Decisions on new treatments in specialised services: Summary guide to consultation
### Document Purpose
Consultations

### Document Name
Decisions on new treatments in specialised services: Summary guide to consultation

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### Target Audience
CCG Clinical Leaders, CCG Accountable Officers, Foundation Trust CEs, Medical Directors, Directors of PH, Directors of Nursing, Local Authority CEs, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs, Interested individuals, patient groups and voluntary sector organisations; industry and commercial partners; Royal Colleges; other health bodies

### Description
This document is a summarised version of the main consultation document which supports NHS England's consultation on a proposed method for making investment decisions in specialised services.

### Cross Reference
Developing a method to assist investment decisions in specialised commissioning: next steps

### Superseded Docs (if applicable)
N/A

### Action Required
N/A

### Timing / Deadlines (if applicable)
Consultation runs from 12 April to 11 May 2016

### Contact Details for further information
Jeremy Glyde
Specialised Commissioning - 6B
Skipton House
80 London Road, London
SE1 6LH

england.scengagement@nhs.net

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Decisions on new treatments in specialised services

How does the NHS in England decide which new drugs, medical devices and treatments should be funded each year?

NHS England is now asking for your views on how it makes these decisions in one important area: treatments for rarer illnesses, where the number of patients needing the treatment is relatively small. These treatments are known as ‘specialised services’.

It is carrying out a public consultation between 12 April and 11 May 2016 and wants to hear your views.

You can take part by completing an online survey. This guide aims to give you some background information that you might find helpful. A more detailed guide to consultation is available at https://www.engage.england.nhs.uk/consultation/investment-decisions

Prioritising new treatments

Specialised services are not available in every local hospital. They have to be provided by specialist teams of doctors and nurses who have the necessary skills and experience needed to treat these complex conditions safely and effectively.

NHS England plans how specialised services are provided nationally. That’s different from most other areas of care which are planned and arranged locally.

It has a large budget for specialised services at around £14 billion per year. But a lot of this money is earmarked for the treatments, devices and care already provided.

With the money that is available for new treatments, NHS England has to make difficult decisions. Each year it has to decide which new drugs, medical devices and treatments would be the best use of those funds. This is taxpayers’ money after all, and it needs to be invested in the best way possible for patients and the public.

A way of making decisions on new treatments

It is important that the process NHS England uses to make decisions on new treatments works well and is fair and transparent.

The process needs to ensure that the new treatments:

- are safe and effective for patients
- are affordable
- offer value for money
The process also has to be able to compare different treatments for different groups of patients. NHS England will have to decide which treatments are more of a priority to get the funding available. It is these treatments that will be made available to patients.

Last year, NHS England consulted on the principles it would use in its decision making. It’s response to consultation can be found here:  

Now it is proposing a method that can be used for comparing new treatments, and for making decisions on which ones should be prioritised and funded by the NHS in England.

Following any changes based on your feedback in the public consultation, NHS England will use the method in June 2016 to prioritise new treatments for the available NHS funds in this financial year 2016/17.

In developing this process for making funding decisions on new treatments, NHS England has taken into account the laws requiring promotion of equality and the reduction of health inequalities between different social groups. The more detailed consultation guide includes an Equality and Inequalities Impact Assessment, and it asks for your views on whether the proposed method will promote equality for patients and reduce health inequalities.

**How do new treatments get considered?**

Each year, a number of new drugs, medical devices and treatments in specialised services are put forward to NHS England. The proposals might come from a number of sources including drugs firms and device manufacturers.

The promising proposals are considered by experts in the field, including doctors, public health experts and lay people. These groups, established by NHS England, are known as Clinical Reference Groups.

The Clinical Reference Groups make detailed assessments of the new treatments. These assessments, along with the views of stakeholders and the public, go to the Clinical Priorities Advisory Group for consideration.

The Clinical Priorities Advisory Group, with an independent chair and membership that includes public and patient representatives, makes recommendations to NHS England on which proposed treatments should get funding.

It is the Clinical Priorities Advisory Group that will use the new method for prioritising treatments for funding in June 2016.

