Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	F03X06		
Policy Title	Clinical Commissioning Policy Proposition: Pre-exposure prophylaxis (PrEP) to prevent the acquisition of HIV in adults		
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Section A - Activity Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 This policy is about preventing new HIV infections through the additional use of antiretrovirals (ARVs) which are usually used to treat people with diagnosed HIV infection. The overall estimated prevalence of HIV in the UK in 2013 was 2.8 per 1,000 population (95% credibility intervals: 2.7, 3.0) [1] Prevalence is much higher among men having sex with men (MSM), the main sub population covered by this proposition, at 58.8 per 1,000 (95% CI: 50.6, 68.9). Among heterosexuals the HIV prevalence is 1.6 (95% CI: 1.5, 1.8) per 1,000 population but higher among black-African heterosexuals (40.8 per 1,000 men (95%CI: 35.3, 49.3) and 70.5 per 1,000 women (95% CI: 63.4, 80.6)). Incidence levels also vary with these being several times higher for MSM hence the particular focus on this population.

	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 PrEP is not currently commissioned. The policy proposition suggests commissioning criteria for access to a sub set of MSM; trans women; trans men; couples with different HIV status (sero different) and heterosexuals clinically assessed as being at similar high risk of HIV acquisition to high risks MSM. Modelling has been undertaken by both Public Health England (PHE) (using a static model which assumes annual eligibility for PrEP) and University College London (UCL) (using a synthesis model which assumes people remain on PrEP for as long as they are having condomless sex and therefore at risk). The total number of MSM eligible based on the policy proposition criteria is estimated to be between c8,000 and 12,000. Estimates of uptake have been modelled based on a range of data to inform an assumption of c.50% take up. This is based on the • number of MSM tested for HIV in GUM clinics who had an HIV test between 42 and 365 days ago (average 2013/14: ~23,000) [2] and • behavioural data about levels of condomless sex which suggests 35.6% [3] to 53% [4] of MSM who tested for HIV in the previous year would have recent high risk behaviour, and • assumption that HIV negative MSM in longer term relationship with an HIV positive partner will be protected against HIV acquisition by treatment of the HIV positive partner, even where condomless sex is occurring. Therefore the potential number of eligible individuals falling under this criterion is minimal, and likely cover the period before viral suppression is achieved after antiretroviral treatment initiation. Estimates for other high risk groups are no greater than 1000 eligible and a similar 50% uptake should be assumed. Because the MSM population is the main population sub group, impact assessment is largely focused on this group. This provides a range of 4500 to 6500 eligible individuals likely to access PrEP in a year. The UCL model estimate potentially higher levels per year taking up PrEP.

		Clinical advice through the PWG indicates that it will probably take 2 years to reach this level based on the experience of recruitment to the UK PROUD study. Therefore the estimate is 2000 in 16/17 and 3000 in 17/18 reaching 5000 per year by year 5 is used although this is based on a number of assumptions which will be tested in practice. It is assumed that local authorities will approve Level 3 GUM services to make the PrEP service available. If local authorities do not prioritise service access, this may impact the assumptions of numbers of people accessing PrEP.
	A1.3 What age group is the treatment indicated for?	A1.3 16 and over (based on age of consent)
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 80% of MMS attending GUM clinics are between 18-44 years [5]. The median age of those in the UK PROUD study was 35 [6]. This policy is applicable to those who are sexually active.
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 MSM at high risk of sexually transmitted infections (STIs) (i.e. those who have had any condomless sexual contact with a new partner) are recommended to have an HIV test and STI screen, and for this to be repeated every three months if risk is ongoing [7]. All men and women registering in general practice and all general medical admissions in areas where diagnosed HIV prevalence exceeds 2 in 1000 population and all sexual partners of men and women known to be HIV positive should be offered an HIV test [8] The number of STI clinics attendees in 2014 was 1,415,942 (104,028 MSM, 497,455 heterosexual men and 814,459 heterosexual women). Of these, the number of people who tested for HIV were respectively 90,719 and 886,992 among MSM and heterosexuals [9] Post-exposure prophylaxis (PEP) is used after HIV risk exposure. This involves use of ARVs via A&E and or GUM attendances. The number

