SPECIALISED SERVICES COMMISSIONING COMMITTEE PAPER
NHS ENGLAND

Title: Pre-Exposure Prophylaxis (PrEP)- HIV Prevention

From: Specialised Commissioning Directorate

Purpose of Paper:

The Committee is asked to consider the role and responsibilities of NHS England in relation to the commissioning of anti-retroviral drugs for the pre exposure prevention of HIV (PrEP).

Actions for the Committee:

The Committee is asked to:

- consider the legal basis for commissioning PrEP and confirm that, on balance, it accepts our external legal advice that NHS England does not have the power to commission PrEP;

- if the committee rejects the advice that NHS England does not have power to commission PrEP (or in the event that a successful legal challenge that may be brought forward results in a judgement that NHS England does have the power), to consider by what process NHS England should consider exercising the power;

- acknowledge that the Secretary of State could delegate the power to commission PrEP to NHS England via Section 7a but note that this would need to be accompanied by appropriate funding;

- re-affirm NHS England's commitment to making up to £2m available over the next two years to support a number of early implementer test sites to research how PrEP could be commissioned in the most clinically and cost effective way;

- be mindful, in particular, of the equality considerations surrounding this treatment.

Specialised Services Commissioning Committee

Pre-Exposure Prophylaxis (PrEP)- HIV Prevention

INTRODUCTION

1. The Committee is asked to consider the role and responsibilities of NHS England in relation to the commissioning of anti-retroviral drugs for the pre exposure prevention of HIV (PrEP).

2. On 21st March 2016, a statement was placed on the NHS England website explaining that PrEP could not be considered for the specialised services annual prioritisation process. Specifically, it said that:

   'As set out in the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013, local authorities are the responsible commissioner for HIV prevention services.

   Including PrEP for consideration in competition with specialised commissioning treatments as part of the annual CPAG prioritisation process could present risk of legal challenge from proponents of other 'candidate' treatments and interventions that could be displaced by PrEP if NHS England were to commission it. '

3. The full statement is included at **Appendix 1**.

4. This decision resulted in challenge from a variety of stakeholder groups and, on 12 April, NHS England received a Judicial Review- letter before claim on behalf of the National Aids Trust (NAT). This letter, which they placed in the public domain, is separately attached at **Annex A**.

5. In light of these representations and the commencement of legal proceedings, NHS England agreed to reconsider the decision it took in March. This paper, including the legal advice at **Appendix 2**, supports the Committee in this task. The Committee is asked to approach this reconsideration with an open mind, and is bound neither by the fact that PrEP was for a time being considered for the specialised services annual prioritisation process, nor by the fact that it was removed from that process.

RECOMMENDATION

6. The Committee is asked to:

   - consider the legal basis for commissioning PrEP and confirm that, on balance, it accepts our external legal advice that NHS England does not have the power to commission PrEP;

- if the committee rejects the advice that NHS England does not have power to commission PrEP (or in the event that a successful legal challenge that may be brought forward results in a judgement that NHS England does have the power), to consider by what process NHS England should consider exercising the power;

- acknowledge that the Secretary of State could delegate the power to commission PrEP to NHS England via Section 7a but note that this would need to be accompanied by appropriate funding;

- re-affirm NHS England's commitment to making up to £2m available over the next two years to support a number of early implementer test sites to research how PrEP could be commissioned in the most clinically and cost effective way;

- be mindful, in particular, of the equality considerations surrounding this treatment.

CONSIDERATION

Background

7. NHS England is the responsible commissioner for HIV care and treatment as a prescribed specialised service. This responsibility includes the commissioning of antiretrorival (ARV) drugs for the ongoing treatment of HIV infection. The purpose of the treatment is to reduce the levels of virus in the body to reduce morbidity and mortality associated with HIV. Effective treatment of people with HIV can also reduce their risk of passing on HIV infection to people who are HIV negative.

8. The vast majority of ARVs are used for treating people with diagnosed and established HIV. However, ARVs can also be used as post exposure prophylaxis. In these circumstances ARVs can be prescribed to people who present after a sexual or occupational exposure that is clinically assessed as having put the person at high risk of being infected with HIV.

9. NHS England has set out a statement of its responsibilities in connection with HIV in the Manual for Prescribed Specialised Services. This explains the commissioning responsibility for specialised services for people with HIV. It also sets out the responsibility for the commissioning of all ARVs. Department of Health guidance produced in 2013 confirmed the expectation that NHS England would fund ARVs used for treatment of people with diagnosed or established infection and for post exposure prophylaxis.

