NHS England

Procedural note: non-submission of data to NICE

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1 Background to NICE Technology Appraisal/Highly Specialised Technologies (TA/HST) process

1.1 The NICE (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 indicate that:

- NICE may make a technology recommendation in relation to a health technology identified in a direction by the Secretary of State
- relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients.

1.2 The Health and Social Care Act 2012 states that in exercising its functions, NICE must have regard to:

- the broad balance between the benefits and costs of providing health services or of social care in England
- the degree of need of people for health services or social care in England and
- the desirability of promoting innovation in providing health services or of social care in England.

1.3 The Regulations within the Act require clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities, to comply with NICE technology appraisal guidance that recommends the relevant health service body provides funding within the period specified. When NICE recommends that a treatment be funded by the NHS, the Regulations require that the period within which the health service must comply will be stated in the recommendations as three months, except when particular barriers to implementation within that period are identified.

1.4 The technology appraisal and highly specialised technologies processes are designed to provide recommendations, in the form of NICE guidance, on the use of new and existing medicines and devices, products and treatments in the NHS.

1.5 The technology appraisal process is specifically designed to appraise a product, device or other technology, for a single indication. The process normally covers new technologies (typically, new pharmaceutical products or license extensions/variations) and enables NICE to publish guidance soon after the technology is introduced in the UK. NICE seeks relevant evidence from several sources. The company submits the principal evidence. The evidence review group (ERG), an external academic organisation independent of NICE, produces a review of the evidence submission. Consultees provide information and selected clinical experts, NHS commissioning experts and patient experts also give evidence.

1.6 An appraisal is based on a review of clinical and economic evidence, mainly provided by the company, supported by testimonies from patients, healthcare professionals and commissioners. Clinical evidence shows how well the

technology works – the health benefits. The evidence includes the impact on quality of life (for example, pain and disability), and the likely effects on mortality. Economic evidence shows how well the technology works in relation to how much it costs the NHS and whether it represents value for money.

1.7 The appraisal committee considers the evidence and decides whether or not the technology should be recommended as a clinical and cost-effective use of NHS resources, or whether it should only be recommended for specific groups of people.

1.8 The appraisal committee provides its recommendations to NICE in either an appraisal consultation document (ACD) or a final appraisal document (FAD). Normally, the committee produces an ACD only if its preliminary recommendations are substantially more restrictive than the terms of the marketing authorisation for the technology being appraised or do not recommend use of the technology. If the committee produces an ACD, then NICE invites consultees, commentators and the public to comment on it. After considering these comments, the committee finalises its recommendations and provides them to NICE in the form of a FAD. The FAD forms the basis of the guidance that NICE issues to the NHS in England.

2 Non-submission to NICE

2.1 NICE aims to ensure that the company prepares the best possible evidence submission for the appraisal committee. NICE will not validate the submission but it will help to clarify substantive issues. If, after all reasonable requests for clarification, NICE is not satisfied that the evidence submission is adequate for the appraisal committee to make a decision or if no evidence submission has been received, the centre director or programme director will recommend to NICE's guidance executive that the appraisal should be terminated. NICE will inform the company that an inadequate evidence submission has been received. NICE will subsequently advise the NHS that the appraisal has been terminated and that NICE is unable to make a recommendation about the use in the NHS of the technology because no evidence submission was received from the company.

2.2 A terminated appraisal can be restarted if the company indicates that it wishes to make a full evidence submission.

3 NHS England response to a non-submission to NICE

3.1 NHS England will consider licensed medicines or medical technologies for routine commissioning where the intervention has not been selected for appraisal by NICE through their TA or HST programmes.

3.2 The NICE process relies primarily on the company to submit data to undertake a TA/HST appraisal. When such evidence is not submitted, NICE are unable to make a recommendation to the NHS and it is important that NHS England takes due consideration of the non-submission.

3.3 Where NICE cannot make a recommendation to the NHS about a medicine/indication or medical technology due to non-submission of data by the company for the indication in question, NHS England's default position will be to not routinely commission the intervention for the stated indication. In other words, NHS England will not place a policy proposition onto the work programme where the company has not engaged with NICE. This is to avoid a potential pathway for circumventing the NICE process.

3.4 In exceptional circumstances, NHS England may consider developing a policy statement to offer an interim clinical commissioning position provided the following conditions have been met:

- the company have indicated that they are now willing to submit evidence to NICE and NICE have indicated they will recommence their appraisal **AND**
- where timescales for consideration of the evidence submission may result in significant harm to the patient population who may benefit from the medicine under consideration **AND**

- there is sufficient evidence of significant clinical benefit that NHS England would wish to commission the medicine prior to publication of final NICE guidance

3.5 The interim clinical commissioning policy statement will be considered following the process described in the Methods: National Clinical Policies document.

3.6 If an interim clinical commissioning policy statement is published supporting an intervention/indication and the final NICE recommendation is not to recommend that intervention/indication within the NHS then the policy statement will be withdrawn with immediate effect and no new patients will be eligible for access to the intervention/indication.

3.7 People already receiving the intervention/indication under the criteria of the clinical commissioning policy statement may continue until they and their NHS clinician consider it appropriate to stop.