Learning from Cancer Drug Fund (CDF) in England: A special reimbursement pathway for high-cost cancer drugs

Dian Faradiba

Issue#23 March 2023

policy brief

Key messages

- The Cancer Drug Fund (CDF) is a dedicated source of funding in England for increasing patient access to high-cost cancer drugs, with a fixed budget of £340 million per year, operating since 2016.
- The CDF follows the appraisal by the National Institute of Health and Care Excellence (NICE) which uses the methods and process for appraising Highly Specialised Technologies (HST) to provide a viable route to reimbursement for high-cost drugs. Drugs evaluated through HST are chosen based on certain criteria that consider patient indication (i.e., rare, chronic and severely disabling diseases) as well as potential very high acquisition cost.
- When there is clinical uncertainty about cancer drugs, NICE recommends a Managed Access Agreement (MAA) with companies. The level of reimbursement is agreed upon during this process, but it is kept confidential.
- Stakeholders are involved throughout the process; this includes clinical and NHS commissioning experts, company representatives, patients' representatives, and caregiver organisations.

The Cancer Drug Fund (CDF)

The Cancer Drug Fund (CDF) is a special pathway for funding cancer drugs in England, established by the National Health Service (NHS). It was started in 2011; however, since July 2016, the CDF has been reformed and has begun operating as a part of the National Institute of Health and Care Excellence (NICE), which provides recommendations and decides on the drugs covered by the NHS.[1] The CDF is one of two special funds that provide patients with early access to promising new drugs in England. The other fund, called Innovative Medicine Fund (IMF), focuses on non-cancer drugs, and was established June 2022. Each fund has a fixed annual budget of £340 million.[2] This piece focuses on CDF which has been in operation for over a decade, to draw lessons for other countries.

Earlier, the CDF had binary options (i.e., yes or no) on deciding whether to include drugs for routine commissioning. Under the new system, NICE aims to review all cancer drugs within 90 days of them getting a licence for use in patients. Now, NICE can make one of three decisions about whether a drug should be available (i.e., "yes", "no" or "recommended for use" within CDF). The CDF now provides a mechanism for early patient access to drugs that show clinical promise, but for which the evidence on cost-effectiveness remains uncertain. This uncertainty is then addressed through data collection, which is often combined with outcomes-based payment schemes.[3]

According to the CDF activity update Quarter 2 (Q2) for 2022-2023, since the new CDF approach began in July 2016, approximately 88,300 patients have been registered for receiving 102 drugs treating 241 different cancer indications. Also, more than 18,600 of these patients have benefited from earlier access to treatments trough the interim funding agreement.[4] CDF-funded cancer drugs and cancer indications are regularly updated on the NHS website. (http://www.england.nhs.uk/publication/cancer-drugs-fund-cdf-activity-update/)

Overview of CDF process

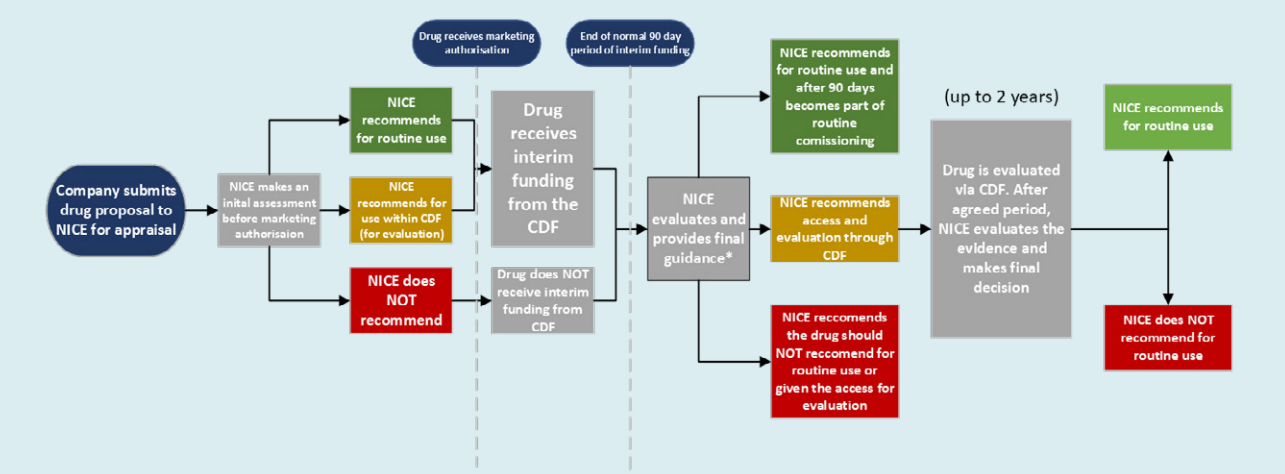
The overall process of CDF can be seen in Figure 1.