		of PEP courses prescribed / number MSM on PEP following sexual exposure (known as PEPSE) in MSM has been increasing over the years and is set out below [10]: 2011 - 2,388 courses / 2,135 MSM 2012 - 3,763 / 3542 MSM 2013 - 4,243 / 3930 MSM 2014 - 5,880 / 5305 MSM
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 Projecting growth in prevalence needs to take account of recent trends and assumptions about testing rates, treatment uptake and behaviours. The number of new HIV infections among MSM have remained high over the past 10 years, increasing steadily from 2,500 in 2005 to 2,800 in 2014 [11]. Among heterosexuals the absolute number of HIV infections acquired in the UK has remained stable at 1,500 per year [11]. Of all new HIV diagnoses, those acquired through heterosexual sex and acquired in the UK has risen from 52% to 59% whilst in MSM infection acquired in the UK remains stable at 76% [12]. Models used by PHE and UCL taking into account the above assumptions estimate without applying the new policy the prevalence of HIV among MSM 15-65 years old in 2, 5 and 10 years will be 10.2%(in 2018), 10.6% (in 2021) and 10.9%(in 2026).
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	A1.7 Data suggest that demand for sexual health services amongst HIV negative MSM is increasing irrespective of this policy proposition. From 2010 to 2014, the number of HIV negative MSM attending GUM clinics increased by between 6,000 to 13,000 year on year [13]. The total number of attendances among MSM increased by between 16,000 to 41,000 year on year [14]. Data on PEPSE uptake also demonstrates an increasing trend. Some anecdotal feedback from social media indicates there is a risk that PEPSE access may be used as a route to access ARVs for PrEP although there is no data to substantiate this.

		In the PHE / UCL model for assessing impact of this policy proposition, for the future years the following assumptions have been used • rate of HIV testing among MSM will remain at the current level • MSM population access GUM is increasing Therefore, according to this model a) the <u>number of HIV tests</u> among MSM in people aged 15-65 years old will be at 2years - 102,236 5years - 103,125 10year - 104,992 **b)** the number of <u>MSM tested for HIV</u> at least once in that year aged 15-65 years old will be at 2 years - 101,778 5 years - 102,647 10 years - 104,587
	A1.8 How is the population currently distributed geographically?	A1.8 HIV prevalence among MSM is higher in London where one in eight are living with HIV, compared to one in 26 outside London [15]. The distribution of HIV-diagnosed MSM seen for HIV care is 50% in London, 18% in North of England, 18% in South of England, and 14% in the Midlands & East of England [16]. The distribution of GUM clinic attendances in MSM is 52% in London, 18% in North of England, 17% in South of England, and 13% in the Midlands & East of England [17].
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	A2.1 Other: The proposition is to extend commissioning of ARVs beyond treatment of HIV positive people to use to prevent HIV infection in HIV negative people at high risk of HIV acquisition. GUM services are commissioned by Local Authorities and provide sexual health/ STI services and HIV prevention interventions, likely to include condom promotion, post-exposure prophylaxis (PEPSE), motivational interviewing, and HIV testing. Initiation and monitoring of drug treatment (including ARVs for PEPSE) for STIs/prevention is part of GUM services. In general the infrastructure to support PrEP delivery is in place and the frequency of attendance would be in line with BASHH

		recommendations.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 Not known
	A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	A2.3 Not applicable
	A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	A2.4Depending on a number of assumptions about eligibility and uptake, the net increase is as follows. Data on the duration on PrEP is not yet known Year 1 - 2,000 on PreP Year 2 - 3,000 on PrEP By Year 5 - 5,000 on PrEP
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	A3.1 As PrEP is not currently commissioned, the current commissioned activity for PrEP is assumed to be zero. Activity which is relevant to NHS England is PEPSE where ARVs are generally reimbursed by NHS England. The number of PEP courses prescribed / number MSM on PEP following sexual exposure in MSM has been increasing over the years and is set out below [10]: 2011 - 2,388 courses / 2,135 MSM 2012 - 3,763 / 3542 MSM 2013 - 4,243 / 3930 MSM 2014 - 5,880 / 5305 MSM This activity is relevant to CCGs where access is via A&E attendance and to local authorities where follow up is via GUM services. NHS England does not commission (attendance) activity associated with the PEPSE pathway. Non commissioned activity would include: • For MSM on PreP via the UK PROUD