10. In 2015, the PROUD study which was examining the use of ARVs as pre-exposure prophylaxis released preliminary results which indicated that use of ARVs in this way had potential as a highly effective part of HIV prevention efforts, particularly amongst high risk men who have sex with men who do not regularly use condoms.

11. NHS England's Clinical Reference Group for HIV recommended that consideration be given to the commissioning of PrEP. A working group was established with wide membership including patients, voluntary organisations, clinicians, epidemiologists, health economists and commissioners, including local authority representatives who are responsible for the commissioning of sexual health and HIV prevention services. The group explored the issue further with early work focused on an evidence review conducted by Public Health England, cost effectiveness modelling undertaken by PHE and UCL and pathway mapping focusing on local authority service commissioning questions.

12. In March 2015, the Blood and Infection Programme of Care Board approved the inclusion of PrEP on its workplan based on the interpretation of the Manual regarding the commissioning responsibility for ARVs and the fact that without a policy position, there was a risk that NHS England would inadvertently fund drugs in an indication in which it had not taken an investment decision. A number of communications (circulars) confirming the current position that PrEP was not commissioned by NHS England were sent for cascade to commissioning teams and these also highlighted the work underway by the working group to assess the clinical and cost effectiveness of PrEP in preventing HIV infections.

13. In December 2015 a draft policy proposal and evidence review were presented to NHS England's Specialised Services Clinical Panel who confirmed that the proposed criteria for commissioning were consistent with the evidence review. Stakeholder testing was conducted in December 2015 / January 2016 whereby registered stakeholders of the HIV Clinical Reference Group had the opportunity to comment on the evidence review and the proposed policy proposition. Twenty one responses were received, the majority from voluntary sector / patient organisations as well as from the healthcare industry, academic institutions, local authorities and professional associations.

14. The majority of responses were supportive of the proposed commissioning criteria although questions were raised about the effect of PrEP on other HIV prevention strategies and commissioning arrangements. These questions were explored further and a more detailed consideration of responsibility undertaken.

15. Based on these considerations and for the reasons set out in the published statement, NHS England subsequently concluded that it was not the responsible commissioner.

Power and Responsibility for Commissioning PrEP

16. The Committee is asked to consider carefully the external legal advice at **Appendix 2**. In summary, this advice argues that:

- NHS England will have power to commission services for preventing HIV transmission, including PrEP, *unless* those services are provided pursuant to the public health functions of the Secretary of State or local authorities.

- Provision of services to prevent the spread of sexually transmitted infection is a legally specified public health function of local authorities, and a role that is explicitly legally assigned to them.

- Preventing the sexual transmission of HIV to uninfected people is not excluded from that local authority function. Therefore, NHS England does not have power to fund PrEP for that purpose.

- There are counter arguments to the conclusion that NHS England does not currently have power to commission PrEP but they are not strong.

- NHS England must be aware that groups sharing certain protected characteristics have a particular interest in PrEP, but NHS England's equality duties cannot expand its legal powers.

17. Of course, this is legal advice which ultimately can only be upheld or dismissed by a judge in a court of law. Nevertheless, the Committee must reach its own view on whether the arguments put forward should determine NHS England's position.

18. The Committee should also consider carefully the pre-action letter received on behalf of the National Aids Trust dated 12 April 2016 (**Annex A**) and in particular paragraphs 5.2-5.3.5 of that letter which sets out the NAT's grounds for arguing that NHS England does have power to commission PrEP.

Does the Committee accept NHS England's legal advice that, on balance, NHS England does not have the power to commission PrEP?

19. Should the Committee agree that NHS England does not have the power to commission PrEP, then it would seem possible that the National Aids Trust could look to re-commence legal proceedings and seek to challenge this decision through Judicial Review. However, we would hope that on reflection and with the benefit of sight of our legal advice that they would look for other ways to work with us and with other commissioners to explore the possible provision of PrEP. If not, though, NHS England would welcome the definitive judgment that this course of action would give rise to.

20. Of course, the Committee itself may disagree with NHS England's legal advice. in which case the funding of PrEP must be given due consideration. As such, there are two possible routes whereby PrEP may need to be considered for relative prioritisation:

- Firstly, because the Committee disagrees with the legal advice and considers NHS England does have the power to commission PrEP and, therefore, the responsibility to *consider* doing so (which does not mean NHS England should subsequently consider that it should do).

