Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1822		
Policy Title	Doravirine for the treatment of HIV-1 in adults Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Rob Coster	**Clinical Lead**	M Nelson
Finance Lead	Jaquelin Low	**Analytical Lead**	Click here to enter text.

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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.

<table>
<tr><th colspan="2">Section A - Activity Impact</th></tr>
<tr><td colspan="2">A1 Current Patient Population & Demography / Growth</td></tr>
<tr><td>A1.1 Prevalence of the disease/condition.</td><td>The number of persons seen for HIV care in England (prevalence) is 85,537 (84,551 adults and 986 children). In 2017 there were 3,973 new cases of HIV diagnosed in England (3,809 adults and 164 children).
Source:
Public Health England 2018, Country and PHE region HIV data tables</td></tr>
<tr><td>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</td><td>77,391
Source: Please see ‘assumptions input’ page of resource impact template.
Please specify.
It is estimated 77,391 people meet the licence criteria and are eligible for doravirine.</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>
The treatment is intended for adults with HIV-1 (over 99% of cases) without past or present evidence of resistance to the Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) class of drugs (or the NRTI drugs lamivudine or tenofovir if taking the fixed dose combination).</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>Persons seen in 2017 for HIV care resident in England by age group.
<table>
<tr><th>Age range</th><th>Prevalence 2018/19</th><th>Eligible population</th></tr>
<tr><td>18 - 24</td><td>1,523</td><td>1,394</td></tr>
<tr><td>25 - 34</td><td>11,238</td><td>10,286</td></tr>
<tr><td>35 - 49</td><td>38,646</td><td>35,374</td></tr>
</table>
</td></tr>
</table>

50 - 64	28,184	25,797
65 and over	4,960	4,540
Total	84,551	77,391

The prevalence estimate for 2018/19 includes in year incidence of 3,809. Please note that the PHE prevalence data is shown for the age bracket 15-24 and an even distribution has been assumed to estimate people aged 18-24.

Source: Public Health England (PHE) Country and PHE region HIV data tables (2018). Public Health England 2018, Country and PHE region HIV data tables

A1.5 How is the population currently distributed geographically?

Unevenly

If unevenly, estimate regional distribution by %:

North	18%
Midlands & East	22%
London	43%
South	17%

Source: Public Health England 2018, Country and PHE region HIV data tables

National HIV surveillance tables - data to end of Dec 2017 (Tables 8-9)

A2 Future Patient Population & Demography

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?

Increasing

	<table><tr><td>Change in epidemiology</td><td>Year 2</td><td>Year 5</td><td>Year 10</td></tr><tr><td>Prevalence in adults</td><td>88,065</td><td>97,855</td><td>111,071</td></tr><tr><td>Incidence in adults</td><td>3,555</td><td>3,061</td><td>2,387</td></tr></table>
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**Not known** 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 and uptake of pre-exposure prophylaxis (PrEP). Also there is an ageing population as people live longer with HIV, maintained on ART. *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?	<table><tr><td>YR2 +/-</td><td>6,470</td></tr><tr><td>YR3 +/-</td><td>9,458</td></tr><tr><td>YR4 +/-</td><td>12,292</td></tr><tr><td>YR5 +/-</td><td>14,979</td></tr><tr><td>YR10 +/-</td><td>26,458</td></tr></table> *Source: Resource impact template – assumptions input sheet.*

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.
A3 Activity	
A3.1 What is the purpose of new policy?	**Confirm routine commissioning position of an additional new treatment** The proposal is to routinely commission doravirine for HIV-1 in adults. This policy would provide an additional treatment option under the following criteria: • for the treatment of adults with HIV-1 • who have no past or present evidence of resistance to the NNRTI class. Treatment with doravirine can be considered for adult patients who are naive to anti-retroviral treatment and those who are looking to switch treatment.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	The estimated annual number of people associated with the existing pathway is estimated to be as follows:

Year 0	77,391
Year 1	80,711
Year 2	83,861
Year 5	92,371
Year 10	103,850

Source: *Resource impact data, based on published data.*

A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?

