

# NHS England's response to the public consultation

***“Commissioning Policies:  
Funding of Treatment outside of Clinical  
Commissioning Policy or Mandated NICE  
Guidance***

***A. In-year service developments***

***B. Individual Funding Requests***

***C. Funding for experimental and unproven  
treatments***

***D. Continuing funding after clinical trials”***





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## 1. Introduction

In October 2016 NHS England launched a 12-week public consultation on a set of four commissioning policies. These so-called 'generic' commissioning policies set out NHS England's position on funding treatments which are not currently routinely commissioned or are not subject to a mandated guidance from NICE.

The four policies consulted on were:

- **In-year service development** – decisions on new commissioning policy for a treatment that takes place outside of the annual commissioning prioritisation process. The policy set out in this document applies only to specialised services.
- **Individual Funding Requests (IFRs)** – applications by clinicians on behalf of their patients, relating to funding for treatment for an individual patient that is not routinely commissioned by NHS England for that patient. Funding for all prescribed services may be considered through this process.
- **Funding for experimental and unproven treatments** – funding experimental or unproven treatments outside a clinical trial and continuing funding following such a trial of a treatment, which should have been previously agreed.
- **Continuing funding after registered clinical trials** – continuing funding after a clinical trial, whether NHS England funded, commercially-funded or non-commercially funded.

The consultation sought views on the content of the four policies, as well as whether they were sufficiently clear and effective in supporting commissioning decisions. It also sets out NHS England's intention to streamline the number of commissioning policies to reduce duplication and provide greater clarity.

This document provides a summary of the key themes identified in the consultation responses and identifies how responses have shaped the new policies.

## 2. The engagement and consultation process

Over the past three years there has been considerable time spent on reviewing and updating the set on eleven interim 'generic commissioning policies' which were adopted when NHS England came into being in 2013. The policies were defined generic as they applied to all of the directly commissioned services for which NHS England has commissioner responsibility, and are not 'service-specific', i.e. relating to a particular healthcare treatment or procedure.

In 2015 NHS England held a series of internal and external workshops and focus groups, to ensure stakeholders were able to shape the development of the policies based on their experience of the implementation of the interim generic policies, and to provide opportunities to identify any relevant issues and gaps not covered by the policies that needed to be addressed prior to consultation.

Engagement activities included a workshop with the Patient and Public Voice Assurance Group (PPVAG), an independently chaired group with membership that includes individual patient representatives as well as representatives from Healthwatch England, Genetic Alliance UK, Specialised Healthcare Alliance, Ataxia UK, the Richmond Group, Sickle Cell Society and National Voices. A mixed-stakeholder workshop, including patient organisations, providers, clinicians, the pharmaceutical industry, partner bodies, Royal Colleges, members of Clinical Reference Groups and commissioners from other divisions of NHS England was also held to test the draft policies with a wider audience.

As an outcome of this activity, it was agreed that the four policies on funding treatments which are not currently routinely commissioned or are not subject to a mandated guidance from NIC should be subjected to formal public consultation to seek views on the clarifications that NHS England had made through the revisions carried out to date.

It was also agreed that the remaining adopted generic policies would be incorporated into existing guidance/policies and would not be the subject of formal consultation. Details on these policies are at [Annex B](#).

The consultation on the four policies was launched on 13 October and run until 15 January. Engagement was promoted in the following ways

- News piece on NHS England news page linking to Consultation Hub
- Article on NHS England specialised commissioning newsletter; Engage; Informed; CCG Bulletin.
- Twitter - Tweet consultation link
- Email to key stakeholders/groups informing about the consultation launch with link to NHS England Consultation Hub.

During the consultation period NHS England held five webinars and one engagement event, attended by a total of 200 consultees from patient organisations and rare diseases organisations, industry and NHS organisations.

A total of 90 responses were received from a broad range of stakeholders, including research and academic organisations, patient organisations and charities, and NHS organisations.

Responses have been analysed by key themes, the detailed analysis and list of respondents can be found at [Annex A](#).

### 3. Consultation findings and NHS England response

The consultation asked questions about each of the policies individually, and about how clear they were as a set of commissioning policies. This section sets out a summary of the responses received on each set of questions, and outlines how NHS England has taken these responses into account in developing the policies.

#### *Individual Funding Requests policy*

Many comments were received through the consultation regarding the Individual Funding Request (IFR) policy. Further work is still ongoing to refine the IFR policy, and associated documents such as the Standard Operating Procedure.

NHS England therefore anticipates that the final version of the IFR policy, and associated documents, will be published later in the year. Alongside these documents, the response to the IFR section of the consultation will be published at the same time. This consultation response does not, therefore, contain information about the IFR policy.

