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

URN: 1702
TITLE: Bictegravir-emtricitabine-tenofovir alafenamide for the treatment of HIV-1 in adults.

CRG: HIV
NPOC: Blood & Infection
Lead: Claire Foreman
Date: 18/07/18

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?	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.			
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 evidence review demonstrated that bictegravir combinations are equivalent in effectiveness to comparator combinations currently commissioned in the NHS.			
Are the clinical benefits demonstrated in the evidence review consistent with the eligible population and/or subgroups presented in the policy? Are the clinical harms demonstrated in the	No. The evidence suggests that B/F/TAF has a similar safety and tolerability profile to comparators for both patients with previously untreated HIV-1 and in adults with virologically supressed HIV-1 switching suppressive antiretroviral therapy. There are two elements to the proposed eligibility criteria and clinical panel supported only one of these elements: 1. The policy includes eligibility for the bictegravir combination as an alternative to standard therapy, where the acquisition cost is equivalent or lower than those of alternative commissioned treatment strategies. Clinical Commissioning Policy: Tenofovir			

evidence review reflected in the eligible and /or ineligible population and/or subgroups presented in the policy?	Alafenamide for treatment of HIV 1 in adults and adolescents, (Reference: NHS England: 16043/P) lays out these criteria in section 6 and a summary of these and the exclusion criteria could be added to this policy as they apply to bictegravir combination for clarity. Clinical Panel accepted this rationale because equivalent effectiveness and tolerability / safety have been demonstrated. 2. The policy also proposed that bictegravir could be used as an alternative treatment if B/F/TAF is considered the most clinically suitable option where alternatives are discussed at a multidisciplinary team (MDT) meeting and considered not suitable due to issues related to tolerability, toxicity, adherence, drug interactions or treatment failure. Clinical Panel did not support these criteria. Panel recognised the theoretical advantage of adding further treatment combinations to those already commissioned but the evidence did not demonstrate a subgroup in which there was a significant benefit over currently commissioned standard treatments. This set of eligibility criteria should be removed from the policy proposition.
Rationale Is the rationale clearly linked to the evidence?	Yes, where bictegravir combinations are proposed as an alternative to existing commissioned treatment combinations. However, the policy also proposed that bictegravir combinations could be used on the basis of MDT opinion, but no clear criteria are provided to identify a sub-group of patients for who bictegravir would offer benefit.
<u>Advice</u> The Panel should provide advice on matters relating to the evidence base and policy development and prioritisation. Advice may cover: • 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	The Clinical Panel noted that the criteria listed in 'Section 8 Proposed Criteria for Commissioning' bullet 1) are insufficiently defined. Panel advise the Policy Working Group (PWG) include the criteria in the NHS England TAF policy (https://www.england.nhs.uk/wp-content/uploads/2017/03/f03-taf-policy.pdf) so that the clinical criteria for use of the bictegravir combination are clear and that it is clear that these would apply only in circumstances in which the bictegravir is provided at an equivalent or lower cost than the alternative commissioned treatments. This could represent the whole of the policy proposition. Alternatively, the PWG may wish to present clear and evidenced based specific clinical criteria which would justify the use of bictegravir in circumstances where its cost exceeds the other routinely commissioned combinations of treatment. Clinical Panel were unable to identify any sub-group from the evidence review. The PWG may conclude that there are no clinical criteria demonstrated in the evidence that identify a sub group likely to benefit significantly more from a bictegravir combination than currently commissioned combinations.

need for policy review.			
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	
		Should be reconsidered by the PWG	

Overall conclusions of the panel

Report approved by:
David Black
Clinical Panel Chair
23/07/18