The entry point to the CDF is when clinically promising oncology drugs are submitted to NICE for technology appraisal. The submission needs to include a proposal for a data collection plan. Then, NICE will conduct an assessment to identify which drugs are appropriate for time-limited funding under the CDF (within 90 days of submission). The NICE Appraisal Committee (AC) reviews the list of candidate drugs and makes recommendations about their suitability for inclusion in the CDF based on decision-making criteria such as type of cancer and the cancer stage at which treatment is provided, promising drug/treatment with clinical uncertainty, and possibility of the drug/treatment to be cost-effective. [3, 5]

A joint committee of NHS England and NICE (the CDF Investment Group) is then convened to confirm the acceptable commercial access arrangement (the financial arrangements which determine the cost of the drug to the NHS, agreed upon between the company and NHS England) and data collection arrangements. Together, these are referred to as the Managed Access Agreement (MAA), which must be in place before accepting the drugs into the fund. [3, 6]

After a period of up to two years on the CDF, NICE reconsiders the drug and makes a final "Yes" or "No" decision based on whether a drug meets the cost-effectiveness threshold set by NICE.[3, 5]

Figure 1. The overall process of the Cancer Drug Fund (CDF)



Source: Daniel Gladwell, Ash Bullement, Warren Cowell, Karl Patterson, Mark Strong,"Stick or Twist?" Negotiating Price and Data in an Era of Conditional Approval, Value in Health, Volume 23, Issue 2, 2020, https://doi.org/10.1016/j.jval.2019.09.001.[5]

*To enter CDF, the company must agree to the NHS England MAA requirement.
CDF, Cancer Drug Fund; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; MAA, Managed Access Agreement.

Drugs can be identified as potential candidates for CDF at three different points of the appraisal process: 1) when a company submits a drug proposal with evidence to NICE for inclusion in the CDF, 2) during the assessment phase for drugs recommended by the Evidence Review Group (ERG) or NICE, and 3) at the first AC meeting. When considering whether a drug is suitable as a CDF candidate, NICE will define the area(s) of uncertainty that must be addressed. [3]

Appraisal Process

NICE is the gatekeeper for national reimbursement in England; it provides comprehensive assessments based on clinical efficacy and cost-effectiveness, as well as recommendations to the NHS for inclusion in the CDF or for routine commissioning. For many new drugs, NICE utilises Single Technology Appraisal (STA) methods; however, for a few innovative drugs, particularly those with high-cost or those treating rare indications, they are assessed as Highly Specialised Technologies (HST). The main difference between HST and STA processes is the willingness to pay threshold, which is higher in the HST process (£100,000/QALY versus £20,000-30,000/QALY). [7, 8]

Topics to be included in the HST must be referred to NICE by Ministers. All topics evaluated via HST must meet all seven criteria listed here: 1. the target patient group for the technology in its licensed indication is so small that treatment will usually be concentrated in very few centres in the NHS; 2. the target patient group is

distinct for clinical reasons; 3. the condition is chronic and severely debilitating; 4. the technology is expected to be used exclusively in the context of a highly specialised service; 5. the technology is likely to have a very high acquisition cost; 6. the technology has the potential for life long use; and 7. the need for national commissioning of the technology is significant. [7]

The Evidence Review Group (ERG), an independent academic centre, will review the topics, documents, and evidence submitted by companies against the seven specific criteria to be considered as an HST. The ERG then prepares a report that includes the evidence submitted by companies as well as personal statements from patient experts and clinical specialists, which is then submitted to the Evaluation Committee (EC). The EC, an independent advisory body comprising NHS, patient and caregiver organisations, academicians, and pharmaceutical and medical device representatives, considers the report and issues a Final Evaluation Determination (FED), which is then forwarded to NICE for guidance and, finally, to NHS for funding approval.[7]

A summary of the key decision points is presented in Table 1 and Figure 3 (next page) presented key players in CDF process.