- Secondly, because any decision taken that we do not have the power to commission might successfully be challenged via a judicial review with NHS England subsequently being ordered to *consider* the commissioning of PrEP (which does not mean NHS England would subsequently conclude that it should do).

21. In either scenario, it is recommended that the most straightforward approach for allowing such consideration to take place would be to re-introduce PrEP into the specialised commissioning prioritisation process following a period of consultation on the proposed commissioning policy.

22. In order to ensure that, in these scenarios, PrEP was not disadvantaged from any delayed decisions or due process that needs to be followed, final decisions around the 16/17 specialised commissioning prioritisation round would need to be delayed as necessary. This would not mean having to delay deliberations by the Clinical Priorities Advisory Group, currently scheduled to take place between 6th and 9th June, but it would mean a delay to confirming final funding decisions for all candidate treatments. Any such delay would have to be for as short a period as possible as it would be postponing the introduction of new effective and affordable treatments for patients (**see Appendix 3 for latest draft list**). If the reason for delay is a judicial review, NHS England would expect to work with a challenger and the Courts to agree an accelerated litigation timetable, failing which it might not be possible to postpone funding decisions further.

The Committee is asked to consider the process by which NHS England might consider the commissioning of PrEP in the event that i) it disagrees with NHS England's legal advice that NHS England has no power, ii) in the event that a Judicial Review is brought forward and is successful.

Public Health Commissioning through Section 7A and areas for consideration

23. Even though it is argued that NHS England does not currently have the power to commission PrEP, given the fact that PrEP must be seen as part of a prevention service and given that it is not currently being commissioned by local authorities, it would be possible and appropriate for the Secretary of State to consider whether he wanted to give NHS England the power to commission it. This is the very purpose of Section 7a- a mechanism by which the Secretary of State can delegate power to NHS England to do something that it otherwise has no vires to do.

24. However, such delegation of power would need to be accompanied by the necessary resources and prioritisation through the Section 7a governance process. Consideration

through this route would need to consider the certainty around the clinical and cost effectiveness of the intervention.

25. Review of evidence to date demonstrates that whilst PrEP is likely to be highly clinically effective in preventing HIV, assurance that it is cost effective is less certain. Achieving cost effectiveness relies on ensuring that PrEP is targeted at those in MSM populations at highest risk of getting HIV and a reduction of at least 50% in the price of ARVs[1]. Even if PrEP is cost effective or even cost saving in the medium to long term, there is no doubt that it represents a significant budget impact in the short term.

26. Reducing the cost of the drugs involved in PrEP will depend on securing one or more of the following: better deals offered by drug manufacturers; evidence and acceptability for use of cheaper alternative drugs or drug dosing; the availability of significantly lower cost generic drugs.

Early Implementer Test Sites

27. Even if the Committee concludes that the power to commission PrEP does not currently exist, NHS England remains committed to HIV prevention and supporting clinically important innovations. That is why the March statement announced that £2m would be made available over the next two years (16/17 and 17/18) to run a number of pilots to answer the remaining questions around how PrEP can be commissioned in the most cost effective and integrated way to reduce HIV and sexually transmitted infections in those at highest risk.

28. It is estimated that at current prices, protection for at least 500 men who have sex with men at high risk of HIV infection could be provided. NHS England also announced it would investigate how support might continue to be provided, where clinically appropriate, to PROUD Study participants for the duration of the pilot period. The intention is to run the pilots over the next two years to test and research the 'real life' cost effectiveness of PrEP as part of an integrated HIV and STI prevention service and answer three outstanding questions to inform future commissioning arrangements:

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[1] CAMBIANO, V., MINERS, A., DUNN, D., MCCORMACK, S., GILL, N., NARDONE, A., DESAI, M., CAIRNS, G., RODGER, A. & PHILLIPS, A. 2015. O1 Is pre-exposure prophylaxis for hiv prevention cost-effective in men who have sex with men who engage in condomless sex in the uk? . *Sex Transm Infect* [Online], 91. Available: http://sti.bmj.com/content/91/Suppl_1/A1.1.abstract [Accessed 23 September 2015].

ONG, K., DESAI, S., DESAI, M., NARDONE, A., VAN HOEK, A. J. & GILL, O. N. The cost-effectiveness of Pre-Exposure Prophylaxis (PrEP) to prevent HIV acquisition by high-risk MSM in England – preliminary results of a static decision analytical model. Poster presentation. Public Health England Annual Conference 15-16 September 2015 Warwick University, UK.

