NHS
England

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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Description	A 12-week public consultation launched in Oct 2017 on four commissioning policies each relating to funding for treatments outside of clinical commissioning policy or mandated NICE guidance. The consultation sought views on the content of the policies. This document provides a summary of the key themes identified in the consultation and identifies how responses have shaped the new policy and supporting documentation.
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Document Status

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Contents

1. Introduction

In October 2016 NHS England launched a 12-week public consultation on a set of four commissioning policies each relating to funding for treatments outside of clinical commissioning policy or mandated NICE guidance. The consultation sought views on the content of the policies, as well as whether they were sufficiently clear and effective in supporting commissioning decisions. It also set out NHS England's intention to streamline the number of commissioning policies to reduce duplication and provide greater clarity.

A consultation outcome report was published in September 2017 alongside the final policies themselves.

At the time of publication, NHS England took the decision to delay publication of one of the four policies considered through the consultation in order to allow further time to refine the policy, and associated documents such as the Standard Operating Procedure in light of the consultation responses.

This policy was:

- **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.

This document provides a summary of the key themes identified in the consultation responses relating to the IFR policy and process and identifies how responses have shaped the new policy and supporting documentation.

2. The engagement and consultation process

A detailed overview of the engagement and consultation process is contained in the consultation response referred to above. In short, engagement on these policies has taken place over the past three years and has included 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.

A formal consultation on the four policies ran between 13 October 2016 and 15 January 2017. 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. A list of consultation respondents can be found at Annex C.

3. Summary findings and NHS England response

This section sets out a summary of key themes arising from the consultation responses specifically relating to the Individual Funding Request policy and outlines how NHS England has taken these responses into account in developing the policy and associated materials. A more detailed breakdown of the feedback received and how this has been themed is attached at Annex A.

The questions asked were:

- *On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the circumstances in which it should be applied and the basis for taking decisions?*
- *On a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the process to be followed in determining whether NHS England will support an IFR?*
- *What are your concerns, if any, with the revised policy for including on determining exceptionality and rarity?*
- *What are your concerns with the process to be followed for IFRs including in urgent circumstances?*

Key themes in feedback	**NHS England Response**
Definition of exceptionality There was a high volume of responses relating to the definitions used in the policy, particularly relating to criteria for determining exceptionality. Respondents highlighted a view that there was an 'incompatibility' in the criteria, given the need to provide clinical evidence whilst demonstrating that a patient's situation is exceptional.	NHS England convened a workshop to review the definitions used in the policy against the consultation feedback and has revised the description of "exceptionality" and the wording used in relation to "cohort". Annex B contains a comparison of how "exceptionality" and "cohort" were defined in the 2013 interim policy and 2016 policy (which was the version published for consultation) and the definition utilised in the final policy. Alongside the publication of the policy we are publishing an information leaflet for patients and the public which explains the process in "Plain English" along with some examples.
Definition of cohort The lack of specificity in the definition of a cohort caused concern, with some respondents expressing the view that this would result in fewer IFRs being successful. Others, by contrast, welcomed the proposal to drop the practice, as described in the previous iteration of the policy, that a cohort would be defined as being more than	NHS England carefully considered reverting to a defined number to represent a "cohort". The conclusion drawn was that on balance, expressing a specific number which would represent a cohort did not reflect operational practice i.e. clinical policy development would likely be triggered before the defined number was reached, and was known to cause undue anxiety among patients and patient groups about equitable treatment of the so called "21st

