Specialised Healthcare Alliance
FOR EVERYONE WITH RARE AND COMPLEX CONDITIONS

SPECIALISED HEALTHCARE ALLIANCE RESPONSE TO NHS ENGLAND CONSULTATION ON GENERIC COMMISSIONING POLICIES
NOVEMBER 2016

The Specialised Healthcare Alliance is a coalition of 120 patient-related organisations and 15 corporate supporters which campaigns on behalf of people affected by rare and complex conditions. The Alliance does not involve itself in individual therapy areas, focusing instead on the overarching policies and structures of specialised care. The SHCA's funding arrangements are declared on its website, www.shca.info.

NHS England's current generic commissioning policies were adopted on an interim basis in March 2013 with a commitment to review them by that October. The Alliance therefore welcomes the launch of the current consultation.

Nevertheless, the SHCA has some fundamental concerns about the proposals being consulted upon, which have the potential to affect patient care adversely. In particular, the document refers to four distinct policies which are in truth interwoven and need to be presented and considered as a unified whole. In that context, the omission of the Clinically Critically Urgent process as part of a coherent package is a serious omission.

EXECUTIVE SUMMARY

- **While consultation on the generic policies is welcome after a period of substantial delay, the overall approach being proposed is highly complex and opaque;**
- **Crucially, it provides clinicians and others with little clarity about the circumstances in which applications could be successful;**
- **The Alliance views the absence of the clinical critical urgency process from the consultation as a serious omission;**
- **There are fundamental concerns about the ability of patients at serious risk of imminent irreversible decline or death to secure urgent funding outside the annual commissioning cycle;**
- **The thresholds set for in-year service developments are extremely demanding and for Individual Funding Requests potentially insurmountable, calling into question the true purpose of the latter process;**
- **The seven documents required as part of an in-year service development risk delaying a process intended, by definition, to take much less than a year to complete;**
- **The need for IFRs to demonstrate exceptionality while providing evidence of clinical and cost effectiveness is contradictory and potentially self-defeating;**
- **NHS England should significantly review and revise these policies as a result of this consultation in order to establish a sensible, realistic and clear set of generic policies to complement its annual commissioning cycle**
- **It also needs in each case to include examples of the types of application which would be successful to help guide potential applicants;**
- **In the Alliance's view, the documents as they stand do not provide an ethical basis for decision-making.**

OVERVIEW

The consultation document describes a set of distinct policies which are in truth closely interrelated. This needs to be acknowledged with perhaps a flowchart demonstrating, for example, when an IFR triggers the need for an In Year Service Development or should more appropriately be considered as an experimental and unproven treatment.

On the financial front, the Alliance is concerned that NHS England seems to make no budgetary provision for IFRs and other treatment outside normal commissioning policies, even though past experience should lend a degree of predictability around the quantum of such costs. The suggestion that individual funding decisions will involve drawing against budgets affecting the care of other patients in-year is unnecessary and divisive.

More fundamentally, the revised proposals seem to have lost some of the intellectual coherence of the current IFR and related policies. In particular, the clear definition of a patient cohort as comprising more than 20 patients nationally has been dropped leaving panels to make a potentially arbitrary judgement in that regard. The Alliance also remains firmly of the view that a highly restrictive approach to individual requests is contingent on an expeditious approach to the development of national commissioning policies, which remains elusive. In the meantime, an ability to consider clinically critically urgent cases remains ethically essential.

In similar fashion, there is ample information about proposals which would not satisfy the criteria for approval under each of the policies but an absence of guidance on what would pass muster. This is particularly the case with Individual Funding Requests where, on a strict reading of the proposal, more than one patient nationwide could potentially render an application ineligible. A conundrum then arises between the need for a patient to be exceptional and the need for evidence of clinical and cost effectiveness which would, almost by definition, be scant. On that basis, the Alliance would favour the policy on funding for experimental and unproven treatments being an integral part of NHS England's approach to Individual Funding Requests. The problem is all the more acute for rarer diseases, where evidence of clinical effectiveness is harder to demonstrate given the nature of the associated evidence base.