Table 1. Summary of key decision points by NICE

Initial appraisal at grant of Marketing Authorisation		
Outcome	**Effect on new patients**	**Effect on any patients already receiving the drugs**
Draft recommendation for routine commissioning	Drug immediately available to patients at the point of Marketing Authorisation (receiving interim funding from CDF budget)	Drug continues to be available.
Draft recommendation for use within the CDF	Drug immediately available to patients at the point of Marketing Authorisation (receiving interim funding from CDF budget)	Drug continues to be available.
Draft "not recommended" guidance	Drug only available if an individual funding request is made and succeeds.	Patients may continue their course of treatment until they/their clinician agree it is appropriate to stop. Funding from original source
Guidance within 90 days of grant Marketing Authorisation		
Outcome	**Effect on new patients**	**Effect on any patients already receiving the drugs**
Recommendation for routine commissioning	Drug immediately available to patients, (funded from the CDF budget for 90 days before moving to baseline commissioning budget)	Drug continues to be available.
Recommendation for use within the CDF	Drug immediately available to patients (funded from CDF budget)	Drug continues to be available.
Not recommended	Drug only available if an individual funding request is made and succeeds.	Patients may continue their NHS funded course of treatment until they/their clinician agree it is appropriate to stop. Funding to be provided by the company.
Guidance within 90 days of grant Marketing Authorisation		
Outcome	**Effect on new patients**	**Effect on any patients already receiving the drugs**
Recommendation for routine commissioning	Drug immediately available to patients (funded from the CDF budget for 90 days before moving to baseline commissioning budget)	Drug continues to be available.
Not recommended	Drug only available if an individual funding request is made and succeeds.	Patients may continue their NHS funded course of treatment until they/their clinician agree it is appropriate to stop. Funding to be provided by the company.

Source: NHS England's consultation on proposals for a new cancer drug fund (CDF) operating model from 1st April 2016[6]

Implementation

The AC will confer with the company, NHS England and Public Health England to develop an appropriate framework for the data collection agreement (DCA), the period for which is usually up to five years. This agreement will further be included in the MAA, which will be approved by the CDF Investment group.

A time-limited MAA must be agreed upon between pharmaceutical companies and NHS England. This is a confidential agreement which will be considered on a case-by-case basis to resolve remaining clinical uncertainty before recommendation for routine commissioning. The agreement contains a proposal to address uncertainty (e.g., plan to collect more evidence in the DCA), duration of the agreement, starting and stopping criteria along the treatment pathway, treatment continuation criteria, list of outcomes for data collection, regularity for reviewing outcomes, funding arrangements, and management of patients receiving treatment who are no longer eligible if a more restricted/ negative recommendation is issued after guidance has been reviewed following data collection.

In the MAA, the level of reimbursement will be determined. Although the level of reimbursement is confidential, it should reflect the decision uncertainty, and the company will need to present an offer that brings the range of potentially plausible cost-effectiveness estimates as determined by NICE to below the relevant cost-effectiveness threshold, i.e., £20,000-£30,000 per QALY or up to £50,000 per QALY for end-of-life care drugs/indication or £100,000-£300,000 per QALY for HSTs. A discount or rebate is applied if a drug does not perform as expected for non-responders.

