**PWG IB (10)05**

**Updating technology appraisals in the context of clinical guidelines – paper for agreement**

Purpose

1. This paper is a product of discussions between DH, NICE and Industry. It clarifies the process for reviewing NICE technology appraisals and describes the criteria used to guide decisions on whether technology appraisals (TAs) should be updated in the context of clinical guidelines (CGs). Following agreement, the criteria will be incorporated into NICE's processes.

Terminology

**Review** - the process for determining whether a specific piece of NICE guidance is up to date in light of developments post-publication e.g. changes to the evidence base or clinical practice. Following internal discussion at NICE, review proposals are subject to consultation with stakeholders.

Broadly, there are three possible outcomes following the review process; update, incorporate or put on the static list.

**(i) Update** – NICE's guidance is reconsidered in the light of significant new evidence or other developments (e.g. changes in clinical practice). A Technology Appraisal (TA) can be updated through the TA process or can be updated in the context of a Clinical Guideline (CG) or a piece of public health guidance (PHG).

If the appraisal is updated in the context of a CG or PHG and the recommendations are changed as a result, the original TA will be withdrawn and the funding direction will cease to apply to the recommendations.

**(ii) Incorporate** – TA recommendations are lifted unchanged from the original guidance and included in a CG or PHG. The original TA guidance stands along with the funding direction.

There are two scenarios where TA recommendations could be incorporated into a CG;

i. There is a relevant CG in development but there have been no significant new developments that require an update of the original TA; or
ii. Following an update of TA guidance in the context of a clinical guideline, the TA recommendations are unchanged.

**(iii) Static** – the original guidance remains current and there is no relevant CG in development that would warrant incorporation of the TA recommendations. The original TA guidance stands along with the funding direction.

It should also be noted that the review decision is made before the development of the scope for a particular guideline. The decision may need to change following scoping. Any changes to the review decision will be subject to consultation.

Context

2. NICE's published MTA and STA process guides explain that TA guidance can, in addition to the TA process, be updated as part of a CG or public health guidance.

3. In 2002, the Government introduced a funding direction that requires Primary Care Trusts (PCTs) to make funding available for treatments recommended by NICE's technology appraisal guidance within three months of final guidance. When a technology appraisal is updated as part of a CG (or PHG) and the recommendations are changed as a result, the original TA guidance is withdrawn and the funding direction ceases to apply. This ensures that there is no conflicting NICE guidance and applies equally whether CG recommendations on the technology originally covered by the TA are more or less restrictive. Withdrawn TA guidance can still be found on NICE's website with a clear message that the guidance has been updated in the CG and is no longer extant.

4. The update of TA guidance in CGs (or PHGs) can be helpful in ensuring that the CG provides comprehensive best practice guidance for NHS organisations on different conditions. However, because the funding direction cannot apply to recommendations that are changed as a result of an update in a CG, it is important to ensure that TAs are only updated in the context of CGs where it is genuinely appropriate to do so.

5. To this end, outlined below are the criteria that will be used by NICE in guiding the review decision for a TA. The criteria seek to minimise the risk of perverse or unintended effects (such as withdrawal of NHS funding for an intervention that is still assessed as clinically and cost-effective) whilst ensuring that NICE still has flexibility in its processes to enable comprehensive guidance.

Criteria

6. Typically, a TA is likely to be suitable for updating in the context of a clinical guideline if;

   i. The technology falls within the scope of a clinical guideline (or public health guidance)

   ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

   iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

   iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;
      - Spending on a treatment for the indication which was the subject of the appraisal continues to rise

- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed
- The treatment is excluded from the PbR tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

7. These criteria relate to technologies covered by an existing TA. CGs will only be used to carry out a first assessment of a significant new medicine or significant licence extension for an existing medicine where it has been agreed by both DH and the manufacturer that this is appropriate.

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