		study – 408 participants remain enrolled. • Individuals purchasing ARVs on line – number unknown
	A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	A3.2 If prioritised and implemented, the new activity from this proposition is expected to be 2,000 – on PreP for HIV prevention in year 1, rising to 3,000 by year 2 and 5,000 by year 5 thereafter. Duration on PrEP is unknown so duration of 1 year is assumed. It is assumed that all those on PrEP would achieve GUM service attendance in line with the BASSH recommendation (x4 per year for monitoring) Based on the PROUD study results, the use of PEPSE reduces significantly if PrEP is available to high risk MSM. The PHE / UCL model suggest a reduction of over 90%. Some generics become available from 2018 which has the potential to significantly impact the cost profile of the policy proposition.
	A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	A3.3 The assumed comparative activity for the Do Nothing approach would be • continuation of current sexual health service provision outlined in this document • continuation of the trends in HIV, STIs and clinic attendance outlined in this document continuation of the increasing trend of PEPSE use
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	A4.1 Local authorities commission sexual health and HIV prevention services. The inclusions and activity are outlined in section **K1**. PEPSE is a specific intervention using ARVs to prevent HIV acquisition in those who have / may have had high risk sexual exposure. The ARVs are reimbursed by NHS England whilst the activity is paid for by CCG (A&E attendance) or local authorities (GUM services). The current patient pathway for access to PEPSE is via A&E or GUM services with access to a 5 day starter pack of ARVs with GUM follow up over a 3-month period (baseline chemistry, 3

		HIV tests and 2 STI screens). The principal difference is that PEP constitutes 3 antiretroviral drugs (2 of which are the regimen for PrEP) taken for 28 days, and PrEP is 2 drugs which could be as frequently as daily during periods of risk. The duration for PrEP is assumed to be 1 year. Since PEP is post-exposure it may well be less effective than PrEP but this is not known for certain.
	A4.2. What are the current treatment access criteria?	A4.2 Clinicians use a risk assessment approach published by British HIV Association (BHIVA) / British Association of Sexual Health and HIV (BASHH). Positive recommendations for treatment are made for the following sexual exposures (condomless sex or where condom fails) • Insertive or receptive anal or vaginal sex with a person known to be HIV positive and not virally suppressed • Receptive anal sex where the partner's status is unknown and they are from a high HIV prevalence area The guidance recommends consideration of treatment in a number of other scenarios where there the partner is confirmed HIV positive with a detectable viral load or where the partner's status is unknown but they are from a high prevalence area. Treatment in low prevalence areas is not recommended.
	A4.3 What are the current treatment stopping points?	A4.3 PEPSE is a 28 course of treatment to prevent HIV acquisition.
A5 Comparator (next best alternative treatment) Patient Pathway	A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	A5.1 There is no 'next best 'alternative. The 'do nothing' existing arrangements are set out above.
	A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the	A5.2 Not applicable

	pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	A6.1 The new pathway will result in C 2000 – 5,000 of 8000-12000 eligible individuals accessing PrEP per year These individuals are expected to have 4 attendances a year 1 new HIV infection is avoided for every 13 people treated with PrEP.
	A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A6.2 The PROUD protocol indicates that PrEP pathway requires a baseline visit and then quarterly monitoring. This is in line with 4 visits a year. MSM will be attending GUM services and it is anticipated eligibility for PrEP is confirmed during routine visits at which point • Only those meeting eligibility will proceed to PrEP. Outcome is achieving HIV risk reduction • Monitoring will identify any issues with adherence, toxicity resulting in discontinuation. As data on safety is strong no discontinuation is assumed. Effectiveness of PrEP also suggests minimal discontinuation would be required due to HIV acquisition. No adjustment made. Outcome is continued risk reduction through PrEP • Treatment may be with a daily regimen or with event driven dosing. Event driven dosing is only relevant to MSM and if they have ongoing and prolonged periods of risk then daily dosing may be required. An assumption has therefore been made that 50% will use event driven dosing so the overall adjustment is to calculate at 75% of PrEP cost.

