

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

Cancer52 consultation response

January 2017

About Cancer52

52 per cent (recent statistics show an increase to **54%**) of UK cancer deaths are from the less common cancers. Despite this, the less common cancers remain severely under represented and under-funded across all areas, including policy, services and research.

Cancer52 is an alliance of **90** organisations working to address this inequality and improve outcomes for patients with these highly challenging diseases.

You can find out more about Cancer52 and our member organisations by visiting:

<http://www.cancer52.org.uk/>

Generic commissioning policies

Q2. 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?

Response: 2

Q3. 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?

Response

Cancer52 considers that there are a number of gaps and questions for clarification within the NHS England consultation document. These are covered below.

- Better clarity is needed on how all of the policies actually link together, particularly given the significant overlap between them. It is not immediately clear which policy is relevant for different treatments, which could potentially be detrimental for healthcare professionals (HCPs) trying to seek access to a drug for a patient. The complexity of the process/policies may also put HCPs off applying all together and prevent appropriate communication with patients about their care.
- There is an express gap for patients between seeking access to a drug on exceptional grounds and through in-year service development. The definition of exceptionality is so narrow that very few, if any, patients are likely to gain access to treatment under the definition. However, the criteria to apply for an in-year service development is such that Individual Funding Request (IFR) considered “cohort” are unlikely to be eligible for policy development outside the NHS England prioritisation process. This has the potential to send

treatment requests round a decision-making circle between IFR and in-year service development, without any likelihood of the treatment ever being commissioned on the NHS. There needs to be a recognition that repeat IFR requests will mean that doctors wish to seek access to a drug/procedure which will benefit their patients.

- There is no clear funding direction within NHS England for accessing treatments outside of normal commissioning. Levels of funding are not expressly stated in the consultation document and in public consultation meetings NHS England have confirmed that there is little to no funding available for the IFR process. This is a worrying gap, as whilst we do not believe all IFRs should be approved, funding for cases where an innovative treatment is required for a patient is vital.
- The IFR process has been tightened to the point that almost no patient will gain access to medicines outside of normal commissioning. This is contrary to public messages, where it has been outlined that decommissioned policies, such as second allogeneic transplants, will be considered under the IFR. The IFR process should not be advertised as a way to access new medicines and communication about its role and purpose need to be clarified for patients and HCPs.

Q4. Do the changes being proposed create any risks, issues or potential adverse impacts for patients/stakeholders generally or for any patient groups?

Response

- Further information is required on how NHS England plan to communicate the outcomes of the consultation and changes to the policies to HCPs. This is particularly important given their role in applying for IFR and also in the additional hurdles they will have to overcome to demonstrate exceptionality. We do not want patients to lose out on access, or have delays in access, as a result of their HCPs not being aware of the changes.
- There is a risk to patient rights under the NHS Constitution. The NHS Constitution confers a right for patients to be subject to “rational and fair decision-making” on access to medicines. This takes into account the IFR process and was underpinned by National Prescribing Centre (NPC) guidance entitled “defining guiding principles for processes supporting local decision making about medicines.” Whilst the NPC is now defunct, we would welcome the continued implementation of the rights conferred on patients within the guidance and similar guidance reproduced to support the patient right to rational and fair decision-making as conferred in the NHS constitution. This is explained in more detail in our specific comments on the IFR process.
- There is a risk to patients with rare and less common types of cancer. Generic NHS England policies cannot be seen in isolation to other policy developments. In particular, the NHS England prioritisation process and the ongoing NICE/NHS England consultation on funding NICE technology appraisals. Across the NHS, treatments and procedures for rare and less common cancers are being withdrawn from NHS funding (such as second allogeneic stem cell transplantation for haematological cancers) and changes to highly specialised

commissioning will lead to reduced access to these medicines and potential increased application to IFR and off-label funding processes. Whilst we know that these policies are not designed to provide routine funding for new drugs, increased applications are symptomatic of wider problems in the NHS budget and the continuing need for the NHS to cut budgets rather than to pay for treatments that improve outcomes. This is an unacceptable situation and we need further public discussion over the value of new medicines, particularly for rare and less common cancers.

- Rare cancers may also lose out due to the lack of the correct expertise involved in decision-making on new drugs and the additional requirement for “high quality evidence” to support decision-making demonstrating exceptionality. This requirement is referenced throughout the document and needs to be clearly defined. Not every clinical intervention will have Phase III trial data attached to it, particularly where a cancer is less common/rare or where trying to demonstrate “exceptionality” (which by its nature, should not have extensive data demonstrating how a treatment works in a single patient). This should be reworded and should acknowledge that trying to demonstrate exceptionality using “high-quality clinical evidence” to support this is contrary and illogical.

