Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1613		
Policy Title	Immediate Antiretroviral therapy for treatment of HIV-1 in adults and adolescents Proposal **for routine commission** (ref A3.1)		
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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.	Public Health England (PHE) estimated that in 2015, 101,200 people (95% credible interval (CrI) 97,500-105,700) were living with HIV in the UK; of those, 13,500 (95% CrI 10,200-17,800), or 13% (95% CrI 10-17%) were unaware of their infection and at risk of passing on the virus to others. The majority, 69% (69,500; 95% CrI 66,300-73,700), were men and 31% (31,600; 95% CrI 30,600-32,800) were women (Kirwan et al., 2016). The HIV prevalence in the UK is estimated to be 1.6 per 1,000 population, or 0.16%. Approximately 6,000 patients are newly diagnosed with HIV each year in the UK. In 2015, 5,512 people were newly diagnosed with HIV in England (Kirwan et al., 2016). *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	In 2015, 88,769 people were living with diagnosed HIV and accessed HIV care in the UK, of whom 81,062 accessed care in England (Kirwan et al., 2016). In 2015, 96% (83,931/87,813) of people with HIV accessing care in the UK were receiving ART. This is a rise from 90% in 2014 and is likely to reflect 2015 HIV treatment guidelines (Waters et al, 2016) and NHS England Treatment as Prevention clinical commissioning policy (NHS England, 2015) which recommend that all people living with HIV are offered treatment to prevent onward transmission. Treatment outcomes in the UK are very good. In 2015, 94% of all those receiving ART were virally suppressed (viral load, < 200 copies/ml) and compare favourably to the UNAIDS 90:90:90 Target (Kirwan et al., 2016). *Source: Policy Proposition section 6* Click here to enter text.

<table>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>Adults</u>
Policy covers adults and adolescents only, as current commissioned practice for paediatric patients means they are able to start on ART regardless of CD4 count linked to their clinical considerations.</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>15-65+
Source: Policy Proposition
Adolescents and adults – 15 years old plus covers over 99% of the population receiving care for HIV in England.</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>21%</td></tr><tr><td>London</td><td>44%</td></tr><tr><td>South</td><td>17%</td></tr></table>Source: Policy Proposition section 6
PHE information used for Policy Proposition
London 40%
Outside of London and Wales 53%
Scotland and Northern Ireland 7%</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>Constant</u>
The number of people newly diagnosed with HIV in the UK has remained stable in recent years; in 2015, 6,095 people were newly diagnosed with</td></tr>
</table>

<table>
<tr><td></td><td>HIV in the UK, of whom 5,512 were diagnosed in England (Kirwan et al., 2016). Whilst patients are living longer with HIV, new diagnosis have reduced over (2016) in some high volume clinics, believed to be linked to increased testing rates associated with accessing PrEP and the implementation of the TasP policy.
Source: Policy Proposition section 6/ PHE HIV Surveillance Tables/ PHE Presentations on diagnosis decreases in high volume clinics</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>
Aging population as patients live longer with HIV, maintained on ART.
Source: Policy Proposition section 6/ PHE HIV Surveillance Tables</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for treatment, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?</td><td><table><tr><td>YR2 +/-</td><td>294 – a</td></tr><tr><td>YR3 +/-</td><td>294</td></tr><tr><td>YR4 +/-</td><td>294</td></tr><tr><td>YR5 +/-</td><td>294</td></tr><tr><td>YR10 +/-</td><td>294</td></tr></table>Source: Policy Proposition section 6/ PHE HIV Surveillance Tables
a- Patients newly diagnosed with CD4 count over 350 who would not qualify for treatment under TASP (all existing patients caught up in year 0 & 1). Anticipated number of new diagnosis year on year with a CD4 count over 350, based on current diagnosis level.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Revise existing policy (expand or restrict an existing treatment</u></td></tr>
</table>