		• Discontinuation due to changes in risk is the key factor. For the purposes of modelling it has been assumed that PrEP is only used when there is condomless sex and risk and that its use is as part of a risk reduction intervention so it is assumed that this is a time limited intervention. Therefore turnover throughout the quarters is expected. The UCL model conservatively assumes that people will stay on PrEP as long as required. The PHE model assumes that on average people will stay on PrEP for 1 year. For modelling an annual figure on PrEP is calculated. Outcome is individuals discontinuing PrEP have achieved a risk reduction. If duration is longer than 1 year, then the numbers accessing PrEP each year may be understated. The new pathway based on the PROUD study is assumed to involve; **Month 0** (baseline, day start PrEP – assuming patient come in for routine HIV/STI consultation and requests for PrEP) Patient consultation (routine counselling, assess PrEP eligibility and provide information on dosing in relation to risk, start PrEP, give 1 month supply) HIV test (4th generation antigen/antibody test plus point of care antibody test if indicated) STI tests (CT/GC 3 site plus syphilis test and Hep C if indicated Renal function monitoring – serum creatinine **Month 1** Patient consultation (check drug management, routine counselling/behavioural risk assessment, top-up PrEP for the next 3 months) **Month 4/7/10** Patient consultation (risk/adherence assessment and routine counselling, top-up PrEP for the next 3 months HIV/STI tests (negative HIV test, STI test (CT/GC 3 site plus syphilis test), and Hep C test (if indicated) Renal function monitoring – urinalysis and additional tests if 1+ or more protein **Month 13/17/20/23** (Year 2) (as per months 4/7/10) Serum creatinine at month 13 if PrEP ongoing

A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.1 Local authority commissioned Level 3 GUM providers only. This may be an Acute Trust: Outpatient (based on assumption of access via hospital based Level 3 GUM) but other providers may more recently been commissioned following service retendering e.g. independent sector providers. A7.2 The infrastructure required to deliver PrEP is as per Level 3 GUM services. These are now commissioned by local authorities who will need to assess capacity.
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.1 All Level 3 GUM commissioned providers to be reimbursed conditional on complying with NHS England contractual requirements for data submission and validation of drugs spend, separately identified via the approved drugs minimum data set (MDS). Activity data (attendances) will be recorded via GUMCAD3. A8.2 The excluded drugs MDS will require further modification for separate recording of ARVs for PrEP use as well as PEP use. PHE are responsible for the GUMCAD system and have developed functionality to record PrEP.
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 Commissioned Level 3 GUM providers will require an NHS contract to enable reimbursement of compliant invoicing. Providers will need to be notified of separate MDS requirements for recording and involving for ARVs for PrEP. STI regulations require the use of anonymised data which mean Blueteq cannot be used. However, it is proposed to explore the potential for other systems for prior approval to provide clinical assurance of compliance without delaying appropriate access.

	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 Separate recording and involving for ARVs for PrEP.
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 Separate recording and involving for ARVs for PrEP. A short PrEP monitoring module has been added to the new national GUMCADv3 specification and this module is currently being piloted in PROUD clinics. The data and information generated will be used to seek Standardisation Committee for Care Information (SCCI) approval (in collaboration with the relevant BASHH clinician steering group), which, once achieved, should lead to adoption of the enhancements across all Level 3 sexual health services in England.
	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 Supplier managers to authorise reimbursement for invoicing where MDS is complete and submission is contract compliant. Liaison with local authority commissioners regarding PrEP activity data reporting will be required at commissioning hub level. Additional contracts for the reimbursement of ARVs for PrEP are expected to be required. Non-NHS and non-specialised HIV care and treatment providers deliver sexual health services which would deliver the PrEP service.
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 No additional dashboard data required by NHS England at this time. Local authorities may wish to ensure outcomes / STI rate data is monitored. PHE analysis from GUMCAD3 is to be explored to ensure the expected outcomes (reduced HIV incidence, no further STI increases) can be monitored.
	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 Whilst there are currently no published NICE quality standards in respect of the use of ARVs, BHIVA has NICE accreditation for production of clinical guidelines. NICE has produced and published pathway guidance for HIV testing and prevention. NICE is due to publish an 'evidence summary for new medicine' for pre-exposure prophylaxis of HIV in uninfected adults at high risk: Truvada (emtricitabine and tenofovir

