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

URN: 1709
TITLE: Vonicog alfa for the treatment and prevention of bleeding in adults with von Willebrand Disease
CRG: Bleeding Disorders
NPOC: Blood & Infection
Date: 20/03/19

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.			
Is the intervention described in the policy similar to the intervention for which evidence is presented in the evidence review?	Yes.			
Are the comparators in the evidence reviewed plausible clinical alternatives within the NHS and are they suitable for informing policy development?	Yes. There was a lack of comparator studies to determine the benefits of this treatment over established treatments.			
Are the clinical benefits described in the evidence review likely to apply to the eligible population and/or subgroups in the policy?	Yes. The sample sizes were small and used subjective measures which makes it difficult to identify appropriate levels of benefit. It is clear though that the product works in stopping bleeding and has the benefit of using small amounts of recombinant factor VIII, which has a wider benefit than for the management of bleeding disorders.			
Are the clinical harms described in the evidence review likely to apply to the eligible and /or ineligible population and/or subgroups in the policy?	Yes.			
The Panel should provide advice on matters relating to the evidence base and policy development and	The rationale is present but not clearly articulated. The rationale should be improved.			

<table>
<tr><td>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</td><td colspan="3">The Panel challenged the pathway outlined in the policy proposition and, in particular, whether it was appropriate for the treatment to be either/or.

It was the majority view that the policy proposition should proceed.

The patient pathway needs to be reviewed and be clear as to the second line element of the pathway. Panel considered an option could be to take forward where the second line treatment is only vonicog alfa or move it to a third line treatment. Panel would need clinical advice as to whether this is appropriate or not.

The Panel seeks further assessment of the pathway management to be clearly articulated before it progresses.</td></tr>
<tr><td>that may result in the need for policy review.</td><td colspan="3"></td></tr>
<tr><td rowspan="4">Overall conclusion</td><td rowspan="2">This is a proposition for routine commissioning and</td><td>Should proceed for routine commissioning</td><td>X</td></tr>
<tr><td>Should be reversed and proceed as not for routine commissioning</td><td></td></tr>
<tr><td rowspan="2">This is a proposition for not routine commissioning and</td><td>Should proceed for not routine commissioning</td><td></td></tr>
<tr><td>Should be reconsidered by the PWG</td><td></td></tr>
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<u>Overall conclusions of the panel</u>
Report approved by:
James Palmer
Clinical Panel Chair
27/03/19

<u>Post Panel Note</u>

The Policy Working Group considered if there was a need for further clarity on the pathway and second line treatment. It was felt that it was appropriate to keep the choice of second line treatment but expect that clinical practice will change over time so that vonicog alfa becomes the main second line treatment. The pathway description has been amended to provide further clarity.