Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	ID010		
Policy Title	Bictegravir-emtricitabine-tenofovir alafenamide for the treatment of HIV-1 in adults Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Rob Coster	**Clinical Lead**	Marta Boffito
Finance Lead	Jaqueline Low	**Analytical Lead**	Click here to enter text.

Integrated Impact Assessment – Index		
Section A – Activity	**Section B - Service**	**Section C – Finance**
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	In 2017, 85,537 people (84,551 adults and 986 children) were seen for HIV care in England, including 3,973 (3,809 adults and 164 children) newly diagnosed cases of HIV. *Source: Public Health England 2018, Country and PHE region HIV data tables*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	12,670 From the prevalent population of 85,537 people, the following estimates are assumed: • 99% (84,551 people) are adults • 98% (82,860 adults) will receive ART • 14% (11,238 adults) will meet the NHS England commissioning policy for TAF (criteria group 1) • 2% (1,432 adults) will require an unboosted integrase inhibitor containing regimen but neither: • raltegravir ; NOR • dolutegravir can be taken due to drug-drug interactions or poor tolerability/toxicity (criteria group 2) This gives a potential eligible population of 12,670 people. *Source: Public Health England 2018, Country and PHE region HIV data tables, clinical opinion* It is expected that c5% of patients will transfer to the new treatment by the end of the first year (634 patients)

<table>
<tr><td></td><td></td></tr>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>Adults</u>
B/F/TAF has a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) for the treatment of <u>adults</u> infected with HIV-1 without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>
<table>
<tr><td>Age range</td><td>Prevalence</td><td>Incidence</td></tr>
<tr><td>18 - 24</td><td>1,523</td><td>323</td></tr>
<tr><td>25 - 34</td><td>11,238</td><td>1,201</td></tr>
<tr><td>35 - 49</td><td>38,646</td><td>1,512</td></tr>
<tr><td>50 - 64</td><td>28,184</td><td>642</td></tr>
<tr><td>65 and over</td><td>4,960</td><td>131</td></tr>
<tr><td></td><td>84,551</td><td>3,809</td></tr>
</table>
Please note that the PHE data is shown for the age bracket 15-24 and an even distribution has been assumed to estimate those aged 18-24.
Source: Public Health England 2018, Country and PHE region HIV data tables
In 2017, more than a third (39%; 33,144/85,537) of people accessing HIV care in England were aged 50 years and above.</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Unevenly</u>
If unevenly, estimate regional distribution by %:
<table>
<tr><td>North</td><td>18%</td></tr>
<tr><td>Midlands & East</td><td>22%</td></tr>
<tr><td>London</td><td>43%</td></tr>
<tr><td>South</td><td>18%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>Please note that the PHE data is shown for the age bracket 15-24 and an even distribution has been assumed to estimate those aged 18-24.

Source: Public Health England 2018, Country and PHE region HIV data tables</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Increasing</u>
<table>
<tr><th>Change in epidemiology</th><th>Year 2</th><th>Year 5</th><th>Year 10</th></tr>
<tr><td>Prevalence in adults</td><td>91,619</td><td>100,916</td><td>113,457</td></tr>
<tr><td>Incidence in adults</td><td>3,448</td><td>2,970</td><td>2,315</td></tr>
</table>
Since 2005 the number of people being newly diagnosed with HIV has generally fallen each year. However the prevalent population seen for HIV care in England has increased each year between 2007 and 2017.

Source: Calculated in the resource impact template</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>Yes</u>
There is an ageing population because people live longer with HIV and are maintained on ART. Therefore, each year the proportion of people with HIV aged over 50 years will increase and so will the number of people who have co-morbidities. These people will be eligible for TAF.</td></tr>
</table>

Also PHE reported in 2018 that a reduction in diagnoses among black African and black Caribbean heterosexuals was largely due to a decrease in migration from high prevalence countries. For the first time there has also been a drop in the number of diagnoses reported among other heterosexuals, which fell by 20% to 849 in 2017; previously, diagnoses had remained stable at around 1,000 diagnoses per year. Diagnosis rates in gay and bisexual men have been falling since 2015. This is due to increases in HIV tests among gay and bisexual men attending sexual health clinics including repeat testing in higher risk men, as well as improvements in the uptake of anti-retroviral therapy following HIV diagnosis.

