Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1806 (CSP ID015)		
Policy Title	Dolutegravir - Rilpivirine for treating HIV-1 in adults Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Rob Coster	**Clinical Lead**	Brian Gazzard
Finance Lead	Click here to enter text.	**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.

<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>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</td></tr>
<tr><td>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</td><td>65,000
It is estimated that 65,000 people meet the licence criteria and are eligible for dolutegravir and rilpirivine. The table below shows the assumptions made arriving at this figure.
<table>
<tr><th>Description</th><th>%</th><th>People</th></tr>
<tr><td>Adults diagnosed with HIV in England (A1.4)</td><td></td><td>84,551</td></tr>
<tr><td>Number of people who receive antiretroviral treatment</td><td>98%</td><td>82,860</td></tr>
<tr><td>Number of people who are virologically supressed (HIV-1</td><td>93%</td><td>77,060</td></tr>
<tr><td>Number of people who meet criteria in A3.1</td><td>84.35%</td><td>65,000</td></tr>
</table>
Published Sources:
Public Health England 2018, National HIV surveillance data tables
UK HIV and AIDS information 2017
PWG estimate (clinical experts):
Around 65,000 people meet the licence criteria (A3.1). This is 84.35% of those who are virologically supressed (HIV-1 RNA <50 copies / ml).</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>
Click here to enter text.</td></tr>
</table>

A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria

Age range	Prevalence 2018/19	Eligible population
18 - 24	1,523	1,170
25 - 34	11,238	8,640
35 - 49	38,646	29,710
50 - 64	28,184	21,667
65 and over	4,960	3,813
Total	84,551	65,000

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 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.

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%

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

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

Change in epidemiology	Year 1	Year 2	Year 5
Prevalence in adults	91,502	94,762	103,568
Incidence in adults	3,382	3,218	2,771

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

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 "people who are heterosexuals 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. Also there is an aageing 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?

YR1 +/-	7,943
YR2 +/-	10,324
YR3 +/-	12,581
YR4 +/-	14,721
YR5 +/-	18,525

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 an average decrease of 5% 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 dolutegravir/rilpivirine as a fixed dose combination tablet for treating HIV-1 in adults. This policy would provide an additional treatment option under the following circumstances:

For adults with HIV-1 who:

<table>
<tr><td></td><td>

Have disease that is virologically suppressed (<50 copies/mL), AND
Are on stable ART, and have been for ≥6 months, with no history of virological failure, AND
Do not have a known or suspected resistance to any NNRTI or INI, AND
Do not have hepatitis B

Approval for the use of dolutegravir-rilpivirine requires an MDT discussion.
Per Section 8 DPP.
</td></tr>
<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 associated with the existing pathway is estimated to be as follows:
<table>
<tr><td>Year -2 (2017/18)</td><td>65,000</td></tr>
<tr><td>Year 0 (2019/20)</td><td>70,434</td></tr>
<tr><td>Year 1 (2020/21)</td><td>72,943</td></tr>
<tr><td>Year 2 (2021/22)</td><td>75,324</td></tr>
<tr><td>Year 5 (2024/25)</td><td>83,526</td></tr>
</table>

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 the proposed patient pathway assumes people would only take up another option (switch treatments) if they experience toxicity, viral resistance or adverse events on their current treatment. This is estimated to be 10% of the annual number of people receiving antiretroviral treatments. From this proportion the company uptake estimates are used to estimate people who take up the policy treatment. It is estimated around 40% of people who take up the policy treatment could have switched to a TAF regimen from a TDF regimen.</td></tr>
</table>

<table>
<tr>
<td></td>
<td>The estimated annual activity associated with proposed policy proposition pathway is:
Annual activity estimates for dolutegravir and rilpivirine
<table>
<tr><th></th><th>Prevalent population (alternative to TDF regimens / abacavir)</th><th>Incident population (alternative to TAF regimens /abacavir -cost criteria)</th><th>Total number of people treated (Policy)</th></tr>
<tr><td>Year 1</td><td>222</td><td>154</td><td>376</td></tr>
<tr><td>Year 2</td><td>478</td><td>336</td><td>814</td></tr>
<tr><td>Year 3</td><td>588</td><td>424</td><td>1,012</td></tr>
<tr><td>Year 4</td><td>639</td><td>471</td><td>1,110</td></tr>
<tr><td>Year 5</td><td>721</td><td>539</td><td>1,260</td></tr>
</table>
Source: Resource impact template based on published data and assumptions.
The above estimates take into account NHSE commissioning criteria for tenofovir alafenamide (TAF). The uptake is based on company estimates which estimate uptake will reach 26% by year 5. This has been profiled over time as 8% Yr1; 17% Yr 2; 21% Yr 3; 23% Yr 4 and 26% Yr 5. The model allows for people discontinuing treatment (5%) based on trial data in the company submission adjusted for clinical expert opinion.</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 the only alternative is the existing pathway, please state ‘not applicable’ and move to A4.</td>
<td>Not applicable</td>
</tr>
</table>

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, raltegravir) boosted with ritonavir or cobicistat, a non-nucleoside reverse transcriptase inhibitor (NNRTI; rilpivirine, efavirenz) or an integrase inhibitor (INI; dolutegravir, elvitegravir/cobicistat, raltegravir, bictegravir).

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.

