

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

## **Consultation Guide**



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## Introduction

1. Specialised services are those provided in relatively few hospitals, accessed by comparatively small numbers of patients but with catchment populations of usually more than one million. These services tend to be located in specialist hospitals that can recruit a team of staff with the appropriate expertise and skills.
2. NHS England is the sole, national commissioner of specialised services for the population of England. Commissioning is the function that drives improvements in quality, efficiency and patient outcomes. The annual commissioning cycle covers a range of activities, from carrying out a health needs assessment for a population, to designing patient pathways. It covers the development of service specifications, contract negotiations and procurement, as well as continual assessment of quality.
3. It also involves making decisions about which new drugs, medical devices and interventions for specialised services should be funded by the NHS in England (except for drugs for which the National Institute for Health and Care Excellence (NICE) has - or is planning to - form a Technology Appraisal or Highly Specialised Technology decision).
4. Although the budget for specialised services in England is considerable, at around £14 billion per year, NHS England has to make difficult decisions on behalf of tax-payers about how to prioritise the funding that is available for new investments in specialised services each year.
5. NHS England must ensure that investment decisions are affordable and offer value for money; that they are supported by convincing evidence of safety and effectiveness; and that they are made using a process that is fair and transparent. To achieve this, NHS England needs a process that enables it to compare competing proposals for new investment so that preferred proposals can be prioritised and adopted.

6. In 2015 NHS England held a public consultation called [Investing in Specialised Services](#). In our response to consultation, we set out the principles that the Board of NHS England agreed would be used to support the process of prioritisation for specialised services for 2015/16 and in future years (and which had been developed in partnership with patient groups and other stakeholders), and we described the further work that we would carry out in 2015/16 to develop a process of relative prioritisation that would be used to make investment decisions from 2016/17 onwards.
7. This document describes the work that we have done, and proposes the method and process that would be used by the Clinical Priorities Advisory Group (CPAG) in June 2016 when it makes recommendations on the prioritisation of new investments in specialised services for 2016/17.
8. During 2016 we will publish a further consultation document which will set out proposals for changes to the arrangements for evaluating the drugs that are considered in NICE's Highly Specialised Technologies programme.

## Background

9. Each year, a significant number of proposals are put to NHS England for investment in new drugs, medical devices or interventions for use by specialised services in England. The proposals are made by a range of stakeholders, including manufacturers of pharmaceuticals and medical devices. Those that are considered to have the potential to provide value to patients are formally proposed by a Clinical Lead endorsed by the specialist Clinical Reference Groups, which comprise clinicians, public health doctors and lay people who are expert in the particular condition or specialty.
10. A 'Working Group' of the Clinical Reference Group builds the detailed proposals to NHS England describing: the nature of the drug, medical device, intervention, or service specification and the clinical problem which it aims to address; the patient population that it seeks to help; the evidence for its safety

and effectiveness (including the outcome of an independent review of the research evidence); the cost and activity impact of adopting the proposal; the views of stakeholders and the public as an outcome of engagement and public consultation; and a consideration of equality issues.

11. NHS England must decide which of these proposals should be funded. It makes this decision after considering recommendations that are made by CPAG, which has an independent Chair and includes patient and public voice representatives.
12. CPAG makes a recommendation on the relative prioritisation of each proposed investment. It does this after considering detailed information about the strength and quality of evidence around clinical effectiveness. It also considers the outcome of public consultation on each proposed investment.

## Progress to date

13. We described in our response to the previous consultation *Investing in Specialised Services*, that we would develop a transparent *method* that can be used by CPAG to aid its process for making recommendations on relative prioritisation.
14. As part of this work, we accepted the suggestion made in the previous consultation that we should take advice from academics and other experts. In September 2015 we convened a summit involving organisations and groups such as NICE; Public Health England; Rare Diseases Advisory Group; as well as academics. We then asked the University of Sheffield to provide an independent analysis of existing methods of prioritisation used by healthcare systems across the world. [View a copy of the report.](#)
15. The Sheffield research indicated that there are suitable methods for assessing the quality of clinical evidence supporting a proposed investment, which we will adopt. However, it concluded that there is no single 'off the shelf' method

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for measuring cost effectiveness and clinical effectiveness that can be directly applied to the diverse portfolio of specialised services for which NHS England is responsible for commissioning. The research suggested that we should use the basic elements of measuring cost effectiveness and create our own method to measure the extent to which each proposal for new investment is supported by good, quality evidence of clinical effectiveness.