Source: Trends in new HIV diagnoses and people receiving HIV-related care in the United Kingdom: data to the end of December 2017, Public Health England 2018

A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

YR2 +/-	1,059
YR3 +/-	1,548
YR4 +/-	2,012
YR5 +/-	2,452
YR10 +/-	4,332

Source: Resource impact template. Service specification proposition section 3.1

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.

No

The starting population from which prevalence and incidence figures are calculated are from PHE figures (Public Health England 2018, Country and PHE region HIV data tables). In 2017 there were 3,973 new cases of HIV diagnosed. Since 2005 the number of people being newly diagnosed with HIV has generally fallen each year. To estimate incidence over the

	next 10 years, 3,973 has been used as the incidence for year 0 and the average decrease has then been applied each year. In 2017 there were 85,537 people seen for HIV care. The prevalence in future years has been calculated as prior year prevalence plus incidence less mortality. It is expected that c5% of the eligible population will transfer to the new treatment by the end of the 1st year.
A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Confirm routine commissioning position of an additional new treatment</u>** The proposal is to routinely commission B/F/TAF for treating HIV-1 in adults. This policy would provide an additional treatment option under the following criteria: B/F/TAF will be routinely commissioned in HIV-1 infected adults in line with cost-based, regional prescribing guidelines: 1. if they meet the commissioning criteria as outlined in the NHS England commissioning policy: tenofovir alafenamide for treatment of HIV-1 in adults and adolescents. Ref: NHS England: 16043/P (see aAppendix I); OR 2. if they require an unboosted integrase inhibitor containing regimen but neither: • raltegravir ; NOR • dolutegravir can be taken due to drug-drug interactions or poor tolerability/toxicity.

<table>
<tr>
<td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td>
<td>The estimated annual number of people who will eligible to receive B/F/TAF are estimated to be as follows:
<table>
<tr><td>Year 0</td><td>12,670</td></tr>
<tr><td>Year 1</td><td>13,214</td></tr>
<tr><td>Year 2</td><td>13,730</td></tr>
<tr><td>Year 5</td><td>15,123</td></tr>
<tr><td>Year 10</td><td>17,002</td></tr>
</table>
The estimate takes into account the people treated from the prevalent and incident populations.
Source: Resource impact template, based on published data and a number of assumptions.</td>
</tr>
<tr>
<td>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</td>
<td>The estimated annual activity for people eligible to receive B/F/TAF are:
<table>
<tr><td>Year 1</td><td>248</td></tr>
<tr><td>Year 2</td><td>501</td></tr>
<tr><td>Year 5</td><td>592</td></tr>
<tr><td>Year 10</td><td>514</td></tr>
</table>
Source: Resource impact template based on published data and assumptions.
Please specify
The estimate takes into account the people treated from the prevalent and incident populations (c5%). The uptake is profiled over time.</td>
</tr>
<tr>
<td>A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If</td>
<td>Not applicable</td>
</tr>
</table>

the only alternative is the existing pathway, please state 'not applicable' and move to A4.	
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	The overall goal of treatment is HIV-1 viral suppression (maintaining an undetectable viral load level). British HIV Association Treatment guidelines (BHIVA) for adults currently recommend the following first-line treatment (Waters et al. 2016): • One of the following nucleoside analog reverse-transcriptase inhibitor (NRTI) backbones: 1. emtricitabine and tenofovir disoproxil fumarate (F/TDF): recommended for individuals who do not show established or significant risk factors for kidney or bone problems. OR 2. emtricitabine and tenofovir alafenamide (F/TAF): preferred option if the individual has established or significant risk factors for kidney or bone problems. OR 3. abacavir and lamivudine: alternative option, although an individual should not be given abacavir if there are contraindications e.g. HLA-B*5701 positive, hepatitis B co-infection or high risk of cardiovascular disease. AND • a third drug: of which the preferred options are atazanavir/ritonavir, or darunavir /ritonavir, or raltegravir or elvitegravir/cobicistat or rilpivirine, or dolutegravir. An alternative option is efavirenz. *Source: DPP section 6*