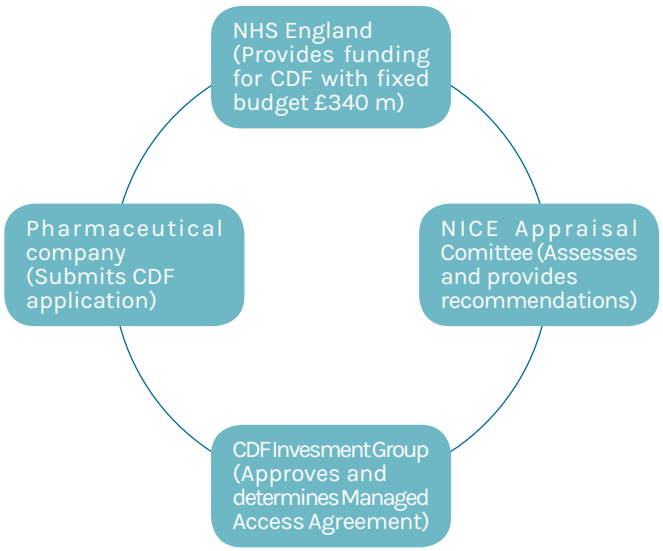
The drug will not enter the CDF or be available to patients unless the company agrees to the MAA. In that case, a NICE Guidance will be issued, but the drug will not be commissioned either for routine use or through the CDF. If the pharmaceutical company offers a new price, the topic may be returned to NICE for further consideration.

Monitoring and Evaluation (M&E)

Clinical evidence on the cancer drugs is gathered until the end date as per the MAA and all eligible patients, as determined by NICE, will have access to cancer drugs, which will be covered by the MAA. As part of the MAA, regular reviews will be conducted to ensure that progress is being made to resolve the uncertainty in clinical evidence. Following this process, NICE will update its guidance and decide whether the treatment should be recommended for routine use in the NHS.

If the evidence shows that the treatment is not a cost-effective use of NHS funds, it will be discontinued from reimbursement under the CDF.

Figure 3. Key players and roles in CDF (simplified)



CDF, Cancer Drug Fund
Source: Adapted and simplified from CDF standard operating procedure[3]

References

1. Morrell L, Wordsworth S, Schuh A, Middleton MR, Rees S, Barker RW. Will the reformed Cancer Drugs Fund address the most common types of uncertainty? An analysis of NICE cancer drug appraisals. BMC Health Services Research. 2018;18(1):393.
2. NHS England. Innovative Medicines Fund [cited 2023 March, 2nd]. Available from: https://www.england.nhs.uk/medicines-2/innovative-medicines-fund/.
3. NHS England. Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund). A new deal for patients, taxpayers and industry 2017 [updated 2017; cited 2023 March, 2nd]. Available from: https://www.england.nhs.uk/publication/cdf-sop-16/.
4. NHS England. Cancer Drugs Fund (CDF) activity update 2023 [cited 2023 March, 2nd]. Available from: https://www.england.nhs.uk/publication/cancer-drugs-fund-cdf-activity-update/#heading-2.
5. Gladwell D, Bullement A, Cowell W, Patterson K, Strong M. "Stick or Twist?" Negotiating Price and Data in an Era of Conditional Approval. Value in Health. 2020;23(2):191-9.
6. NHS England and NICE. CONSULTATION ON PROPOSALS FOR A NEW CANCER DRUGS FUND (CDF) OPERATING MODEL FROM 1ST APRIL 2016 [cited 2023 March, 2nd]. Available from: https://www.engage.england.nhs.uk/consultation/cdf-consultation/supporting_documents/cdfconsultationdoc.pdf.
7. National Institute for Health and Care Exellence (NICE). Interim Process and Methods of the Highly Specialised Technologies Programme Updated to reflect 2017 changes: NICE; 2022 [cited 2023 March, 1st]. Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf.
8. National Institute for Health and Care Exellence (NICE). Technology appraisal guidance 2022 [cited 2023 March, 2nd]. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance#:~:text=An%20independent%20academic%20centre%20is,and%20prepares%20an%20assessment%20report.

Acknowledgement

This policy brief is a part of the research project titled "Development of policy options to support reimbursement decisions on high-cost health interventions in Thailand's public healthcare system". HITAP was commissioned by the National Health Security Office (NHSO) in Thailand to conduct this study with funding from the Health Systems Research Institute (HRSI). This policy brief has been written in consultation with Prof. Alec Morton from University of Strathclyde UK, and Saudamini Dabak and Assoc. Prof. Wanrudee Isaranuwatchai from HITAP.

About the author

Dian Faradiba, Project Associate, Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand.

Contact: hiu@hitap.net

This policy brief can be downloaded from www.hitap.net