	<u>threshold / Add an additional line of treatment / stage of treatment</u> Remove threshold so all diagnosed patients can access treatment.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	85, 218 patients currently diagnosed with HIV and on ART treatment *Source:* PHE/ Policy Proposition 96% of diagnosed patients currently on treatment either because they fall under the existing treatment policy (CD4 count under 350) or they fall under the Treatment as Prevention (TasP) policy.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	In 2015, 39% (2,350/6,028) of those diagnosed presented with a CD4 count <350 cell/mm3 and would be eligible to start ART under the current clinical commissioning policy. 83% patients with CD4 count over 350 qualify for treatment under TasP =1973. Under the proposed policy: 833 patients in the current year based on 25% of patients not on ART with CD4 over 350 with 90% uptake based on current uptake rate in year 0. Patients will be offered ART at next routine appointment to reduce administration costs associated with the scheme, set at 25% in current year and 75% in first year. Year 1 uptake would see a further 1,909 patients based on 75% of patients not on ART with CD4 over 350 with 90% uptake based on current uptake rate in year 0. Numbers have been phased to account for those patients not on ART with a CD4 count between 350-499, as a percentage of these will move onto ART in year as their disease progresses. Modelled at 20% per annum. 294 patients from year 2 onwards, potentially reducing if new diagnosis number reduction seen in some large London centres in 2016 continues. *Source: PHE HIV Surveillance Tables*

A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable – only alternative would be existing pathway, modelled as a "Do nothing" scenario) *Source: required* Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Patients currently access ART treatment for their diagnosed HIV infection through specialised commissioned HIV treatment centres. Treatment is initiated when their CD4 count drops to below 350, or if they meet the Treatment as Prevention (TasP) policy which enables patients at risk of transmitting HIV to others to start treatment earlier. This policy has had a large uptake, with 63% of patients currently on ART treatment having a CD4 count over 499. *Source: PHE HIV Surveillance Tables*
A4.2. What are the current treatment access and stopping criteria?	Treatment access – CD4 count under 350 or meet TasP criteria (below). No criteria for stopping treatment. *Source: f03pc Clinical Commissioning Policy: Treatment as Prevention (TasP) in HIV infected adults* Treatment as Prevention will be routinely commissioned where all of the commissioning criteria below are met • Laboratory confirmed diagnosis of HIV infection, and • Sexually active, and

	• TasP is offered by the clinician, and • Discussion between clinician and patient has identified significant risk of HIV transmission to partners without TasP, and • TasP is prescribed as part of a full assessment of risk factors by the clinical team and is part of a risk reduction plan discussed with the patient, and • Patient has considered the information relating to TasP and understands the risks and benefits of treatment to prevent onward HIV transmission, and • Regimen selected is the lowest cost, clinically appropriate option.
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?	If not known, please specify Click here to enter text. a) 3% b) 0% c) 90% d) 94% based on current compliance rates e) N/A – treatment is life long *Source: PHE HIV Surveillance Tables*
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*	**No** If yes, Click here to enter text. *Source: required*

• *Actual or estimated eligibility and uptake*	
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?	Total estimated eligible a) enter % b) enter % c) enter % d) enter % e) enter % *Source: required*
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 Click here to enter text. a) 100% b) 0% c) 90% d) 94% - based on current compliance rates e) N/A *Source: PHE HIV Surveillance Tables*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long** For time limited treatments, specify frequency and/or duration. Click here to enter text. *Source: Policy Proposition/ International guidance and best practice*

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:
Click here to enter text.

