

## **SPECIALISED HEALTHCARE ALLIANCE RESPONSE TO NHS ENGLAND'S CONSULTATION ON DEVELOPING A METHOD TO ASSIST INVESTMENT DECISIONS IN SPECIALISED COMMISSIONING**

**MAY 2016**

The Specialised Healthcare Alliance (SHCA) is a coalition of 120 patient organisations, with 16 corporate supporters, which campaigns on behalf of people with rare and complex conditions requiring specialised care. The SHCA was established in 2003 and focuses exclusively on the overarching policies and structures of specialised care, without involvement in individual therapeutic issues.

The Alliance welcomes the opportunity to comment on NHS England's proposed process and methods for assessing investment decisions in specialised commissioning. This response provides the Alliance's views on the relevant consultation questions.

### **1. 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, and has described in this document the process for developing the proposed method. Do you agree with the proposed method?**

The Alliance broadly considers that the proposed method provides a reasonable basis for relative prioritisation for patients requiring specialised services, but have serious reservations about the applicability of the proposed methods to highly specialised services. . The Alliance also notes the challenge in developing an alternative method for consideration within the 30 day consultation period.

On the whole, the Alliance believes that NHS England needs to provide greater clarity in a number of key areas.

**Rarity:** While the Alliance notes the provision for rarity to be considered within the consultation document, there is as yet little detail or sufficient reassurance that the Clinical Priorities Advisory Group (CPAG) will be able to undertake equitable prioritisation of highly specialised services against more common specialised services. The consultation document rightly recognises that the evidence base for treatments for rare conditions may be more limited, and should be considered in accordance with the rarity of the condition.

In finalising its processes, NHS England must provide clarity on the definition of rarity being used, including whether or not this relates exclusively to services considered by the Rare Diseases Advisory Group (RDAG). The requirements of these services should be reflected more explicitly in the overarching prioritisation process. At present, it is not clear how an intervention for a very small number of patients would be able to secure prioritisation over a technology aimed at a far greater number of patients and, as a result, with a more sophisticated evidence base and most probably lower per capita costs.

Unless these requirements are properly reflected, the process would discriminate

against small patient populations, at odds with the NHS Constitution's commitment to leave no one behind and hence unfit for purpose.

**Transparency:** The consultation guide does not mention the importance of transparency in ensuring that decisions have, and are seen to have, legitimacy. A sophisticated decision-making process is redundant if the relevant stakeholders and wider public are not able to understand the basis of the associated decisions. For this reason, full details of CPAG's rationale for prioritisation decisions should be published, along with the relevant discussions held at the Specialised Commissioning Oversight Group and Specialised Commissioning Committee meetings. CPAG should also make available the data and informational inputs, and NHS England should ensure that there is a mechanism for contesting prioritisation decisions in the event of process error, as is common in public policy.

Clarity should also be provided on the interpretation of advice provided by the Rare Disease Advisory Group (RDAG). Where an adjustment has been made to the CPAG's baseline recommendation, both the baseline and adjusted recommendations should be made available alongside an explanation of the adjustments made.

**Accountability:** It is unclear under the current framework whether stakeholders would be able to re-submit proposed investments not selected for funding in a particular year, or initiate an appeal of CPAG's recommendations. In setting out whether appeals can be lodged, NHS England should establish the grounds on which an appeal can be made, along with a potential timeline for appealed decisions. Clarity will also be needed on whether and how proposals can be re-submitted in future years, when for example prices may have changed.

NHS England should also encourage independent reviews of CPAG's decisions, not just where an issue has been raised.

**Accelerated access:** publication of the government's Accelerated Access Review (AAR) has been repeatedly delayed but it is nonetheless important that NHS England's approach to prioritisation is compatible with the ambitions of the review. In particular, the Alliance believes this process should mirror the AAR's commitment to timely and predictable processes focused on the patient interest.

## **2. Do you agree that the method proposed by NHS England:**

- **Is transparent**
- **Will facilitate rational and consistent decision-making**
- **Has, at its foundation, the core principles of demonstrating an evaluation of cost effectiveness in the decision making**

As stated above, the Alliance believes that NHS England needs to provide greater clarity on the transparency of the proposed prioritisation process.

In terms of consistency of decision making, the Alliance believes that NHS England must allow CPAG members to exercise their clinical and patient-related judgement. The wealth of expertise within CPAG should not be placed in a procedural

straightjacket; instead, given the diversity of specialised conditions, CPAG members should be able to apply independent judgement in appropriate areas recognising the resources available.

The Alliance welcomes NHS England's holistic approach which considers clinical and cost effectiveness in tandem. However, NHS England needs to provide greater clarity on what constitutes high, medium, or low costs. At present, the consultation document does not set out whether this is an assessment of the numerical value per patient population, or the cost relative to treatments in the same or comparative therapy areas. If the former, there is concern that this could see rare disease drugs fall automatically into the high cost category by virtue of their small patient populations, which in combination with an inherently smaller evidence base could lead to the systematic prevention of access.

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

- **NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness;**
- **NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness;**
- **NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to patients;**
- **The treatment or intervention should demonstrate value for money.**

Although the Alliance believes that the above points have largely been implemented at the appropriate stage, there is a definite need for clarity in some areas.

With respect to clinically reliable evidence for prioritisation, the Alliance believes that NHS England must set out clearer guidelines as to what constitutes reliable evidence. In particular, these criteria need to apply to drugs and devices fairly, especially as the nature of clinical effectiveness can be harder to garner through device evaluations.

Furthermore, NHS England needs to provide a robust definition of what constitutes rarity. Although it is clear that highly specialised treatments will be granted special consideration for their rarity, NHS England must allow these safeguards to apply to rare conditions outside the highly specialised category. At present, these conditions – which are often of significantly higher cost – can only reach a cost-benefit rating of 3. This potentially means that rarer, non-highly specialised conditions could lose out within the prioritisation process. Therefore, the Alliance believes that extending these safeguards to rarer conditions will contribute towards developing an equitable prioritisation process for all patients.

**4. 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?**

The Alliance believes that NHS England should provide greater clarity on assessing clinical benefit for rare and ultra-rare diseases. In these fields, it is inherently difficult to capture real patient experience given the numbers of patients involved and the nature of product development.

Similarly, the Alliance believes NHS England should provide greater clarity on its proposal to “infer benefit [to children and young people] from the available clinical evidence including those relating to comparable interventions for adults”. The Alliance believes that NHS England must set out what process will be applied where there is not a comparable adult population or comparable intervention.

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

- **Does the treatment or intervention significantly benefit the wider health and care system?**
- **Does the treatment or intervention significantly advance parity between mental and physical health?**
- **Does the treatment or intervention significantly offer the benefit of stimulating innovation?**
- **Does the treatment or intervention significantly reduce health inequalities?**

The Alliance is broadly supportive of the prioritisation adjustments outlined as part of NHS England's proposals. However, NHS England will need to demonstrate that these adjustments have been applied meaningfully, rather than as an afterthought. If eventual prioritisation decisions simply map to clinical vs cost effectiveness, there will be doubts over whether these further principles have been applied.

The Alliance agrees that societal benefit is an important component of the benefits of new interventions and NHS England should be free to consider these as appropriate.

The Alliance agrees with NHS England's inclusion of innovation principle as specialised commissioning is an important route for innovation to enter the NHS. Specialised services often operate at the forefront of medical science. As such, prioritising treatments with an innovative potential can deliver benefits over time to the wider health system.