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

URN: 1702
TITLE: Bictegravir-emtricitabine-tenofovir alafenamide (B/F/TAF) for the treatment of human immunodeficiency virus type 1 (HIV-1) in adults
CRG: HIV
NPOC: Blood and Infection
Lead:
Date: 18 September

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?	Partly. Panel determined that the evidence base supports the use of this fixed dose combination for patients meeting the criteria for a tenofovir alafenamide and needing an integrase inhibitor containing regime, as equivalent in effectiveness to other licensed drug treatments. Panel understands the commissioning mechanism and agrees that this combination may be offered where its acquisition cost is the same or less than comparable commissioned treatments combinations. The Panel did not support the commissioning criteria for patients 'needing' a single tablet regime. No evidence was presented to support this and there are no other clinical commissioning policies for HIV where single tablet regimes are commissioned in preference to multi-tablet regimes. This precedent would require a clear evidence base. The Panel did support the inclusion of criteria for patients unable to take alternative integrase inhibitor regimes but considered the side effect advantages were relatively limited.			
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.			
Are the clinical benefits described in the	The clinical benefits of this single tablet bictegravir containing regime were not demonstrated in the evidence			

evidence review likely to apply to the eligible population and/or subgroups in the policy?	base. This criterion should be removed. The side effect profile of bictegravir (fixed dose 50 mg bictegravir 200 mg, emtricitabine and 25, mg tenofovir alafenamide) appears to differ from that of fixed dose 50 mg dolutegravir, 600mg abacavir and 300mg lamivudine. The Wohl et all 2018 paper compared a large number of side effects at several time points and some showed a significant difference in favour of the bictegravir combination (except hair loss / changes which favoured the comparator). However, Clinical Panel were uncertain of the clinical significance of these; some differences in side effects fluctuated over time and panel noted that in the comparator studies overall discontinuation rates were very low and the non-significant difference reported did not consistently favour the bictegravir combination. Panel noted that cardiovascular risk was specified in the list of side of side effect criteria. Panel could not ascertain where in the evidence base this specific risk was referenced to justify its inclusion alongside a set of side effects that do not represent a clinical risk per se but may affect quality of life. Panel requested that the policy and evidence review further quantify the evidence based side effect benefits. This is necessary to allow a well-informed judgement to be reached on the magnitude of benefit of bictegravir compared with alternative regimes. This will be important if the cost of the bictegravir combination exceeds that of the currently commissioned alternative treatments and may therefore need to be compared with other investments in care and treatment at prioritisation. Panel recognised the potential benefit of providing greater choice of treatments and the potential benefit in optimising the minimisation of side effects for individual patients. However, the low discontinuation rates and high degree effectiveness of the current range of treatments commissioned was noted. .
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	Panel requested that single tablet related clinical commissioning criteria are removed. If this remains, a robust evidence base needs to be identified.

<table>
<tr><td>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.</td><td colspan="3">Explanation of the magnitude of side effects advantages to be included within the policy and evidence review.

TAF policy criteria to be included within the policy to clearly lay these out for the use of this bictegravir combination.

The cardiovascular risk criteria need to be referenced to the evidence base with an explanation as to why existing treatments do not already meet this need.

The revised CPAG summary report and policy proposition to be submitted to the Clinical Effectiveness Team for sign off if possible. It may be necessary to refer to the chair and indeed, the policy may need to return to Panel if there remains a significant gap between the view of the Panel and the policy put forward by the Policy Working Group.

Panel also discussed briefly whether a treatment algorithm could be useful clinically and to assist in wide understanding of the approach to the treatment of HIV. However given the large number of treatments and the changes in therapeutics that continue to take place in HIV, an algorithm may be impractical to develop. The Clinical Reference Group may wish to consider this idea.</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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Report approved by:
David Black
Deputy Medical Director Specialised Services
20 September 2018

Post meeting note:

[Input how actions requested by Clinical Panel have been addressed]