20 people.	patient" i.e. IFRs submitted for patients after the cohort number had been reached and policy development triggered.
Key themes in feedback	**NHS England Response**
IFR process and urgent cases Whilst many respondents welcomed the clarification that the IFR panel meets every two weeks some felt that the process is still too slow, particularly for urgent cases.	NHS England has listened to feedback and increased the number of IFR panel meetings from once every two weeks to an average of three times a month. This will further improve the timeliness of decision making. The SOP document clearly describes the timeframe for decisions to be taken. Screening of applications is undertaken on at least four days each week. Responsibilities on clinicians and provider trusts treating to the patient have been clarified as well as confirmation that costs will be reimbursed retrospectively for cases that are subsequently approved by the IFR panel.
Triggering clinical commissioning policy development Concern was expressed about the robustness of the process for IFR "cohorts" triggering commissioning policies and the length of time that process can take.	IFR activity is just one element considered by NHS England to trigger the consideration of whether clinical commissioning policy development is required. Clinicians submit proposals directly into NHS England (for specialised services) when they consider there is a clinical and unmet need that needs addressing. The new Service Development Policy explains the policy development process and decision making.
Transparency of decision making There is a perceived lack of transparency about decision-making. This included: • the screening process • how decisions were reached • how and when decisions are communicated to the clinician/patient. • Role and membership of the IFR panel	Alongside the new IFR policy, NHS England is publishing a revised Standard Operating Procedure (SOP) which details the process that is followed for IFRs. NHS England has listened to this feedback and have revised the letters that are sent to clinicians and patients advising them of the decision reached by the panel. In future, both parties will be sent a short letter notifying them of the decision and the clinician will receive the full decision framework pertaining to the case which they can share with patients as part of a discussion about their treatment options.

	In addition NHS England is producing materials for patients including a refreshed information leaflet explaining the process. These include key elements of IFR applications to help people understand the concept of exceptionality. These materials are being developed with input from patients who have been through the IFR process. The Terms of Reference for the panel will be published.
Key themes in feedback	**NHS England Response**
Appeals process Respondents suggested that the appeals process would be improved if appeals were considered by a separate group rather than members of the IFR panel	The Terms of Reference for the IFR Review Panel will be published as an appendix of the SOP. The process for considering appeals is detailed on page 15 of the SOP and confirms that appeal requests are not reviewed by members of the IFR panel that originally considered the case.
Support for clinicians to make an application A prevalent view among service providers / industry / health professional respondents was that clinicians need more support to submit high quality applications that have a chance of success.	Guidance for clinicians will be published on the IFR page of the NHS England website. Immediately following the publication of the policy, the National Medical Director for Specialised Commissioning and a team experienced in the IFR process will begin meeting with clinical leads in provider organisations that most regularly make IFR applications to help them to understand the revised policy and process.

4. Conclusion

NHS England welcomed the valuable feedback received through the consultation events, and through the written consultation responses. As this report demonstrates the insights provided have helped to inform the final policy.

The updated policy and supporting materials which have been described in this consultation response are now available on the NHS England website.

Annex A: Analysis of responses to the NHS England consultation

1. Overview

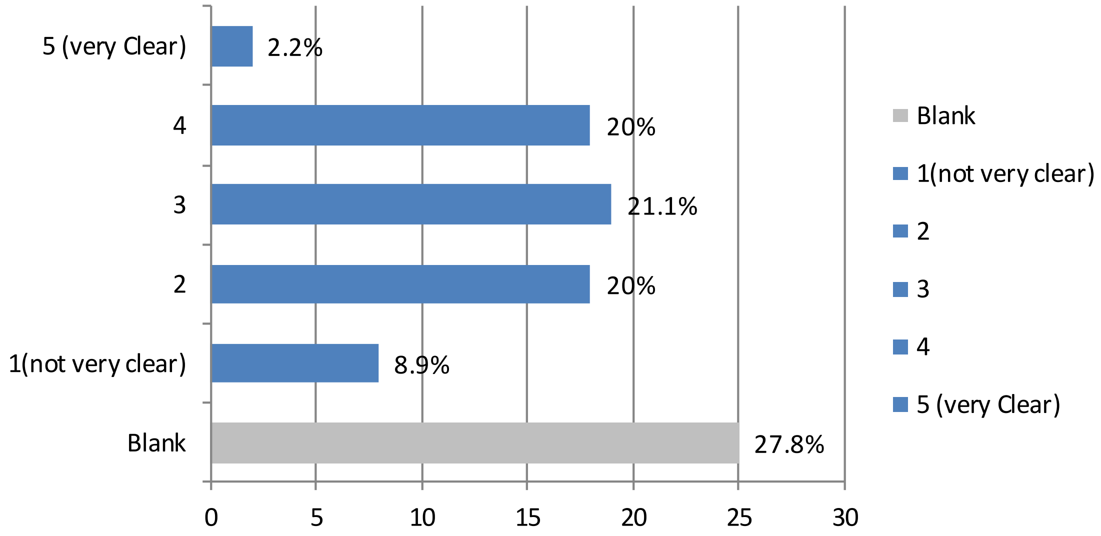
NHS England received 90 responses through the online survey on the consultation hub and by letter. Respondents represented a broad range of stakeholders including patient organisations, professional bodies, charities and industry. A list of the organisations who responded is at Annex C.

