Consultation Report

Topic details

Title of policy or policy statement:	Bictegravir-emtricitabine-tenofovir alafenamide for the treatment of HIV-1 in adults
Programme of Care:	Blood and Infection
Clinical Reference Group:	HIV
URN:	1702

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposal.

2. Background

Human immunodeficiency virus, or HIV, is the virus that causes Acquired Immunodeficiency Syndrome (AIDS). HIV treatment with antiretroviral therapy (ART) has transformed the outlook for people living with HIV from that of a significantly shortened lifespan to a manageable long term chronic condition. Consequently, people living with HIV are more likely to develop age-related medical conditions. Careful management of those conditions alongside their HIV infection is important. HIV management involves lifelong treatment with ART. As a result, HIV clinicians should aim to maximise tolerability and quality of life while minimising harm.

Bictegravir-emtricitabine-tenofovir alafenamide (B/F/TAF) contains bictegravir which is a new treatment for HIV-1. Bictegravir is only available as a '3 in 1' pill combined with 2 other drugs. The evidence review looked at how safe and effective B/F/TAF is when switching from other ART drug regimens. The evidence showed the B/F/TAF is comparable to the treatments people were switched from in terms of maintaining HIV control and other important outcomes to minimise harm.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 22nd February to 25th March 2019. Consultation comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?

- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to made to this document, and why?

4. Results of consultation

A total of nine responses were received, including 3 from patients, 4 from clinicians, 1 from patient groups and 1 from a pharmaceutical company. In total, 8 responses indicated support for the proposition. The main theme from the comments received was the potential of the policy to decrease side effects from ART.

The pharmaceutical company who manufactures the drug suggested clarifications to the commissioning criteria to make wording clearer. These were considered by the PWG and agreed in part and changes made accordingly. Although one respondent disagreed that all the evidence had been considered and the impact of the policy had been accurately identified, the response did not include any detail therefore the PWG were unable to consider and potentially make any amendments based on this feedback.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility.

6. Has anything been changed in the policy as a result of the consultation?

Following consultation, the PWG made a slight change to the wording in section 8 relating to commissioning criteria to clarify that either criteria is an indication for use rather than both criteria.

The Programme of Care Board considered the stakeholder feedback recommending that consultation takes place for 60 days however, the Board agreed that 30 days would be appropriate because there was no extenuating circumstances requiring a longer period of consultation.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

No.