### 3.1 Generic Commissioning Policies

#### 3.1.1 Consultation questions

- *On a scale of 1 (not clear) to 5 (very clear) how clear are the revised set of policies overall in setting out how NHS England makes funding decisions?*
- *What are the potential gaps in the set of generic policies? Are there any foreseeable cases that would not be addressed by this suite of policies?*
- *Do the changes being proposed create any risks, issues or potential adverse impacts for patients/stakeholders generally or for any particular groups?*

#### 3.1.2 Summary of comments

The first section of the consultation sought views and suggestions about the clarity of the set of generic commissioning policies as a whole, including the relationship between the policies. As shown in the analysis of consultation responses at Annex A, there were two main themes in the responses:

- **Uncertainty about how the policies link together:** respondents set out a need for greater clarity on how the policies relate to one another. The respondents indicated that it was not clear which route clinicians (acting on behalf of patients) should take to seek funding.
- **Call for greater clarity on the decision-making processes:** many respondents suggested that there should be greater transparency around the decision-making processes set out in the policies, particularly for IFRs and in-year service

developments. A number of respondents requested greater clarity on how decisions are made and communicated, not just with the clinician who applied but also with the wider public.

### 3.1.3 NHS England response

Following consideration of all of the comments received through the consultation process, and in particular the themes outlined above, NHS England is undertaking the following actions:

- A new **[‘Service Development’ policy](#)** has been developed. This policy sets out how NHS England makes decisions on which new services and treatments to routinely commission, and on which routinely commissioned services should be updated in line with best practice.

The Service Development policy brings together the processes previously described in separate documents, including: the in-year service development process, the prioritisation process for making funding decisions; and the process for assessing clinically critically urgent cases.

The purpose of bringing together all of these policies in one Service Development policy is to provide greater clarity about how the overall process works, including decision-making, and brings together previously published policies in one place.

- In addition, a supporting **[Service Development Methods](#)** document has been developed, bringing together and updating previously published Methods.
- To support the aim of providing greater clarity on how NHS England’s Service Development process works, a **process map** has been developed which provides a visual representation of the steps in the process.

All of these documents are being made available on the NHS England website.

## 3.2 In-year service development

### 3.2.1 Consultation questions

- *On a scale of 1 (not clear) to 5 (very clear) how clear is the in-year service development policy on circumstances in which it should apply?*
- *On a scale of 1 (not clear) to 5 (very clear) how clear is the policy on the process to be followed, including the role of the Clinical Priorities Advisory Group and the required information?*
- *How could the in-year service development policy be improved, in terms of the clarity and the process to be followed?*
- *How could the in-year service development policy be improved to provide greater certainty in dealing with clinically critically urgent cases in a fair and open way?*



### 3.2.2 Summary of comments

This section of the consultation sought views particularly on how clear the In-year Service Development policy and process seemed to respondents, and whether there were any areas that needed further clarification. There were two main themes in the responses:

- **Lack of clarity about funding outside prioritisation round:** respondents noted that the policy was unclear about the circumstances in which funding could be made available for in-year service developments, outside of the prioritisation process.
- **Clinically critically urgent cases (CCUs):** many respondents noted that the procedure for critically clinically urgent (CCU) cases was not specifically addressed by the documents within the consultation, and recommended that further detail was needed on how that process works and how it works alongside the other decision-making processes.

### 3.2.3 NHS England response

Following consideration of the responses, NHS England has done the following:

- **Developed a ‘Service Development Policy’ to provide clarity on the process for making commissioning decisions:** The Service Development policy sets out NHS England’s approach for making decisions about which new treatments and interventions to routinely commission, and its approach for updating existing service specifications or creating new ones. This policy is accompanied by the relevant Methods documents: [Methods: National Clinical Policies](#) and [Methods: Service Specification](#) which set out the processes in detail. The policy includes the process for considering cost-neutral and cost-saving policy propositions, as well as those policy propositions which require investment.
- **Procedure for urgent cases has been brought into the Service Development process:** In order to provide greater clarity and oversight, the procedure for assessing urgent cases has been brought into the Service Development process, and is therefore reflected in the new Service Development policy document and revised methods. The policy describes the circumstances in which a clinical commissioning policy can be put in place on an interim basis, including in urgent cases, and the process for assessing and agreeing such policies.
- **Further clarifications have been made in the new Service Development policy:** in particular the policy clarifies that the relative prioritisation process (used for making investment decisions) will occur twice a year, and the policy clarifies that propositions which are not agreed for investment may be re-entered into the Service Development process up to a maximum of three occasions (including the original prioritisation round)

### 3.3 Funding for Experimental and Unproven Treatments

#### 3.3.1 Consultation questions

- *On a scale of 1 (not clear) to 5 (very clear) how far does the policy on experimental and unproven treatments provide clarity on the circumstances in which funding can be sought?*
- *How could the policy on experimental and unproven treatments be improved? And how could we provide greater clarity and certainty?*

#### 3.3.2 Summary of comments

There were two main themes in the responses:

- **Process for assessing requests for experimental and unproven treatments:** the majority of comments highlighted a desire for more information about the process for assessing requests for funding for experimental and unproven treatments.
- **More explanation wanted on how it fits with other policies:** respondents requested greater clarity on how this policy relates to the IFR policy and the service development policy.

#### 3.3.3 NHS England response

Following consideration of the responses, NHS England has decided that the policy on Funding Experimental and Unproven Treatments will no longer be a stand-alone document. Instead, it will be covered in the revised IFR policy and standard operating procedure. NHS England has also included a reference to this policy area in the 'continuing funding after the completion of a clinical trial' policy, to clarify how these areas link together.