- How can PrEP be integrated into the wider offer of HIV and STI prevention services offered by local authorities and how will it impact on these?

- How can PrEP deliver improvements in patient experience and outcomes by reducing HIV infections and other sexually transmitted infections and what data can we use to demonstrate this?

- How can PrEP be delivered to those who can benefit most, in the most cost effective and planned way possible?

29. These results will be useful generally in considering commissioning PrEP whether in local government or the NHS. Working with DH and PHE, the aim is to design the criteria for patient and provider selection and the framework for measuring the finding of the pilots. Expressions of interest will then be sought from local authority areas via a process that would be launched following the Committee's deliberations.

30. The legal advice received confirms that whilst NHS England cannot routinely commission PrEP because the necessary power does not exist, the proposal for early implementer test sites is within the function and power of NHS England as part of the duty to promote innovation and research.

The Committee is asked to reaffirm the previous commitment made to invest up to £2m over the next two years to support a number of early implementer test sites.

Appendix 1

Update on commissioning and provision of Pre Exposure Prophylaxis (PREP) for HIV prevention

21 March 2016 - 17:42

Work to date

Over the last year, doctors, patient groups, Public Health England (PHE), NHS England and the Department of Health (DH) have worked together to investigate the role that Pre Exposure Prophylaxis (PrEP) could play in preventing HIV in those at the highest risk

PrEP is a new way of using anti-retroviral drugs (ARVs) – usually used for treating people with diagnosed HIV – to stop those at very highest risk from contracting the virus.

Recent evidence – including from the UK PROUD study – shows this approach can be highly effective in preventing HIV as long as the drugs are taken regularly. Evidence of effectiveness is strongest for men who have condomless sex with multiple male partners.

So far, published studies suggest that PrEP does not lead to increases in other sexually transmitted infections, although longer term data is needed to be certain that PrEP can make a significant contribution to sexual health and well-being.

Commissioning PrEP – the legal framework

As set out in the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013, local authorities are the responsible commissioner for HIV prevention services.

Including PrEP for consideration in competition with specialised commissioning treatments as part of the annual CPAG prioritisation process could present risk of legal challenge from proponents of other 'candidate' treatments and interventions that could be displaced by PrEP if NHS England were to commission it.

Expanding PrEP funding – next stages of rollout

While NHS England is not responsible for commissioning HIV prevention services, we are committed to working with local authorities, Public Health England, the Department of Health and other stakeholders as further consideration is given to making PrEP available for HIV prevention.

Specifically, given the potential benefits in this area, NHS England is keen to build on the excellent work to date and will be making available up to £2m over the next two years to run a number of early implementer test sites.

These will be undertaken in conjunction with Public Health England and will seek to answer the remaining questions around how PrEP could be commissioned in the most cost effective and integrated way to reduce HIV and sexually transmitted infections in those at highest risk. These test sites will aim to provide protection to an additional 500 men at high risk of HIV infection as well as inform future arrangements for the commissioning and provision of this innovative intervention.

In addition, NHS England is keen to explore how a period of further support can be offered to the participants enrolled in the PROUD study and is committed to making funding available where there is a clinical need for additional help.

NHS England and Public Health England will launch a process to seek expressions of interest for the test sites from local authority areas with a view to confirming successful applications by June 2016. These will run over the next two years and will aim to test the 'real life' cost effectiveness and affordability of PrEP as part of an integrated HIV and STI prevention service.

The DH and partners will consider the relevant findings from the test sites to inform respective commissioning responsibilities for HIV care and treatment and HIV prevention.

In July 2015 NHS England approved a policy for the earlier treatment of people with diagnosed HIV to help reduce the onward transmission of the virus. It is intended that the benefits of this policy together with the PrEP early implementer sites will continue to reduce new HIV infections.

Appendix 2

Memo

LEGAL ADVICE

1. This memo advises whether NHS England has the legal power to commission the use of anti-retroviral drugs for PrEP. It considers the legal position under the National Health Service Act 2006 ("2006 Act"), the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013 ("2013 regulations") and the NHS public health functions agreement 2016-17 ("2016-17 agreement").

Executive summary:

- NHS England will have power to commission services for preventing HIV transmission, including PrEP, unless those services are provided pursuant to the public health functions of the Secretary of State or local authorities
- Provision of services to prevent the spread of sexually transmitted infection is a public health function of local authorities
- Preventing the sexual transmission of HIV to uninfected people is not excluded from that local authority function. Therefore NHS England does not have power to fund PrEP for that purpose.
- There are tenable counter arguments to the conclusion that NHS England does not currently have power to commission PrEP but they are not strong.
- NHS England must be aware that groups sharing certain protected characteristics have a particular interest in PrEP, but NHS England's equality duties cannot expand its legal powers.