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	98%	82,860
Number of people who are virologically supressed (HIV-1	93%	77,060
Number of people who meet criteria in A3.1	84.35%	65,000
Of whom: Number of people who meet criteria if they meet criteria in A3.1 and cannot have TDF based regimens.	30.77%	20,000

	Source: DPP section 3 / Resource impact template
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. There may also be short- and long-term toxicity concerns and drug-drug interactions which are other reasons for switching treatments. People 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?	Public Health England data [Public Health England report 2018] shows 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% b) 98% receive ART x 93% HIV-1 RNA<50 copies mL x 84.35% licence criteria c) 100% d) 100% e) 90% *Source:(a) & (b) Public Health England 2018, Country and PHE region HIV data tables & PWG clinical opinion –people who meet licence criteria; (c), (d) &(e) clinical opinion assumed all people choose to initiate treatment and would initially comply with around 10% of people switching treatment each year due to toxicity.*
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% b) 98% c) 10% of people switch d) 100% e) 95% *Source:* (a) & (b) *Public Health England 2018, Country and PHE region HIV data tables, IIAR for IART; (c) & (d) clinical expert opinion,- actual*

<table>
<tr><td></td><td>uptake of the treatment is estimated to reach 26% (of the 10% of people who switch) by year 5 ;(e) trial data and clinical opinion - 5% of the eligible population are expected to cease treatment because of non-response to treatment or tolerability issues or inability to adhere to treatment.</td></tr>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Life long</u></td></tr>
<tr><td colspan="2">A7 Treatment Setting</td></tr>
<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>
Please specify:
Homecare delivery or hospital pharmacy dispensed. Clinical opinion is that only 5-10% are delivered by homecare.</td></tr>
</table>

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**	☒

<table>
<tr><td></td><td>
<table>
<tr><td>Other**</td><td>☒</td></tr>
</table>
**If National Return, Clinical database or other selected, please specify:
HARS database and local drug use and pharmacy reporting
</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:
<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>
HARS database and local drug use and pharmacy reporting
</td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Not already specified in current NHS England Drugs List document</u>
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:

Lead commissioner to speak to the pharmacist lead for HIV about including dolutegravir/rilpivirine in the HIV tender framework.</td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u></td></tr>
</table>

<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>
I
NCBPS14A HIV ADULT SPECIALIST SERVICES FOR PATIENTS INFECTED WITH HIV</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><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>
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:</td></tr>
</table>

	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** 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**

<table>
<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></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:
Dolutegravir/rilpivirine would provide another treatment option

Source: Equalities Impact Assessment</td></tr>
<tr><td colspan="2">B3 Implementation</td></tr>
</table>

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**
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

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.

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

NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	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 Dolutegravir 50mg / Rilpivirine 25mg is £699.02 (excluding VAT) for 30 tablets. The tablet is taken orally once daily with a meal.
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.	N\A

<table>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>N/A</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><th></th><th>Average cost per patient £</th></tr>
<tr><td>YR1</td><td>£9,155</td></tr>
<tr><td>YR2</td><td>£9,155</td></tr>
<tr><td>YR3</td><td>£9,155</td></tr>
<tr><td>YR4</td><td>£9,155</td></tr>
<tr><td>YR5</td><td>£9,155</td></tr>
</table>

The above costs are based on the annual cost of 1 patient receiving Dolutegravir-rilpivirine for a full year at the list price inclusive of VAT/Homecare delivery costs.

Dolutegravir + 3TC is a regimen that is currently being prescribed as separate tablets and for which a single tablet is expected to receive its licence in July 2019. The uptake of dolutegravir-rilpivirine is likely to be impacted by the availability of dolutegravir/3TC fixed dose combination; this appears to be a more favoured regimen amongst HCP’s and will be suitable for both naïve and experienced patients. In addition, as 3TC is</td></tr>
</table>

<table>
<tr><td></td><td>available generically, the financial proposition is greater with significant saving opportunities afforded by the fixed dose combination

Above costs are based on list prices. Many comparator treatments (which affect net cost per patient above) are likely to become generic within this timeframe. The resource impact is based on NHSE policies agreed at this point in time. Uptake estimates for dolutegravir and rilpivirine may be affected by new treatments which are being considered in future.</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>

<table><tr><th>Year</th><th>£k</th></tr><tr><td>YR 1</td><td>£209.6k</td></tr><tr><td>YR 2</td><td>£447.0k</td></tr><tr><td>YR 3</td><td>£539.2k</td></tr><tr><td>YR 4</td><td>£575.8k</td></tr><tr><td>YR 5</td><td>£642.2k</td></tr></table>
NHS England will routinely commission dolutegravir-rilpivirine as a fixed dose combination tablet according to the circumstances outlined in A3.1 above. The cost pressure over 5 years at list prices for both dolutegravir-rilpivirine and the comparators is £2.4m.</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>
</table>

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?	Not applicable
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: **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** See C3.1
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 are no material financial risks to implementing the policy in line with the policy proposal. The treatment is one of many options.
C6.2 How can these risks be mitigated?	Not applicable.
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 dolutegravir/rilpivirine will depend on the price compared to its comparators. If dolutegravir/rilpivirine is similarly priced to its comparators then around 1,200 people could be treated with it by year 5. This would have a negligible effect on overall resource impact as the treatment would be cost neutral. If dolutegravir-rilprivine costs more than its comparators (as current list prices indicate for TDF based regimens) a cost of £0.6m (C3.1) is estimated by year 5. This is comparing dolutegravir/rilpivirine with an average cost of comparator options at list prices.
C6.4 What scenario has been approved and why?	The scenario approved for the policy reflects PWG consultation feedback. The point raised was that treatment with dolutegravir and rilpivirine would be based on clinical decisions. The estimated resource impact of the policy is £0.6 million by year 5. If the treatment were mainly to be used as an alternative to TAF based regimens (based on cost criteria), a saving of £0.5m is estimated by year 5.

<table>
<tr><th colspan="2">C7 Value for Money</th></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>
<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><th colspan="2">C8 Cost Profile</th></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>Not applicable</td></tr>
</table>