### 3.4 Continuing Funding after Clinical Trials

#### 3.4.1 Consultation questions

- *On a scale of 1 (not clear) to 5 (very clear) how far does the policy on continuing funding after clinical trial provide clarity on the circumstances in which funding can be sought?*
- *Do you think there are any areas of the continuing funding after clinical trial policy that require further clarity?*

#### 3.4.2 Summary of comments

This section of the consultation sought feedback on how clear the policy was about the circumstances in which funding could be provided. There were two main themes in the responses:

- **Funding mechanisms for on-going access to treatment:** many respondents requested more clarity about the criteria, the process and the funding responsibilities

for on-going access to treatment following the end of a clinical trial, in particular for commercially funded clinical trials.

- **Excess treatment costs:** many respondents suggested that the policy should specify how it relates to the existing NHS England's 'Guidance on Excess Treatment Costs', as it was not clear.

### 3.4.3 NHS England response

In response to the feedback received NHS England has refreshed the 'continuing funding after the completion of a clinical trial' policy in order to:

- Signpost to the process for securing funding for research, linking to the current mechanisms by which the NHS highlights areas of potential research interest to the research community;
- Signpost to the policy on excess treatment costs that are part of the agreements with specified research bodies;
- Provide clarify on NHS England's funding responsibility once a positive commissioning decision has been reached; and
- Set out how the Commissioning through Evaluation framework could apply to funding experimental and unproven treatments.

## 4. Update on additional 'generic policies'

As the consultation noted, when NHS England was first established a set of eleven so-called 'generic commissioning policies' were published to guide its decision-making for all directly commissioned services. They were called 'generic' as they applied to all NHS England's clinical commissioning responsibility, rather than being service-specific.

Upon reviewing the set of policies, it became clear that some of the policies could be streamlined, particularly those which were already covered by existing Department of Health policy or NHS England policy. In addition to NHS England's consultation on those policies which are still required, those policies which are no longer required will be removed from the NHS England website.

Annex B details those policies which are no longer required, with a link to the existing policy which will be used in its place.

## 5. Conclusion

NHS England welcomed the valuable feedback received through the consultation events, and through the written consultation responses.

The updated policies which have been described in this consultation response are now available on the [NHS England website](#) . Further update on the IFR policy will follow shortly.

## 6. List of respondents

AbbVie
Antony Nolan
Association of British Healthcare Industries (ABHI), Commissioning through Evaluation group (Boston Scientific, Abbott Vascular, St Jude Medical, Johnson & Johnson, W L Gore)
Association of British Pharmaceutical Industries (ABPI)
Association of Medical Research Charities
Brain Tumor Research
British Kidney Patients Association
British Society for Rheumatology
Cancer 52
Cancer Research UK
European Medicines Group (EMG)
Faculty of Public Health
Federation of Specialist Hospitals
Genetic Alliance UK
IFR Panel
Individual - CCG Commissioner
Individual – NHS Service Director
Individual - Specialised Commissioning Manager
MAP BioPharma
Clinical Reference Group for Blood and Marrow transplantation (BMT)
Muscular Dystrophy UK
National AIDS Trust (NAT)
Neurological Alliance
NHS Health Research Authority (HRA)
NHS National Institute for Health Research (NIHR)
NHS Research and Development Forum
Parkinson's UK
PHG Foundation
Provider- Clinical Trials Unit
Rare Autoimmune Rheumatic Disease Alliance (RAIRDA)
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Physicians
Shire
Specialised Healthcare Alliance
The Royal College of Anaesthetists
Tuberous Sclerosis Association
Vertex
40 respondents identified themselves as Service provider / Industry / Professional
12 respondents identified themselves as Patient / Public

## Annex A: Analysis of responses to the NHS England consultation

### 1. Overview

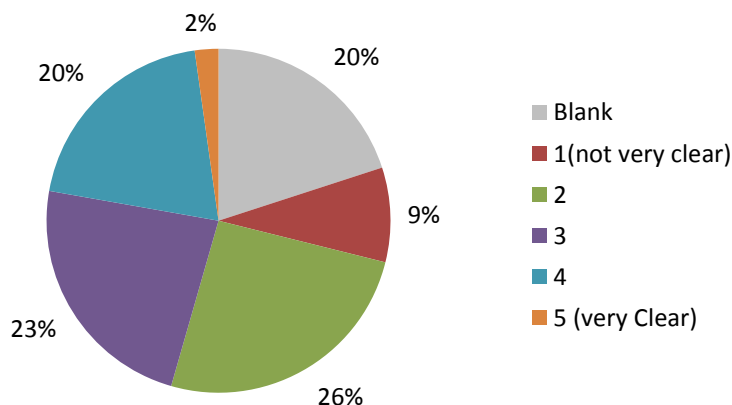
NHS England received 90 responses through the on line survey on the consultation hub and by letter. Respondents represented a broad range of stakeholders including patient organisations, professional bodies, charities and industry. A list of the organisations who responded is at page 19.