16. We have therefore taken the recommendations from the Sheffield report, and developed a method that relies on an understanding of the relative benefit offered to patients by the proposed drug, medical device or intervention, and the cost, coupled with a thorough consideration of the available evidence and the expert judgement of CPAG members.

17. We believe that the method that we have proposed is transparent; will facilitate rational and consistent decision-making and has, at its foundation, the core principles of demonstrating an evaluation of cost effectiveness in the decision making.

## Consultation

### Scope of consultation

18. We are consulting on a process and methods which, we propose, is used by CPAG to compare competing proposals when it meets to agree recommendations on the relative prioritisation of new investments in specialised services for the 2016/17 round. This method is described at paragraphs 23 to 39.

19. We are not consulting again on the principles that support the process of relative prioritisation, which were agreed by the Board of NHS England in 2015 following the previous consultation.

## CPAG: process and qualifying principles

20. In order for proposed investments to be considered by CPAG, it will first want to be assured that NHS England has followed proper process in how it worked up the supporting documentation that is described in paragraph 10. If CPAG is not content that the **process principles** in Appendix A have been properly followed for an individual proposal, that proposal will be deferred to a later meeting (as an in year service development) so that the deficiency in the process may be corrected.

21. There are also three **qualifying principles** that must be met by each proposed investment. These are listed in Appendix B. The extent to which each proposed investment meets these principles will be reported to CPAG by a Specialised Commissioning Clinical Panel, comprising senior medical and nursing professionals from within NHS England, and public health doctors from Public Health England.

## The proposed method of prioritisation

22. Proposals for investment that have met the process principles and qualifying principles will be considered for prioritisation by CPAG.

23. Members of CPAG will be asked to form recommendations on the relative prioritisation of the policy proposals using four principles that were adopted by NHS England following public consultation in 2015. They are:

NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness
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NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to patients
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NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness
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The treatment or intervention should demonstrate value for money
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24. CPAG will first be asked to categorise each policy proposal as either High Benefit / Medium Benefit / Low Benefit. CPAG will be required to agree an equal number of proposals in each category so that there is an even spread across the categories of prioritisation (thus enabling NHS England to deliver a *relative* prioritisation process).

25. In order to do this, CPAG members will consider a summary report for each proposed investment, prepared by NHS England's Clinical Effectiveness Team, that summarises:

- the **patient benefit** offered by the drug, device or intervention, as described in an independent review of the clinical evidence; and
- the quality of the **evidence** of clinical effectiveness

26. **Patient benefit** can be demonstrated in a number of ways. A drug, medical device or intervention could be life-saving, life-extending or life-improving; or it can reduce the risk of developing a condition or disease. The potential benefit of each proposed investment will be described to CPAG using these metrics (though not all metrics will be relevant to each drug, device or intervention):

- Survival
- Progression free survival
- Mobility
- Self-care
- Usual activities
- Pain
- Anxiety / depression
- Replacement of more toxic treatment
- Dependency on care giver / supporting independence
- Safety
- Other health metrics determined by the independent evidence review