	A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	A9.7 A prior approval system is recommended to provide clinical assurance of policy compliance but the issues regarding anonymised data need to be resolved.
Section B - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 This would be a new component of a sexual health / HIV prevention service. The commissioning of the service (excluding the drug treatment) will be by local authorities, working in collaboration with NHS England commissioning hubs. Given that those at highest risk of HIV acquisition are likely to have a range of support needs including STI testing and treatment, partner notification, behavioural interventions for risk reduction, referral to services such as drug / alcohol services, it is expected that the provider selection criteria will focus on Level 3 GUM services and reflect likely geographical distribution.
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 This proposition significantly extends the scope of commissioning for ARVs from the treatment of people with diagnosed HIV in specialised care and treatment services (as per Prescribed Specialised Services Manual) to use in HIV negative individuals for HIV prevention. NHS England is not the responsible commissioner for sexual health services. Collaborative commissioning will be required to put in place access to both ARVs and the PrEP services to manage access and monitor use and outcomes. Local authorities may decide to review the model of sexual health care for high risk individuals to enable access to PrEP within existing resources.
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Not applicable. This is a new service. GU services are self-referral, open access services.

	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 Not applicable
	B2.3 Is the new policy likely to improve equity of access?	B2.3 Not applicable – new service
	B2.4 Is the new policy likely to improve equality of access / outcomes?	B2.4 The policy aims to reduce HIV acquisition.
B3 Implementation	B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	B3.1 Yes. Local authority approval of Level 3 GUM services will be required to confirm services will provide access to PrEP drugs. Each local authority will be responsible for determining whether it will make access available. A process of provider selection is recommended to ensure providers meet the infrastructure requirements and local need.
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 Not applicable
	B3.3 Is there a change in provider staffing required?	B3.3 Overall, it is not anticipated that the introduction of this policy will require a change in staff as the eligible patients are expected to be in contact with services and skills / competencies required are in line with Level 3 GUM services. However, each local authority will need to determine whether any changes are required.
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 No new dependencies / adjacencies are recommended. GUM services will benefit from strong referral pathways to drug and alcohol services.
	B3.5 Are there changes in the support services that need to be in	B3.5 No changes are recommended. Stakeholder engagement demonstrates the role of the voluntary sector in providing information,

	place?	signposting and support to eligible patients.
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 Not applicable. Any changes in provider governance would be led by local authority commissioners with involvement of NHS England as it relates to reimbursement for use of ARVs for PrEP.
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 This proposal is not anticipated to lead to a change in the number of commissioned providers for Level 3 GUM.
	B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	B3.8 NHS England will notify providers and commissioners of the rules for access and reimbursement for ARVs for PrEP.
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 The HIV pathway offers many benefits of collaborative commissioning with local authorities and possibly CCGs. PrEP offers an opportunity to explore this.
Section C - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 ARVs are tariff excluded drugs. Excluded drugs commissioned by NHS England are reimbursed as 'pass through' payments where compliant drug reporting is provided. GUM services are no longer subject to national tariff arrangements. An indicative national tariff is

		available and some local authorities are using the Integrated Sexual Health tariff developed by Pathway Analytics. However, local authorities are thought to commission using a range of currencies and prices.
	C1.2 Is this treatment excluded from national prices?	C1.2 Yes
	C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	C1.3 ARVs are funded as excluded drugs. Reporting for PrEP will need to ensure use is separately recorded from use for treatment of HIV positive people. GU attendances for PrEP would be coded accordingly via GUMCAD system
	C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?	C1.4 At July 2016, no new price has been offered for use of Truvada for PrEP. A commercially confidential price is available to the NHS for use of the drug in people with diagnosed HIV infection. During August / September 2016, the manufacturers of drugs subject to policy propositions to be assessed in October / November are being asked to submit improvements in pricing (including Truvada). This is in order to make this proposal more affordable. Local authorities are responsible for negotiating GUM attendance prices with providers. Bottom up costing indicates that there may be a marginal increase in costs for providing a PrEP service. This will also be affected by individual provider services, capacity, expected demand and local sexual health needs. Agreement about the impact on price / funding will be subject to negotiation with local authorities including demonstrating improvement in individual and public health outcomes. There is a low risk of double charging. A prior approval system for drugs and GUMCAD reporting for service is recommended to further mitigate this risk.
	C1.5 is VAT payable (Y/N) and if so has it	C1.5 Modelling has assumed that VAT is payable. Where selected providers have

