and one non-randomised open-label phase II trial (n = 282). Panel recognised that the condition is relatively uncommon and thus that the evidence base is likely to be limited.			
Are the clinical harms described in the evidence review likely to apply to the eligible and /or ineligible population	There were harms however, these were not significantly different between the rituximab and control group in the randomised control study.			

and/or subgroups in the policy?			
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.	Degree of benefit demonstrated appears to be limited and below the threshold that Panel considered sufficient to take forward as a for routine commissioning recommendation. The policy should progress as a not for routine clinical commissioning policy.		
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
07 December 2018

Post Panel Note: The policy was revised for not routine commissioning and proceeded to stakeholder testing in line with the standard Methods. However, following stakeholder testing and consultation, where concerns were raised about the commissioning position the Clinical Panel Chair agreed to the reverse the proposition back to a routine commissioning position as it presented improved event free survival.