

**SPECIALISED COMMISSIONING - CLINICAL EVIDENCE EVALUATION  
 CRITERIA FOR A PROPOSITION FOR A CLINICAL COMMISSIONING POLICY  
 NOT FOR ROUTINE COMMISSIONING**

URN: 1779

TITLE: Hyperbaric oxygen therapy for diabetic lower limb ulceration (diabetic foot ulcer) NPOC: Trauma

Lead: [REDACTED]

Date: 20 June 2018

| This policy is being considered for:  | For routine commissioning  | Not for routine commissioning | X |
|---|--|-------------------------------|---|
| 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, 'dose' of hyperbaric oxygen treatment varies (no standardisation).  |                               |   |
| 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?  | No. The studies are variable and best available wound care is the appropriate comparator but at best evidence of effectiveness in comparison is limited. |                               |   |
| <p>Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy?</p> <p>Are the clinical harms demonstrated in the evidence review reflected in the eligible and /or ineligible population and/or</p> | <p>Not demonstrated.</p> <p>Recognised hazards.</p>  |                               |   |

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| <p>subgroups presented in the policy?</p>  |  |
| <p>Rationale<br/>Is the rationale clearly linked to the evidence?</p>  | <p>Supported the not for routine commissioning position based on the lack of evidence of efficacy.</p> <p>The PWG has expressed concerns about how these studies have been compared and conclusions reached about the robustness and applicability of the studies. The PWG have stated '<i>In our opinion, the decision to consider the trial by Londahl et al less reliable than Fedorko et al is unfounded and the endorsement of a speculative mechanism for the non-existent difference in outcomes misleads further</i>'.</p> <p>Clinical Panel recognised the careful consideration and hard work of the PWG to date. Panel also recognised the process that is used to develop the evidence reviews to inform policy and also understood that process needs to be followed in order that there is consistency in policy production. Then PWG concerns have been considered by the evidence reviewers and some amendments have been made. Panel understands that these do not address all the concerns of the PWG.</p> <p>Panel determined that the policy should progress to the stakeholder and consultation and that the consultation process has the potential to generate comments on the policy and evidence base that informs it. If received, these will be considered through the policy development process. Panel noted that the PWG were not advising that the differences between the PWG interpretation of the evidence and that contained in the independent evidence review were sufficient to result in a change in the proposed policy position.</p> |
| <p><u>Advice</u><br/>The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover:</p> <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</li> </ul> | <p>Proceed as NRC.</p>   |

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| <p>ensuring policy is applied appropriately</p> <ul style="list-style-type: none"> <li>Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review.</li> </ul> |   |  |   |
| Overall conclusion  | This is a proposition for routine commissioning and     | Should proceed for routine commissioning                     |   |
|   |   | Should reversed and proceed as not for routine commissioning |   |
|   | This is a proposition for not routine commissioning and | Should proceed for not routine commissioning                 | X |
|   |   | Should be reconsidered by the PWG                            |   |

Report approved by:  
Dr David Black  
Deputy Medical Director, Specialised Services  
13 July 2018