In conclusion, as part of a transparent approach to funding decisions outside normal commissioning policy, NHS England needs to show a genuine desire to facilitate the treatment of appropriate patients, even if narrowly drawn. The weakness of the current proposals is that they can be read as providing carte blanche to deny funding in virtually all conceivable circumstances.

CLINICAL CRITICAL URGENCY

Where patients are at clear risk of substantial and irreversible deterioration in their condition, or death, within three months, NHS England has had in place a process to handle requests for treatment funding expeditiously in the absence of a national policy.

Given that this links so closely to the in-year service development and IFR policies, the Alliance has been clear for many years that the clinical critical urgency (CCU) process should be considered alongside those policies. Its omission from this consultation, as indicated on page 11 of the consultation document, therefore represents a serious flaw from the SHCA's perspective.

The close links between this process and the others are indicated by the multiple references to cases of urgency throughout the consultation document. In these instances, it is unclear whether the provisions in the consultation document, eg an IFR Panel meeting every two weeks, or the contents of the CCU standard operating procedure, take precedence.

The case for urgency

Returning to first principles, it is vital that the NHS has an effective mechanism for rapidly assessing and making available interventions which can prevent or ameliorate substantial deterioration in a patient's condition, or death, outside its usual processes. There may be occasions where a patient would otherwise become eligible for a treatment too late.

It is also clear that such a process would apply to relatively few patients, given that the majority of healthcare interventions will already be covered by clinical commissioning policies. As such, NHS England's potential cost and process exposure is low.

In the absence of a CCU policy, patients and their clinicians are faced with only the IFR or, more often, the in-year service development processes to call upon. These are clearly unfit for purpose in the case of clinical urgency. The seven reports required for an in-year service development policy, as well as the need to await a CPAG meeting, mean that this process is inappropriate. Equally, the IFR process screens out cohorts (now at an unspecified and potentially even lower threshold than before) and is therefore not appropriate either.

NHS England must urgently put in place a clear process to give clinicians, patients and their representatives the clarity they need on how those at serious risk of death or irreversible decline within three months can apply for funding outside the annual commissioning cycle. The related criteria need to be practicable within the intended timeframe with examples of applications which would and would not prove successful. The current CCU process does not satisfy these criteria.

IN-YEAR SERVICE DEVELOPMENTS

The proposals for in-year service developments bring some clarity to the definition and scope of the policy.

Process

By definition, the in-year service development policy needs to be relatively rapid in order to be completed part-way through any given year.

To date, even where the need for an in-year policy has been recognised, this has often failed to transpire. NHS England should audit its performance in delivering in-year service policies where work has begun.

As such, the Alliance is concerned about the burdensome process outlined in the consultation document. While it is understandable that NHS England wishes to apply similar rigour to in-year service developments as to annual prioritisation proposals, the need for seven separate reports to be prepared on each in-year service development seems unduly bureaucratic.

Moreover, unless Clinical Reference Groups are always ready and prepared to begin work on preparing those documents, there will be added delay in seeking to fit an in-year service development within a CRG's existing workplan. In practical terms, unless there is an abbreviated process for in-year service developments, the majority are likely to fall into the next annual prioritisation round regardless. The proposals do not therefore meet the primary objective for an in-year process.

While the SHCA welcomes the flexibility in the process to forgo public consultation in the case of urgency in the development of an in-year service development, this alone is insufficient to form an accelerated process.

In a fair system, where the value of a product outside national policy has been demonstrated via an IFR or as an in-year proposal, access should be facilitated pending implementation of a policy via IFRs with the removal of the exceptionality criteria. This would see clinically and cost effective products available for patients who can benefit from them without a hiatus due to NHS England administration.

Concerns on how in-year service developments align with CRG work programmes also point to a wider concern on meeting CPAG deadlines. If proposals must wait for the next meeting of CPAG to be confirmed, the likelihood is of a very lengthy process indeed. NHS England should model the proposed route for an in-year service development from initiation to completion, ensure that it is fit for purpose and otherwise determine if there is scope for greater efficiency and timeliness.