In detail:

2. Under s.2 of the 2006 Act (all section references are to this Act) NHS England may do anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any function conferred on it by that Act. "Function" means any duty or power.

3. Under s.1(H) NHS England is subject to a duty (and a primary function) to "*continue the promotion in England of a comprehensive health service designed to secure improvement— (a) in the physical and mental health of the people of England, and (b) in the prevention, diagnosis and treatment of physical and mental illness*".

4. However that duty does not apply "*in relation to the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities*" (s.1H (2))

Therefore the essential question is whether prevention of HIV infection by PrEP is within a service provided in pursuance of the public health functions of the Secretary of State or local authorities.

5. The public health functions are: "*the functions of the Secretary of State under sections 2A and 2B and paragraphs 7C, 8 and 12 of Schedule 1"*, and "*the functions of local authorities under sections 2B and 111 and paragraphs 1 to 7B and 13 of Schedule 1"* (S.1H(5*)*) Only sections 2A and 2B are relevant here.

6. S.2A requires the Secretary of State to *"take such steps as the Secretary of State considers appropriate for the purpose of protecting the public in England from disease or other dangers to health"*.

7. S.2B is in similar terms, save that it imposes a duty on local authorities to take steps to improve (not protect) health, and a power on the Secretary of State to do the same.

8. S.6C, which provides that *"(1)Regulations may require a local authority to exercise any of the public health functions of the Secretary of State (so far as relating to the health of the public in the authority's area) by taking such steps as may be prescribed, (2) Regulations may require a local authority to exercise its public health functions by taking such steps as may be prescribed*" The steps that are prescribed in regulations must be public health functions. The regulations under this section are the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013.

9. Paragraph 6 of those regulations as relevant needs to be set out at length (emphasis added):

   (1) Subject to paragraphs (4) and (5), each local authority shall provide, or shall make arrangements to secure the provision of, open access sexual health services in its area—

   (a)...[by arranging contraceptive services] *and*

   (b) ***by exercising its functions under section 2B of the Act—***

   (i) ***for preventing the spread of sexually transmitted infections****;*

   (ii) for treating, testing and caring for people with such infections; and

   (iii) for notifying sexual partners of people with such infections.

   (2) In paragraph (1), references to the provision of open access services shall be construed to mean services that are available for the benefit of all people present in the local authority's area.

   ...

   (5) ***The duty of the local authority under paragraph (1)(b) does not include a requirement to offer services for treating or caring for people infected with Human Immunodeficiency Virus***.

10. First, we can see that preventing the spread of sexually transmitted infections generally is within the duty set out in s.2B. Despite the wide discretion that would otherwise apply to that duty it cannot be open to a local authority to argue that it does not include preventing the spread of sexually transmitted infections.

11. The duty to provide or secure open access sexual health services extends to services for preventing the sexual spread of HIV, unless the caveat in regulation 6(5) applies. That caveat plainly does not apply, at least, not across the board. There are two reasons. The first reason is regulation 6(5) only carves out services for people infected with HIV. However PrEP is by definition not a service for a person infected with HIV. Therefore it is not excluded by regulation 6(5). The second reason is regulation 6(5) carves out services for treating or caring for people. Services for treating or caring for people with sexually transmitted infections are referred to in regulation 6(1)(b)(ii). Preventing the spread of infection is a different service referred to in regulation 6(1)(b)(i). The exclusion for treating and caring does not cover preventing the spread.

12. Local authorities must provide a service that inter alia seeks to prevent the sexual spread of HIV. Although PrEP is one way to prevent the sexual spread of HIV it does not follow that local authorities must provide it or must provide it on any particular terms (although they must consider providing it). They might decide that the provision of information and/or condoms is sufficient. Equally they could commission a service including PrEP. It would be a matter for them, provided they acted reasonably.

13. What does this mean for NHS England and its power to commission PrEP? We said above that there was such a power, unless PrEP was within "*the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities* ". We have seen that provision of a service to prevent the sexual transmission of HIV is a public health function of local authorities, but that they do not have to make PrEP available as part of that service. The question then becomes what does " part of the health service" etc. mean. If it means preventing the spread of sexually transmitted infections including HIV, then clearly that is a public health function of local authorities and NHS England has no power[2].

