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NHS ENGLAND ANNOUNCES MAJOR EXTENSION OF NATIONAL HIV PREVENTION PROGRAMME WITH PUBLIC HEALTH ENGLAND AND FUNDING FOR TEN NEW SPECIALISED TREATMENTS

NHS England will fund a major extension to the national HIV prevention programme led by Public Health England with the aim of supporting those most at risk and reducing the incidence of HIV infection.

It has also decided to routinely commission ten new specialised treatments as part of the annual prioritisation process for specialised treatments.

The new HIV initiative is joint between NHS England and Public Health England, and follows the recent Court of Appeal ruling that NHS England, alongside local authorities, has the power, although not the obligation, to fund the provision of anti-retroviral drugs for the prevention of HIV, known as pre-exposure prophylaxis (PrEP).

The first phase of implementation will be the launch of a large scale clinical trial in early financial year 2017/18. Although the evidence around the clinical effectiveness of PrEP is strong, advice from Public Health England has highlighted significant outstanding implementation questions that should be answered prior to using PrEP in a sustained way on a substantial scale in England. These questions will be answered by the clinical trial, paving the way for full rollout.

It is anticipated that the clinical trial phase will include at least 10,000 participants over the next three years. NHS England will fully fund the cost of the clinical trial phase and will work in partnership with local authorities, the Local Government Association and Public Health England to implement the findings as part of a wider national rollout.

Detailed planning will now take place to ensure the launch and the clinical trial phase can begin as swiftly as possible. Up to £10 million will be made available over the next three years to fund all aspects of the trial. Next steps will include asking both the manufacturer of the branded PrEP drug Truvada, as well as generic manufacturers to make proposals to participate in the trial.

Dr Jonathan Fielden, Director of Specialised Commissioning and Deputy National Medical Director, NHS England said:

“We’re pleased to be able to announce funding not only for ten new specialised treatments but also a new ground breaking national programme for PrEP that will benefit at least 10,000 people.

“This has, in part, been made possible by the willingness of many pharmaceutical and device companies to come forward with lower and more responsible prices. Continuing this constructive joint working will enable us to fund more new drugs and treatments in the future.

“We have however, had to make some tough decisions over what we are not able to fund at this point in time within the resources we have available. We will ensure those treatments have the opportunity to be considered as part of the next annual prioritisation round in spring 2017.”

Professor Kevin Fenton, Director of Health and Wellbeing at Public Health England said

“Currently 13,500 people are living in the UK with undiagnosed HIV and we are still seeing around 5,000 new infections each year. Given we are in the fourth decade of this epidemic there are too many new infections occurring, and we need to use all tools available to save lives and money. We’re delighted to be working in partnership with NHS England on this major new addition to the

national HIV prevention programme. This comes after much planning and preparation to ensure we can successfully coordinate this extremely important and large scale clinical trial.

“We encourage all those who may be at risk of HIV to ensure they get tested and we are again working with local authorities to fund the HIV home-sampling test kit as well as issuing joint guidance for the first time with NICE, which supports increased uptake of HIV testing.”

Cllr Izzi Seccombe, Chairman of the Local Government Association’s Community Wellbeing Board, said:

"We are pleased that NHS England has acted quickly and chosen to fund the commissioning of this trial and rollout of PrEP. We now want to stand united with the NHS to defeat the spread of HIV.

"PrEP is a ground-breaking method of treatment that has the potential to save lives and councils want to work with the NHS to help roll out the trial.

"Local authorities have invested millions in providing sexual health services since taking over responsibility for public health three years ago, and we firmly believe that PrEP could significantly reduce levels of HIV in the community."

Dr Ian Williams, Senior Lecturer and Hon Consultant Physician, Central and North West London NHS Foundation Trust and Chair of NHS England’s Clinical Reference group for HIV said:

“This announcement demonstrates NHS England’s commitment to fund PrEP and provides the chance to best prepare England for optimal roll out following this large scale clinical trial. For now, the trial will provide access to PrEP for thousands of people most at risk of acquiring HIV.

“I’m delighted that the work of many people from the HIV Clinical Reference Group, including clinicians and patient advocates, is providing the foundations for this trial. Now we look ahead to working with partners in PHE, the voluntary sector and local government to get the trial underway across England, helping us to better understand how to integrate PrEP as part of comprehensive HIV prevention service aimed at preventing transmission of HIV and other STIs.”

The decision to routinely commission ten new specialised treatments is based on advice from NHS England's clinical priorities advisory group which assessed the relative priority of investing in a new range of specialised treatments and interventions. This took into account revised prices submitted by some manufacturers since provisional investment decision were published in July.

The list of treatments that will now be routinely commissioned are below:

- Pegvisomant for acromegaly as a third-line treatment for adults
- Auditory brainstem implants for congenital abnormalities of the auditory nerves or cochleae
- Haematopoietic stem cell transplant : Lymphoplasmacytic lymphoma /Waldenstrom’s Macroglobulinaemia (adults)
- Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex

- Rituximab for immunoglobulin-G4 related disease (IgG4-RD)
- Microprocessor controlled prosthetic knees
- Tolvaptan for hyponatraemia secondary to the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) for patients who require cancer chemotherapy
- Ivacaftor for children (2-5 years) with cystic fibrosis (named mutations)
- Sodium oxybate for symptom control for narcolepsy with cataplexy (children)
- Pasireotide for Cushing's Disease

Both the decision to fund a new national HIV prevention programme and to routinely commission the ten new treatments follow consideration by NHS England's Specialised Services Commissioning Committee.

Background

- The PrEP clinical trial will answer questions raised by Public Health England about six key outstanding questions:
 1. What proportion of genitourinary medicine (GUM) clinic attendees will be assessed as eligible for PrEP?
 2. How to identify, engage and maintain other eligible PrEP users?
 3. What proportions of the eligible will accept PrEP and will choose daily or intermittent dosing?
 4. For how long will those beginning at high risk stay on PrEP?
 5. What impact will PrEP have on HIV incidence?
 6. What impact will PrEP have on STI incidence?
- Public Health England and NICE have also announced the rollout of new guidance to increase the uptake of HIV testing <https://www.nice.org.uk/guidance/NG60>
- Public Health England has been working closely with St Stephen's AIDS Trust in developing the trial proposal (<http://www.ssat.org.uk/>)
- The three proposals with the lowest cost/benefit priority are not currently affordable and will not be routinely commissioned at this time. These policies will have the opportunity to be considered again next year in the relative prioritisation process in spring 2017. The list of proposals not funded as part of this year's prioritisation are as follows:
 - Eculizumab for treatment of recurrent C3 glomerulopathy post-kidney transplant
 - Riociguat for pulmonary arterial hypertension
 - Second allogeneic haematopoietic stem cell transplant for relapsed disease (all ages)

For more information call the NHS England press office on 0113 825 0958

For interviews please call Public Health England 0207 654 8400