Is NICE being *nice* in their re-evaluation of oncology drugs in the Cancer Drugs Fund in England?

Foxon G[1], Wolfram V[1], Bailey S[1], Butler E[1], Craddy P[2]
[1]Remap Consulting, Cheshire, United Kingdom; [2]Remap Consulting, Zug, Switzerland

Introduction/objective

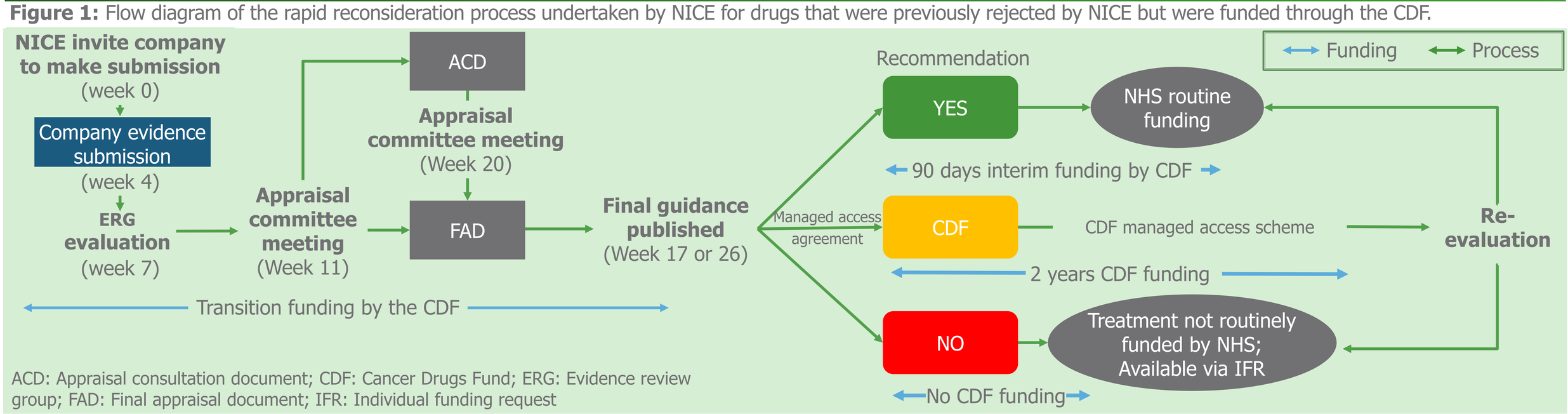
- Prior to 2016, the Cancer Drugs Fund (CDF) in England provided funding for previously rejected oncology treatments and for those not yet assessed.
- In July 2016, NICE took over responsibility for the CDF which at the time contained 25 drugs for 33 indications.
- NICE is currently evaluating all existing treatments in the CDF to assess if they should be recommended for routine use by NHS England; retained in the CDF to gather additional evidence or not recommended.
- CDF treatments previously evaluated by NICE have undergone a rapid re-consideration process (Figure 1) whereas treatments not previously evaluated by NICE are assessed under NICE's standard single technology appraisal (STA) or multiple technology appraisal (MTA) processes.
- This study investigates NICE's evaluation of existing CDF treatments and its potential impact on funding and patient access.

Methods

- Publicly available data from NICE were analyzed to determine the outcome of the 33 evaluations for oncology indications previously funded through the CDF.
- Information was collected on:
  - NICE evaluation process for products within the CDF
  - The stage of the NICE evaluation process for each product
  - The outcome of the NICE assessment
    - Recommended; recommended for use in CDF; not recommended
  - Conditions of acceptance for routine use such as patient access schemes and restricted patient population.

Results

Figure 1: Flow diagram of the rapid reconsideration process undertaken by NICE for drugs that were previously rejected by NICE but were funded through the CDF.

