Interim Addendum to the Diagnostics Assessment Programme Manual

Access proposals from the sponsors of diagnostic technologies

Introduction

1. This document is an addendum to the NICE Diagnostics Assessment Programme Manual published in December 2011. The purpose of the addendum is to set out how NICE deals with access proposals put forward by companies in the course of evaluations on the Diagnostics Assessment Programme (DAP), in particular during public consultations on draft guidance. An access proposal may involve an arrangement that allows the NHS to acquire a product at a price lower than the normal NHS acquisition price. An access proposal was received from a manufacturer in an early DAP topic. This addendum was developed to provide a formal basis for handling any future access proposals.

General Considerations

2. In diagnostic assessments, cost effectiveness analysis is normally undertaken with the aim to incorporate the entire treatment pathway facilitated by the diagnostic and not the direct cost of the diagnostic test alone. In many cases, the cost of the diagnostic test is a small proportion of the cost of the overall pathway. Therefore, access proposals are likely to apply mainly where the NHS acquisition cost of the diagnostic test contributes a relatively large proportion of the overall treatment pathway costs.

3. NICE only considers access proposals in circumstances where:

    a. the Diagnostics Advisory Committee (DAC) has accepted that the diagnostic delivers measurable clinical benefit **and**;
    b. the most plausible incremental cost effectiveness ratio (ICER) is higher than the normal threshold range; **and**
    c. the acquisition cost of the diagnostic is a key driver of the incremental cost effectiveness ratio, taking into account the overall pathway costs included in the evaluation.

4. In considering access proposals for diagnostics, the level of confidentiality required by the sponsor are taken in to account, with transparent pricing proposals being considered more favourably. NICE balances this consideration with the potential clinical importance of NHS patient access to the diagnostic technology under evaluation. NICE must be satisfied that sufficient information can be communicated to stakeholders to explain the guidance recommendations. In addition, the NHS must have access to the revised price when final NICE guidance is made available, so Trusts and commissioners are able properly to account for the access proposal in their local procurement.

5. NICE only considers proposals from companies that involve a straightforward adjustment to the acquisition cost to the NHS. Outcome based proposals are not considered and proposals should not involve additional clinical reporting requirements, such as collection of outcome data. This is to avoid placing an excessive administrative burden on the NHS.

Acquisition costs in assessing diagnostics

6. NICE aims to capture a realistic acquisition cost as a standard component of the diagnostic assessment report. Care is taken to ensure that the acquisition cost used in analyses is representative of the normally available acquisition price across the NHS. Where acquisition cost information is inconclusive, Specialist Committee Members are asked to advise on realistic figures. The external assessment group also explores residual uncertainty about acquisition costs in scenario analysis. Consultees are able to make comments during public consultation if they consider costings to be inaccurate.

Process for handling a**ccess proposals from the sponsors of diagnostic technologies**

7. NICE will normally only accept access proposals during the first public consultation period on its draft guidance. Where a company wished to propose a price to the NHS lower than its normally available price at the beginning of the assessment, NICE would incorporate this into the assessment as long as the price was transparent.

8. If, during consultation, an access proposal is received from a sponsor, the NICE DAP team arranges a meeting or teleconference with the sponsor to clarify the terms and details of the proposal.

9. The proposal along with relevant information from the sponsor meeting is considered by the DAP Associate Director and DAC Chair. An access proposal report (APR) is prepared including:

    a. **The relevance of the proposal:** Taking account of the issues outlined in paragraph 3, the relevance of the proposal is considered. In cases where the committee considered that there was not sufficient evidence to make a reasonable estimate of clinical outcome benefits, the proposal is not considered further. The external assessment group may be requested to explore the impact of the proposal on the cost effectiveness of the diagnostic. Where the acquisition cost of the technology is a minor component of the care pathway cost the proposal is also not considered relevant.

    b. **The level of transparency / confidentiality requested in the proposal:** NICE has a strong preference for transparent pricing and in all cases NICE must be satisfied that sufficient information can be communicated to stakeholders to explain the guidance recommendations. In addition, the NHS must have access to the revised price when final NICE guidance is made available, so Trusts and commissioners are able properly to account for the access

proposal. Proposals including a confidential NHS access price are considered only in exceptional circumstances and at the discretion of NICE.

c. **The workability and efficiency of the proposal:** The proposal should be a simple, financially based proposal. Practical arrangements for operating the proposal should be straightforward, effective and auditable. The NICE Health Technologies Adoption Programme team may approach Trusts, Clinical Networks and others to seek further information from the NHS on the practicability of implementing the scheme.

d. **Recommendations:** The APR will include a recommendation on whether or not to consider the access proposal further.

10. The APR is sent to the NICE Programme Director and/or Centre Director for review and approval.

11. Where the APR includes a recommendation for the further consideration of the access proposal, NICE requests further economic analyses by the external assessment group based on the revised price in the proposal. If sensitivity analysis on cost has already been undertaken as part of the initial assessment, the cost effectiveness of the technology may have already been assessed at the access proposal price, in which case further economic analysis is not necessary.

12. The APR is presented to the DAC and considered along with all consultation comments at the second DAC meeting for the topic. Where possible, the second DAC meeting for the topic will be held on the date scheduled and communicated on the NICE website at the start of the assessment. In some cases, however, this will not be possible and the topic will be rescheduled (see section 15 below).

13. If, as a consequence of the access proposal or any other consultation comments, the DAC significantly changes the guidance recommendations, a further consultation may be required as detailed in the Diagnostics Assessment Programme Manual section 7.3. NICE will not accept further access proposals presented during the second or subsequent consultations, from any of the sponsors with products included in the assessment.

14. NICE will not discuss the outcome of access proposals with sponsors outside of the normal DAP processes. As registered stakeholders, sponsors receive consultation documents 5 working days before the public consultation and may also participate in the resolution stage of the process allowing access to the proposed final guidance before publication. Following publication of the final guidance, sponsors may also request a debrief meeting where the access proposals as well as any other issues related to the DAP assessment may be discussed with the NICE team.

15. Where possible, NICE will consider and incorporate access proposals within normal topic timelines. However, in some cases it is likely that responding to

an access proposal will affect the development time of the guidance. The process and indicative timeline for considering access proposals is outlined in Table 1 and Figure 1.

Timeline for considering access proposals

Table 1 *Diagnostics Access proposal phase timelines*

Stage	Days (average) since phase began
Access proposal submitted to NICE by sponsor during the DCD consultation period	0
NICE holds a meeting/teleconference with the sponsor to clarify their proposal	1-2
NICE considers the proposal against the relevance criteria (as defined in section 4)	3
NICE considers the need to reschedule the topic to the next available DAC slot or whether to continue on the original schedule, depending on the need for further analysis*	5
If further analysis is required, NICE requests this from the EAG	Variable, as required
Where requested, the EAG provides additional analysis to NICE for consideration by the DAC	Variable, as required
NICE signs off a report on the sponsor's proposal for the DAC	Variable
The DAC meets to consider consultation comments and additional documentation relating to the access proposal	As scheduled

** Topics will only be rescheduled when in-depth additional analysis is required. Where possible, topics will be considered by the Diagnostics Advisory Committee as originally scheduled.*

Figure 1 ***Steps in diagnostics access proposal process***