

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

URN: 1621

TITLE: Inhaled therapy for levofloxacin for people with cystic fibrosis chronically colonised with pseudomonas aeruginosa

CRG: Specialised respiratory

NPOC: Internal medicine

Lead: Ursula People

Date: 16/11/16

This policy is	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?	There is a difference. The policy is recommending this as a fourth line treatment. The evidence is based on a non-inferiority study in comparison with a second line treatment. However, the panel concluded that given the limitations of the evidence base and the way in which treatments are used in rotation, this difference does not prevent the policy proceeding.			
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 was against Tobramycin and not against third line inhaled treatment or IV antibiotics. However, the panel concluded that given the weaknesses in the evidence base fourth line use described in the policy may be appropriate.  There is an opportunity for data collection through the CF registry as a fourth line treatment.			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?	The studies have demonstrated non-inferiority against Tobraamicin. However, a study comparing treatment against placebo did not show benefit. This study had methodological weaknesses and panel agreed that there was evidence of effectiveness. The criteria in the policy take into account the uncertainty in the evidence base.			
Are the clinical harms demonstrated in the	The clinical harms have been reflected.			

evidence review reflected in the eligible and /or ineligible population and/or subgroups presented in the policy?			
Rationale Is the rationale clearly linked to the evidence?	The evidence based is limited but the proposed criteria do account for this and the rationale is clearly linked to the evidence base.		
<u>Advice</u> The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover: <ul style="list-style-type: none"> <li>• Uncertainty in the evidence base</li> <li>• Challenges in the clinical interpretation and applicability of policy in clinical practice</li> <li>• Challenges in ensuring policy is applied appropriately</li> <li>• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.</li> </ul>	<p>The policy proceeds as a routine commissioning policy.</p> <p>There are elements of the policy proposition that need correcting with the advice of the Clinical Effectiveness Team.</p>		
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:

James Palmer

Clinical Panel Chair

12/12/16