14. Our view is that the reference to "part of the health service" must be a reference to services for prevention of the transmission of sexually transmitted diseases generally, and that it is not right to treat the provision of one specific method of blocking transmission as a stand alone part of the health service. First, this accords with the normal meaning of the words: if asked what the parts of the health service were, a patient would refer to a function or maybe a location, not a treatment. A GP surgery is "part of the health service", the specific drug he or she prescribes is not. The same natural language seems to apply to sexual health clinics and PrEP.

15. Second, it would be an odd result if NHS England had a patchwork power (which it would then be under a duty to consider using) to commission whatever parts of a sexual health service any given local authority happened not to provide. The scope of services provided could vary from authority to authority, and NHS England's functions as regards the remaining treatments not being provided would similarly vary. That seems unlikely, particularly as the same argument would apply to all other public health functions. The effect would be that NHS England would have to keep under review all possible public health activities, discount those that were actually being provided by local authorities or the

[2] save for post exposure prophylaxis for HIV as that is excluded from the local authority function by regulation 6(5)

secretary of state, and then have to take a lawful decision whether or not it ought to provide any of the remaining possible services that were not being provided. If that were truly the intended role of NHS England it seems likely that this would have been pointed out (and funded) by now.

16. Finally we turn to s.7A, which provides *The Secretary of State may arrange for a body mentioned in subsection (2) to exercise any of the public health functions of the Secretary of State.* A function listed in any arrangement made under s.7A must have been considered to be part of the public health functions of the Secretary of State.

17. The 2016-17 agreement does not cover HIV prevention. Therefore NHS England is not currently empowered to commission a service including PrEP under s.7A

18. Pausing here, this does not seem out of line with expectations set when commissioning responsibility for most sexual health services passed to local authorities. In A Framework for Sexual Health Improvement in England [3] the DoH advised that local authorities would commission "*any sexual health specialist services, including young people's sexual health and teenage pregnancy services, outreach, HIV prevention and sexual health promotion, services in schools, colleges and pharmacies*." and NHS England would commission " *HIV treatment and care (including drug costs for post-exposure prophylaxis after sexual exposure*)". The specific references to HIV prevention generally as a responsibility of local authorities and only to drug costs of post exposure prophylaxis for NHS England are consistent with our analysis.

The Mandate

19. We have considered the Mandate, which contains a reference to avoidable ill health, albeit in a context which seems unlikely to be intended to refer to sexually transmitted diseases. NHS England must seek to achieve the objectives in the mandate (s.13(7)). However we do not think that the mandate alone expands NHS England's legal powers, i.e., it does not follow that because something is referred to in the mandate and because NHS England must seek to achieve the objectives in the mandate that there is a power to do anything that could be argued to be within the mandate.

Equalities

20. NHS England needs to be aware that PrEP is of particular interest to some groups who will share a protected characteristic, for example sexual orientation, particular racial heritage, or disability. (HIV infection is defined as a disability, and PrEP will be of special interest to people with HIV who are in a serodiscordant relationship and possibly others.) While NHS England will be mindful of the need to eliminate unlawful discrimination and advance equality of opportunity, and that this may mean taking steps (including more favourable treatment) to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it; those obligations cannot expand NHS England's legal powers.

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[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/142592/9287-2900714-TSO-SexualHealthPolicyNW_ACCESSIBLE.pdf

Appendix 3

Specialised Commissioning Clinical Policy Work Programme (2015/16) to be considered by the Clinical Priorities Advisory Group (CPAG) for Investment in 2016/17