This report illustrates the percentage responses for the quantitative (ranking) questions and the analysis of the key recurrent themes emerging from the responses to the qualitative (free text) questions that specifically relate to the Individual Funding Requests policy (questions 8 – 11). Analysis of the responses to the consultation questions relating to the other policies considered under this consultation process is published in the separate consultation response report.

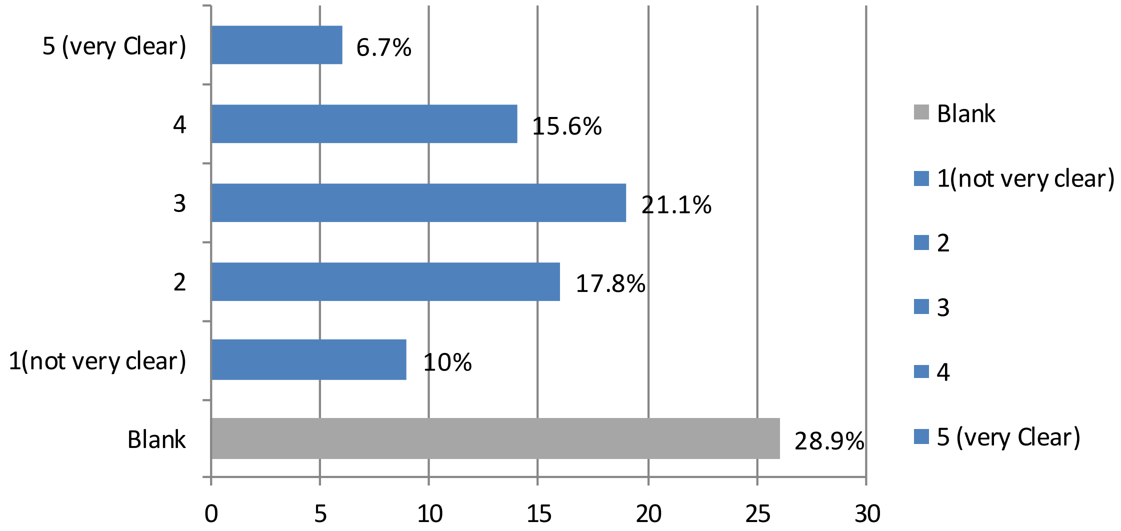
Where relevant, quotes have been used to illustrate the issues raised as well as suggestions for alternative approaches.

2. Analysis of responses

2.1 Question 8: on a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the circumstances in which it should be applied and the basis for taking decisions?



2.2 Question 9: on a scale of 1 (not clear) to 5 (very clear) how clear is the IFR policy on the process to be followed in determining whether NHS England will support an IFR?



2.3 Question 10: What are you concerns, if any, with the revised policy for including on determining exceptionality and rarity?

2.3.1 Definition of "Exceptionality"

- A high volume of comments related to the criteria of 'exceptionality' as defined in the policy published for consultation. While respondents generally agree that only clinical factors should be taken into account when assessing exceptionality, this could be made clearer in the policy.