	been included in the costings?	outsourced pharmacies, these should be used. Use of home delivery of these treatments needs careful consideration to avoid undermining access to other risk reduction interventions.
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 Yes. However an alternative to Blueteq will need to be explored as existing STI regulations mean that patient identifiable data from users of GUM services is not available to commissioners.
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 The range for the revenue cost per patient in year 1 (full year effect) c£4,000 - £4,800. The calculation of cost per patient is impacted by a number of assumptions and factors • Price of PrEP drug (affected by price offer and availability of generics over the next 6 years) • Targeting of PrEP drug to those at highest risk of HIV • Adherence to and duration of PrEP (assumed that those at highest risk accessing and remain on PrEP for 1 year) • Pricing of GUM attendances for PrEP service On price, list price can be used, although commercially confidential agreements are in place for use in people with diagnosed HIV, although a price for PrEP is yet to be confirmed. Service costs have been calculated so far assuming bottom up costing and use of tariff rather than block arrangements. The potential range of cost scenarios was produced in February 2016 by PHE and UCL cost effectiveness models outlined below Modelling undertaken by Public Health England (PHE) estimates the revenue cost per person on PrEP in Year 1 is £4,784 assumes a) 50% patients given daily PrEP whilst the remainder 50% given intermittent PrEP at 4 tablets per week; b) prices at current BNF list price of £4,331 per person per year, plus 20% VAT, making up to £4,084 (this is known to be overstated as confidential prices are in place for use in people with diagnosed HIV);

		c) GUM clinic cost of £208 (based on the assumption that there will be two additional follow-up attendances on top of current rate, at £104 per attendance, source: GOV.UK 2016/17 National Tariff Payment Systems: draft prices, first published: 22 December 2015, last updated: 11 January 2016, last accessed: 29 January 2016); d) HIV incidence of 3.3 per 100 person-years plus 20% increase in HIV incidence as a proxy for risk compensation (to 3.96 per 100 person-years); e) PrEP effectiveness of 64% compared with the revenue cost per person in a 'do nothing' scenario of £437 (assuming 39% of those infected diagnosed within the same year, no cost if undiagnosed). The calculations are based on an average revenue cost per HIV positive person in care of £9,433 (of which: £4,692 is HIV care and £4,741 ARV costs. This is also known to be overstated compared to commercially confidential discounts for ARVs and the funding arrangements in place for HIV care). It was further assumed that there are no HIV-related costs in undiagnosed individuals. PHE estimate the net revenue cost per person on PrEP compared with 'do nothing' alternative (no PrEP) in year 1 (year 2016/17) is £4,347.
	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 Whilst the inputs per patient remain constant in terms of drug and service in subsequent years, the revenue cost is impacted by the potential for reductions in drug prices either through discounting or where patents expire and generics become available. The net revenue cost is also impacted by the cumulative effect of the cost of new HIV diagnoses avoided over time. The minimum drug discount assumed is 0% where no price reduction is offered or where no generics are available. The estimated maximum level of drug cost reduction is 90% based on other examples of generic discounting. Generics for PrEP are expected to become available between 2018 – 2022. These are all assumptions as drug pricing is not yet confirmed. Therefore revenue cost per patient in future years could range from • c£4,200 per person per year continuing indefinitely based on highest cost

		scenario (no discounts, generics in 2022) • c£1,000 per person per year from Year 3 based on the lowest cost scenario (generic components available at the earliest opportunity and discounted at 90%) The earliest year that generic components may be available is 2018/19. The date for generic Truvada is later. Without further assurance on drug pricing and generic availability, the Year 1 revenue cost per patient is assumed to continue until Year 6.
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.1 The impact of this policy on NHS England is in providing time limited access to ARVs for PrEP now for those at highest risk of getting HIV in order to avoid the life-time costs of HIV care and treatment, which is the commissioning responsibility of NHS England. The proposition will be a cost pressure to NHS England, most likely until Year 6. Modelling demonstrates provision of PreP may be cost effective (based on drug price and targeting access for those at highest risk of HIV) and potentially cost saving over a lifetime. The cost impact and cost effectiveness of PrEP is affected by a number of sensitivity analyses including the price of ARVs used, uptake, eligibility in terms of those at highest risk accessing PrEP, adherence and duration on PrEP. The timing and availability of generics for PrEP as well as for HIV treatment impacts the cost profile for each year. C3.2 The assumptions on cost impact are set out below and are based on a range of assumptions.
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). C4.2 Indicate whether this is cost saving, neutral, or cost	C4.1 CCGs are not expected to incur costs but may – over a life time – gain savings associated with the reduction in HIV incidence although it is not possible to quantify this. For provider impact see **M4.** C4.2 This policy • Will be a cost pressure initially to NHS England and is likely to be cost saving

