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

This is an edited version of the document e-mailed to NHS England as our consultation response in January 2017.

About the Neurological Alliance

The Alliance is the only collective voice for 80 organisations working together to make life better for millions of people in England with a neurological condition. We work with our member organisations to ensure better services and outcomes for all those with a neurological condition. For more information about the Neurological Alliance, please see www.neural.org.uk

Summary

This consultation response covers the NHS England consultation exercises on four proposed generic commissioning policies:

- In-year service developments
- Individual Funding Requests
- Funding for experimental and unproven treatments
- Continuing funding after clinical trials

We welcome the opportunity to comment on these proposed policies. NHS England's current generic commissioning policies were adopted on an interim basis in March 2013 with a commitment to review in the same year. The adoption of permanent policies is therefore long overdue. However, we have concerns about the proposed policies as they currently stand, particularly around the extremely high thresholds and lengthy processes proposed for In-Year Service Developments (IYSDs) and Individual Funding Requests (IFRs). In addition, we are concerned about the absence from this consultation of a policy for access to clinically critically urgent treatment outside established policy. There is currently an interim policy for funding treatments for patients at clear risk of substantial and irreversible deterioration in their condition, or death, within three months, but it is not included in this consultation exercise. It is essential to patients' welfare that there is a clear process for accessing funding in these cases.

General comments

It is positive that NHS England is now putting forward proposals to replace the interim generic commissioning policies established in 2013. However, it is a serious concern that a policy for clinically critically urgent (CCU) cases has not been included. It is not clear whether the interim policy will be retained or whether a permanent policy is planned. Given the life-threatening nature of these cases, it is absolutely essential for

patients that a clear process is in place to access treatments that are not routinely commissioned, and that the process will be responsive and efficient.

Our specific comments relate to the proposed IFR and IYSD processes and are set out below. We are very concerned about a number of aspects of the proposed policies, including:

- **Lack of clarity on acceptance criteria:** the language used to define the acceptance criteria of applications made through the proposed processes is unclear, and does not provide useful guidance for clinicians or patients. This creates uncertainty for patients, at a time when they are likely feeling a high level of anxiety anyway, and may lead to a higher number of unsuccessful applications, placing an avoidable strain in the application process. NHS England should provide examples of successful applications and clear definitions of all eligibility criteria. Please see comments on the IFR and IYSD processes below.

- **Excessively high acceptance thresholds**: the high acceptance thresholds proposed for the IFR and IYSD processes, while often unclear, also appear excessively demanding. For example, the proposed IFR evidence requirements do not appear to take into account the exceptional and rare nature of IFR cases. 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. Please see further comments below.

- **Lengthy processes:** we are extremely concerned that the proposed processes are unnecessarily lengthy and bureaucratic, and that this will undermine their effectiveness. For example, the need for seven separate reports to process an IYSD application makes it highly unrealistic that the proposed service developments will be able to be assessed in-year as intended, without running to the next annual prioritisation round. Please see comments on the IFR and IYSD processes below.

- **Monitoring and review:** 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.

Individual Funding Requests (IFR)

The proposed IFR policy removes the threshold of 20 patients to represent a 'cohort', adding instead the criterion that it should be "unlikely that there are other patients with similar clinical conditions." This unjustifiably extends the exceptionality requirement for IFRs and creates uncertainty around the definition of a cohort. NHS England should retain an objective standard for defining a patient cohort in order to provide clarity to patients and to clinicians submitting requests on their behalf.

The consultation document sets out requirements for "high quality published evidence" of treatment effectiveness. This is a dangerous approach, creating unfair obstacles in

cases where patients require a treatment for which evidence is limited - for example, when the rarity of a condition limits the availability of research evidence, or where a treatment cannot be subjected to blind testing. It is essential that people affected by rare conditions are not unfairly disadvantaged by the IFR process, and that evidence requirements are not set at an impractically high level. In addition, 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. The proposed evidence requirement therefore appears to completely contradict and undermine the purpose of the IFR process.

The proposed IFR process requires sign-off by the Medical Director of an applicant clinician's trust. This will introduce further delay into the process and take up a Medical Directors' time unnecessarily. Individual clinicians must be trusted to assess the needs of their patients and judge for themselves the need for an IFR application, in consultation with the patient.

In-year service developments (IYSD)

The proposed IYSD process, involving seven separate reports, appears burdensome and time-consuming. Clinical Reference Groups, which rely on time volunteered by clinical and patient representatives, will struggle to prepare these documents in a timely manner while fulfilling their existing duties. This is highly likely to create additional delays in the process. This defeats the object of IYSD, which is intended to be an accelerated process.

The proposed policy includes a criterion that IYSD proposals that are not cost-neutral or cost-saving must demonstrate "an exceptional degree of improved patient outcomes." This is unclear and is not defined further. A clear definition of what constitutes an "exceptional degree" of improvement is needed. This could also help to reduce the volume of applications that do not meet the defined criteria. Similarly, the proposed policy needs more clarity on NHS England's desire for proposals to ordinarily be cost saving or cost neutral over a five year period. This should include consideration of whether cost savings accruing to commissioners other than NHS England (i.e. Clinical Commissioning Groups) would fulfil this requirement.

Clinical critical urgency

NHS England currently has in place an interim policy for funding treatments for patients who are at clear risk of substantial and irreversible deterioration in their condition, or death, within three months. We are very concerned that this policy has not been included alongside the IYSD and IFR policies within this consultation. It is essential to patients' welfare that there is a system in place for patients to access non-routinely commissioned treatments more rapidly than the IFR or IYSD policies allow, if there is a clinically urgent need to do so. This would apply only to a relatively small number of patients.

It is clear that the IFR and IYSD policies set out in this consultation are not fit for purpose. The IFR process screens out patient cohorts and is therefore not appropriate for individuals in this position. The IYSD process requires seven submitted reports and approval at a **Clinical Priorities Advisory Group** meeting, and consequently takes too much time for patients in the most urgent need. NHS England should urgently consult on a permanent policy on clinically urgent treatments in order to introduce it alongside the other proposed policies. In order to fulfil the requirements of an effective process for clinically urgent cases, the approval criteria must be clearly set out and deliverable within a short timeline.

I would be happy to meet with you or members of your team to discuss our concerns in more detail and provide whatever support we can on improvements to the proposals outlined in the consultation.

Yours sincerely,

Sarah Vibert
Chief Executive
The Neurological Alliance