This report illustrates the percentages of responses for those questions which required numerical rating, and the analysis of the key themes emerging from the responses to the open ended questions. The key themes reflect issues raised by a majority of respondents.

Where relevant, quotes have been used to highlight the issues raised as well as suggestions for alternative approaches.

### 2. Analysis of responses

**Question 1: On a scale of 1 (not clear) to 5 (very clear) how clear are the revised set of policies overall in setting out how NHS England makes funding decisions?**



**Question 2: What are the potential gaps in the set of generic policies? Are there any foreseeable cases that would not be addressed by this suite of policies?**

**Question 3: Do the changes being proposed create any risks, issues or potential adverse impacts for patients/stakeholders generally or for any particular groups?**

The first group of questions sought general feedback on the set of policies as a whole. The emerging main themes are described below:

#### How the four policies link together

Many respondents suggested that the policies should be brought together, including the policy on annual prioritisation, showing clearly the interactions and interdependencies

between each policy, and for a flow diagram to graphically represent which process to be followed under which circumstance.

*"What is needed is a coherent representation of how access to proven and unproven treatments will be evaluated (that includes the CCU policy, in-year policy development and commissioning policies). This should be presented complete with timelines and guidance notes as a helpful practical aid to accountable transparency".* Tuberous Sclerosis Association.

Some comments highlighted that the policies do not provide guidance on when commissioning responsibility lies within NHS England or with CCGs.

*"When does an IFR become one for NHS England under 'specialised services' and when is it one for a CCG body to consider?"* Service provider / Industry / Professional.

It was also suggested that the policies should align with the policies that set out the commissioning of primary care and CCGs commissioned services

*Ref. Primary care services are out of scope for this consultation, as are services that are commissioned by Clinical Commissioning Groups. "NHS England should act to ensure that policies for its directly commissioned services align with those in these fields so that research taking place across sectors has clarity and consistency".* NHS Health Research Authority

### **Outcomes of policy decisions**

Many respondents advised that the outcomes of policy decisions should be made public, across all of the areas considered in the consultation, for the purpose of ensuring transparency of the processes, transparency, supporting monitoring and for accountability.

*"We would favour publication of data, aggregated to preserve patient confidentiality, concerning the number of IFRs submitted and approved in different clinical fields, including those screened out before formal consideration."* The Federation of Specialist Hospitals.

Many respondents supported the idea of publishing the outcomes of policy decision for education purposes, to learn from successful applications.

*"NHS England should provide examples of successful applications."* The Neurological Alliance.

### **Relation to NHS England annual prioritisation process**

Several respondents noted concerns about how the policies fit with NHS England annual prioritisation process, both in relation to the transparency and accountability of the process and ability to cater for rare conditions due to the comparative nature of the process.

*"The BSR is concerned with the prioritisation process which occurs within the annual commissioning priorities round [...] Our concerns included the comparative nature of the process, the lack of flexibility to accommodate the unique requirements of rare conditions*

*such as lack of evidence and higher costs, the lack of clarity around terminology, lack of transparency and accountability on decisions, the metrics used to assess patient benefit."*  
The British Society for Rheumatology.

### **NHS England approach to exceptionality and rarity in commissioning decisions**

Whilst some respondents supported the principles that exceptionality should be solely assessed on the basis of clinical factors, some comments highlighted the confusion around whether a condition that is rare is also by definition exceptional.

*"The Faculty supports the position of NHS England in only considering clinical factors when assessing exceptionality. However, [.....] we feel that the proposed policy would be significantly improved if this position were to be explained in more detail at the outset".*  
Faculty of Public Health.

*"I think exceptional cases are defined well, but rarity is not mentioned enough throughout the document and there are circumstances whereby the process differs in exceptional versus rare cases particularly around the evidence base"* Provider/ Industry / Professional.

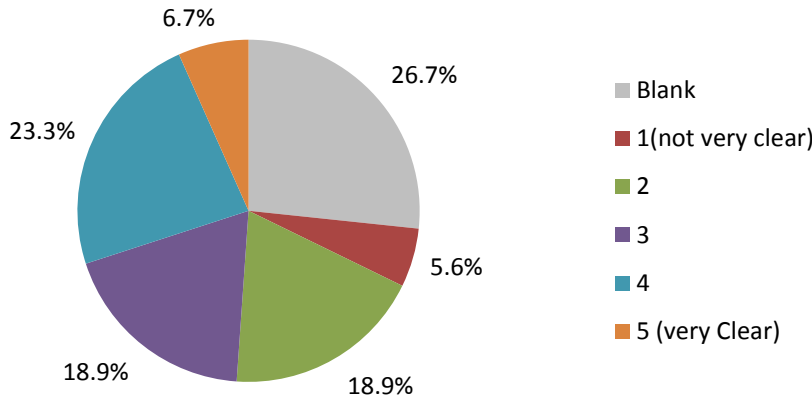
Many respondents also noted concern that NHS England criteria for assessing rarity may pose a challenge for clinicians to make the case for rarity, as they felt that the criteria imply that a patient's circumstances need to be practically unique as opposed to simply rare.

