Specialised Healthcare Alliance
FOR EVERYONE WITH RARE AND COMPLEX CONDITIONS

SHCA Briefing: NHS England's 'Standard Operating Procedure for funding requests for clinically critically urgent treatment outside established policy'
June 2015

On 11th June 2015, NHS England published its SOP for urgent treatment funding. This followed a prolonged hiatus following the expiry in March 2014 of Specialised Services Circular 1315 on Individual Funding Requests for Clinically Urgent Treatment Outside Established Policy.

The new policy is intended for cases where no national clinical commissioning policy, policy statement or NICE Technology Appraisal exists, and where a patient is otherwise at risk of "imminent significant and irreversible clinical deterioration (life threatening or major loss of function) i.e. within the next 4 months".

While the publication of the policy is an advance on the previous situation, under which there was no visible mechanism by which patients could access treatment before a national policy was developed, there remain fundamental issues.

The Alliance is concerned that the high thresholds for evidence of effectiveness and the ambiguous criteria for cost-effectiveness, alongside a potentially lengthy IFR panel decision-making process, risk undermining the purpose of the critical funding procedure.

In particular, this represents a major departure from the 2013/14 critical access policy, which was said to provide the basis for the new SOP and set out the clear principle that, for critically urgent patients, 'any funding decisions take second place to the clinical needs of the patient.'

Commentary on the new SOP

1) Cost-effectiveness thresholds

The new SOP makes repeated references to 'usual' levels of cost-effectiveness used by NHS England, without defining these. This is a serious weakness of the policy and without a clear definition of the cost-effectiveness levels required the merit of the policy is impossible to judge.

For example, the policy states that:

"*because this process cannot be as comprehensive in approach as the clinical commissioning policy development process in order to reach rapid decisions, the strength of the evidence base must be convincing and likely to be* ***cost-effective well within usual thresholds***" (p6)

Additionally:

"*An interim commissioning position to commission the service in-year (until a definitive decision is reached through the in-year service development process or*

annual prioritisation round) ***will not be approved unless*** *NHS England can reach a clear conclusion that the following tests are satisfied:* ***the proposed service development is both supported by strong sufficient evidence that it is clinically effective and cost effective well within usual thresholds"*** (p8)

Furthermore, there are potential practical difficulties in the implementation of the policy, given that a criterion for funding is:

"What is the overall net cost of the proposed intervention and does it represent good value for money? The intervention must demonstrate a ***high probability of being cost effective well within usual thresholds used by the NHS."*** (p7)

NHS England must provide a clear definition of "high probability". It is unclear how applicant clinicians will be able to ascertain the answers to these criteria without undue delay. The SOP arguably confuses the need to take a rapid treatment decision for an individual patient in urgent clinical need with an evaluation of the treatment for a cohort of patients. It also fails explicitly to recognise the impact of rarity on the evidence base and cost of treatments.

2) Timeframes

The urgent access process is limited to patients in critical need within a maximum of four months. For this reason, it is vital that the urgent access process functions as rapidly as possible.

In that context, it is of potential concern that the urgent access process gives no indication of maximum or expected timeframes. Secondly, the instruction within paragraph six that clinicians acting on behalf of a patient in urgent critical need must first apply for funding through the Individual Funding Request (IFR) route, even if the patient would clearly form part of a cohort and therefore be ineligible for an IFR.

The SOP goes on to say that:

"The IFR Policy and SOP will initially apply but where a request is declined as an IFR because the patient is representative of a cohort and an individual funding request is not appropriate, and the request meets the criteria in paragraph 1 above, an application may proceed under the arrangements outlined below." (p5)

This gives little reassurance that the urgent access policy has safeguards in place to ensure swift enough treatment for patients in critical need. It seems a contradiction in terms and highly inefficient to put in place a procedure for people in urgent clinical need who are ineligible for an IFR and then to insist that their treating clinicians apply for an IFR.

3) Formation of an interim commissioning policy

Under the SOP, an IFR Panel must decide whether to "give approval, creating an interim commissioning position", or "decline to approve, creating an interim

commissioning position".

The twinning of a decision on a critically urgent individual's case with the creation of an interim commissioning position is problematic.

The purpose of the SOP is to allow individual patients within a cohort urgent access to treatment and the risk is that the generalising of an individual decision into an interim commissioning position raises the burden and evidence thresholds for decisions on an individual's care.

Furthermore, if a weak first application was rejected, a generalised policy would prevent stronger future applications for other patients in the same cohort.

While setting an interim policy to reduce the burden on future applicants could make sense in certain cases, the approach of the 2013/14 policy would seem preferable, focusing on limited, individual access for a patients in critical need pending expeditious work on a national commissioning policy through the usual processes.

4) Links with other documents

This SOP is inextricably bound up with the principles of NHS England's prioritisation framework and three further generic policies: the In-Year Service Development policy, the Individual Funding Request policy and the policy on NHS England's Approach to Treatments Not Yet Assessed and Prioritised.

Without opportunity for public comment on each of these documents, the strength of the suite as a whole cannot be assessed. In particular, the policy on NHS England's Approach to Treatments Not Yet Assessed and Prioritised must urgently be consulted upon alongside this SOP.

5) Monitoring requirements

The inclusion of monitoring requirements within the process where interim funding is agreed is a sensible inclusion which can help to generate further evidence to inform a future national commissioning policy.