In-year Service Development Policy

Q5. On a scale of 1 (not clear) and 5 (very clear) how clear is the in-year service development policy on circumstances in which it should apply.

Response: 2

Q6. 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?

Response: 2

Q7. How could the in-year service development policy be improved, in terms of the clarity and process to be followed?

Response

It is of vital importance that NHS England has a clear policy in place to allow for the adoption of new technologies outside of the yearly prioritisation process. To improve the clarity and process of the in-year service development policy, we think the following improvements should be made:

- Define and make clear what is meant by “high-priority” to NHS England. This is vaguely done in the policy and it would be beneficial to the stakeholders making the case for a treatment/technology to expressly state what the criteria is. Whilst this may be available in other NHS England policies, it is important to expressly outline this within the policy.
- It is important for the policy to be clear on the decision-making stages and timelines for in-year service developments. These are currently quite vague.

- How will IFR requests be monitored via NHS England? Given the emphasis that is given on “cohort requests” within the IFR process document, more clarity needs to be given on how repeat IFR requests will feed into the in-year service development process. In addition, the proposed policies require a more detailed outline of how they will ensure fairness and transparency on what constitutes a cohort request – this is something expressly outlined in the previous policy.
- Clarity should be provided on whether NHS England will consider treatments that have already been removed from the NHS England Prioritisation Process (e.g. second stem cell transplants) if there are a substantial number of IFR’s submitted.
- Specific clarity is required for rare and less common cancers. Information needs to be given on how the Clinical Priorities Advisory Group (CPAG) will involve relevant expertise on decision-making particularly in rare cancers and on what the role of the rare disease advisory committee will be in this.
- Information is required on ultra-conditions and how this policy will tie into the proposals in the NHS/NICE Consultation on highly specialised technologies.

Q8. 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?

Response

Cancer52 considers that the in-year service development policy can be improved and clarified by:

- Laying out how the IFR and Clinically Critically Urgent (CCU) policies differ, so doctors are clear on the correct process for applying for a new medicine. In addition, make clear who is responsible for making applications through the CCU.
- Outlining the types of evidence required to demonstrate clinical and cost-effectiveness of a critically urgent intervention and who is responsible for this.
- Outlining how the policy will adhere to the patient rights to fair and rational decision-making conferred in the NHS Constitution.

Individual Funding Requests Policy

Q9. 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?

Response: 2

Q10. On a scale of 1 (not clear) and 5 (very clear) how clear is the IFR policy on the process to be followed in determining whether NHS England will support an IFR?

Response: 2

Q11. What are your concerns, if any, with the revised policy for including on determining exceptionalism and rarity?

Response:

Cancer52 has a number of concerns about the revised policy for determining exceptionalism and rarity. Whilst the IFR process is not designed to provide routine commissioning for drugs that are not NICE approved, we do not agree that patients are having their NHS Constitution right to “fair and rationale decision-making” upheld in this consultation.

Our comments on the revised policy are as follows:

- Exceptionality has been narrowed down substantially in the consultation. NHS England has anticipated almost every possible argument for exceptionalism and specified that it cannot be used. It is difficult to see how a patient would receive funding through this process without demonstrating that they are unique, which is legally dubious. Narrowing it down to one patient per financial year across NHS England and limiting exceptionalism, will stop most IFR requests.
- The definitions of exceptionalism and cohorts are particularly difficult for relapsing remitting diseases. For example, in its definition of exceptionalism is NHS England looking at a whole patient population across all stages of a disease or just within a single stage of a disease?
- A definition of rarity needs to be made clearer and how this differs to exceptionalism. The comment on rarity not constituting exceptionalism similarly requires explanation.
- It would be useful for NHS England to outline the arguments which might be used by doctors to demonstrate exceptionalism and rarity to ensure time isn't wasted on applications which will not be considered.
- NHS England should provide communication to HCPs on their responsibility to complete the IFR forms and what their role is in demonstrating cost-effectiveness (if any). Given the pressures within hospital clinics, doctors do not always have the capacity and time necessary to do this and to read through the extensive and detailed guidance documentation that supports the IFR forms. The administrative burden of IFRs should be made as simple as possible and major changes, such as those outlined in this consultation, need to be made very clear to them.
- The new definition of “high-quality published evidence that the requested treatment is likely to be clinically effective for this individual patient”, needs to be clarified. Whilst we are aware that decisions have always required provision of evidence to support exceptionalism, the requirement to provide “high-quality published evidence” is unreasonable and contradictory to the idea of being an “exceptional” case. Most high-quality, published evidence relates to large ongoing trials which, by their nature, show results based on a cohort of patients. We think this requirement should be changed, particularly for less common cancers where there may be less published information on a treatment.

