PCN286

What impact does NICE's modified Cancer Drugs Fund process mean for patient access to new oncology pharmaceuticals in England?

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Introduction/objective

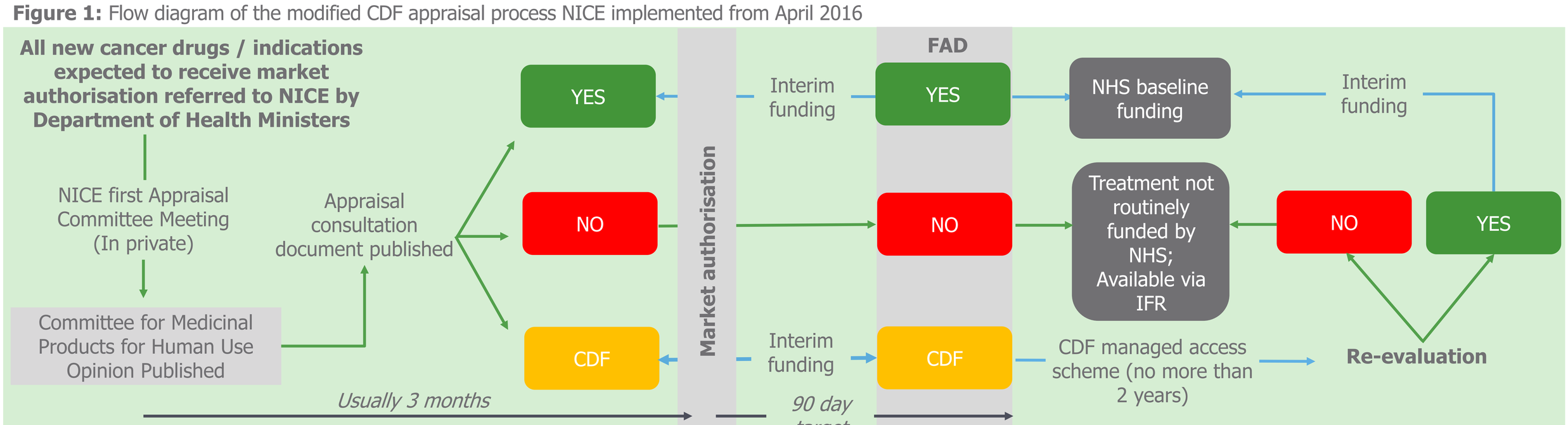
- In April 2016, NICE modified the Cancer Drugs Fund (CDF) appraisal process in England, to review all new oncology indications and publish final guidance within 90 days of marketing authorisation. Additionally, 14 existing legacy indications from the previous CDF had not undergone a NICE assessment and required review.
- The new CDF has a fixed budget of £340m and treatments appraised under this process may; be recommended for routine use by NHS England; be retained in the CDF to gather additional evidence; not be recommended. In some cases, positive recommendations may be subject to confidential patient access schemes or restricted to specific patient populations.
- This study investigates NICE evaluations of new cancer indications and of legacy CDF indications (not previously assessed by NICE), within the new CDF.

Methods

- Publicly available data from NICE were analyzed to determine the outcome of the 41 evaluations for oncology indications using the modified CDF process. Of these, three appraisals were terminated due to manufacturer non-submission and were not evaluated in this study.
- Information for the remaining 38 evaluations was collected on:
  - The stage of the NICE evaluation process for each indication
  - The funding status (i.e. has baseline / interim funding been secured?)
  - The outcome of the NICE assessment:
    - Recommended; recommended for use in CDF; not recommended.
- Data extraction was conducted June 2017.

Results

Figure 1: Flow diagram of the modified CDF appraisal process NICE implemented from April 2016



CDF: Cancer Drugs Fund; FAD: Final appraisal determination; IFR: Individual funding request; NICE, National Institute for Health and Care Excellence.

- As of June 2017, NICE have reviewed 24 new indications, making 18 positive recommendations (allowing for routine NHS funding), and two negative recommendations (no NHS funding), whilst four indications are recommended for use with CDF managed access schemes (Figure 2).
- Of the 18 indications that are recommended for routine NHS use:
  - All were recommended on condition of a patient access scheme
  - Two were recommended with a restricted patient population (Figure 3).

Figure 2: Outcomes of NICE appraisals for new cancer indications appraised using the new CDF process between April 2016 and June 2017