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

<table>
<tr><td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td><td><u>No</u>
Please specify:
Patients already accessing care in outpatient setting, so just an increase in prescribing.
Source: PHE Surveillance Tables</td></tr>
<tr><td colspan="2">A8 Coding</td></tr>
<tr><td>A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity</td><td>Select all that apply:
<table><tr><td>Aggregate Contract Monitoring *</td><td>☒</td></tr><tr><td>Patient level contract monitoring</td><td>☐</td></tr><tr><td>Patient level drugs dataset</td><td>☐</td></tr><tr><td>Patient level devices dataset</td><td>☐</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☐</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr><tr><td>Clinical Database**</td><td>☒</td></tr><tr><td>Other**</td><td>☒</td></tr></table>**If National Return, Clinical database or other selected, please specify:
HARS database and local drug reporting systems</td></tr>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Select all that apply:</td></tr>
</table>

	<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☐</td></tr><tr><td>Treatment function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☒</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☒</td></tr></table>
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<u>Already specified in current NHS England Drugs List document</u>** If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication: All commissioned ARTs are listed as excluded drugs If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead: Click here to enter text.
A8.4 **Identification Rules for Devices:** How are device costs captured?	**<u>Not applicable</u>** If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance). Click here to enter text. If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. Click here to enter text.

<table>
<tr><td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u>
If activity costs are already captured please specify the specialised service code and description (eg NCBPS01C Chemotherapy).
High Cost Drugs funded on pass through costs
If activity costs are already captured please specify whether this service needs a separate code. Choose an item.
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.
Click here to enter text.
If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.</td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<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>Yes - population of clinical databases</u>
Please specify
HARS database will capture CD4 count and ART initiation to demonstrate policy implementation.</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>
</table>

A9.3 **Business intelligence** Is there potential for duplicate reporting?	**No** If yes, please specify mitigation: Click here to enter text.
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** 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.
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**Yes** If yes, specify how routine performance monitoring data will be used for dashboard reporting. HARS data already used to populate dashboards. If no, will one be developed? Click here to enter text.
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?	**No** If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)	Specialised HIV treatment clinics arranged in local networks across regions. *Source: required*

<table>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u>
Please specify:
Click here to enter text.
Source: required</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>
Please specify:
Click here to enter text.</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:<table><tr><td>GP</td><td>☒</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☒</td></tr></table>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>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>Increase</u></td></tr>
</table>

	Please specify: Currently patients who do not meet the TasP policy and do not have a low CD4 count are unable to access treatment, which is out of line with clinical best practice guidelines. *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** Please specify: Evidence demonstrates that early initiation of ART reduces co-morbidities and later complications if treatment is initiated as close to diagnosis as possible, regardless of CD4 count, improving patient outcomes. New policy removes inequity of access which TasP policy introduced (where patients could access treatment regardless of CD4 count for the prevention of onward transmission, but not for benefits to the individual patient). *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Finance action** Please specify: Increase in budgets in the first year to pay for initial cohort of patients. Moving forward budgets should remain stable based on reductions in new infections and treatment costs already being accounted for.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:**	Choose an item.

<table>
<tr><td>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</td><td>If yes, outline the plan:
Click here to enter text.</td></tr>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u>
Please specify:
Click here to enter text.</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>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>
Please specify:
Click here to enter text.</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>
Please specify:
Click here to enter text.</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>
Please complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future
State expected range</td><td>Provisional or confirmed</td></tr>
</table>
</td></tr>
</table>

North			select
Midlands & East			select
London			select
South			select
Total			select

Please specify:
Click here to enter text.

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

Publication and notification of new policy	☒
Market intervention required	☐
Competitive selection process to secure increase or decrease provider configuration	☐
Price-based selection process to maximise cost effectiveness	☐
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** Please specify: Click here to enter text.

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	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☐
	Partially paid by National Tariffs	☐
	Partially paid by Local Tariffs	☒
	Part/fully paid under a Block arrangement	☒
	Part/fully paid under Pass-Through arrangements	☐
	Part/fully paid under Other arrangements	☐

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.	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. As such, an average cost of £5,000 per patient per year is used for modelling purposes, based on previous work to determine the average ART treatment cost per patient.
C1.3 **Device Costs** 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.	N/A
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 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?	**No** Please specify: Click here to enter text.
C2 Average Cost per Patient	

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

YR1	£5,000
YR2	£5,000
YR3	£5,000
YR4	£5,000
YR5	£5,000

Are there any changes expected in year 6-10 which would impact the model?