NHS England will consider the recommendations of the Clinical Priorities Advisory Group when making final decisions on which treatments will be funded. Treatments that are not funded will not be available for patients in the NHS in England.
The proposed new method for deciding priorities – in more detail

The Clinical Priorities Advisory Group will assess each of the new drugs, medical devices or treatments against principles that were agreed by NHS England following last year’s consultation.

These are:

- NHS England will normally prioritise treatments only where there is reliable evidence of clinical effectiveness - but treatments for rarer conditions may be funded even though there may be more limited evidence of effectiveness
- NHS England will normally prioritise treatments that offer clear benefit to patients
- The treatment should offer value for money

NHS England, following expert advice, has developed a new method for carrying this out these assessments. It would work as follows.

### 1.1 Benefit to patients

The Clinical Priorities Advisory Group will categorise each proposed treatment as having either: high benefit, medium benefit or low benefit for patients. Equal numbers of new treatments will be put in each category.

The group will do this having considered a report on the patient benefit offered by the drug or medical device, and the quality of the medical evidence for it. The report is informed by an independent review of the available evidence (such as research papers following trials or evaluations).

The benefit of a drug, medical device or treatment can be shown in different ways. A treatment might increase the chances of survival. It might extend how long patients might expect to live. It could improve patients’ quality of life while living with a condition.

There are likely to be a small number of new treatments for rarer conditions that need to be considered as part of this process. It is often more difficult to get the same level of evidence for such “highly specialised” treatments, as there are fewer patients with the condition. As an outcome of last year’s consultation, NHS England has agreed that the Clinical Priorities Advisory Group may recommend to prioritise treatments for these rarer conditions where there is more limited evidence.

### 1.2 Level of priority

The Clinical Priorities Advisory Group will have agreed each new drug, device or treatment as being of low, medium or high benefit. Each one will then be placed on a
square grid, according to its “benefit” and to the actual “cost per patient” that benefits from the treatment.

For example, a new treatment that offers high benefit and low cost will be in Box A. Treatments with low benefit and high cost will be in Box I.

The boxes in the square grid will determine what level of priority is recommended for each new drug, medical device or treatment.

- Those in Box A will have the highest recommended priority for receiving NHS funds – Level 1. These are those with greatest patient benefit and lowest cost.
- Treatments in boxes B and C will be given the second recommended level of priority.
- Boxes D, E and F will be the middle or third recommended priority level.
- Drugs and medical devices in boxes G and H will be in priority level four.
- While those high cost and low benefit treatments in Box I will have the lowest recommended priority – Level 5.

### 1.3 Final check

Before making its final recommendations, the Clinical Priorities Advisory Group will decide if any adjustments should be made by giving a treatment a higher priority based on whether it significantly:

- benefits the wider health and care system
- helps put the treatment of mental health on a par with physical health
- will stimulate innovation and the development of new approaches to health care
- reduce health inequalities

These four principles were agreed by NHS England following last year’s consultation.
The Clinical Priority Advisory Group’s final recommendations on which new drugs, medical devices and treatments should be considered will then be presented to NHS England using these five levels of prioritisation.

NHS England will consider the recommendations made by the Clinical Priorities Advisory Group. NHS England has a legal duty to make decisions that are affordable, which means that even treatments that have been given a higher priority by the Clinical Priorities Advisory Group may not be affordable within the funding that is available.

New drugs, medical devices and treatments that NHS England agrees to fund will be adopted by NHS England for “Routine Commissioning”. This means that patients in England meeting the clinical criteria will be able to receive them.

Those treatments that aren’t successful in receiving funding will be adopted for “Non-Routine Commissioning”. This means that patients will not be able to receive these treatments.

Public consultation – asking for your views

The public consultation on this method for deciding which new treatments are a priority for NHS England funding is now open. And it is open to everyone until 11 May 2016.

There is an online survey https://www.engage.england.nhs.uk/consultation/investment-decisions where you can submit your views. All questions relating to the consultation will be found at this link.

What happens next?

All responses to these questions in the online survey will be independently analysed, and then reported to NHS England.

NHS England will consider this report before making a final decision on the method that will be used by the Clinical Priorities Advisory Group when it meets in June 2016.