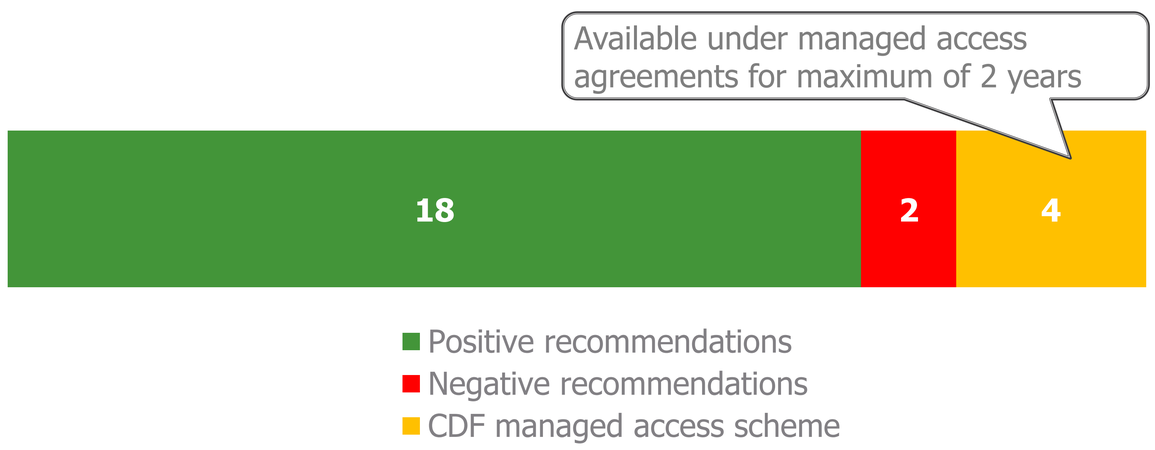
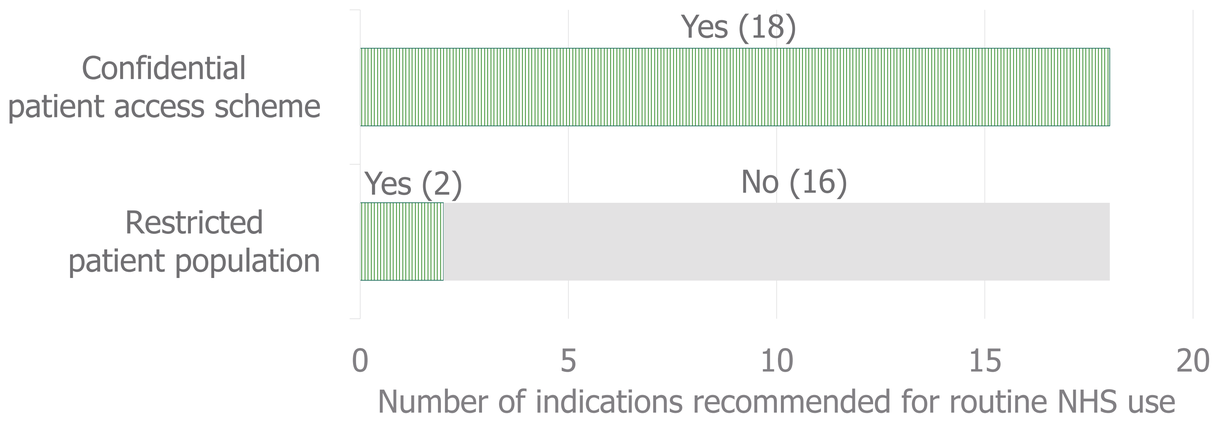
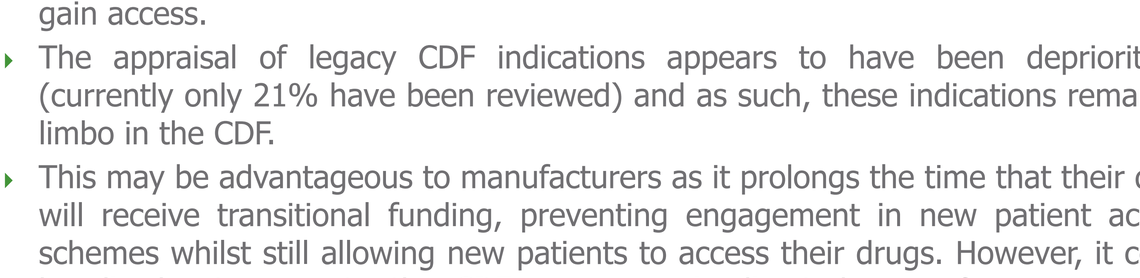


Figure 3: NICE approval of the 18 indications was on the condition that the manufacturer provided a patient access scheme or a restricted patient population



- Furthermore, NICE has reviewed three legacy CDF indications, with 11 still to be evaluated. Indications for which guidance has not been published are currently receiving transitional funding (Figure 4).

Figure 4: Appraisal status of legacy CDF indications without prior NICE evaluations



Discussion and conclusion

- The majority (75%) of new indications appraised by the modified CDF process are receiving approvals.
- For new indications, it appears the new NICE appraisal process is efficient and enabling faster access to patients.
- Nevertheless, all newly approved indications have patient access schemes in place, highlighting that manufacturers are providing significant discounts on list price to gain access.
- The appraisal of legacy CDF indications appears to have been deprioritised (currently only 21% have been reviewed) and as such, these indications remain in limbo in the CDF.
- This may be advantageous to manufacturers as it prolongs the time that their drug will receive transitional funding, preventing engagement in new patient access schemes whilst still allowing new patients to access their drugs. However, it could be disadvantageous to the CDF as money is diverted away from more cost-effective oncology treatments within the CDF fund.

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