Costs based on average of year of care tariffs as outlined above.

If yes, please specify:

Cost of ARTs is likely to continue to reduce with introduction of further generics, therefore may be overstated above, especially from year 3 onwards.

C3 Overall Cost Impact of this Policy to NHS England

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.

Cost pressure

Please specify:

Cost of policy over 10 years modelled at £49.2m.

The majority of cost is in years 1-3 £22.8 up to £38.9m by year 5. By year 9 the impact year on year between present and policy cost is zero. Spend is phased over 2 years to align implementation with patient's routine follow up appointments.

The costs associated with this policy are the bringing forward of costs that would eventually be incurred (when a patient's disease progression met the current threshold for treatment)

Cost avoidance to health economy from reduction of onward transmission estimated as £12k annually per infection stopped. Estimated 1 onward infection stopped for every 9 patients treated = £2.9m cost avoidance in

	year one. Drug costs likely to reduce with further introduction of generic alternatives and contract negotiations, reducing the cost pressure identified above. Costs could also be influenced by other initiatives to improve outcomes.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	N/A
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?	N/A
C4 Overall cost impact of this policy to the NHS as a whole	
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: **Cost neutral** Please specify: Infrastructure costs to provide treatment already in place for 96% of patients in care, therefore not a material impact on services.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Please specify: Cost of policy over 10 years modelled at £49.2m. The majority of cost is in years 1-3 £22.8 up to £38.9m by year 5. By year 9 the impact year on year between present and policy cost is zero. Spend is phased over 2 years to align implementation with patient's routine follow

	up appointments. The costs associated with this policy are the bringing forward of costs that would eventually be incurred (when a patient's disease progression met the current threshold for treatment) Cost avoidance to health economy from reduction of onward transmission estimated as £12k annually per infection stopped. Estimated 1 onward infection stopped for every 9 patients treated = £2.9m cost avoidance in year one. Drug costs likely to reduce with further introduction of generic alternatives and contract negotiations, reducing the cost pressure identified abovand contract negotiations, reducing the cost pressure identified above Costs could also be influenced by other initiatives to improve outcomes.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	N/A
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**Yes** Reduction in comorbidities and onward infections likely to reduce demand for social care associated with complex patients.
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.	None – majority of cost is bringing forward of costs that would be occurred at a later date (as the patients CD4 count drops). Costs associated with year 1 higher due to "bringing forward" treatment costs of patients already in care that would qualify for treatment over the next 2-5 years.
C6 Financial Risks Associated with Implementing this Policy	

C6.1 What are the material financial risks to implementing this policy?	Increase in demand over that modelled.
C6.2 How can these risks be mitigated?	Modelling based on current ART average costs which are likely to reduce over time.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	100% compliance modelled to consider impact of every diagnosed patient being treated, but not felt to reflect patient choice in relation to accepting treatment, as evidenced by levels of non-treatment in already eligible patients. Modelling of impact of including all undiagnosed patients considered, but no evidence that these patients will be diagnosed and current rates of new diagnosis may be reducing based on impact of prevention treatment (TasP and PrEP) which would offset any increase in patients in care through identification of undiagnosed patients.
C6.4 What scenario has been approved and why?	Uptake has been based on the current level of patients who already qualify for treatment based on their CD4 count but not on ART treatment. Assumed this level of uptake would be consistent for patients who have a higher CD4 count.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**Published evidence indicates the treatment is cost-effective** See Evidence Review and Policy Proposition
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 ☐

	<table><tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr><tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☒</td></tr><tr><td>Other data has been identified</td><td>☐</td></tr><tr><td>No data has been identified</td><td>☐</td></tr><tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr><tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr></table> Please specify: Ability to reduce comorbidities and prevent onward transition increases the value for money achievable from this investment.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range:
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.