Timelines

In the short term, the policy will need greater explanation given the irregularity of the annual commissioning cycle. Since 2013, the annual prioritisation process was held in June 2014, July 2015 and July 2016, with the latter subject to successful legal challenge and further delay. Given that NHS England plans to align its commissioning cycle with the start of financial years, and that in 2017 it is anticipated that an annual prioritisation process will again be held mid-year, the timelines for in-year service developments need to be clarified. In effect, if the commissioning cycle for 2017/18 is much less than a year, there will not be an in-year process.

Outcomes

Where an in-year service development is not cost neutral or cost saving, NHS England stipulates that proposals need to demonstrate "such an exceptional degree of improved patient outcomes" to be eligible. However, there is no further

explanation of criteria to define these outcomes, leaving such assessment entirely within the gift of NHS England.

For the process to be meaningful, clinicians, patients and companies need to have a much better if not complete understanding of the circumstances and interventions which might be eligible as in-year service developments to aid their planning.

Costs

The revised in-year service development policy describes NHS England's desire for proposals "usually" to be cost saving or cost neutral over a five year period. It would be helpful if NHS England elaborated on the associated figures, to clarify whether upfront expenditure with savings accruing in later years is eligible. Moreover, if such savings fell to another commissioner, eg Clinical Commissioning Groups, whether this would change NHS England's assessment.

There is also ambiguity in the consultation document's reference to affordability. This suggests that, even if proposals met all criteria for an in-year service development and also secured a recommendation for in-year funding from CPAG, the introduction of the treatment in-year could be delayed or prevented given broader affordability concerns.

This also highlights a further question on the funding for the in-year service development process. Given that the previous year's annual commissioning round will have allocated all discretionary investment for specialised commissioning, what arrangements is NHS England putting in place to enable in-year service developments meeting the criteria in the consultation to receive funding? It should be clear to all stakeholders that NHS England is able to deliver on the potential funding outlined in this process, rather than working under a presumption that qualifying proposals will not be approved or in practice delayed until the following year's annual prioritisation decisions.

INDIVIDUAL FUNDING REQUESTS

The proposals for Individual Funding Requests are of significant concern for the Alliance. Taken as a whole, the policy represents a further substantial clampdown on IFRs and makes it very unlikely that many will be accommodated in future. Given the clear need for a functioning process to recognise individual exceptionality, this is a problem.

Cohorts

NHS England's proposal to remove the threshold of 20 patients to represent a 'cohort', taken together with the criterion that it should be "unlikely that there are other patients with similar clinical conditions" essentially raises the exceptionality requirement to unrealistic levels. NHS England would have carte blanche to define a cohort, rather than having this set out more objectively.

Evidence requirements

Another area where the consultation document sets out impractical requirements is in relation to evidence of clinical and cost effectiveness. Given the very stringent criteria for patient exceptionality, the likelihood of "high quality published evidence" is negligible, particularly when coupled with evidence of cost effectiveness on an individual patient basis, a contradiction in terms. While the Alliance recognises the need for evidence and value to help inform IFR decisions, the import of the consultation document is that rigid standards are set so high as to be frankly unachievable.

Sign off

The SHCA was also confused by the inclusion of an additional layer of sign off in the Individual Funding Request process involving the Medical Director of an applicant clinician's trust.

Specialists in the particular field will generally be best placed to know the needs of their patients and act in their best interests. They should also be trusted not to submit vexatious claims. The concern is that, as well as frustrating the clinical workforce, this additional requirement introduces further delay to the IFR application process.

Appeals process

While welcoming the inclusion of an appeals process within the IFR policy, the Alliance is concerned that any appeals appear to be made to the same IFR panel which handled the first application. For good governance, appeals should be directed elsewhere.

EXPERIMENTAL AND UNPROVEN TREATMENTS

The Alliance has no comments on the draft policy as such. However, given the very restrictive terms applicable to IFRs, it seems likely than many would need to be considered as experimental and unproven treatments if they were to receive funding at all. On that basis, it would seem sensible to integrate the two policies more closely if not completely.