A4.2. What are the current treatment access and stopping criteria?	All people diagnosed with HIV are eligible for treatment. People may switch to an appropriate alternative antiretroviral therapy if there is a non-response to treatment or tolerability issues. They may also switch to an appropriate alternative antiretroviral therapy if there are clinically suitable or less expensive options available.
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	98% of people diagnosed with HIV are currently receiving ART. People who accept treatment with ART will always be treated with one of the options. If the current treatment is unsuitable then people will switch to an alternative. a) 100% - all people will be clinically assessed for treatment b) 0% - all people diagnosed with HIV are eligible for treatment c) 98% - based on current uptake rates of ART d) 95% - based on clinical opinion e) 100% *Source: Public Health England 2018, Country and PHE region HIV data tables, IIAR for IART*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No**

A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	N/A
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify a) 100% - all people will be clinically assessed for treatment b) 14% - of people are estimated to meet the criteria for group 1 2% of people are estimated to meet the criteria for group 2 c) 98% - based on current uptake rates of ART d) 95% - based on clinical opinion e) 94% - 6% of the eligible population are expected to cease treatment because of non-response to treatment or tolerability issues *Source: Public Health England 2018, Country and PHE region HIV data tables, IIAR for IART*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long**
A7 Treatment Setting	

A7.1 How is this treatment delivered to the patient?

Select all that apply:

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☐
Acute Trust: day patient	☐
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☒
Other	☐

Please specify:

A7.2 What is the current number of contracted providers for the eligible population by region?

NORTH	56 clinics
MIDLANDS & EAST	50 clinics
LONDON	30 clinics
SOUTH	46 clinics

A7.3 Does the proposition require a change of delivery setting or capacity requirements?

No

A8 Coding

A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	☒
Patient level contract monitoring	☐
Patient level drugs dataset	☐
Patient level devices dataset	☐
Devices supply chain reconciliation dataset	☐
Secondary Usage Service (SUS+)	☐
Mental Health Services DataSet (MHSDS)	☐
National Return**	☐
Clinical Database**	☒
Other**	☒

**If National Return, Clinical database or other selected, please specify:
HARS database and local drug use and pharmacy reporting

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

OPCS v4.8	☐
ICD10	☐
Treatment function code	☐
Main Speciality code	☒
HRG	☐

	<table><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☒</td></tr></table> HARS database and local drug use and pharmacy reporting
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**Not already specified in current NHS England Drugs List document**
A8.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). **NCPDS14Z HIV Outpatient activity. High Cost Drugs funded on pass through costs. Note that there will be no increase in outpatient (or inpatient) activity associated with this policy.** If activity costs are already captured please specify whether this service needs a separate code. **No** If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. **N/A**
A9 Monitoring	

<table>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u></td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:
<table><tr><td>Drugs or Device MDS</td><td>☒</td></tr><tr><td>Blueteq</td><td>☐</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table>Please specify:
Local ART reporting, HARS and PharmEx feeds.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
If yes, please specify contract monitoring requirement:
Drug usage and spend on ARTs already part of routine contract monitoring for HIV services as excluded from tariff.</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>Yes</u>
HARS data already used to populate dashboards.</td></tr>
<tr><td>A9.6 NICE reporting
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?</td><td><u>No</u></td></tr>
</table>

<table>
<tr><th colspan="2">Section B - Service Impact</th></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Specialised HIV treatment clinics arranged in local networks across regions.

Source: IIAR for immediate antiretroviral therapy for HIV</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u>

Source: IIAR for immediate antiretroviral therapy for HIV</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u></td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
GP ☒
Secondary care ☒
Tertiary care ☒
Other ☒
Please specify:
Referrals come from any organisation where a positive diagnosis of HIV has been made, e.g. GUM, GP, secondary care, A&E services.</td></tr>
</table>

B2.2 What impact will the new policy have on the sources of referral?	**No impact**
B2.3 Is the new policy likely to improve equity of access?	**No impact**
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** Please specify: B/F/TAF would provide another treatment option *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No**

