The challenge of confidential commercial arrangements in health technology assessment: how often do they feature in NICE technology appraisal evaluations?

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Background

The commercial landscape for pharmaceuticals is becoming increasingly complex with increasing numbers of interventions being recommended by the National Institute for Health and Care Excellence (NICE) with confidential commercial arrangements. These interventions subsequently become part of the treatment pathway in future NICE technology appraisals. The number of NICE technology appraisals where inclusion of other confidential commercial arrangements results in the intervention company not being able to clearly understand the true cost-effectiveness of its new intervention is increasing. This study reviewed published NICE guidance to assess how many NICE technology appraisals included technologies with confidential commercial arrangements.

What we did and why

NICE technology appraisal guidance published between April 2021 and April 2022 was identified.

For each appraisal identified, information on confidential commercial arrangements was extracted for:

- Intervention treatment(s)
- Combination treatment(s)
- Comparator treatment(s)
- Subsequent treatment(s)

Terminated appraisals were excluded.

This was done to identify the number of NICE technology appraisals that included confidential commercial arrangements, allowing for the assessment of the scale of the challenge around balancing transparency in NICE decision making and protecting confidential pricing information.

Table 1: Confidential commercial arrangements in technology appraisal guidance published between April 2021 and April 2022

7 pm 2021 and 7 pm 2022		
	Percentage	Pieces of guidance
Guidance published between April 2021 and April 2022	100%	76
Confidential commercial arrangement anywhere in the treatment pathway	94.7%	72
No confidential commercial arrangements for any treatments	5.3%	4
Confidential commercial arrangement for the intervention only	26.3%	20
Confidential commercial arrangement for non-intervention treatments only	3.9%	3

Outcomes and impact

Seventy-six pieces of guidance were published between April 2021 and April 2022 (excluding terminations).

Seventy-two appraisals (94.7%) had a confidential commercial arrangement in the treatment pathway.

- Sixty-nine (95.8%) of these had a commercial arrangement for the intervention, of which 49 (71.0%) also had a confidential commercial arrangement elsewhere in the pathway.
- Three appraisals (4.2%) had no commercial arrangement for the intervention but had a confidential commercial arrangement elsewhere in the pathway.

Only four appraisals (5.3%) had no commercial arrangements for any of the treatments in the treatment pathway.

Types of confidential commercial arrangements

Simple Patient Access Schemes (PASs)^{1, 2}

- Fixed price or percentage discount on the list price that is applied at source across all indications for a technology.
- Always the preferred option as they require less monitoring and minimise administrative burden on NHS organisations.

Confidential Commercial Arrangements (CCAs)³
Example formats for CAAs include budget caps, price and/or volume agreements, and cost sharing arrangements.

CAAs are at the discretion of NHS England and may be considered when:

- The company proposes an enhanced value offer
- Unusual or unique circumstances mean launching a product is particularly challenging or commercially unviable

What we learnt

Almost all NICE Technology Appraisal evaluations now include treatments that have a confidential commercial arrangement.

Where there are confidential commercial arrangements for treatments in the pathway other than the intervention, NICE is unable to publish the committee's decision-making incremental cost-effectiveness ratio and the intervention company may not know its true cost-effectiveness. This is an increasingly common problem affecting NICE guidance production.

Work continues to find a solution that balances transparency of the intervention's cost-effectiveness with protecting confidential pricing information of other treatments in the appraisal.

"The credibility of the guidance produced by NICE depends on the transparency of the committee's decision-making process."

NICE²

"We have...expanded the commercial flexibility offered to the industry for the best value new treatments, delivering the greatest clinical benefits at the lowest cost. We expect this to benefit patients, the NHS, individual companies and the life sciences sector more broadly."

NHS England³

References

- Department of Health and Social Care (2018) The 2019 voluntary scheme for branded medicines pricing and access
- 2. NICE (2022) NICE health technology evaluations: the manual
- 3. NHS England (2021) NHS commercial framework for new medicines

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