	pressure to the NHS as a whole.	after c6-10 years. • May be a cost pressure initially for LAs and is likely to be cost saving over a lifetime • May be cost neutral or a minimal cost pressure to providers initially and then likely to be cost saving over a lifetime
	C4.3 Where this has not been identified, set out the reasons why this cannot be measured.	C4.3 Not applicable
	C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.4 Local authority spend on sexual health services [1] STI testing and treatment, prescribed functions) was £382 Million in 2013/14 and £379 Million in 2014/15; [2] Advice prevention and promotion, non-prescribed functions was £84 Million in 2013/14 and £86 Million in 2014/15 (Source: Local Authority Revenue and Financing; https://www.gov.uk/government/collections/local-authority-revenue-expenditure-and-financing The budget impact of PrEP depends on • Changes in cost per attendance for the provision of PrEP is identified compared to current local authority pricing • The currency and pricing currently in place • Changes in attendances rates compared to current baseline by local authority to the x4 per annum per BASHH recommendations The background level of demand and whether increased attendances, testing, detection and treatment of STIs resulting from greater engagement with services through PrEP is seen as an investment to improve public health
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-*	C5.1 The HIV CRG has identified a number of commissioning for value propositions to use lower cost acquisition drugs, greater use of generics and switching drug treatments to reduce spend on ARV for treatment of people with diagnosed HIV to enable investment in ARVs for PrEP.

	effective services	
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy?	C6.1 The material financial risks are • Ensuring eligibility criteria are enforced so only those at demonstrably high risk of HIV acquisition have access to PrEP, in line with the evidence for clinical and cost effectiveness. If those not at risk have access to PrEP, cost effectiveness is undermined. • Availability and use of generics / drug price discounts
	C6.2 Can these be mitigated, if so how?	C6.2 Use of a prior approval or detailed audit programme is recommended to ensure appropriate compliance with criteria. Drug pricing issues are addressed through procurements and guidance recommending use of generics when available. The HIV CRG is providing assistance
	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.3 Variations in patient uptake • Cost of drugs for PrEP and for treatment (including discounts on current branded medicines and potential scale of price reductions on generics after brand patent expiry dates), • effectiveness (64% to 86%), proportion of patients on intermittent regimen changing levels of sexual risk behaviour / testing rates
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	C7.1 NICE is due to publish an 'evidence summary for new medicine' for pre-exposure prophylaxis of HIV in uninfected adults at high risk: Truvada (emtricitabine and tenofovir disoproxil) in 2016. The policy proposition evidence review identified seven full-text publications, assessing the cost-effectiveness of PrEP in high income countries. Most focused on delivery to target high risk groups. The level of PrEP efficacy in base case estimates ranged from around 44% to 50%, although in sensitivity analyses additional levels of efficacy were considered. Dynamic, static and number needed to treat models were used. These base-case efficacy estimates (44%-50%) were lower than the 86% reported in both the PROUD and IPERGAY trials.

		In the papers that evaluated PrEP targeted at MSM only, the incremental cost-effectiveness ratios (ICER) depended on assumptions about the target population: their age, HIV incidence, HIV prevalence, PrEP drug cost, level of condom use, adherence to PrEP or efficacy, rate of HIV diagnosis in the population and PrEP toxicity.
	C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.2 Two cost-effectiveness analyses have been conducted specific to the current English context. One led by UCL is based on the Synthesis model , and the other is a static model using GUMCAD data (PHE model). Based on the Synthesis model, the use of intermittent PrEP among MSM in the UK is cost-saving (when considering a life time frame) when PrEP is offered to MSM, in the context of a clinical risk assessment (i.e. they need to attend a GUM clinic and have an HIV test), with the eligibility criteria used in the PROUD study. However, for the first 20 years it does represent a cost pressure.
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs* C8.2 If so, confirm the source of funds to meet these costs.	C8.1 No