Examining the Effectiveness of the Cancer Drugs Fund: Are Data Collection Plans Working as Intended?

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OBJECTIVES

- We aimed to review NICE CDF exit evaluations to identify whether the data collection plans were met and whether these sufficiently addressed the uncertainty raised in the original NICE evaluation.

BACKGROUND

- The Cancer Drugs Fund (CDF) is a source of funding for cancer drugs in England that enables access to promising new cancer technologies, conditional on additional evidence collection to address clinical uncertainty (**Figure 1**).[1]
- In 2016, the CDF process was updated, with the National Institute for Health and Care Excellence (NICE) playing a greater role in determining the terms of access to, and exit from, the CDF.
- Drugs with the potential for routine commissioning but with outstanding uncertainty regarding their clinical data can be recommended for reimbursement within the CDF, allowing for collection of further, agreed-upon, clinical evidence.[2] Following a period of managed access on the CDF, the technology is reappraised by NICE against the original decision problem before a final recommendation is made.[3]
- Further changes to the process for drugs to exit the CDF were made in February 2022. Rather than being reappraised against the original scope, technologies exiting the CDF can now be rescoped to allow for changes in clinical pathways, new evidence and commercial options following the managed access period.[4]

METHODS

- Appraisals of technologies that exited the CDF between 1 October 2016 and 15 June 2022 were reviewed. A new approach to the CDF appraisal method was introduced on 29 July 2016, therefore it was decided to extract results from October 2016 onwards to ensure that all technologies were evaluated under the same approach.
- NICE Committee papers and final appraisal documents from both the original and CDF exit evaluations were reviewed. For each appraisal, a pre-formatted extraction grid was used to capture relevant information, which focused on the following points:
  - Details of the intervention and indication
  - Information from the original appraisal including key issues of uncertainty and the planned data collection
  - Information from the CDF exit appraisal including whether the data collected matched the original data collection plan and whether the committee considered the uncertainty from the original appraisal had been addressed
  - Uncertainty was classed as either fully addressed, partially addressed or not addressed

RESULTS

- One technology appraisal was terminated prior to being reappraised, due to the evidence collected during the data collection period not showing a significant treatment benefit in the patient population.[5] Excluding this technology, 20 technologies were identified as having exited the CDF (**Table 1**).
- Median time between CDF entry and exit was 35 months.
- 5/20 (25.0%) CDF exit evaluations presented data that did not align with the original data collection plan, mainly due to trial data remaining immature or the Systemic Anti-Cancer Therapy (SACT) dataset failing to collect the appropriate data.
- Of the 15 CDF exit evaluations that presented data aligned with the original data collection plan, only 7 of these (46.7%) fully addressed the uncertainty from the original evaluation.
- Overall, 12/20 (60.0%) CDF exit evaluations did not fully resolve the uncertainty from the original evaluations, though ultimately 11/12 (91.7%) achieved a positive recommendation.
- Only one of the appraised technologies was not recommended following CDF exit evaluation. This was due to unresolved uncertainty around adjustments made to overall survival to account for treatment switching and treatment effect duration meaning that the incremental cost-effectiveness ratio (ICER) was above the range that NICE considers as cost-effective.[6] Overall, 90% of the 21 technologies that were previously in the CDF are now recommended through routine commissioning.

1 Summary of NICE CDF entry and exit process

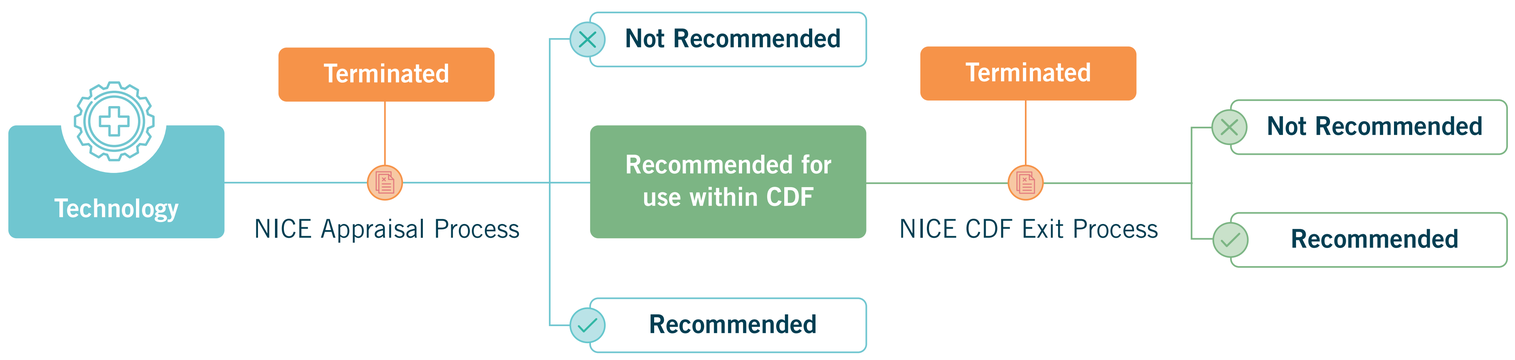

Diagram of the NICE CDF process between July 2016 and February 2022. **Abbreviations:** CDF: Cancer Drugs Fund; NICE: National Institute of Health and Care Excellence.

