Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	**F03X08**		
Policy Title	**Tenofovir Alafenamide for treatment of HIV 1 in adults and adolescents**		
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Section A - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 Overall HIV prevalence in 2014 was 1.9 per 1000 people over the age of 15 (Public Health England (2015) HIV in the UK – Situation Report 2015 Incidence, prevalence and prevention)	
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 The number of patients eligible is made up of those currently treated with Cobicistat, elvitegravir, emtricitabine, TDF and treatment naïve patients who fit the commissioning criteria for ART. Existing patients c.1,630 (NHS England prescribing data) 5,370 patients initiated ART treatment in 2013 (Public Health England (2015) HIV in the UK – Situation Report 2015 Incidence, prevalence and prevention) Maximum Total eligible 7,000 (not all new patients expected or likely to take up this regime).	

	A1.3 What age group is the treatment indicated for?	A1.3 This treatment is indicated for adults and adolescents over the age of 12 and with a body weight in excess of 35kg
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 48% of all patients with HIV were aged 45 years or older in 2014 and 55% of new diagnosis was in the age group 25-44 years (Public Health England (2015) HIV in the UK – Situation Report 2015 Incidence, prevalence and prevention)
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 The currency for HIV activity is Year of Care rather than attendance, so the total current activity is the same as the existing number of HIV patients in this cohort c1,630 (see A1.2)
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 Predicted growth in diagnosis of HIV is running at around 6,000 new cases per annum (Public Health England (2015) HIV New Diagnoses, Treatment and Care in the UK) 12,000 in 2 years 30,000 in 5 years 60,000 in 10 years However this policy will not directly affect this expected rate due to its application as a replacement drug treatment for an existing regimen
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	A1.7 The underlying growth of activity remains unchanged under the policy proposal at around 4.4% per year. Year 2 1,781 Year 5 2,026

		Year 10 2,512
	A1.8 How is the population currently distributed geographically?	A1.8 41% of patients with HIV are currently treated in London (Public Health England (2015) HIV New Diagnoses, Treatment and Care in the UK)
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	A2.1 This policy effectively substitutes a currently routinely commissioned treatment as described above
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 The growth in patient population will not be affected by this treatment. It is likely that other interventions will have greater impact.
	A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	A2.3 No
	A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	A2.4 There will not be a net increase in the number of patients accessing ART due to this policy
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in	A3.1 The annual activity for the target population is 2,010 which is c1,630 existing patients (see A1.2) plus c80 patients transferring

	accompanying excel sheet.	from other treatments.
	A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	A3.2 There is no change to the activity associated with this policy.
	A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	A3.3 The activity would remain the same under both the 'Do Nothing/Next Best Alternative' comparators.
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	A4.1 This pathway is mostly associated with drug costs, there is unlikely to be any other significant changes in activity
	A4.2. What are the current treatment access criteria?	A4.2 The current commissioning criteria for ART will remain in place for this new treatment
	A4.3 What are the current treatment stopping points?	A4.3 As above
A5 Comparator (next best alternative treatment) Patient Pathway	A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	A5.1 Not applicable
	A5.2 Where there are different stopping points	A5.2 Not applicable

	on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A6.1 The patient pathway for treatment does not differ from the current commissioning of ART A6.2 Not applicable
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Day case/ Outpatient o Mental Health Provider: Inpatient/Outpatient	A7.1 Treatment setting remains outpatient and homecare drug delivery routes

	○ Community setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.2 No change
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.1 ART prescribing datasets and the excluded drug MDS A8.2 Pass through drug payments as currently recorded in line with commissioning policies and patient identification rules
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? A9.2 If this treatment is a drug, what pharmacy monitoring is required? A9.3 What analytical information /monitoring/ reporting is required? A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.1 No A9.2 As with current ART treatments for HIV patients A9.3 Monitoring of frequency of prescribing different ART regimens will be continued A9.4 No changes required.

	A9.5 Is there linked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 There are no changes to reporting except to provide an additional option for treatment
	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 No
	A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	A9.7 No – however this policy is linked to a wider substantial commissioning for value proposal
Section B - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 Specialised centres and networks
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 It will not change the way the service is organised
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Via new diagnosis and CD4 monitoring of patients within the service
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 No

	B2.3 Is the new policy likely to improve equity of access?	B2.3 No
	B2.4 Is the new policy likely to improve equality of access / outcomes?	B2.4 There is evidence of some improvement for patients with renal toxicity issues at least in the short term.
B3 Implementation	B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	B3.1 The lead in time relates the planned switching of patients to avoid drug wastage.
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 No
	B3.3 Is there a change in provider staffing required?	B3.3 No
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 No
	B3.5 Are there changes in the support services that need to be in place?	B3.5 No
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 No
	B3.7 Is there likely to be	B3.7

	either an increase or decrease in the number of commissioned providers?	No
	B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	B3.8 Providers will be advised by circular once the policy has been agreed.
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 There is some local interest in collaborative commissioning of HIV services, particularly in London, however there are no current plans to formally devolve responsibility.
Section C - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 There is a nationally mandated Year of Care currency for HIV which is locally priced. HIV drugs are pass through payments with prices secured through tenders
	C1.2 Is this treatment excluded from national prices?	C1.2 Yes, both the Year of Care costs and HIV drugs are excluded from national prices
	C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	C1.3 The Year of Care tariffs are locally negotiated. HIV drugs are covered under tender prices negotiated within the regional structure. There are no costs attributable with other clinical services.

	C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?	C1.4 The total amount of ART prescribed is closely monitored and this will ensure that there is not double charging for existing and new drug regimens for the same patient
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 VAT has been included for the estimated 30% of patients not accessing the treatment via Homecare.
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 No
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 £6,285
	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 £6,285
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	C3.1 This is cost saving of approximately £1.1m compared to existing regimens in Year 1 only. From Year 2 this may become a cost pressure due to the move to generic pricing of other HIV drugs of c£2m per year.
	C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.2
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	C4.1 This does not impact on other parts of the NHS

	C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	C4.2 Cost saving in Year 1 only.
	C4.3 Where this has not been identified, set out the reasons why this cannot be measured.	C4.3
	C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.4 No - NHS England is responsible for all ART drug costs
C5 Funding	C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. *e.g. decommissioning less clinically or cost-effective services*	C5.1 Not applicable (see C6.2 re Year 2 onwards).
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy?	C6.1 There are no material risks to implementation in line with the policy proposal. The only financial risk is from non implementation which will prevent the realisation of savings in Year 1. See C6.3 re Year 2 onwards.
	C6.2 Can these be mitigated, if so how?	C6.2 Not applicable
	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.3 There is a wider piece of work ongoing to consider the most cost effective prescribing of all ART regimens
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE*	C7.1 The current costs of the drug treatments are central to the policy proposal. If the drug

	appraisal, clinical trials or peer reviewed literature	prices change the policy will be revoked. The cost effectiveness of ART has been widely reviewed and this remains in line with commissioning of ART
	C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.2 Not applicable
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	C8.1 No
	C8.2 If so, confirm the source of funds to meet these costs.	C8.2