27. The description of patient benefit will **not** include non-clinical factors: societal benefit; financial cost; affordability; potential financial savings; the number of patients that need to be treated to give rise to patient benefit; prevalence of the underlying condition/illness. Also, although metrics such as “usual activities” are included, CPAG will not be asked to take a view on which “usual activities” are more or less worthy - reflecting an important principle of equity between patients.
28. The quality of the **evidence** on the effectiveness of the drug, medical device or intervention will be described to CPAG using established methods for grading research evidence. From 2017/18 we propose to apply the GRADE method used by NICE in its clinical guidelines programme. As an interim measure we will use the Scottish Intercollegiate Guidelines Network (SIGN) in 2016/17<sup>1</sup>. Both are similar in that they assess the quality of the available research papers, and their applicability to the subject matter.
29. A small number of proposals are likely to relate to treatments for rare conditions. In recognition that the evidence base for treatments for rare conditions may be more limited, CPAG may agree to recommend the prioritisation of treatments for **rare conditions** where there is limited published evidence on clinical effectiveness. For policy proposals relating to highly specialised services for rare conditions an additional summary will be provided to CPAG members which will describe the feasibility of generating evidence given the rare nature of the condition. A distinction will be made on the feasibility of generating future evidence compared with the evidence presented to support the policy proposal. Where it is deemed that the generation of further evidence is feasible, and the evidence presented is insufficient, CPAG will be advised of this. Conversely, if the limited evidence available is considered to be appropriate to the rarity of the condition, and generation of additional evidence is deemed unfeasible, CPAG would be provided with that advice. CPAG will also consider advice from NHS England’s

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<sup>1</sup> As adoption of the GRADE approach will require a change in how the independent review of research evidence is undertaken, we are unable to retrospectively apply it to the evidence reviews that were delivered in 2015.

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*Rare Disease Advisory Group*<sup>2</sup> on the extent to which the proposal meets NHS England's agreed principles.

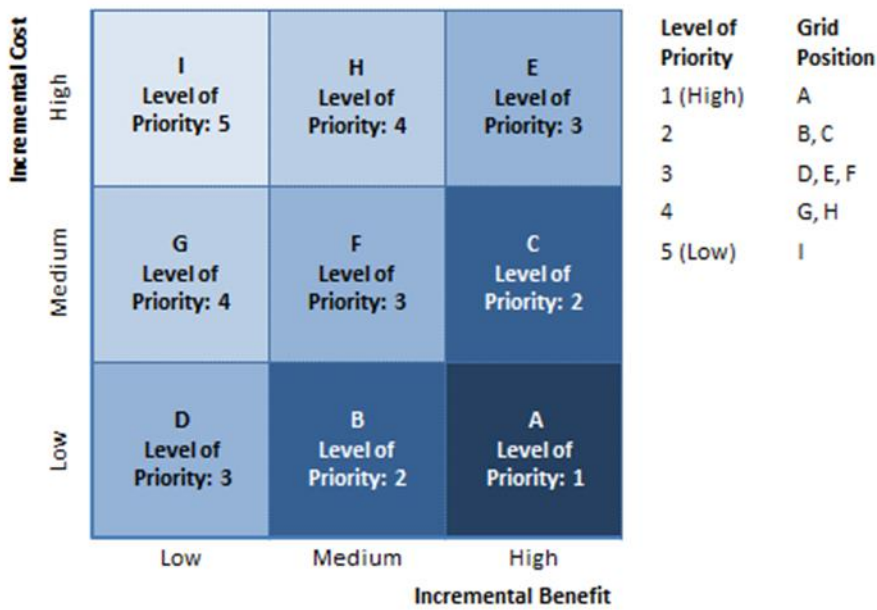
30. Once CPAG has agreed whether each proposed investment offers High Benefit / Medium Benefit / Low benefit based on a consideration of the potential patient benefit and quality of the evidence (ensuring an equal number of proposals in each category) the policy proposals will be placed on the following matrix, which assesses the costs and effectiveness of each proposal by measuring incremental cost against the incremental benefit to the patient.
31. Plotting cost against benefits on a chart is a frequently-used approach for illustrating cost and effectiveness. The horizontal axis sets out the clinical benefit in terms of 'high', 'medium' and 'low', based on the CPAG recommendations. For the vertical axis, the proposal is to use a set of thresholds to convert the linear scale into three categories costs has 'high', 'medium' and 'low'.
32. The "incremental cost" of each proposal will be determined by the 'cost per patient who benefits'<sup>3</sup> over five years from the drug, medical device or intervention. These figures will be extracted from the financial impact assessment that is worked up by NHS England, and the categories of Low Cost to High Cost will be determined using the actual range of figures presented by the proposals in each commissioning round (in other words, they are likely to differ for each commissioning round).
33. Thus, a proposed investment that offers Low Benefit and High Cost will be placed in Box I; a proposed investment that offers High Benefit and Low Cost will be placed in Box A. The seven remaining boxes B to H reflect the other permutations of Cost and Benefit.

