PDG43

ARE PATIENT ACCESS SCHEMES AND COMMERCIAL ACCESS AGREEMENTS ESSENTIAL FOR NICE TO RECOMMEND ACCESS? A COMPARISON OF ONCOLOGY AND NON-ONCOLOGY APPRAISALS

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Introduction/objective

- In England, the National Institute of Health and Care Excellence (NICE) uses the cost of treatment per quality adjusted life year (QALY) as the basis for its' decision-making. In general, technologies will only receive a positive NICE recommendation if their estimated cost per QALY is below the £20,000 to £30,000 incremental cost-effectiveness ratio (ICER) threshold (although higher thresholds are used for products meeting end-of-life criteria).
- In order to achieve a cost per QALY below this threshold and demonstrate cost-effectiveness, manufacturers often agree confidential financial agreements with NHS England. Financial agreements are often in the form of patient access schemes (PAS) or commercial access arrangements (CAA) (Table 1).
- In recent years, there has been a trend of cancer drugs launching with increasingly high prices and clinical data uncertainty[1], suggesting there may be a greater need for financial agreements for oncology vs. non-oncology drugs. This study aimed to compare the use of financial agreements for oncology and non-oncology appraisals.

Table 1: Definitions of financial agreements implemented by NHS England

Type of financial agreement	Definition
PAS	The standard way for pharmaceutical manufacturers to make drugs cost-effective for NHS England when they are routinely commissioned
Simple PAS	Manufacturer agrees a confidential discount with NHS England
Complex PAS	May include: provision of free stock, dose caps or payments by results contracts agreed with NHS England
CAA	The general term used to refer to financial agreements made by pharmaceutical companies to make cancer drugs cost-effective for NHS England when they are entering the Cancer Drugs Fund (CDF) or if they are a drug transitioning from the old (pre-July 2016) CDF

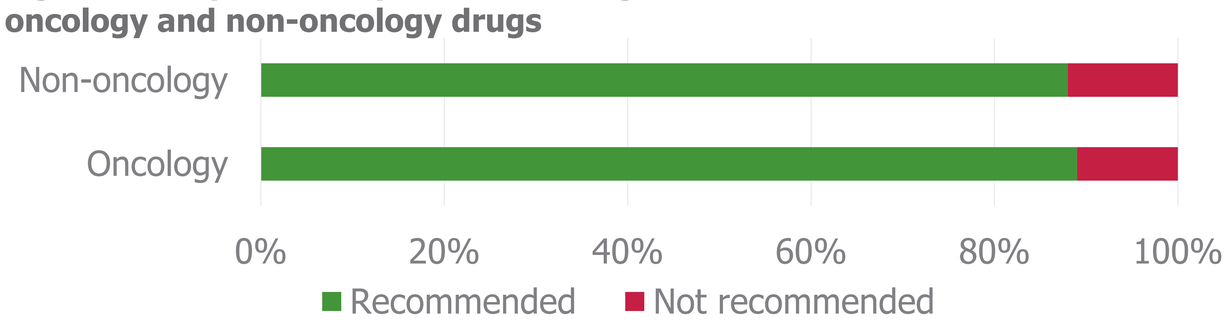
Methods

- NICE single technology appraisals published between January 2017 and January 2019 were analysed from publicly available sources.
- For each of the appraisals, both the outcome of the appraisal and the use of a financial agreement (i.e. the type of agreement) was extracted. In the case of negative appraisals, reasons specified for negative outcomes were also noted.
- The data were analysed and compared for oncology and non-oncology appraisals.

Results

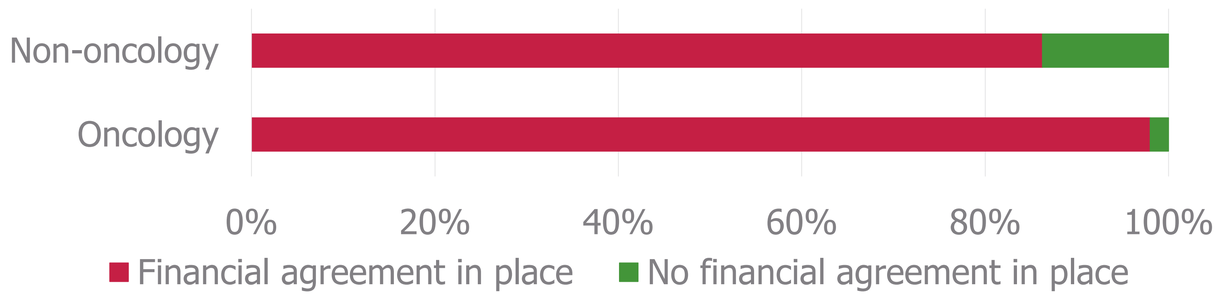
- A total of 98 appraisals were identified, of which 66% and 34% were oncology and non-oncology appraisals, respectively. Overall, of the 98 appraisals identified, 89% received positive recommendations, of which only 11% did not have any financial agreement in place. A similar percentage of oncology and non-oncology appraisals received positive NICE outcomes (89% and 88%, respectively, Figure 1).

