Inclusion of new strategies in the UK's Cancer Drugs Fund: what was decided in France?

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Objectives

In 2011, National Health Service England (NHSE) introduced the Cancer Drugs Fund (CDF)[1], with the following objectives:

- Provide maximum support to NHSE patients
- Put clinicians and cancer specialists at the heart of decision-making, consistent with the Government's wider policy of empowering healthcare professionals and enabling them to use their professional judgement about what is right for patients
- Act as an effective bridge to the Government's aim of introducing a value-based pricing system for branded drugs in 2014

Those objectives were revised in 2016[2]:

- Provide patients with faster access to the most promising new cancer treatments
- Drive better value for money for taxpayers in drugs expenditure
- Offer pharmaceutical companies that are willing to price their products responsibly a new fast-track route to NHSE funding for the best and most promising drugs via an accelerated National Institute for Health and Care Excellence (NICE) appraisal process and a new CDF managed access scheme

In this new setting, a drug can be recommended for use in the CDF following NICE appraisal, when NICE considers that there is plausible potential for the drug to satisfy the criteria for routine commissioning (i.e. an incremental cost-effectiveness ratio [ICER] of £20,000–£30,000 per quality-adjusted life year [QALY] or up to £50,000 per QALY for end-of-life treatments), but where there is significant remaining clinical uncertainty.[2]

An initial budget of £200 million per annum was allocated to the CDF in 2011.[1] This annual budget is now fixed at £340 million.[2] During the 2018–19 financial year, 11,160 patients benefitted from the CDF, for an annual cost of £240 million.[3]

In France, unlicensed drugs (i.e. those without marketing authorization) can gain early market access through a compassionate-use programme (Autorisation Temporaire d'Utilisation - ATU).[4] In 2018, approximately 22,000 patients benefited from an ATU programme in France.[5]

However, once marketing authorization is acquired in France, there is no interim funding provision similar to the English CDF. Accessibility to reimbursement is directly assessed by the Transparency Committee (TC) of the French National Authority for Health (Haute Autorité de santé [HAS]).[6]

The first outcome of this assessment is 'clinical benefit', which indicates whether the medical benefit associated with the drug is sufficient for the national health insurance fund to contribute financially. For drugs having sufficient clinical benefit, the 'clinical added value' (CAV) then assesses the therapeutic (or diagnostic) progress provided by the drug – in terms of efficacy or safety – compared with existing alternatives. The pricing level that is subsequently negotiated depends on the CAV, which can take five values[7]:

- No clinical improvement (CAV V): the drug can be listed only if the costs are less than those of the comparators (i.e. lower price or induces cost savings)
- Minor clinical added value (CAV IV): there is a possibility of a higher price than those of the comparators
- Moderate, important or major clinical added value (CAV III, II or I, respectively): these treatments gain faster access to the market (due to price notification instead of negotiation) and a European price guarantee for 5 years

The objectives of this study were to identify how NICE and the HAS make decisions differently in the presence of uncertainty, and to assess how drugs that have been included in the English CDF have been evaluated in France.

Methods

Treatments that are included in the CDF at the time of writing (v1.136) and their corresponding assessments from the French TC were identified.

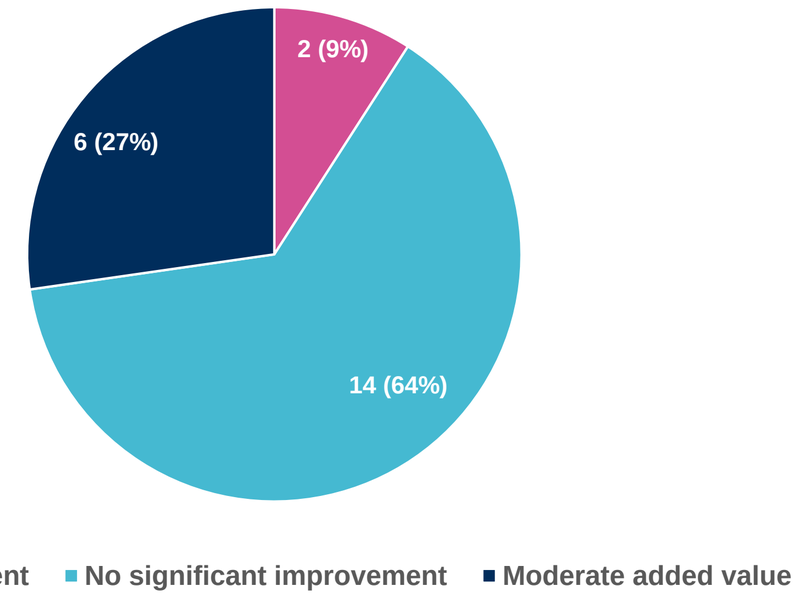
Three outcomes were extracted from the TC notices: the clinical benefit, the clinical added value and any request for complementary data to be submitted. In addition, whether the drugs had been eligible for an ATU and the corresponding number of patients that benefitted from this programme were also identified in the TC notices.

Results

Excluding treatments that transitioned from the older to the new version of the CDF, 28 managed access schemes were identified for 16 drugs. Published TC opinions were identified for 24 of these schemes, with two indications being merged into one single opinion in two cases.

Two opinions (9%) did not recommend reimbursement for the strategy (insufficient clinical benefit). Six (27%) of the TC opinions awarded 'moderate added value' (CAV III), acknowledging the innovative nature of the strategy in a population comparable to that detailed in the CDF. In the remainder (N = 14, 64%), the TC recommended reimbursement without recognizing any significant improvement compared to current practice (CAV V or CAV IV).

Figure 1: Assessment of Cancer Drugs Fund treatments by the French Transparency Committee



When reimbursement was recommended (N = 20), the TC requested complementary data to subsequently update the decision in 65% of cases (N = 13); this was not correlated to clinical added value level (P = 0.42, Fisher's exact test). The complementary data were required once available, on an annual basis or within a maximum of 2 years.

The proportion of drugs that benefitted from an ATU prior to the marketing authorization was approximately 60% (N = 13).

Both treatments that were ultimately not recommended for reimbursement benefitted from an ATU and were used to treated more than 700 patients.

For the drugs that were recommended for reimbursement (N = 20), an ATU was previously allowed in 11 cases; this was not correlated with the final CAV level (four out of six treatments that received CAV III, and seven out of 14 treatments that received CAV V or IV; P = 0.64, Fisher's exact test). When documented (N = 9), the number of patients that benefitted from those drugs during the ATU programmes ranged from 3 to 1,325.

Conclusions

Strategies for which English authorities underlined uncertainty and preferred to gather more data through the CDF directly received favourable reimbursement conditions from the French authorities in 27% of cases. Benefitting from an ATU programme before receiving market authorization did not necessarily predict favourable reimbursement conditions.

Finally, the reimbursement decision was generally, but not systematically, conditional upon obtaining complementary data in the future. These data were required within a maximum of 2 years.

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