WP:Indication	WP:Intervention	Programme of Care
Acromegaly as a third-line treatment (adults)	Pegvisomant	A - Internal Medicine
Acromegaly as a third-line treatment (adults)	Pasireotide	A - Internal Medicine
Children (2 to 5) with Cystic Fibrosis (named mutations)	Ivacaftor	A - Internal Medicine
Complex primary hyperparathyroidism	Cinacalcet	A - Internal Medicine
Cushing's Disease	Pasireotide	A - Internal Medicine
Dermatomyostitis and polymyostis in adults	Rituximab	A - Internal Medicine
Giant cell arteritis	Toculiziumab	A - Internal Medicine
Hidradenitis suppurativa	Infliximab	A - Internal Medicine
Hyponatraemia secondary to the Syndrome of Inappropriate Antidiurectic Hormone (SIADH) for patients who require cancer chemotherapy	Tolvaptan	A - Internal Medicine
Immunobullous Diseases	Rituximab	A - Internal Medicine
Immunoglobulin G4-related disease (IgG4-RD)	Rituximab	A - Internal Medicine
Inhaled Therapy for Adults and Children with Cystic Fibrosis (Aztreonam)	Aztreonam	A - Internal Medicine
Interstitial lung disease associated with connective tissue disease (CTD-ILD)	Rituximab	A - Internal Medicine
Liver metastases of ocular melanoma	Chemosaturation	A - Internal Medicine
Oesteogenesis imperfecta (adults)	Teraparitide	A - Internal Medicine
Prevention and treatment of recurrence of C3 glomerulopathy post-transplant	Eculizumab	A - Internal Medicine
Prevention of organ rejection following heart transplantation	Everolimus	A - Internal Medicine
Primary Sjogren's Syndrome (PSS) (adults)	Rituximab	A - Internal Medicine
Pulmonary Arterial Hypertension	Riociguat	A - Internal Medicine
Pulmonary hypertension	Selexipag	A - Internal Medicine
Recurrent acute pancreatitis	Total Pancreactectomy with Islet Autotransplant	A - Internal Medicine
Resistant Hypertension	Renal Denervation	A - Internal Medicine
Severe and Complex Obesity	Complex obesity surgery (Children)	A - Internal Medicine
Standard treatment resistant idiopathic membraneous nephropathy	Rituximab	A - Internal Medicine
Surgical management of enlarged aortic root (adults)	Personalised External Aortic Root Support (PEARS)	A - Internal Medicine
Takayasu Arthritis	Tocilizumab	A - Internal Medicine
1st and 2nd line treatment of angiosarcoma	Pegylated liposomal docorubicin (Caelyx)	B - Cancer
1st and 2nd line treatment of sarcoma in patients with cardiac impairment v	Pegylated liposomal doxorubicin (Caelyx)	B - Cancer
1st line low grade lymphoma, with Rituximab	Bendamustine	B - Cancer
1st line mantle cell lymphoma	Bendamustine	B - Cancer
1st line treatment of primary sarcoma of the heart and great vessels	Pegylated liposomal doxorubicin (Caelyx)	B - Cancer
1st or 2nd line metastatic pancreatic neuroendocrine tumours	Everolimus	B - Cancer
1st or 2nd line symptomatic splenomegaly in primary myelofibrosis, post pc	Ruxolitinib	B - Cancer
2nd and subsequent CLL	Bendamustine	B - Cancer
2nd line fibromatosis	Pegylated liposomal doxorubicin (Caelyx)	B - Cancer
3rd line treatment of low grade gliomas of childhood	Bevacizumab	B - Cancer
3rd line treatment of metastatic non-adipocytic soft tissue sarcoma	Pazopanib	B - Cancer
Acute lymphoblastic leukaemia as a bridge to transplant	Clofarabine	B - Cancer
Acute myeloid leukaemia as a bridge to transplant	Clofarabine	B - Cancer
Adults with Parkinson's Tremor and Familial Essential Tremor	Stereotactic radiosurgery	B - Cancer
Advanced gastrointestinal stromal tumour after failure of at least previous	Regorafenib	B - Cancer
After primary surgery for breast cancer	Radiotherapy	B - Cancer
Angiomyolipomas associated with tuberous sclerosis	Everolimus	B - Cancer
Benign urethral strictures (in adult men)	Urethroplasty	B - Cancer
Bladder cancer	Robotic assisted surgery	B - Cancer
Bone Pain	Palliative Radiotherapy	B - Cancer
Bortezomib naive relapsed multiple myeloma	Bortezomib	B - Cancer
Bridge to allograft transplant for the treatment of anaplastic large cell lymp	Brentuximab	B - Cancer
End stage erectile dysfunction	Penile Prostheses	B - Cancer
Ependymoma, haemangioblastoma, pilocytic astrocytome and trigeminal schwannoma	Stereotactic radiosurgery/radiotherapy	B - Cancer
Gastropaerisis	Gastric Pacing	B - Cancer
Hepatocellular carcinoma or cholangiocarcinoma	Stereotactic ablative body radiotherapy	B - Cancer
Kidney cancer	Robotic assisted surgery	B - Cancer
Male infertility	Surgical sperm retrieval for male infertility	B - Cancer
Metastatic basal cell carcinoma, or locally advanced BCC inappropriate for su	Vismodegib	B - Cancer
Oesophago-gastric cancers	Robotic assisted surgery	B - Cancer