Figure 1: Proportion of positive and negative recommendations for oncology and non-oncology drugs



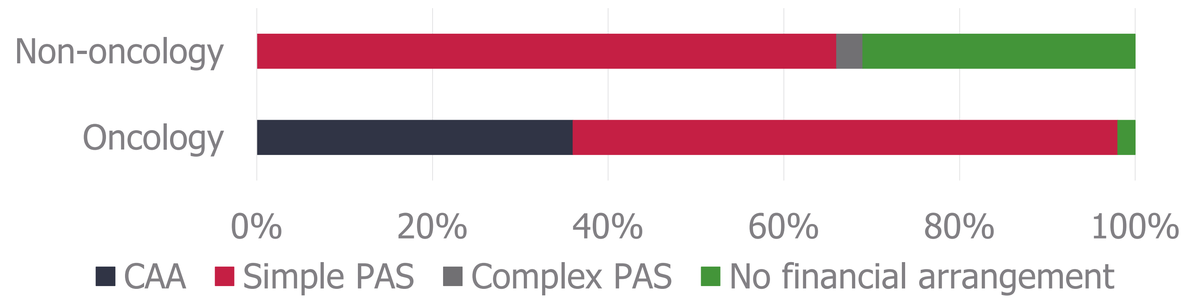
- Of the positive appraisals, financial agreements were in place for 98% of oncology appraisals and 69% of non-oncology appraisals (Figure 2).

Figure 2: Use of financial agreements for oncology and non-oncology drugs receiving positive recommendations



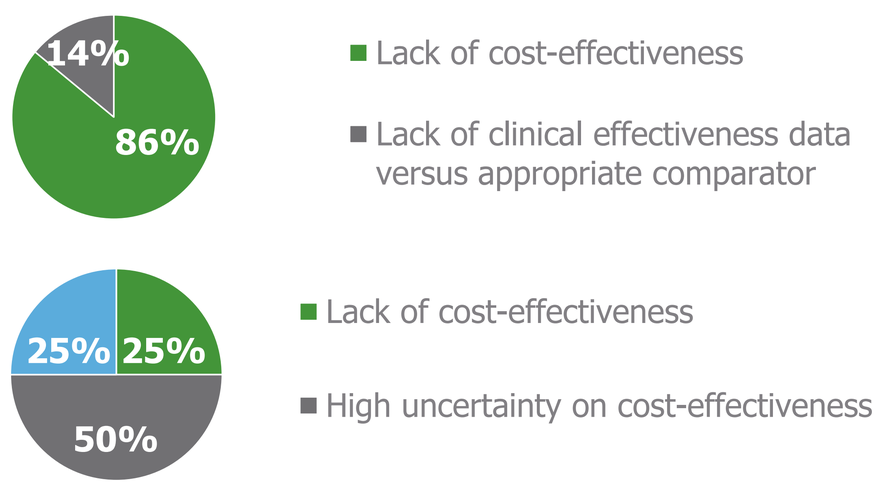
- Of those oncology appraisals with financial agreements in place, 61% were subject to a PAS and 36% were subject to a CAA (Figure 3). All PAS involved simple discounts only. NICE recommended 32% of technologies for use within the Cancer Drugs Fund (CDF).
- For non-oncology appraisals, the majority (95%) of financial agreements were in the form of simple discounts and only one product (5%) was subject to a complex PAS.

Figure 3: Type of financial agreements in place for oncology and non-oncology drugs receiving positive recommendations



- Negative recommendations were received by 11% and 12% of oncology and non-oncology appraisals, respectively.
- For oncology indications, negative recommendations were primarily due to a lack of cost-effectiveness (86%). In 83% of cases, this was even with a PAS proposal. For non-oncology indications, negative decisions were mainly due to high uncertainty on cost-effectiveness (50%).

Figure 4: Reasons for which oncology (A) and non-oncology (B) technologies received negative appraisal decisions from NICE



Discussion and conclusion

- It was hypothesised that there was likely to be a greater requirement for financial agreements for oncology drugs vs. non-oncology drugs, due to their increasingly high prices and clinical data uncertainty.
- The high need for financial agreements for oncology drugs was proven true in this study, with 98% of cancer appraisals between the study period requiring a financial agreement. In addition, the need to reduce clinical uncertainty was reflected by the approximately one-third of products recommended for use within the CDF.
- The analysis also demonstrated that whilst it is to a lesser extent, financial agreements are also required for the majority of non-oncology appraisals (69%).
- For both oncology and non-oncology drugs, financial agreements were mostly in the form of confidential discounts (simple PAS). This is supportive of previous analysis of PAS in England[2] and is perhaps reflective of the additional administrative burden considered to be associated with complex PAS.
- Overall, this analysis suggests that to demonstrate cost-effectiveness and gain access in England, financial agreements, (particularly confidential discounts which lower the list price but minimise international reference pricing implications) are likely to be required. Such agreements are likely to be essential for access for oncology drugs and are also very likely to be needed for non-oncology drugs.

CAA=Commercial Access Agreements; CDF=Cancer Drugs Fund; ICER=Incremental cost-effectiveness ratio; NHS=National Health Service; NICE=National Institute For Health and Care Excellence; PAS=Patient Access Scheme; QALY=Quality Adjusted Life Years; STA=Single Technology Assessment

References: 1. Cohen, D. Cancer Drugs: high price, uncertain value. BMJ 2017;359:j4543; 2. Spoors, J and Kusel, J. The evolution of patient access schemes. Value in Health, 2016;19(7)

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