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| **Engagement Report** |

**Topic details**

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| **Title of policy or policy statement:** | Tenofovir alafenamide for treatment of HIV-1 in adults and adolescents |
| **Programme of Care:** | Blood and infection |
| **Clinical Reference Group:** | HIV |
| **URN:** | 2302 |

* + 1. **Summary**

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. During stakeholder engagement, four responses were received three of which were not supportive but partially or with additional caveats of the proposition. Changes were recommended to the draft document from stakeholder engagement.

* + 1. **Background**

This policy proposition has been developed by a Policy Working Group made up of clinical specialists in HIV medicine, Public Health, pharmacy and Commissioning leads and a patient and public voice representative.

* + 1. **Engagement**

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to ‘make arrangements’ to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 12th May 2022 to 26th May 2022. The 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 proposition might be recommended.

A 13Q assessment has been completed following stakeholder testing.

Stakeholders were asked the following questions:

* Do you support the changes (significant changes are highlighted) to the commissioning policy for tenofovir alafenamide (TAF) for HIV-1 treatment through routine commissioning based on the criteria set out in this document?
* Do you believe that there is any additional information that we should have considered? If so, please give brief details.
* Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
* Do you have any further comments on the proposal?
* If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial ‘sense check’.
* Do you support the updated inclusion and exclusion criteria (highlighted in the proposal)?
* Do you support the Equality and Health Inequalities Impact Assessment?
* Please declare any conflict of interests relating to this document or service area.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

* + 1. **Engagement Results**

Four responses were received in stakeholder engagement. This included two representatives of industry, and two responses from a national association.

Three of responses were supportive of the Policy Proposition, but partially or with caveats. Changes were recommended to the policy.

In line with the 13Q assessment it was deemed that further public consultation was required but only after a process of revision (e.g. another evidence base review).

* + 1. **How has feedback been considered?**

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following themes were raised during engagement:

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| **Keys themes in feedback** | **NHS England Response** |
| **Relevant evidence** | |
| Two respondents highlighted additional evidence in the consultation process.  A respondent highlighted an article focused on the safety data between tenofovir alafenamide versus tenofovir disoproxil fumarate. The respondent also highlighted the following points for consideration:   * The risks of bone and renal adverse effects when TDF is boosted within an ART regimen * The safety data for TAF maybe favourable in the short-term, but questioned longer-term data   A respondent also highlighted that the policy states that it will be reviewed in light of new evidence, but that the past evidence review was conducted in 2016. The respondent highlights the considerable evidence produced over this time and suggests a repeat evidence review, with reference to an article Gupta et. al 2015, which demonstrates person/years use and risk of TAF compared with TDF. | The articles were reviewed by the Public Health Lead, these articles would not have been part of the evidence reviewed as it was published after the evidence review was conducted.  The PWG have discussed the lack of recent evidence included within the policy and have referred this to the Clinical Policy Team for consideration of an up to date evidence review to be conducted and therefore included within this policy revision.  A brief was presented to Clinical Panel on the 15th February 2023 seeking a decision on whether a repeat evidence review was required. Recent evidence was presented with potential impact on the policy proposition. All evidence discussed supported the policy proposition, with no potential impact. Clinical Panel agreed that a repeat evidence review was not required at this time. |
| **Additional sources of evidence** | |
| Two respondents highlighted the lack of bone parameters in the policy to determine when TAF would be more appropriate than TDF. They noted that this is a clinical factor which needs justification if it is removed from the policy.  Two respondents also reference the soon to be updated BHIVA guideline, as the 2016 guideline is mentioned within the Clinical Policy. | The PWG considered this, however, do not consider an evidence review would change the outcome at this time and is not currently warranted.  The BHIVA guidelines were reviewed (December 2022) and the policy proposition amended accordingly. |
| **Language clarity** | |
| A respondent highlighted the use of “patients” and “individuals” within the policy. | The PWG considered this and the language has been used consistently throughout a policy proposition revision. |
| **Drugs included within the policy** | |
| A respondent highlighted ART combinations should be more clearly stated in the policy, including which are adolescent approved.  A further respondent suggested that the policy wording should be amended to include any TAF containing regimen (as the respondent discussed it is often prescribed not within a fixed dose combination).  The comment also discussed how NHSE/I mentioned clinical and also cost effectiveness, which may be at odds with the recommendations from the BHIVA guidelines. | The PWG considered this and felt that the inclusion of named products was beyond the scope of this policy proposition as referenced is the summary of product characteristics (SmPC) for prescribers to seek additional information.  NHSE commission based on clinical effectives, safety and also cost-effectiveness, so consideration would be given to the BHIVA guidelines, but other parameters may also be considered in commissioning of TAF containing regimens. |
| **Policy inclusion/exclusion criteria** | |
| Comments included:   * Suggestion to amend the renal threshold to align with the SMPC and the BHIVA associated guidelines (1 comment) * Clarity on the use of “progressive renal decline definition” (2 comments) with the suggestion of an international definition (1 comment) * Suggestion that the adolescent age range should be included within the medium risk factors (1 comment) | The PWG reviewed these suggestions and have made the following changes:   * The renal threshold parameters have been reviewed by the PWG and feel the threshold of < 50 mL/min/1.73m2 is appropriate. * The PWG considered the KDIGO renal definition proposed but consider this reflects thresholds associated with aging and therefore the definition within the policy remains unchanged. * The PWG considered the proposed age threshold for adolescents and as the indication and duration of use with PrEP therapy is different for HIV-1 treatment, the PWG did not feel any amendments to the age threshold was required. |
| **Potential impact on equality and health inequalities** | |
| Respondents highlighted that the EHIA could be amended to include more specific data on pregnancy and breast feeding based on a combination treatment TAF/FTC rather than TAF as an individual agent. | NHS England has identified in the Equalities and Health Impact Assessment (EHIA) that this policy proposition does not negatively impact on other protected characteristics and offers a treatment option for individuals who experience the challenges of other ART regimens. |
| **Changes/addition to policy** | |
| Changes were suggested by either respondent to the proposal. | The following changes have been amended following publication of the updated BHIVA 2022 guidelines:   * Addition of sentence to page 2 paragraph 5 “Recommended two drug regimens include one NRTI with an INI or a PI/b.” * Updated figures page 2 paragraph 7 “Effectiveness of ART is measured by its ability to reduce viral load to undetectable levels on routine tests (usually to less than 50 copies/mL). In 2021, of people receiving ART where a viral load result was reported, 98% were virally suppressed (UK Health Security Agency (UKHSA), 2022). * Page 3 paragraph 5 updated to reflect BHIVA 2022 guidance and changed to: **Recommended for most people with HIV**:   + tenofovir disoproxil and emtricitabine or tenofovir alafenamide and emtricitabine or abacavir and lamivudine plus dolutegravir   + tenofovir alafenamide and emtricitabine and bictegravir   + Lamivudine and dolutegravir   + **Recommended in some clinical situations**: Darunavir plus cobicistat or ritonavir plus emtricitabine plus tenofovir alafenamide or tenofovir disoproxil   + Doravirine plus emtricitabine or lamivudine plus tenofovir alafenamide or tenofovir disoproxil   + Efavirenz plus emtricitabine or lamivudine plus abacavir or tenofovir alafenamide or tenofovir disoproxil (only in pregnancy or during tuberculosis treatment)   + Raltegravir plus emtricitabine plus tenofovir AF or tenofovir DX * Addition of sentence to page 6 paragraph 1 “TAF usage has been associated with significant weight gain in clinical trials (BHIVA. 2022).” * Amendments to “first line therapy” definition page 8 with the addition of “Lamivudine or lamivudine/abacavir are also recommended in combination with dolutegravir. When clinically appropriate, lamivudine and emtricitabine can be considered interchangeable” * Addition of “second line third agents” definition with the addition of “The use of alternative non-NRTIs agents where first line options cannot be used for reasons of potential or actual intolerance, drug-drug interactions or transmitted HIV drug resistance. Alternative 3rd agents include: the NNRTI rilpivirine or nevirapine, the INIs elvitegravir/cobicistat, and the PI/r lopinavir/ritonavir or atazanavir/ritonavir or cobicistat. Drug selection depends on side effects profile, tolerability, resistance profile, drug-drug interactions and cost.” |

* + 1. **Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?**

Changes were suggested as part of the engagement response. The viewpoints of the stakeholders were considered by the Policy Working Group and the Programme of Care. The table above lists the changes that were made to the policy proposition as a result of stakeholder testing and consultation

**Equality and Health Inequalities Impact Assessment:**

Nil change.

* + 1. **Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?**

There are no remaining outstanding concerns.