Oligometastatic disease	Stereotactic ablative body radiotherapy	B - Cancer
Papillary or follicular thyroid cancer that is inoperable or metastatic disease	Sorafenib	B - Cancer
Ph+ ALL with the T315I mutation	Ponatinib	B - Cancer
Previously irradiated tumours of the pelvis, spine and nasopharynx	Stereotactic ablative body radiotherapy	B - Cancer
Primary lung cancer	Robotic assisted lung resection surgery	B - Cancer
Prostate Cancer	Proton Beam Therapy	B - Cancer
Prostate cancer	Stereotactic ablative body radiotherapy	B - Cancer
Relapsed low grade NHL	Bendamustine	B - Cancer
Relapsed mantle cell lymphoma	Bendamustine	B - Cancer
Relapsed multiple myeloma	Bendamustine	B - Cancer
Relapsed Waldenstroms Macroglobulinaemia	Bortezomib	B - Cancer
Relapsed/ refractory mantle cell lymphoma	Bortezomib	B - Cancer
Relapsed/ refractory multiple myeloma with prior response to bortezomib	Bortezomib	B - Cancer
Renal cancer	Stereotactic ablative body radiotherapy	B - Cancer
Rituximab refractory low grade NHL	Bendamustine	B - Cancer
Symptomatic, locally advanced (unresectable) or metastatic medullary thyr	Vandetanib	B - Cancer
T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymp	Nelarabine	B - Cancer
Throat and voice box cancers	Robotic assisted trans-oral surgery	B - Cancer
Treatment of advanced neuroendocrine tumours	Peptide receptor radionucleotide therapy	B - Cancer
Treatment of progressive, unresectable locally advanced or metastatic med	Cabozantinib	B - Cancer
Unresectable or metastatic, well-differentiated pancreatic neuroendocrine	Sunitinib	B - Cancer
Adults with cardiac failure	Extra corporeal membrane oxygenation service	D - Trauma
Children with deficient or missing auditory nerves	Auditory brainstem implants	D - Trauma
Chronic inflammatory demyelinating polyneuropathy (CIDP), multifocal motor neuropathy (MMN), vasculitis of the peripheral nervous system and IgM paraprotein-associated demyelinating neuropathy (Adults)	Rituximab	D - Trauma
Chronic refractory cancer pain	Ziconitide	D - Trauma
Hearing loss (all ages)	Bone conducting hearing implants (BCHIs)	D - Trauma
Lambert Easton Myasthenic Syndrome	Amifampridine phosphate	D - Trauma
Lower limb loss	Prosthetics (Microprocessor limbs)	D - Trauma
Multiple indications	Hyperbaric Oxygen Therapy	D - Trauma
Multiple Sclerosis (adults)	Fampridine	D - Trauma
Osteochondral lesions of the talus (adults)	Autologous Chondrocyte Implantation	D - Trauma
Post stroke pain	Deep Brain Stimulation	D - Trauma
Spinal fusion	Bone morphogenic protein-2	D - Trauma
Vision	Argus II prosthesis	D - Trauma
Adolescents with persistent gender identity disorder	Cross sex hormones	E - Women and Children
Allergic asthma (children)	Temperature controlled laminar airflow device	E - Women and Children
Primary Ciliary Dyskinesia (all ages)	Dornase Alfa Inhaled therapy	E - Women and Children
Stem Cell mobilisation	Plerixafor for Paediatrics	E - Women and Children
Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex	Everolimus	E - Women and Children
Symptom control for narcolepsy with cataplexy (children)	Sodium oxybate	E - Women and Children
Acute disseminated encephalomyelitis and autoimmune encephalitis	Intravenous immunoglobulin	F - Blood
All ages	Haematopoietic Stem Cell Transplantation	F - Blood
Cytopaenia complicating primary immunodeficiency	Rituximab	F - Blood
Haematopoietic Stem Cell Transplantation	Treatments for Graft versus Host Disease (GvHD) following	F - Blood
Haemophilia (all ages)	Immune Tolerance Induction	F - Blood
Human immunodeficiency virus	Tenofovir Alafenamide containing treatments	F - Blood
Prophylactic treatment of hereditary angioedema (HAE) types I and II	Plasma-derived C1-esterase inhibitor	F - Blood
Relapsed disease (adults)	Second allogeneic haematopoietic stem cell transplant	F - Blood
Transfused and non-transfused patients with chronic inherited anaemias	Treatment of iron overload	F - Blood