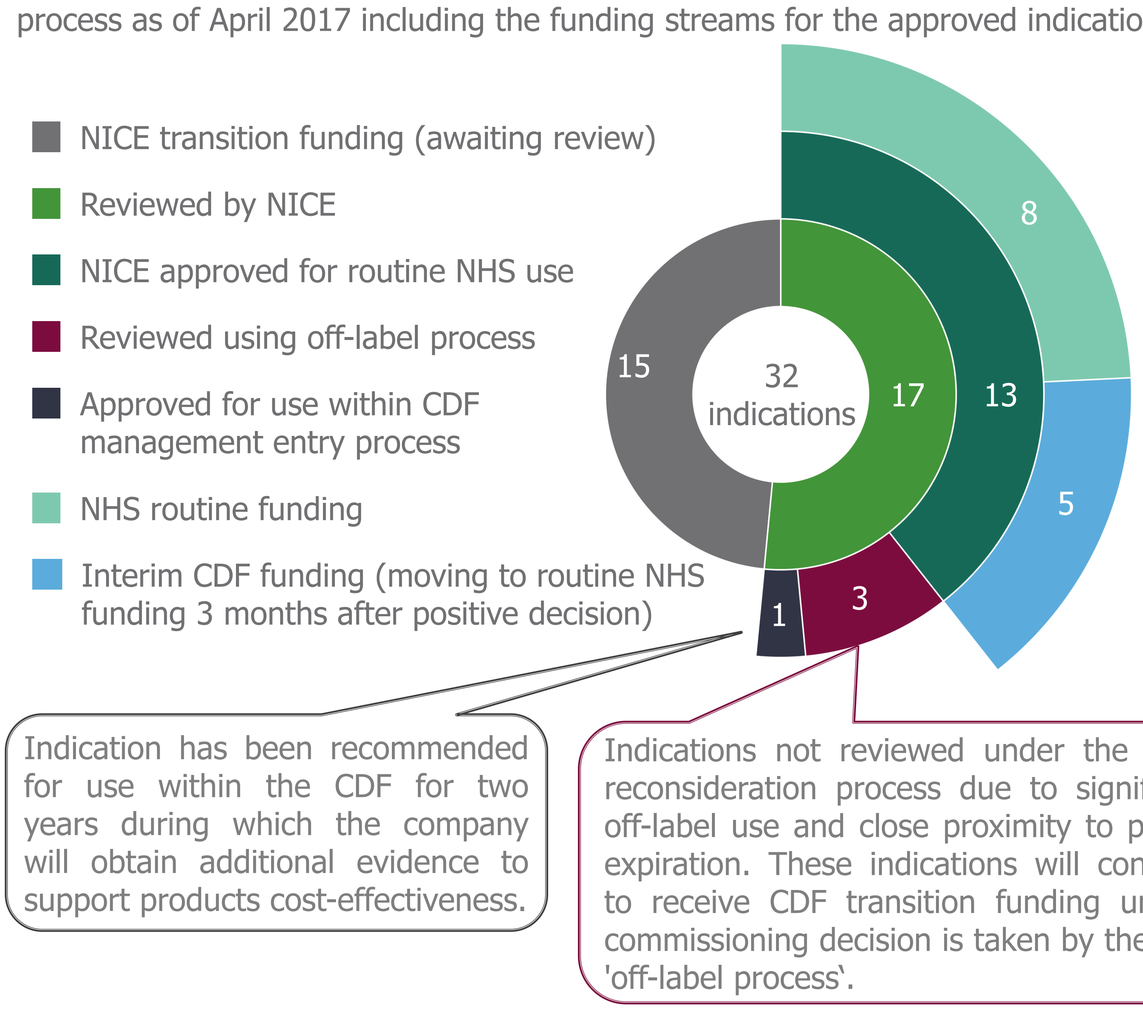


ACD: Appraisal consultation document; CDF: Cancer Drugs Fund; ERG: Evidence review group; FAD: Final appraisal document; IFR: Individual funding request

Of the 33 indications previously funded by the CDF, manufacturers agreed to receive transition CDF funding for 32 indications whilst NICE undertakes an evaluation of their treatments.

- Following discussions with NICE, one company decided not to provide an additional evidence submission. This treatment is no longer available to new patients.
- 18 indications previously rejected by NICE were scheduled for the rapid reconsideration process (Figure 1) with manufacturers providing additional economic evidence.
- 14 indications which were on the CDF but had not previously been appraised by NICE were scheduled for the standard STA or MTA evaluation process.

Figure 2: Summary of the results of NICE Cancer Drugs Fund rapid reconsideration process as of April 2017 including the funding streams for the approved indications.



Indication has been recommended for use within the CDF for two years during which the company will obtain additional evidence to support products cost-effectiveness.

Indications not reviewed under the rapid reconsideration process due to significant off-label use and close proximity to patent expiration. These indications will continue to receive CDF transition funding until a commissioning decision is taken by the CDF 'off-label process'.

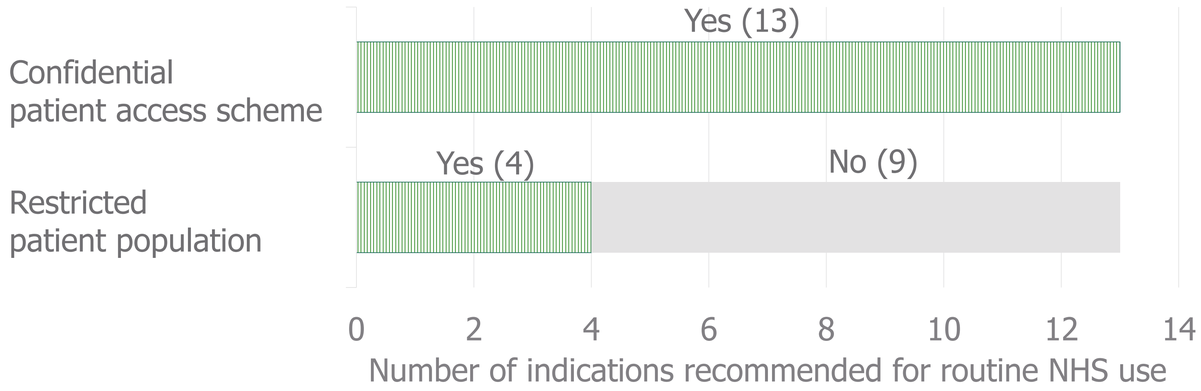
As of April 2017, all but one indications scheduled for rapid reconsideration process have been assessed by NICE (14 drugs to treat 17 indications (Figure 2)).

Of the 13 indications that received a recommendation for routine NHS use:

- All were recommended on condition of a patient access scheme
- Four were recommended with a restricted patient population (Figure 3).

Of the 15 indications that have not been reviewed, 14 will be reviewed under the standard STA or MTA process with results published before December 2017. Funding for these products will be provided through transition CDF funding.

Figure 3: NICE approval of the 13 indications was on the condition that the manufacturer provided a patient access scheme or a restricted patient population.



Discussion and conclusion

- Our analysis shows that NICE have approved, through the rapid reconsideration process, the majority of oncology treatments previously funded through the CDF. This may be as a result of 23 treatments being removed from the CDF before NICE took ownership of the fund.
- As a result, NHS England need to find the financial resources to fund these 13 treatments for routine NHS use.
- Manufacturers had to engage in patient access schemes, mainly in form of discounts, for their drugs to be considered cost effective and gain patient access.
- This analysis confirms the need for companies to demonstrate a solid health economic case to secure NHS funding.
- Companies also need to be prepare a real-world evidence plan, to gain entry into the CDF, if they believe their evidence-base is not sufficient for a positive NICE recommendation.

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