1 Summary of extracted technology appraisals

TA Ref	Intervention	Indication	Was the intervention recommended?	Did the presented data align with the original data collection plan?	Was the uncertainty from the original appraisal addressed?
TA780	Nivolumab with ipilimumab	Advanced renal cell carcinoma	Yes	Yes	Yes
TA770	Pembrolizumab with carboplatin and paclitaxel	Untreated metastatic squamous NSCLC	Yes	Yes	Yes
TA739	Atezolizumab	Untreated PD-L1-positive advanced urothelial cancer when cisplatin is unsuitable	Yes	Yes	Yes
TA691	Avelumab	Untreated Metastatic Merkel cell carcinoma	Yes	Yes	Yes
TA655	Nivolumab	Advanced squamous NSCLC after chemotherapy	Yes	Yes	Yes
TA524	Brentuximab vedotin	CD30-positive Hodgkin lymphoma	Yes	Yes	Yes
TA629	Obinutuzumab with bendamustine	Follicular lymphoma after rituximab	Yes	Yes	Yes
TA687	Ribociclib with fulvestrant	HR-positive, HER2-negative advanced breast cancer after endocrine therapy	Yes	Yes	Partly
TA683	Pembrolizumab with pemetrexed and platinum chemotherapy	Untreated, metastatic, non-squamous NSCLC	Yes	Yes	Partly
TA653	Osimertinib	EGFR T790M mutation-positive advanced NSCLC	Yes	Yes	Partly
TA531	Pembrolizumab	Untreated PD-L1-positive metastatic NSCLC	Yes	Yes	Partly
TA692	Pembrolizumab	Locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	No	Yes	No
TA766	Pembrolizumab	Completely resected stage 3 melanoma	Yes	Yes	No
TA736	Nivolumab	Recurrent or metastatic Squamous cell carcinoma of the head and neck after platinum-based chemotherapy	Yes	Yes	No
TA684	Nivolumab	Completely resected melanoma with lymph node involvement or metastatic disease	Yes	Yes	No
TA674	Pembrolizumab	Untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	Terminated	Yes	N/A
TA725	Abemaciclib with fulvestrant	HR-positive, HER2-negative advanced breast cancer	Yes	No	Yes
TA796	Venetoclax	Chronic lymphocytic leukaemia	Yes	No	Partly
TA713	Nivolumab	Advanced non-squamous NSCLC after chemotherapy	Yes	No	Partly
TA783	Daratumumab	Relapsed and refractory multiple myeloma	Yes	No	No
TA784	Niraparib	Relapsed, platinum-sensitive Ovarian, fallopian tube and peritoneal cancer	Yes	No	No

Technology appraisal case studies

	CDF Entry	Data collection plan	Remaining uncertainty
TA796	Venetoclax monotherapy entered the CDF to enable SACT data to be collected to address the uncertainty surrounding the generalisability of the trial data to the UK patient population and a lack of comparative data.	No — The data collection plan was not fully met as SACT was unable to collect efficacy data on the comparator (BSC).	Partly — Uncertainty around comparative efficacy was not addressed. SACT data did support the generalisability of the venetoclax trial data.
TA684	Nivolumab originally entered the CDF to enable more mature trial data to be collected on overall survival and recurrence-free survival, as well as real-world data to inform subsequent treatment distribution.	Yes — The data collected matched the data collection plan, however overall survival data from the trial were still immature.	No — Cost-effectiveness estimates remained uncertain due to the immature overall survival data. However, the committee concluded that the most likely ICER estimate was less than £30,000 per QALY gained.

Abbreviations: BSC: best supportive care; CDF: Cancer Drugs Fund; EGFR: epidermal growth factor receptor; HER2: human epidermal growth factor receptor 2; HR: hormone receptor; ICER: incremental cost-effectiveness ratio; NSCLC: non-small cell lung cancer; PD-L1: programmed death-ligand 1; QALY: quality-adjusted life year; SACT: Systemic Anti Cancer Therapy; TA: technology appraisal; UK: United Kingdom.

CONCLUSIONS

- The data collected within the CDF period did not always align with the original data collection plan and a majority of exit evaluations did not fully address the clinical uncertainty identified in the original evaluation.
- Despite this, recommendation rates of technologies exiting the CDF were found to be high. However, with the introduction of rescoping to the CDF exit process as part of the updated NICE methods, it will be interesting to see the impact this has on recommendation rates for technologies exiting the CDF over time.

Footnote

A small error picked up in the abstract results during the poster development process has now been corrected. The data collected for one technology was incorrectly noted as partly rather than fully matching the data collection plan.

References

1. National Health Service (NHS). Cancer Drugs Fund. Available at: https://www.england.nhs.uk/cancer/cdf/ [Last accessed 31 August 2022]; **2.** National Health Service (NHS). Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund). Available at: https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf [Last accessed 31 August 2022]; **3.** Cancer Research UK. Cancer Drugs Fund (CDF). Available at: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/access-to-treatment/cancer-drugs-fund-cdf [Last accessed 8 September 2022]; **4.** National Institute for Health and Care Excellence (NICE). Changes we're making to health technology evaluation. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation. [Last accessed 22 September 2022]; **5.** Merck Sharp & Dohme (MSD). Overview of clinical data and the decision to proceed with a termination. Available at: https://www.nice.org.uk/guidance/ta674/evidence/msd-cancer-drugs-fund-termination-engagement-meeting-presentation-pdf-9016373053 [Last accessed 22 September 2022]; **6.** National Institute for Health and Care Excellence (NICE). Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinumcontaining chemotherapy. Available at: https://www.nice.org.uk/guidance/ta692/resources/pembrolizumab-for-treating-locally-advanced-or-metastatic-urothelial-carcinoma-after-platinumcontaining-chemotherapy-pdf-82609437160645 [Last accessed 22 September 2022].

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