The estimated annual activity for the proposed patient pathway assumes people who are naive to anti-retroviral treatment and those who are looking to switch treatment may take up doravirine. The annual percentage of people estimated to switch anti-retroviral treatment is 10%.The estimated annual activity associated with the proposed policy proposition pathway is:

Estimated number of people who take up doravirine

	Doravirine as a single tablet regimen	Doravirine as a third agent	**Total**
Year 1	37	68	105
Year 2	121	224	345
Year 5	298	553	851
Year 10	411	764	1175

	Source: Resource impact template based on published data and PWG assumptions. Please specify The above estimates take into account people treated from the prevalent and incident populations. The uptake is based on PWG consensus from clinical experts (meeting 08th January 2019). The estimated uptake is profiled over time as 1% in Yr1; 3% in Yr2 and 5% from Yr3 onwards. The resource impact model also allows for people discontinuing treatment each year due to adverse effects or because the treatment becomes ineffective. The PWG estimated this to be 6% of the number of people receiving treatment.
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.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Currently HIV is usually managed with a combination of three drugs including two nucleoside reverse transcriptase inhibitors (NRTIs; tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine, abacavir, lamivudine) and either a protease inhibitor (PI; darunavir) boosted with ritonavir or cobicistat, a non-nucleoside reverse transcriptase inhibitor (NNRTI; rilpivirine, efavirenz) or an integrase inhibitor (INI; dolutegravir, elvitegravir/cobicistat, raltegravir). Patients typically start on a 3-drug regimen and only move to another if there is lack of virological response, treatment failure, or tolerability issues. Additional issues include pill burden and dose frequency which

may affect adherence. Considerations related to potential for drug-drug interactions are particularly relevant as people with HIV are living longer, which means they may become more likely to take medication for age-related comorbidities.

Newer treatments are coming in which are dual therapy. These are anticipated to change current practice over the next 5 years.

The eligible population is estimated to be:

Estimated number of people eligible for treatment in Year 0

Description	%	People
Adults diagnosed with HIV in England (A1.4)		84,551
Number of people who receive antiretroviral treatment (ART)	98%	82,860
Percentage of people who are resistant to NNRTi and NRTi treatment	6.6%	5,469
Eligible population		77,391

Source: DPP section 3 / Resource impact template; HIV drug resistance data:

http://www.hivrdb.org.uk/hiv-drug-resistance-uk

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 an 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) 98% receive ART less 6.6% NNRT/NRTI (lamivudine or tenofovir) resistant = 91.4% c) 100% d) 100% e) 90% (e) 10% of people switch treatment each year due to toxicity / efficacy per expert opinion. *Source:* (b) PHE 2018 Country & PHE region HIV data tables; and HIV drug resistance UK data: (c), (d) and (e) – clinical expert opinion.
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:	N/A

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?	
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% b) 98% receive ART less 6.6% NNRT/NRTI (lamivudine or tenofovir) resistant = 91.4% c) 10% d) 100% e) 94% (c) 10% people who switch treatment each year; uptake of doravirine estimated to reach 5% by year 3. Uptake in treatment naïve population also 5% by year 3 (e) Annual discontinuation rate of doravirine is estimated to be 6% *Source:* Per A4.3 above.
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long**
A7 Treatment Setting	

<table>
<tr>
<td>A7.1 How is this treatment delivered to the patient?</td>
<td>Select all that apply:
<table>
<tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr>
<tr><td>Acute Trust: inpatient</td><td>☐</td></tr>
<tr><td>Acute Trust: day patient</td><td>☐</td></tr>
<tr><td>Acute Trust: outpatient</td><td>☒</td></tr>
<tr><td>Mental Health provider: inpatient</td><td>☐</td></tr>
<tr><td>Mental Health provider: outpatient</td><td>☐</td></tr>
<tr><td>Community setting</td><td>☐</td></tr>
<tr><td>Homecare</td><td>☒</td></tr>
<tr><td>Other</td><td>☐</td></tr>
</table></td>
</tr>
<tr>
<td>A7.2 What is the current number of contracted providers for the eligible population by region?</td>
<td>
<table>
<tr><td>NORTH</td><td>56 clinics</td></tr>
<tr><td>MIDLANDS & EAST</td><td>50 clinics</td></tr>
<tr><td>LONDON</td><td>30 clinics</td></tr>
<tr><td>SOUTH</td><td>46 clinics</td></tr>
</table>
</td>
</tr>
<tr>
<td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td>
<td><u>No</u></td>
</tr>
<tr>
<td colspan="2"></td>
</tr>
</table>

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	☐
SNOMED	☐

	Clinical coding / terming methodology used by clinical profession ☒ 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** 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: NHSE (Rob Coster) to speak to the pharmacist lead for HIV about including doravirine in the HIV tender framework.
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

<table>
<tr><td></td><td>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <u>N/A</u></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>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</td><td><u>Yes</u></td></tr>
</table>

