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

URN: 170094P
TITLE: Trientine dihydrochloride for Wilson disease

CRG: Metabolic Disorders
NPOC: Women & Children
Lead: [redacted]
Date: 18/04/18

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| 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? | The policy is focussed on the symptomatic population with Wilson disease. The Panel considered that it would be appropriate to have a comment on the management of patients with asymptomatic disease in the section 'Criteria for commissioning'. This is because many patients respond to treatment, become asymptomatic and maintenance treatment options become important. | | | |
| 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? | The benefits are consistent with the policy. There are limitations in the evidence base, however trientine dihydrochloride has been in common use for some years and is not a new treatment. | | | |

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| Are the clinical harms demonstrated in the evidence review reflected in the eligible and /or ineligible population and/or subgroups presented in the policy? | Yes. There are a number of harms which are clearly described. | | |
| Rationale<br>Is the rationale clearly linked to the evidence? | The Panel agreed that the rationale was linked to the evidence base, understanding the limitations of the evidence base. | | |
| <u>Advice</u><br>The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover:<br>• Uncertainty in the evidence base<br>• Challenges in the clinical interpretation and applicability of policy in clinical practice<br>• Challenges in ensuring policy is applied appropriately<br>• Likely changes in the pathway of care and therapeutic advances that may result in the need for policy review. | A substantial rewrite of the CPAG Summary Report is required, to better describe the benefits of the policy taken as a whole, and not consider separately use of trientine as monotherapy, in combination etc.<br><br>A revision of Section 8 'Criteria for Commissioning' is needed. Criteria apply to patients with symptomatic disease and intolerant of penicillamine. However, patients who become intolerant of penicillamine after a significant period of treatment may not be symptomatic. The potential role of zinc in these patients needs to be considered. The section headed 'Pre-existing conditions/circumstances' needs to be revised so that it is clear which are absolute contraindications for penicillamine and thus trientine is indicated and which require penicillamine use to be monitored closely. The policy should drive evidence based use of trientine, but restrict use to where there is a significant and demonstrable clinical reason to use trientine over other agents in order to optimise use of resources.<br><br>The amended version should be signed off by the Head of Clinical Effectiveness before going to stakeholder testing. | | |
| 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 | |

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| | | 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:
The policy was amended to

- clarify the role of zinc in the treatment pathway
- clarify the commissioning criteria for trientine