*"It is highly unlikely that any published clinical data will be of such high quality in these circumstances because trials tend not to be conducted on these patient cohorts which therefore means that most requests are unlikely to be approved".* Service provider / Industry / Professional.

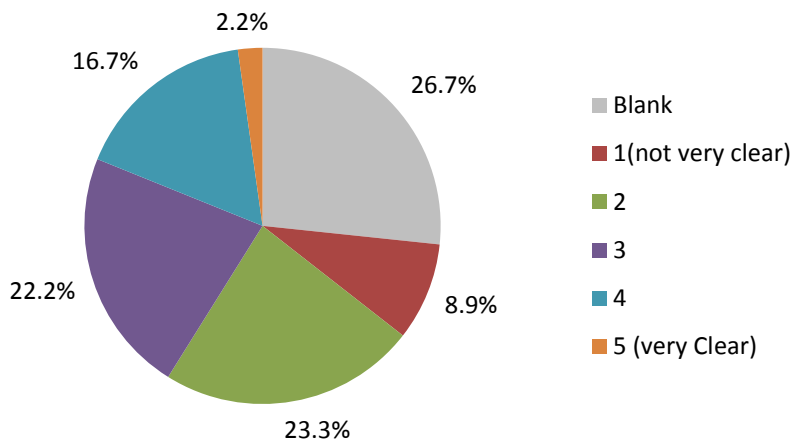
Overall, respondents felt that that the policies need to better articulate whether a patient with a rare disorder is considered exceptional solely on the basis of the rarity of their condition and NHS England approach to rarity, particularly when making decision about individual funding requests.

### 3. In-year Service Development (IYSD)

**Question 4: on a scale of 1 (not clear) to 5 (very clear) how clear is the in-year service development policy on circumstances in which it should apply?**



**Question 5: on a scale of 1 (not clear) to 5 (very clear) how clear is the policy on the process to be followed, including the role of the Clinical Priorities Advisory Group and the required information?**



**Question 6: How could the in-year service development policy be improved, in terms of the clarity and the process to be followed?**

**Question 7: How could the in-year service development policy be improved to provide greater certainty in dealing with clinically critically urgent cases in a fair and open way?**

#### **Criteria and process for the evaluation of service development proposals**

An area that received substantial feedback concerned the definitions of the criteria for the evaluation of proposals for in-year service development. Many respondents requested NHS England to provide examples of what constitutes an “exceptional degree” of improvement, and some suggested that a clearer definition could also help to reduce the volume of applications that do not meet the defined criteria.



*“The consultation provides no measures for demonstrating ‘exceptional improvement’ in patient outcomes in order for them to be eligible for consideration. This ambiguity could be interpreted in many different ways by NHS England, and others, with the risk of creating a vacuum of care”.* Service provider / Industry / Professional.

With regards to the process, whilst respondents appreciated that the policy suggests omitting the step of going through public consultation, they felt that overall it would not necessarily speed up the process. In particular, it was noted that the high burden of documentation poses additional onus to clinicians and delay to the process.

*“The Alliance is concerned about the burdensome process outlined in the consultation document [...]The need for seven separate reports to be prepared on each in-year service development seems unduly bureaucratic”.* Specialised Healthcare Alliance.

Conversely, there was support for close scrutiny of in-year service developments from some respondents

*“The current wording gives the impression that innovations or developments that might result in in-year service developments are not uncommon when in fact, experience shows that the described situation, in which the proposed development is cost neutral or cost saving, is an extremely rare event. Consequently, the requirement for additional resources to fund an in-year service development means that this policy should only be invoked in very specific circumstances”.* Faculty of Public Health.

Many commented that the outline of the process to be followed to make service development proposals policy is opaque. The general suggestion was to have in the policy further details in the policy on the steps to be followed, the accountability for the process and the timeline.

*“The policy could be improved by giving further detail and clarification into the exact points in the process that patients, the public, and/or manufacturers of a medicine or technology are able to advise and input evidence and opinion. How to engage and the time points for this should be very clearly described so that all patient groups and manufacturers are given appropriate opportunity. This is currently not clear in either the commissioning policy, or the national clinical policies methods guide”.* Service provider / Industry / Professional.

*“Further details should be provided around the likely anticipated timescale for an in-year service development in order to set expectations for clinicians and patients”.* Service provider / Industry / Professional.

Again, respondents have suggested that NHS England should provide examples to demonstrate the process and how it can be managed within the timeframe.

### Costing method

Several respondents felt that the policy does not provide sufficient information about the methodology that is used for determining whether a service development is cost-neutral, cost-saving and whether wider system savings, for example savings accrued by CCGs, are included in the analysis.

*"The definitions of what might constitute an in-year service are a helpful clarification. However, important points of elaboration are needed, including whether this saving or cost neutrality is only in relation to the specialised commissioning directorate, or whether neutrality/savings to CCGs for example would affect the decision".* European Medicines Group (EMG).

### Funding

Concerns were raised about funding for in-year service developments through reallocation of other resources. Some respondents enquired about what arrangements are in place to enable in-year service developments meeting the criteria in the consultation to receive funding given that the previous year's annual commissioning round will have allocated all discretionary investment for specialised commissioning decisions.

*"We consider the chief risk here to be the proposal, as we understand it, that funding for in-year developments will have to be found by reallocating funding which was previously agreed during the prioritisation round. This would have an adverse impact on any patient group which loses funding it was previously allocated. It may also undermine trust in the prioritisation process. It also risks setting on condition area against another in a more explicit- and public - fashion than is already the case through the prioritisation round. This may compromise the integrity of the process".* National AIDS Trust.

Some comments explicitly suggested that the default policy position should be to not commission any proposed development.

*"We would advise that any revision [to the policy] should make explicit that, in respect of a proposed service development in the absence of a specific policy, the default commissioning position should be not to routinely commission that proposed development ahead of a policy because of the inequity that would be introduced as a result of transferring resources away from already agreed priorities".* Faculty of Public Health.

In relation to the issue about effective allocation of resources, some responses suggested that NHS England should provide information on the decommissioning of services, and also assess the impact and effectiveness of its commissioning policies regularly

*"We would like to see more clarity on how services will be decommissioned: Will decisions on decommissioning be run through CPAG and will they be subject to public consultation/any other stakeholder scrutiny? What are the criteria for therapies to be decommissioned?"* ABHI.

*“In order to assess the impact and effectiveness of its commissioning policies, NHS England should set out how it will monitor their impact on an ongoing basis, and should schedule a regular review of the policies once implemented”.* Neurological Alliance.

### **Critically, clinically urgent (CCU) procedure**

Many respondents reported that they felt that procedure for critically clinically urgent cases CCU should have had more prominence in the consultation

Some noted that the procedure is in contrast with the principles of the ethical framework that govern resource allocation within NHS England, and that it may undermine the default commissioning position which is that any new interventions are not commissioned ahead of policy development, by providing a route by which unassessed treatments may be offered to patients while is being considered as an in year service development

*“The concept of a clinically critically urgent case runs contrary to the principles of the ethical framework that govern resource allocation within NHS England. [...] resources must be allocated as equitably as possible. A range of interventions must be assessed for their value compared to the resources they require. [...] It is our view that this undermines the safeguards against inequity represented by the primacy of the prioritisation process and the expressed default commissioning position which is that any new interventions are not commissioned ahead of policy development”.* Faculty of Public Health.

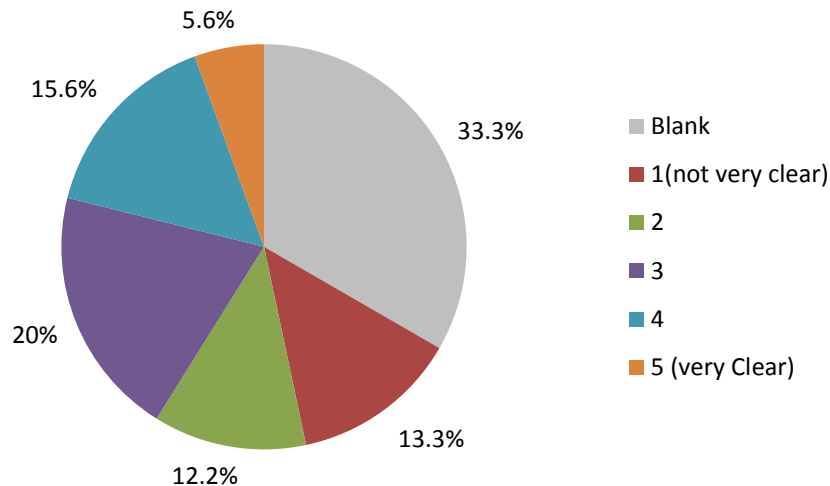
Furthermore, respondents felt that is not clear how the panel makes decision on CCU with regards to whether the treatment is for an individual or for a cohort. In either case it was suggested that the decision-making criteria should be made explicit in the procedure documents and that decision should be justified.

Respondents have also reported lack of clarity on how the CCU procedure relates to the in-year service development process and advised that the CCU procedure should be separate from the in-year service development policy to avoid ambiguity.

*"It is unclear what the plans are for clinically critically urgent cases, which are omitted from this consultation yet referred [sic] to in other NHS England policies. It is vital for patients that there remains a clear route for such requirements to receive appropriate consideration, when delay could for example lead to death or loss of transplant. We are very concerned that there is no defined plan to deal with clinically urgent cases”.* British Kidney Patient Association.

## 4. Experimental and Unproven Treatments

**Question 12: On a scale of 1 (not clear) to 5 (very clear) how far does the policy on experimental and unproven treatments provide clarity on the circumstances in which funding can be sought?**



**Question 13: How could the policy on experimental and unproven treatments be improved? And how could we provide greater clarity and certainty?**

### Decision-making process and funding criteria

The feedback received on this policy echoed the general comments about the clarity of the processes and assessment criteria for each of the policy areas. Several respondents were of the opinion that the policy does not explicitly states the process and criteria for assessing requests for funding for experimental treatments

*"There is no commitment to timely decision-making in the Experimental and Unproven Treatment policy. A lack of explicit reference to process and timelines in the policy creates uncertainty for patients, clinicians and NHS England. We would urge that a more detailed framework is included in the final policy document".* Shire.

In particular, respondents felt that the policy is confusing as it seems to indicate that funding for the use of unproven treatments should be addressed through research routes, however it also describes the circumstances for funding requests to support individual patients or groups of patients to participate in a research study. Overall, there appeared to be a belief that this policy was the main reference document describing the NHS relationship with research practices.

*"Ref. "It would be difficult to justify funding a treatment with uncertain outcomes, when there are many treatments with clear benefits that the NHS is not able to afford". Progress in healthcare requires better evidence, through well-conducted research such as that funded by NIHR and its partners and delivered through the NIHR CRN".* NHS National Institute for Healthcare Research.

It was noted that the use of the term ‘adequate’ with regards to the number of trials to support decision-making is not specific and that the source for data should also be made clear

Many respondents also felt that information within the policy about the funding criteria should be expanded and clarified.

*“It might be helpful to spell out that funding experimental treatment specifically relates to funding outside of the context of a clinical trial. Without this context, some of text is ambiguous [...]. The option to consider funding in rare clinical situations where a trial is impossible on the “condition that the patient enters a properly conducted ‘n of 1’ trial” needs explanation“.* NHS Health Research Authority.

### **Relation to other NHS England policies: in-year service development, IFR and Excess Treatment Costs policy**

According to many respondents the policy, is fundamentally linked both to the in-year service development policy and the IFR policy, however the three policies don’t seem to be explicitly aligned.

*“We suggest that greater cross referencing would support the interpretation and implementation of all three policies [...]. We would suggest that this policy is revised to include the processes and structures which would be necessary in order for NHS resources to be confidently committed to an experimental treatment when other, proven, treatments remain non-commissioned“.* Faculty of Public Health.

Whilst many respondents supported the proposal for experimental and unproven treatments to be considered to receive funding through IFR, there was a concern that this provision might create a perverse scenario whereby an IFR for a proven treatment may be denied whilst an unproven treatment for which evidence is lacking may be funded.

Ref. *“There are some treatments that become available at short notice where there is a strong impact on clinical outcomes supported by the highest quality clinical research that need additional resources to introduce. The In-year Service Development policy allows these to be considered.” This introduction and the reference to new treatments with strong impact on clinical outcomes appears to be at odds with one of the listed types of in-year service developments ‘Requests to fund a number of patients to enter a clinical trial and commissioning a clinical trial, including excess treatment costs“.* Specialised Healthcare Alliance.

A considerable number of comments were made, both in response to this policy and to the policy on continuing funding after clinical trials, about the absence of a clear linkage with NHS England guidance on Excess treatment Costs (ETC).

*“Further detail is required on the appropriate route for organisations conducting NIHR-funded clinical trials to take in order to secure funding to support Excess Treatment Costs. The policy seems to imply that there is a prioritisation process, rather than indicating that NIHR-funded trials will automatically be able to access funds for Excess*

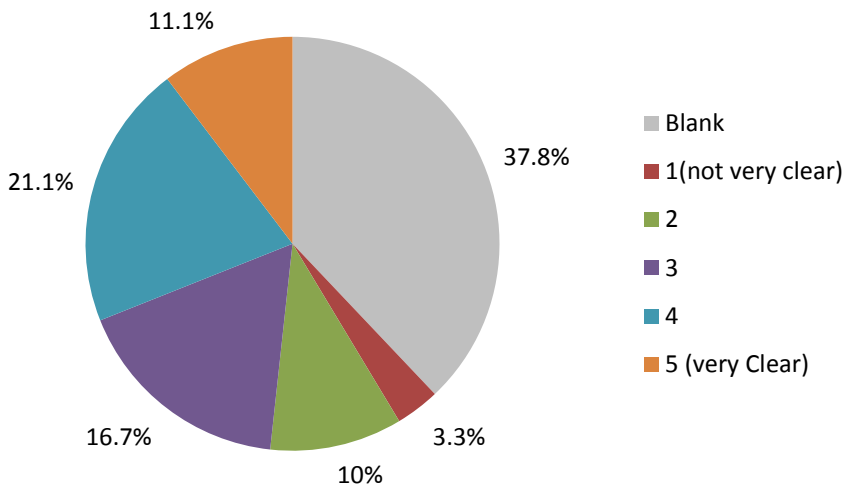
*Treatment costs which is how the funders present this [...]. Accessing ETCs is especially challenging in the context of complex interventions and interventions that may require staff time e.g. psychological therapy. In this context, NHS staff not routinely involved in clinical trials are asked to fit in delivery of a research intervention alongside their existing NHS workload". Provider - Clinical Trials Unit.*

Finally, some respondents queried whether the Commissioning through Evaluation (CtE) programme falls under the remit of the Experimental and Unproven Treatments Policy and advised that NHS England should provide more clarity about the programmes currently in place to assess new technologies, and where responsibility for their operation lies.