Specify whether a dashboard exists for the proposed intervention?	If yes, specify how routine performance monitoring data will be used for dashboard reporting. HARS data already used to populate dashboards.
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**
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:* IIAR for immediate antiretroviral therapy for HIV (policy ref 1613).
B1.2 Will the proposition change the way the commissioned service is organised?	**No** *Source:* IIAR for immediate antiretroviral therapy for HIV (policy ref 1613).
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care**
B2 Geography & Access	

<table>
<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></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u></td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>No impact</u>
Please specify:
Doravirine would provide another treatment option.
Source: Equalities Impact Assessment</td></tr>
<tr><td colspan="2">B3 Implementation</td></tr>
<tr><td>B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?</td><td><u>No action required</u></td></tr>
<tr><td>B3.2 Time to implementation:</td><td><u>No - go to B3.4</u></td></tr>
</table>

Is a lead-in time required prior to implementation?	If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
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	**No change**

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	☐

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	☐

		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. 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 list price of doravirine is commercial in confidence. A proxy list price is used for resource impact purposes. This was provided by the company. Single tablet regimen – doravirine, lamivudine and tenofovir disproxil fumarate (30 tablets) = £708 (including VAT) 3rd Agent Doravirine (30 tablets) = £576 (including VAT). Both tablets are taken orally once daily.
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 **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**	N/A

<table>
<tr><td>Include descriptions and estimates of all key costs.</td><td></td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u></td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<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>£1,260</td></tr>
<tr><td>YR2</td><td>£1,260</td></tr>
<tr><td>YR3</td><td>£1,260</td></tr>
<tr><td>YR4</td><td>£1,260</td></tr>
<tr><td>YR5</td><td>£1,260</td></tr>
</table>
The estimates above are using the net resource impact of doravirine divided by the actual number of people estimated to receive treatment each year.
The costs include VAT on 30% of costs for treatment received via secondary care. It is assumed 70% of treatment is received via homecare where a 10% admin fee has been assumed.

The above costs are based on list prices and include a proxy list price for doravirine. Many comparator treatments are likely to become generic within this timeframe and will affect the net cost per person, listed above.</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></td></tr>
</table>

<table>
<tr><td></td><td>The policy is estimated to have a small cost pressure using the proxy list price given by the company and list prices of other treatments. The resource impact in years 1, 2, 5 and 10 is shown in the table below.
<table><tr><td>Year</td><td>£000s</td></tr><tr><td>1</td><td>132</td></tr><tr><td>2</td><td>435</td></tr><tr><td>5</td><td>1,071</td></tr><tr><td>10</td><td>1,481</td></tr></table>
The above figures are from the resource impact template and based on population estimates in A 4.1 above and activity assumptions in A3.3 above. An average cost of comparator options has been used in the resource impact template (per commissioner advice). For the fixed dose combination regimen this is £8,937 per person per year and for 3rd agents this is £3,178 per person per year (at list prices).
VAT is assumed to apply to 30% of costs for treatment received via secondary care. It is assumed 70% of people receive treatment via homecare for which a 10% admin fee is applied. This is consistent with other NHSE policies for HIV treatments.</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>N/A</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>N/A</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 commissioning ART drugs.
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 see C3.1 above.
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?	**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	

<table>
<tr><td>C6.1 What are the material financial risks to implementing this policy?</td><td>There are no material risks to implementing the policy in line with the policy proposal.</td></tr>
<tr><td>C6.2 How can these risks be mitigated?</td><td>N/A</td></tr>
<tr><td>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</td><td>The assumptions used for estimating uptake of doravirine are from PWG clinical expert opinion. These are higher than estimates from the company and therefore produce a maximum resource impact. The list price of the treatment is confidential. HIV medicines are procured by an annual tender framework on behalf of NHSE therefore market share of the treatment is likely to be influenced by this process.</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>The resource impact template provides an estimated cost using a proxy list price. The estimated annual resource impact using 5% uptake by year 5 (including VAT and homecare fees) is as follows:
<table>
<tr><th>Year</th><th>Uptake %</th><th>£000s</th></tr>
<tr><td>1</td><td>1%</td><td>132</td></tr>
<tr><td>2</td><td>3%</td><td>435</td></tr>
<tr><td>3</td><td>5%</td><td>801</td></tr>
<tr><td>4</td><td>5%</td><td>945</td></tr>
<tr><td>5</td><td>5%</td><td>1,071</td></tr>
</table>
The resource impact compares the cost of doravirine as a fixed dose combination and as a 3rd agent with an average price of comparator options in these regimens (see C3.1 above). This is in line with commissioner advice and consistent with previous policy workings.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td>The clinical evidence review for this technology found no studies relating to cost effectiveness.</td></tr>
</table>

<table>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<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></td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u></td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>N/A</td></tr>
</table>