"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

"Clinicians will still submit inappropriate applications as they still don't understand exceptionality and rarity. Why don't you include figures to help define rarity and include examples? Also include things you don't consider exceptional as examples e.g. social background or occupation…" Service provider / Industry / Professional

- Some respondents felt there was an incompatibility in the assessment criteria for IFRs, questioning the feasibility of presenting high quality evidence while demonstrating that a patient's situation is exceptional. Many suggested that NHS England should provide examples of what a clinically exceptional patient would look like based on the criteria provided to guide clinicians.

"EMG believes the specified requirements are at odds with one another; for example, the simultaneous need to demonstrate patient exceptionality as well as high quality published evidence is so restrictive, that it makes it unlikely that any requests would be approved". European Medicines Group (EMG)

"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

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

"A definition of rarity needs to be made clearer and how this differs to exceptionality. The comment on rarity not constituting exceptionality similarly requires explanation." Cancer 52

"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

- Some respondents went further, raising concerns that the IFR policy as it stands may disadvantage patients affected by rare diseases.

"People affected by rare conditions should not be unfairly disadvantaged by the IFR process[…] given that IFR applications by definition relate to exceptional cases, it is highly likely that the availability of evidence will be limited by rarity and exceptionality […]. Additionally, the criterion that it should be "unlikely that there are other patients with similar clinical conditions" appears both vague and extremely demanding, potentially excluding almost all patients at the discretion of NHS England". Neurological Alliance

"The IFR policy includes patients whose disease (and its treatment) is sufficiently rare that no service development policy is appropriate. The form, however, does not have questions or acceptance criteria to fit this group. The requirement remains to demonstrate exceptionality relative to others with same stage of disease. In the event of a very rare disease, the applicant is not arguing that the [patient] is exceptional relative to others with the same disease, rather than the disease itself is so rare that no policy can be expected. The form needs to be amended to reflect this." Service provider / Industry / Professional

2.3.2 Definition of cohort

- Questions and concerns about the definition of cohort were a consistent theme amongst the responses to the questions on the IFR policy. There was general concern about removing a defined value (n = 20) from the definition of cohort and that it would lead to much smaller cohorts to be allowed through the process. Many respondents were therefore in favour of keeping the principle of a number to clearly define a cohort, with some suggesting that the threshold of 20 specifically should be kept.

"It is unclear what would be defined as a 'patient cohort'. This should be more specifically clarified. A numerical measure may be helpful." Muscular Dystrophy UK

"The removal of the definition of 20 patients representing a cohort from this policy, in addition with the criteria that it is unlikely there are other patients with similar clinical conditions raises 'exceptionality' to unrealistic expectations." Service Provider/ industry/ Professional

"The BSR's key concern about […] NHS England's ability to determine rarity and clinical exceptionality as a requirement for an IFR, is that the consultation document does not indicate what would constitute a cohort [...] We are concerned that lack of specificity will result in the number defining cohorts will be lowered, only allowing for patients with ultra-rare conditions to be considered for IFRs. Therefore, the BSR recommends NHS England still attach a numerical value to allow for a consistent approach." The British Society for Rheumatology

"Regarding IFR - to make IFR automatically not applicable if there are more than 5 patients requiring a treatment is a nonsensical decision. This then refers the Clinician back to NHSE & Commissioning. BUT, what if there is no plan to review commissioning for that treatment? The patient is left in limbo without access to treatment." Service provider / Industry / Professional

2.4 Question 11: What are your concerns with the process to be followed for IFRs including in urgent circumstances?

2.4.1 IFR process and urgent cases

- There were mixed views about the stated approach to handling urgent cases. Many respondents welcomed the clarification the policy provides and felt that the panel meeting every fortnight was a positive development.