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<sup>2</sup> The Rare Diseases Advisory Group makes recommendations to NHS England on developing and implementing the strategy for rare diseases and highly specialised services. It makes recommendations to the Clinical Priorities Advisory Group about how highly specialised services should be commissioned.

<sup>3</sup> In some cases, not all patients who receive a drug, device or intervention will benefit from it. Thus, a focus on the number of patients who benefit from it, rather than a focus on the number of patients who are estimated to receive it, offers a more accurate description of cost effectiveness. However, we may adopt a "cost per patient" approach for 2016/17 if the information contained in the reviews of clinical evidence for the policy proposals does not enable us to identify the "cost per patient benefitting" this time round.

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34. The position of each policy proposal on the matrix will determine the batching of the proposals into five priority levels of prioritisation, as shown above.

35. CPAG’s final recommendations to NHS England will be presented using these five levels of prioritisation. Proposed investments in Level 1 represent the highest level of prioritisation, and proposed investments in Level 5 represent the lowest level of prioritisation.

36. Before making its final recommendations on prioritisation to NHS England, CPAG will be asked to consider whether any adjustments should be made to the baseline recommendations, based on a consideration of four principles which were agreed by NHS England following public consultation in 2015, and which reflect NHS England’s broader strategic ambitions. They are:

	<b>Does the drug, device or intervention significantly:</b>
i	Benefit the wider health and care system?
ii	Advance parity between mental and physical health?
iii	Offer the benefit of stimulating innovation?
iv	Reduce health inequalities?

37. CPAG will determine the extent to which, if any, a proposal meets any of the four principles and the extent to which, if any, compliance with the principles should result in an adjustment of the batching into five levels of prioritisation. Although a consideration of these principles will rely upon CPAG's judgement it will be guided by evidence where this is possible, such as an inequalities impact assessment for each proposal and, where appropriate, the independent review of evidence and views of stakeholders as submitted during engagement and consultation.
38. Once adjustments to the baseline recommendations have been made (if any), both the baseline recommendations and the adjusted recommendations will be presented to NHS England, representing CPAG's recommendations on relative prioritisation. A narrative will be provided by CPAG to explain the reasoning of any adjustment to inform NHS England's process of decision making.
39. It will then be for NHS England's Specialised Commissioning Oversight Group to make a final recommendation to the Specialised Commissioning Committee on which proposed investments should be funded within the confirmed financial envelope available for discretionary investment.
40. The Specialised Commissioning Committee will make the final decision on investment based upon the advice that it receives, recording its reasoning for any variation from the advice. The decisions will be subsequently published by NHS England, and clinical commissioning policies will be adopted for each policy proposal. Clinical commissioning policies for "Routine Commissioning" will be adopted for proposals that have been agreed for funding; and clinical commissioning policies for "Non-Routine Commissioning" will be adopted for proposals that have not been agreed for funding.

## **Consideration of equality and health inequalities**

41. There are legal duties on NHS England to have due regard to the promotion of equality (Equality Act 2010) and the reduction of health inequalities (Health and Social Care Act 2012) when making decisions or developing new policies,

guidance or processes. We have given due regard to these legal duties in the development of the proposed method for relative prioritisation of specialised services and will continue to do so through the process of public consultation and eventual decision making. An equality and inequalities impact assessment is included as [Appendix C](#).

## Consultation questions

42. NHS England would like to hear your views on the following questions, which can be answered via the online survey ([LINK](#)):

***IMPORTANT NOTE: In line with standard requirements regarding transparency of payments by the pharmaceutical industry, all respondents should disclose any payments, grants or other funding received by their organisation from the pharmaceutical industry in the last three years, specifying the source of funding and sums involved in each of the last three years.***

Q1. NHS England has concluded that there is no existing method for relative prioritisation that could be directly applied to the process of prioritising proposed investments in specialised services. Do you agree / disagree / don't know

Q1b. If you disagree, please provide details of alternative method(s):

Q2. Do you agree that the method proposed by NHS England:

2a. is transparent;

2b. will facilitate rational and consistent decision-making

2c. has, at its foundation, the core principles of demonstrating an evaluation of cost effectiveness in the decision making.

Q3. Please comment on whether the following four principles are applied at the appropriate point in the proposed method of relative prioritisation:

3a. NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness

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3b. NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness

3c. NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to patients

3d. The treatment or intervention should demonstrate value for money.

Q4. Do you have any comments on how NHS England's Clinical Priorities Advisory Group (CPAG) should interpret and consider 'patient benefit', including the list of excluded factors?

Q5. Please comment on whether a proposed treatment of intervention should have a higher relative prioritisation if it meets one of the following principles:

5a. Does the treatment or intervention significantly benefit the wider health and care system?

5b. Does the treatment or intervention significantly advance parity between mental and physical health?

5c. Does the treatment or intervention significantly offer the benefit of stimulating innovation?

5d. Does the treatment or intervention significantly reduce health inequalities?

Q6. Would adoption of the proposed method unfairly discriminate against any group with protected characteristics?

Q7. Would adoption of the proposed method assist NHS England in promoting equality and in reducing health inequalities?

## **Analysis of responses and next steps**

43. The consultation is open to everyone. All responses received via the online consultation will be collated and summarised and a report of the consultation findings will be considered by NHS England.

44. Final detail of the method will be published following the close of consultation.

## Appendix A: The Process Principles

Principle
NHS England will follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the



Principle
process
NHS England will involve the diversity of stakeholders including the public and patients in the development of proposals and take appropriate account of their view;
NHS England will take into account all relevant guidance
Compliance with the Equality Act 2010 (equality) and Health and Social Care Act 2012 (inequalities) by delivery of an equality / inequalities impact assessment for each policy proposal

## Appendix B: The Qualifying Principles

Principle
NHS England will normally only accord priority to treatments or interventions where the intervention should offer equal or greater benefit than other forms of care routinely commissioned by the NHS
While considering the benefit of stimulating innovation, NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available
The intervention must be available to all patients within the same patient group (other than for clinical contra-indication)

## Appendix C: Equality and Inequalities Impact Assessment to support public consultation on method of prioritisation for specialised services

## The legal duties on NHS England

There are legal duties on NHS England to have due regard to the promotion of equality (Equality Act 2010) and the reduction of health inequalities (Health and Social Care Act 2012) when making decisions or developing new policies, guidance or processes. We have given due regard to these legal duties in the development of the proposed method for relative prioritisation of specialised services and will continue to do so through the process of public consultation and eventual decision making.

Equality Act 2010 - NHS England should understand the potential effect of adoption of a new process on people with characteristics that have been given protection under the Act, especially in relation to their health outcomes. This means that NHS England has legal obligations to have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not;
- Foster good relations between people who share a protected characteristic and those who do not.

These are often referred to as the three aims of the general equality duty and apply to the following protected characteristics:

- Age
- Disability
- Gender
- Gender reassignment
- Pregnancy and maternity
- Race
- Religion or belief
- Sexual Orientation

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- Marriage and Civil partnership (but only in regards to the first aim - eliminating discrimination and harassment)

### Health and Social Care Act 2012 - NHS England must:

- Have regard to the need to reduce inequalities between patients in access to health services and the outcomes achieved (s13G)
- Exercise its functions with a view to securing that health services are provided in an integrated way, and are integrated with health-related and social care services, where it considers that this would improve quality and reduce inequalities in access to those services or the outcomes achieved (s.13N)

The duty to “*have regard to the need to reduce*” means health inequalities must be properly and seriously taken into account when making decisions or exercising functions, including balancing that need against any countervailing factors. The Act does not define a list of groups impacted by the duties. Any group experiencing health inequalities is covered. The duties in this regard therefore apply to the national population for whom NHS England commissions specialised services.

### **Where in the proposed process are equality and inequality issues addressed?**

The Clinical Priorities Advisory Group will receive formal impact assessments from the relevant National Programmes of Care. The impact assessments will report on the potential equality and inequalities implications of adoption of each policy proposition. The same information will be considered by NHS England for the purpose of making a final decision.