*"There should be a 'rapid review' system in place where new evidence and data is available, so technologies can be taken out of the CtE programme and made available to patients instantly". ABHI.*

## 5. Continuing Funding After Clinical Trials

**Question 14: On a scale of 1 (not clear) to 5 (very clear) how far does the policy on continuing funding after clinical trial provide clarity on the circumstances in which funding can be sought?**



**Question 15: Do you think there are any areas of the continuing funding after clinical trial policy that require further clarity?**

Of all the policies object of this consultation, this has received the least number of comments. Feedback has been categorised in the following themes.

### Clarity on processes and funding mechanisms

Respondents provided very specific comments and suggestions on how to make the policy more clear about the assessment criteria, process and funding arrangements that are in place. The comments below summarise the issues that were voiced most often:

*“In the policy, it is stated that where a clinical trial of a treatment has been initiated and sponsored by a manufacturer of pharmaceuticals or medical devices, funding responsibility for on-going access to a treatment rests with those parties. The policy would benefit from additional wording which clarifies this responsibility once national reimbursement of the treatment is secured i.e. once a treatment receives national reimbursement, responsibility for funding the treatment switches to NHS England. Without this wording, there is less clarity where this responsibility lies, and manufacturers should not be expected to provide continual funding for chronic treatments which have since received a positive national reimbursement decision”. Provides/ professionals/ Industry.*

*“Ref. Paragraph 6.3 NHSE Funded trials - this uses criteria of "formal clinical review" and "clinical benefit to patients", neither of which are defined. This requires much more clarity in terms of the relative benefit, particularly in relation to outcomes. These benefits should be agreed at the outset of the trial, particularly given that NSHE are funding the trial, with clear clinical outcomes identified and thresholds/criteria agreed for continuation of the proposed treatment at the end of the trial period (if appropriate).CCG Commissioner.*

*“The policy does not address studies funded by a commercial organisation but sponsored by a non-commercial organisation, leaving a potential area for confusion”. NHS Health Research Authority.*

### **NHS England funding responsibilities**

Some respondents noted that the previous version of the policy clearly set out NHS England funding responsibility for patients under new commissioning policies, and suggested that a the specific statement should be reinstated.

*"The previous policy included a clear statement that, once a positive commissioning decision had been reached (through NICE or by NHS England), that NHS England assumed responsibility for all patients on the treatment on that commissioning policy. It would be helpful to include a clear statement to this fact in the final policy document."* ABPI.

### **Excess treatment costs**

Several respondents noted there is no reference within the policy to NHS England's existing 'Guidance on Excess Treatment Costs' and suggested that the policy should provide more information about excess treatments costs.

*“It is unclear whether the intention of the proposed policy is that all excess treatment costs (and treatment cost savings) incurred by healthcare research, within the service scope of the document, are to be subjected to the processes outlines or whether there remains the expectation that excess treatment costs are usually met within NHS organisations (e.g. on the basis that such costs are included within tariff), with exceptional cases escalate”. NHS Health Research Authority.*

Furthermore, according to some respondents the policy conflicts with the current guidance for funding non- commercial studies.

*“We consider this draft policy to conflict with current guidance and duties to fund eligible non-commercial research treatment and excess treatment costs in the NHS”. NHS Research and Development Forum.*

Others pointed out that the policy appears to rely on there being explicit local arrangements in place with providers before a trial commence, but that it is an inconsistent practice across the country and therefore some elements of that decision making should be agreed nationally.

*“This policy relies on there being explicit local arrangements in place to arrange Excess Treatment Costs and other discussions with providers before trials. This is inconsistent across the country and some elements of that decision making need to be agreed nationally”. IFR Panel.*



## Annex B: update on additional ‘generic policies’

As the consultation noted, when NHS England was first established a set of eleven so-called ‘generic commissioning policies’ were published to guide its decision-making for all directly commissioned services. They were called ‘generic’ as they applied to all NHS England’s clinical commissioning responsibility, rather than being service-specific.

Upon reviewing the set of policies, it became clear that some of the policies could be streamlined, particularly those which were already covered by existing Department of Health policy or NHS England policy. In addition to NHS England’s consultation on those policies which are still required, those policies which are no longer required will be removed from the NHS England website.

Annex B details those policies which are no longer required, with a link to the existing policy which will be used in its place.

<b>Policy</b>	<b>Previous NHS England policy</b>	<b>Policy now to be used</b>
Policy on choice	<a href="https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-11.pdf">https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-11.pdf</a>	<a href="https://www.gov.uk/government/publications/the-nhs-choice-framework">https://www.gov.uk/government/publications/the-nhs-choice-framework</a>
Policy on patients changing responsible commissioning	<a href="https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-10.pdf">https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-10.pdf</a>	Policy now covered by CCGs’ own policies.
Policy on boundaries between public and private care	<a href="https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-12.pdf">https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-12.pdf</a>	<a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404423/patients-add-priv-care.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404423/patients-add-priv-care.pdf</a>
Policy on implementation and funding of NICE guidance	<a href="https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-05.pdf">https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-05.pdf</a>	Policy covered by existing legislation