<table>
<tr><td></td><td></td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u></td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>No change</u></td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table><tr><td>Publication and notification of new policy</td><td>☒</td></tr><tr><td>Market intervention required</td><td>☐</td></tr><tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr></table></td></tr>
</table>

	Any qualified provider ☐ National Commercial Agreements e.g. drugs, devices ☒ Procurement ☐ Other ☐ Please specify: Click here to enter text.
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:* **Drugs**: Not separately charged – part of local or national tariffs ☐ **Drugs**: Excluded from tariff – pass through ☒ **Drugs**: Excluded from tariff - other ☐ **Devices**: Not separately charged – part of local or national tariffs ☐ **Devices**: Excluded from tariff (excluding ZCM) – pass through ☐

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>Excluded from tariff (excluding ZCM) – other</td><td>☐</td></tr>
<tr><td></td><td>Via Zero Cost Model</td><td>☐</td></tr>
<tr><td rowspan="7">Activity</td><td>Paid entirely by National Tariffs</td><td>☐</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☒</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☒</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>C1.2 Drug Costs
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Multiple ART regimens are commissioned and prescribed depending on the clinical indications of the patient and the regional prescribing guidelines.
ART regimens are procured through the Commercial Medicines Unit, through which NHS England receives discounted prices from the list price of a given regimen. The prices are commercially sensitive and vary across regions and regimens. The regional frameworks are re-tendered on a two-yearly basis, with 1 of the 4 regions being re-tendered six-monthly. There are also opportunities to reduce prices mid contract term to reflect lower prices in the market, ensuring that the best value is achieved on the cost of ART (and other high cost drugs).

The UK list price is £879.51.</td></tr>
<tr><td>C1.3 Device Costs</td><td>N/A</td></tr>
</table>

Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	N/A
C1.5 **Activity Costs covered by Local Tariff** List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Activity costs already captured and funded under local arrangements (block/ cost and volume/ attendance based tariffs depending on local agreement). No additional activity generated through this policy.
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	N/A
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**No**
C2 Average Cost per Patient	

<table>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR1</td><td>£TBC</td></tr><tr><td>YR2</td><td>£TBC</td></tr><tr><td>YR3</td><td>£TBC</td></tr><tr><td>YR4</td><td>£TBC</td></tr><tr><td>YR5</td><td>£TBC</td></tr></table>Above costs are based on list prices.</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u>
Year 1 - £TBC
Year 2 - £TBC
Year 5 - £TBC
Year 10 - £TBC</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not applicable</td></tr>
<tr><td>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</td><td>Not applicable</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
</table>

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **No impact on providers** Please specify: NHS England is responsible for all ART drug costs
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Year 1 - £TBC Year 2 - £TBC Year 5 - £TBC Year 10 - £TBC
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No**
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.	CPAG prioritisation reserve

C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	There is a risk that the number of people eligible for TAF, and therefore eligible for B/F/TAF, will increase in future years. As the HIV population ages and are maintained on ART, there will be more people with comorbidities who require treatment with TAF.
C6.2 How can these risks be mitigated?	The increase in numbers is likely to be low in the short-term. Also there are likely to be more new treatments coming to market in the short to medium term whose introduction is likely to further affect the number of people treated with B/F/TAF.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	According to clinical opinion uptake of B/F/TAF will depend on the price compared to its comparators. If B/F/TAF is more expensive than its comparators then only a small proportion of the eligible population will be treated with it, resulting in a cost pressure as specified in C4.2. If B/F/TAF is the same price as its comparators then 1.5 times as many people could be treated with it, however this will have a negligible effect on overall resource impact. If B/F/TAF is cheaper than its comparators then 2 times as many people could be treated with it and this would result in a saving.
C6.4 What scenario has been approved and why?	Uptake in the resource impact template assumes that B/F/TAF is more expensive than the comparators. This is the most conservative estimate.
C7 Value for Money	

C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	The clinical evidence review for this technology found no studies relating to cost effectiveness
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☐ Available clinical practice data suggests the new treatment has the potential to improve value for money ☐ Other data has been identified ☐ No data has been identified ☒ The data supports a high level of certainty about the impact on value ☐ The data does not support a high level of certainty about the impact on value ☐
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable