DEAL OR NO DEAL: TWENTY YEARS OF PRICING AND ACCESS AGREEMENTS IN PRODUCTS ASSESSED BY NICE

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BACKGROUND/INTRODUCTION

At the turn of the century, UK pharmaceutical prices were generally high relative to other jurisdictions, e.g. southern European markets, reflecting the UK's status as a 'free pricing' market. New technologies were typically launched as early as possible in the UK, following European marketing authorisation, taking advantage of international reference pricing regulations.

However, with the introduction of the National Institute for Health and Care Excellence (NICE) in 1999 and the formal application of cost-effectiveness analyses in the appraisal of new technologies, the UK's position as an early launch market can no longer be assumed. It has become increasingly difficult to achieve reimbursement in the UK at a European "target price" or even at a price within a typical European price corridor.

Patient Access Schemes (PAS) can mitigate against this and were introduced as a formal component within Health Technology Assessments (HTA) in the 2009 Pharmaceutical Pricing Regulation Scheme (PPRS) (1). The 2014 PPRS additionally included definitions for simple and complex schemes (2). The 2019 update to this scheme (3) committed NHS England to publishing a commercial framework, which lays out these schemes in addition to other commercial options (e.g. managed access agreements) (4).

Such schemes are designed to reduce decision uncertainty, for example by gathering additional evidence in the period following reimbursement or by implementing a discounted price for the NHS that remains confidential and does not affect the published list price.

Since their introduction, access arrangements such as the PAS have become increasingly common in the UK. As manufacturers continue to optimise pricing for new technologies, the landscape around commercial and confidential arrangements evolves. Here we examine the shift in the type of arrangements adopted by NICE approved products over time.

OBJECTIVE(S)

The objectives of this analysis are:

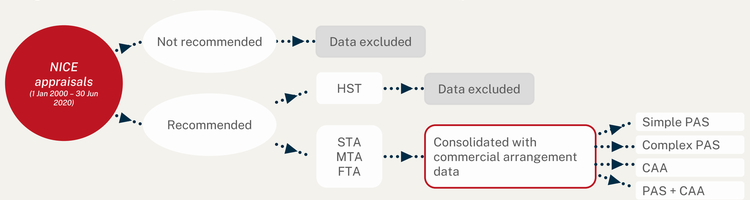
- To describe the trends in uptake of commercial arrangements over time and;
- To compare different arrangements that have been implemented for National Institute for Health and Care Excellence (NICE) recommended medicines.

METHODS

A complete list of non-specialised technology appraisals undertaken by NICE between 1 January 2000 and 30 June 2020 was extracted from the NICE guidance and advice list (5). Published details of Technologies recommended by NICE that include a commercial arrangement were also downloaded from the NICE website (6), and the data on inclusion and type of commercial arrangement was consolidated with the corresponding appraisal. Commercial arrangements were classified as simple PAS, complex PAS, commercial access arrangement (CAA) or PAS + CAA.

Products receiving a negative recommendation from NICE were excluded from data analysis. Products assessed through the highly specialised technology (HST) appraisal route were also excluded due to the significantly higher cost-effectiveness threshold used in the process (£100,000 per QALY). Decisions from multiple technology appraisals assessing more than one product or indication were counted as discrete outcomes.

The number of commercial arrangements (total and by type) was calculated for each year using the number of positive recommendations in that year as the denominator.



RESULTS

A total of 956 discrete decisions relating to 639 appraisals were analysed, of which 739 (77%) were positive. Of these:

- 462 decisions related to 145 multiple technology appraisals (MTA);
- 490 decisions were from standard technology appraisals (STA);
- 4 decisions were the result of fast-track appraisals (FTA).

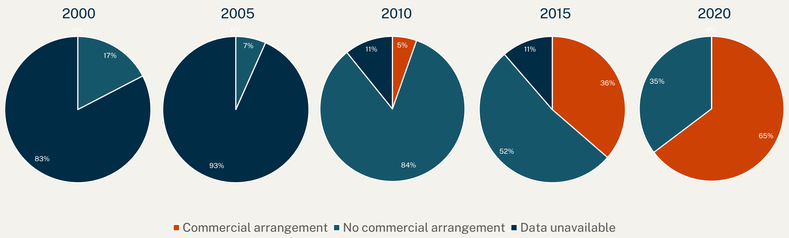
Details of 249 commercial arrangements were available for download, of which 243 related to STA, MTA or FTA. Data was missing or unavailable for 23% of positive recommendations that were subsequently updated and replaced, although the presence of missing data decreased over the analysis period.