"I think this is fair, and pleased to see an agreement to fund retrospectively if an application has been submitted under urgent grounds." Service provider, Industry, Professional

"It allows for providers to use 'rule of rescue' and go ahead at risk with the option remaining for retrospective decision-making. Providers and clinicians need to be more mature about taking those decisions to treat at risk and avoid using the risk of imminent death or loss of function as a lever to gain decisions" Service provider, Industry, Professional

"The definition of "urgent" is so broad that most IFRs are flagged as urgent which devalues this categorisation. By stripping out the perceived need to make an IFR application for non-exceptional cases, it may be that stratification by urgency is no longer required with the frequency of screening panels underpinning the process." Service provider/ Industry/ Professional

- However, some respondents felt that the process is still too slow, particularly for urgent cases.

"The urgency of the IFR process is already too slow. Genuinely urgent cases need to be screened for urgency and prioritised, not reviewed fortnightly; this is far too long in the majority of cases. The communication between NHS E and providers need improvement once a decision has been reached". Service provider/ Industry/ Professional

"Even if urgent, the turn round is presently too slow. Cases may take months to resolve. The policy should set rigid guidelines as to turnarounds (in all cases, including urgent)" Cancer Charity

2.4.2 Cohorts triggering commissioning policy development

- A number of comments were about the link with the processes for in-year service developments in the event that a patient is determined not to be "exceptional", and risks that gaps in the process may pose to a timely provision of treatments.

"The best case scenario for a patient whose IFR has been declined by virtue of failure to demonstrate exceptionality is a potentially lengthy wait for a decision to be reached by NHSE in relation to a relevant commissioning policy. The risk here is that NHSE may fail to pro-actively recognise the need for a service development through horizon scanning and may fail to evaluate a new treatment in a timely manner where a cohort exists. Any such failure will expose patients to preventable harm. This calls into question the rationale for (and ethical acceptability of) denying access pending policy development. The numbers of patients being put forward for IFRs for a given product in these circumstances, and therefore budget impact, will be small." Tuberous Sclerosis Association.

2.4.3 Transparency of the decision-making

- While some respondents felt the decision process was clear within the policy, feedback highlighted a perceived a lack of information about the composition of the IFR panel, and the criteria for appointment. In particular, some respondents asked for information about the clinical involvement on the panel, particularly specialist clinical knowledge relevant to the IFRs being considered.

"The process and decision-making framework is well articulated and depicts some good scenarios about what should and shouldn't be considered. It does well to set out the decisive and non-decisive factors particularly around value judgements. It's a good document in that regard." Service provider / Industry / Professional

"The document attempts to lay out clear processes. However there is inevitably a risk of introducing subjectivity. It will be important that the policy is (and is seen to be) applied

consistently and in a way which is appropriately responsive to justifiable need.” Royal College of Physicians

"The expertise of the panel and how the panel members are chosen can be important. Panel members should have the knowledge and experience in the area to make clear and informed decisions, and have no conflicts of interest”. The Royal College of Ophthalmologists.

- Some felt that there was a lack of transparency about how the panel reaches to a decision and insufficient information provided when decisions are communicated to clinicians and patients.

“The communication between NHSE and providers needs improvement once a decision has been reached.” Service provider, Industry, Professional

- Several respondents advised that the outcomes of policy decisions should be made public, for the purpose of ensuring transparency of the processes, 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

2.4.4 Appeal Process

- Respondents positively noted the presence of an IFR appeal panel, however some voiced a perceived lack of transparency on the criteria and the timing for appeals, and about where decision-making responsibilities lies. Respondents were particularly concerned that any appeal, once reviewed by the IFR review panel, is handed back to the IFR panel which handled the first application.

"The BSR is concerned that the IFR Review Panel's singular role to ensure the IFR Panel has followed NHS England procedures, with the Review Panel unable to authorise funding and the decision returning to the IFR Panel, who are unlikely to review their decision unbiasedly. The BSR recommends the IFR Review Panel should have the responsibility for the decisions after an appeal." The British Society for Rheumatology.

“We appreciate the introduction of an IFR appeal panel, but would wish to see NHS England adopt a similar process to NICE on this, by having a separate panel to hear appeals rather than having the heard by the same panel that turned down the appeal”. British Kidney Patients Association.