The information presented would report on:

- Responses to public consultation on individual policy propositions that address the promotion of equality and reduction of health inequalities (this would be a specific question for respondents to consultation);
- Whether – and how - adoption of the policy proposition would advance or hinder the promotion of equality for people with protected characteristics;

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- Whether the clinical criteria (such as inclusion and exclusion criteria) described in the policy proposition would prejudice any particular group with protected characteristics, and if so, whether the clinical criteria is supported by reliable clinical evidence;
- Whether adoption of the policy proposition would increase or reduce inequalities between people in the general population in access to health services and the outcomes achieved (for example, whether the policy would make it more difficult in practice for a specific group to access services compared with other groups).

### **Would adoption of the method help to reduce health inequalities?**

We have also considered whether adoption of the proposed method would help NHS England reduce inequalities between people in the general population in access to health services and the outcomes achieved.

We have adopted the principle that proposed interventions may be given a higher relative prioritisation if they significantly reduce health inequalities. This recommendation may be made for individual policy propositions by the Clinical Priorities Advisory Group based, in part, on a consideration of the information in the impact assessment.

### **Would adoption of the proposed method discriminate against people with protected characteristics?**

We have considered whether our proposal for a process of relative prioritisation that measures the quality of evidence relating to patient benefit and clinical effectiveness would, if adopted, discriminate against any group with protected characteristics. In this regard we have identified the following characteristics as being particularly relevant:

**Age:** We have considered whether adoption of the proposed method would discriminate against people on the basis of age. We are content that this is not the case. Specifically we have considered whether the proposed method would discriminate against treatments and interventions for **children and**

**young people** given that there is often a more limited evidence base for paediatric treatments. However, when assessing the *measurable benefit* of a proposed intervention for children and young people and where direct evidence of patient benefit is not available, we are content that it is appropriate to infer benefit from the available clinical evidence including those relating to comparable interventions for adults.

We have considered the suggestions made in the previous public consultation *Investing in Specialised Services* (2015) that treatments and drugs that benefit children should have higher relative priority in funding decisions. We do not propose to adopt this as policy as the proposed method for prioritisation would, if adopted, measure *patient benefit* consistently and equitably across a range of treatments and interventions and across all ages.

**Disability:** We have considered whether adoption of the proposed method would discriminate against people on the basis of disability. We are content that this is not the case. Specifically we have considered whether the method would discriminate against **people with rare conditions**. We have considered the comments submitted during the previous consultation *Investing in Specialised Services* (2015) about the more limited evidence base for treatments for rare conditions, and we have addressed this in the proposed method through adoption of the principle that “*NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness*”.

We have also considered whether the proposed method would discriminate against **people with mental health problems**. We have concluded that proposals for investments in specialised mental health services should be assessed using the same criteria of evidence of effectiveness and patient benefit in the interests of ensuring safe, effective services that will deliver good quality outcomes for patients. We have also adopted the principle that proposed interventions may be granted higher relative prioritisation if they “*significantly advance parity between mental and physical health*” in view of NHS England’s broader strategic ambition in this regard.

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**Gender reassignment:** We have considered whether a method of relative prioritisation that relies upon an assessment of the quality of evidence on clinical effectiveness may discriminate against proposed investments in services for **transgender and non-binary people** given the limited availability of clinical research evidence in this specialty. We have noted the observation made by the intercollegiate guidance<sup>4</sup> in the United Kingdom that there is a paucity of research evidence in this field, but we are also aware of the potential for the development of good quality research given that gender variance is not uncommon<sup>5</sup>, and that the number of people seeking treatment in gender identity clinics has increased rapidly over several years in this country and internationally. As such, it would be inappropriate to apply a lower threshold to the quality of evidence for proposed investments in transgender services both in terms of ensuring safe, effective services for transgender and non-binary people, and in ensuring an equitable approach in commissioning health services for the general population.

### Questions for consultation:

#### *Would adoption of the proposed method:*

- *Assist NHS England in promoting equality and in reducing health inequalities?*
- *Unfairly discriminate against any group with protected characteristics?*

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<sup>4</sup> Royal College of Psychiatrists “CR181:Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria” (2013)

<sup>5</sup> P13 Intercollegiate guidance