- With the requirement for high-quality published evidence to support exceptionality, and requests where no published evidence exists being considered under the unproven/experimental treatments policy, there is a potential gap in the middle for some conditions where there some or only limited evidence to support its use. Clarification of what constitutes high and low quality evidence would help understanding of the evidence requirements to support funding applications for new drugs.
- NHS England need to look at other models being developed in the UK on IFR to see if there are more appropriate ways of making decisions on local access and on the potential of considering different ways of looking at exceptionality.

Q12. What are your concerns with the process to be followed for IFRs including urgent circumstances?

Response:

Cancer52 has a number of concerns and questions about the IFR process, which we outline below.

- NHS England IFR teams, particularly the IFR screening employees, should be more proactive in seeking out missing information from IFR forms. IFRs are often turned down unnecessarily, when only a small piece of information is missing. Information provided on the IFR forms will also be improved through implementation of the recommendation above on improving communication and training with HCPs on the IFR process.
- It is important that the NHS constitution commitment to implementing a right to “fair and rationale decision-making” on access to medicines decisions is renewed. The existing documents that support this right for patients through the IFR process need to be updated to support this, these include:
 - The NHS England Handbook
 - The National Prescribing Centre “Supporting Rational Local Decision-Making about Medicines (and treatments).”
- The policy should specify a minimum level of expertise to be involved in the IFR screening and decision-making panels. This is something particularly important for rare and less common cancers where they require a high-level of expertise involved in their decision-making. Where the panel does not have expertise on a specific subject, an expert should be sought out and involvement in the decision-making.
- Transparency of the process should also be improved for patients, families and clinicians including ensuring clear and detailed rationale is made available when decisions are turned down. Cancer52 members have seen a wide-range of subjective and unclear decisions being made on IFRs, particularly relating to the rationale for turning them down.
- Information should be provided on the make-up of IFR panels involved in appeals. It is important that appeals panels are not made up of people involved in the original decision.
- Criteria is required on patient rights during an appeal (i.e. length of time it takes to undertake a decision on this) and how the patient and family will be communicated with

during the appeal process. This would be supported by refreshing the above mentioned documents supporting the NHS constitution for patients.

- It is important that information is provided on how an IFR panel will assess cost-effectiveness of a treatment. Cancer52 questions the appropriateness of an IFR panel basing a decision on what might be an arbitrary figure based on an assessment of cost-effectiveness that may not be robust.

Funding for Experimental Treatment and Unproven Treatments Policy

Q13 On a scale of 1 (not clear) to 5 (very clear) how far does the policy on funding for experimental and unproven treatments provide clarity on the circumstances for which funding can be sought?

Response: 2

Q14 How could the policy on experimental and unproven treatments be improved? And how can we provide greater clarity and certainty?

Cancer52 has the following questions and comments on the experimental and unproven treatments policy:

- More clarification is required on the process for applying through this policy, particularly for doctors and who makes the decisions on whether funding should be approved (i.e. is it still the IFR panel?) There is a lot of crossover between the generic commissioning policies and there maybe confusion as to which policy is relevant for specific types of treatment.
- Can the decisions made using the policy be appealed on the same basis as the IFR appeal process? It is important that an appeal process is clearly set out and that patients have their NHS constitutional rights upheld.
- We are aware of a number of patients being prevented accessing compassionate use programmes on the ground these are “experimental”. This is despite good quality trial data demonstrating effectiveness. This policy should not be used to stop access to these types of treatment.

Continuing funding after clinical trials policy

Q15. On a scale of 1 (not clear) to 5 (very clear) how far does the policy on continuing funding after clinical trials provide clarity on the circumstances in which funding can be sought?

Response: 3

Q16 Do you think there are any areas of continuing funding after clinical trial policy that require further clarity?

Response:

Whilst this may be outside of the scope of this consultation, the clinical trial policy does not expressly make clear whether patients can re-join NICE and NHS England approved pathways from

the point at which they left when joining a clinical trial. Given that participation in clinical trials offers the NHS and other stakeholders a wide range of benefits, participants should be entitled to re-join the treatment pathway where they left it, so they are entitled to the same levels of treatment as other patients and are not penalised for their involvement.

In addition to this, where there are large NHS trials, commissioners and trial managers should work together to find ways of funding a treatment pathway for patients once they exit the trial – as the NHS pathway of treatments may not be relevant to them anymore. Patient rights in this regard should be made extremely clear to them prior to joining the clinical trial, as this may affect their decision-making.

-ends-

13th January 2017

info@cancer52.org.uk

www.cancer52.org.uk