“Whilst it is crucial to have a process for reviewing decisions, we are concerned that any appeals, once considered by the IFR review panel, are then passed back to the same IFR Panel which handled the first application. Furthermore, there doesn't seem to be an avenue of appeal for decisions made by the IFR Team, except where a request is

classified as an in-year service development." Patient / Public

2.4.5 Support for clinicians in making applications

- A number of respondents suggested how clinicians could be supported to make appropriate and effective requests.

"Huge steps need to be made to educate clinicians of the correct approach to IFRS so patient success is maximised. Why should a patient in a small DGH be disadvantaged compared with one at a large specialist centre where consultants know the rules of the game better?" Charity

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

Annex B – Revised definitions

1. Exceptionality

2013 policy definition of exceptionality	"The word 'exception' means 'a person, thing or case to which the general rule is not applicable'. "[1]In an exceptional case, a patient seeks to show that he or she is an 'exception to the rule' or policy and so may have access to an intervention that is not routinely commissioned for that condition. In contrast, an individual funding request arises when a treatment is requested for which the [commissioning organisation] has no policy. This may be because: • it is a treatment for a very rare condition for which the [commissioners] have not previously needed to make provision, or • there is only limited evidence for the use of the treatment in the requested application; or • the treatment has not been considered by the [commissioners] before because it is a new way of treating a more common condition. This should prompt the development of a policy on the treatment rather than considering the individual request unless" [1]Faculty of Public Health. FPH Position Statement. Describing exceptionality for funding panels. 2012. Available from: www.fph.org.uk/policy_reports
2016 policy definition of exceptionality (consultation version)	"NHS England will only provide funding in response to an Individual Funding Request, if it is satisfied that the case meets all of the following criteria: • There is evidence of 'clinical exceptionality' i.e. when a clinician believes that their patient is clearly different to other patients with the same condition, and • Where their patient might benefit from the treatment in a different way to other patients"
Final policy definition of exceptionality	NHS England will only provide funding in response to an IFR, if it is satisfied that the case meets **all** of the following criteria: • There is evidence that the patient presents with exceptional clinical circumstances, that is:

	○ There is a relevant NHS England clinical commissioning policy in place (whether to fund or not fund a particular treatment) in relation to the patient's condition, but a clinician can demonstrate that their patient is clearly different to other patients with the same presenting condition substantially at the same stage of the condition’s progression and their patient might benefit from the treatment in a different way to other patients and because of that difference, is expected to respond in a way that exceeds that seen in other patients; OR ○ There is not a relevant NHS England clinical commissioning policy in place for the management of the patient's condition or combination of conditions, and the patient’s clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken and • There is a basis for considering that the requested treatment is likely to be clinically effective for this individual patient; and • It is considered that the requested treatment is likely to be a good use of NHS resources.

2. Cohort

2013 policy definition of “Cohort”	“A cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy. In these circumstances, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort”.
2016 policy definition of “cohort” (consultation version)	“[…] Patients will be regarded as forming a cohort if the information in the application, supplemented by other published sources if needed, leads NHS England to believe that there are likely to be other patients across the whole of England in any single financial year: • Who are in the same or similar clinical circumstances as the

	patient who is the subject of the request or their clinical condition is such that they could make a similar request; and • Who could reasonably be expected to benefit from the requested treatment to the same or a similar degree as the patient on whose behalf the request is made.”
Final policy definition of “cohort”	This is defined through the IFR criteria: • There is evidence that the patient presents with exceptional clinical circumstances, that is: o There is a relevant NHS England clinical commissioning policy in place (whether to fund or not fund a particular treatment) in relation to the patient's condition, but a clinician can demonstrate that their patient is clearly different to other patients with the same presenting condition substantially at the same stage of the condition’s progression and their patient might benefit from the treatment in a different way to other patients and. because of that difference, is expected to respond in a way that exceeds that seen in other patients; OR o There is not a relevant NHS England clinical commissioning policy in place for the management of the patient's condition or combination of conditions, and the patient’s clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken

Annex C - 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 Tumour 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