The proportion of approved products with a commercial arrangement of any type generally increased from 2007 to 2020, with a peak of 91% (50 of 55 recommended products) in 2018. Over the last 5 years, approximately two thirds of all positive recommendations were supported by a commercial arrangement of some form (**Table 1, Figure 1**)

Table 1 Proportion of NICE recommended products with and without commercial arrangements, 2000-2020

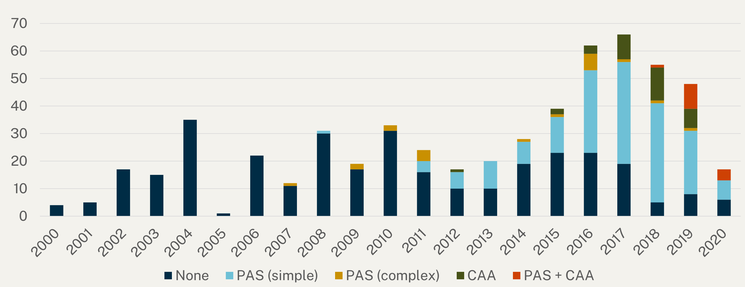
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Commercial arrangement	0%	0%	0%	0%	0%	0%	0%	4%	3%	10%	5%	32%	32%	45%	32%	36%	61%	64%	91%	83%	65%
No arrangement	17%	17%	44%	54%	71%	7%	52%	48%	88%	81%	84%	64%	45%	45%	68%	52%	36%	26%	9%	17%	35%
Data unavailable	83%	83%	56%	46%	29%	93%	48%	48%	9%	10%	11%	4%	23%	9%	0%	11%	3%	11%	0%	0%	0%

Figure 1 Use of commercial arrangements by NICE recommended technologies



The most common type of arrangement since 2007 was the simple PAS (mean=61%). We identified a shift away from use of the complex PAS, towards more frequent use of commercial access agreements (CAA, with or without associated PAS) over the last 5 years (from 14% to 36%). The change in types of commercial arrangement over time are displayed in **Figure 2.**

Figure 2 Change in types of commercial arrangement, 2000-2020 (excluding cases where data is not available)



CAA, Commercial access arrangement; PAS, Patient access scheme.

DISCUSSION

Commercial arrangements have become increasingly common since their introduction, and over the last 5 years, more than half of all NICE recommended technologies are subject to them. Companies may use commercial arrangements to reach an incremental cost effectiveness ratio (ICER) value that falls under the acceptable threshold of £30,000 per QALY, with the NHS preferred method being the submission of a simple PAS for review by the Patient Access Scheme Liaison Unit (PASLU). Indeed, the highest proportion of commercial arrangements are classified as simple PAS across the analysis period.

In general, the number of complex schemes have remained low. Of the 19 recorded over the 20-year period, 14 were based on provision of free stock (primarily in immunology, owing to schemes for certolizumab pegol and golimumab).

However, there has been an increasing trend towards the CAA, both alone and in combination with the PAS. These are particularly prevalent amongst oncology products. In fact, 33 of 34 total CAAs were for products indicated to treat various cancers, and 18 products are subject to recommendation via the Cancer Drug Fund (CDF) which allows for a period of additional data collection prior to later review and update. Similarly, 13 of the 14 products which are subject to a CAA + PAS are oncology treatments falling under the CDF.

Commercial arrangements could theoretically present an opportunity for manufacturers to address uncertainty in a way that is acceptable to the NHS, without the disadvantages of introducing a complex PAS. Complex schemes require full price transparency from the manufacturer, and result in higher burden for the NHS. In contrast, CAAs could be used to negotiate confidential deals that may have historically been subject to inclusion through a complex PAS, where the product is expected to have "value propositions at or below the lower end of the standard NICE cost effectiveness threshold range" (4).

CONCLUSIONS

- Regardless of the route, confidential agreements, in the form of the simple PAS or CAA, are preferred by manufacturers, and continue to be accepted by NICE and the NHS to continue to support reimbursement of many drugs in England.
- There has been an increasing trend towards confidential agreements (both simple PAS and CAA) since 2007. In part this is likely to reflect the challenges of achieving UK access in a wider context of global markets and price referencing.
- CAAs could represent an opportunity for manufacturers with valuable therapies to negotiate deals that may have previously been classified as a complex PAS.
- With the increasing prevalence of high-cost therapies, this is a trend that is set to continue.

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