**CLINICAL PRIORITIES ADVISORY GROUP**

**10 January 2024**

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| **Agenda Item No** | 2.1 |
| **National Programme** | Blood and Infection |
| **Clinical Reference Group** | HIV |
| **URN** | 2302 |

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| **Title** |
| Tenofovir alafenamide for treatment of HIV-1 in adults and adolescents |

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| **Actions Requested** |  |
|  | 1. Recommend its approval as an IYSD |

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| **Proposition** |
| Service delegation status – suitable and ready for greater ICS leadership.  This is a proposition for an update to the existing policy “[Tenofovir alafenamide for treatment of HIV-1 in adults and adolescents](https://www.england.nhs.uk/publication/clinical-commissioning-policy-tenofovir-alafenamide-for-treatment-of-hiv-1-in-adults-and-adolescents/)”.  The main changes to the policy are:   * Use of new policy template * Update to references and epidemiology * Removal of reference to specific TAF-containing fixed dose combinations * Simplification of eligibility criteria using clinically available measures to determine patient cohorts   The proposed updates to the policy also align with the Pre-Exposure Prophylaxis (PrEP) indication for tenofovir alafenamide (TAF) (2112 PrEP reimbursement policy).  This proposed policy update has been undertaken by a Policy Working Group (PWG) consisting of HIV experts, a public health specialist and specialised commissioner for NHS England. The update retains the current policy recommendation that TAF is made available as an option for adults and adolescents living with HIV who meet the criteria outlined in the proposition.  This proposed update to the Clinical Commissioning Policy outlines the commissioning criteria for the use of TAF for Human Immunodeficiency Virus type 1 (HIV-1) treatment in adults and adolescents and was first published in July 2016 and updated and re-published in February 2017.    The aim of antiretroviral therapy (ART) is to supress the virus, reducing the consequences of immunosuppression which include increased mortality, morbidity, and poor health related quality of life.  If the virus is supressed, the ability for an individual to transmit the virus is negligible.    TAF is a drug used for the treatment of HIV, and is available in fixed dose combinations, with one or multiple other HIV drugs. This proposition outlines the use of tenofovir alafenamide as a bioequivalent alternative to tenofovir disoproxil fumarate (TDF) in people for whom TDF is contraindicated at treatment initiation or who develop complications during treatment. TAF offers benefits of reduced toxicity in individuals at certain risk of renal or bone impairment.  Key recent evidence was identified and impact assessed​, Clinical Panel advised a repeat evidence review was not required. |

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| **Clinical Panel recommendation** |
| The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy proposition. |

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| **The committee is asked to receive the following assurance:** | |
| 1. | The Head of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of governance steps and includes an: Evidence Review; Clinical Panel Report. |
| 2. | The Head of Acute Programmes confirms the proposition is supported by an: Impact Assessment; Engagement Report; Equality and Health Inequalities Impact Assessment; Clinical Policy Proposition. The relevant National Programme of Care has approved these reports. |
| 3. | The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal. |
| 4. | The Director of Clinical Commissioning (Specialised Commissioning) confirms that the service and operational impacts have been completed. |

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| **The following documents are included (others available on request):** | |
| 1. | Clinical Policy Proposition |
| 2. | Engagement Report |
| 3. | Evidence Review – not updated for the policy revisions. |
| 4. | Clinical Panel Report |
| 5. | Equality and Health Inequalities Impact Assessment |

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| **Patient Impact Summary** |
| **The condition has the following impacts on the patient’s everyday life:**     * **mobility:** Patients have severe problems in walking about * **ability to provide self-care:** Patients have severe problems in washing or dressing * **undertaking usual activities:**Patients are unable to do their daily activities * **experience of pain/discomfort:** Patients have severe pain or discomfort * **experience of anxiety/depression:**Patients are extremely anxious or depressed |
| **Impact upon carers:**  Carers most likely will have been with the patient throughout their HIV journey, from the initial diagnosis, through trials of different ART medications and then potentially into the complications of immunosuppression.    This can place a significant emotional and psychological burden on patients, carers and their wider families as they may require more assistance, have greater care needs and require help to complete household activities.    Patients may have declining health, for example poor kidney function or bone problems, which can limit their ability to perform family roles such as caring responsibilities for children and work roles.  This can place additional pressure on carers and wider families emotionally, physically and also financially. |

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| **Considerations from review by Rare Disease Advisory Group** |
| Not applicable. |

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| **Pharmaceutical considerations** |
| This clinical commissioning policy proposition recommends tenofovir alafenamide (TAF; as part of a TAF-containing regimen) as a treatment option in adults and adolescents with HIV with high risk or medium risk factors associated with the use of tenofovir disoproxil fumarate. TAF is licensed as a treatment for HIV in adults; some TAF containing products are also licensed as a treatment for HIV in adolescents (aged 12 years and older). TAF-containing medicines are high-cost drugs detailed in the NHS Payment Scheme Annex A 2023/24, i.e. they are excluded from tariff. |

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| **Considerations from review by National Programme of Care** |
| The proposal received the full support of the Blood and Infection PoC on the 23 May 2023 |