

INTRODUCTION:

The changing regulatory landscape brings new challenges to Health Technology Assessment (HTA). Marketing authorizations are being granted as the evidence base evolves to facilitate timely patient access to promising health technologies. Consequently, some products come to HTA bodies sooner in their development cycles with less evidence, which ultimately leads to greater uncertainty in decision making. A key challenge for payer and HTA bodies is providing access to promising medicines while the evidence is still emerging, in a financially sustainable way.

METHODS:

Changes to the Cancer Drugs Fund (CDF) have resulted in a managed access fund for cancer medicines in England. The National Institute for Health and Care Excellence (NICE) can now recommend a treatment for use within the CDF if there is plausible potential to satisfy the criteria for routine use in the National Health Service (NHS) at its current price, but the evidence is not robust enough and associated with significant uncertainty. Further evidence is then generated in clinical trials, through observational data collection, or a combination of the two, while the drug's price reflects the decision uncertainty. At the end of the managed access period, NICE reviews the guidance to determine if the treatment can be recommended for routine commissioning.

RESULTS:

The first treatment recommended for use within the new CDF was osimertinib for non-small cell lung cancer (1). At the time of NICE appraisal, there was considerable uncertainty in osimertinib's clinical and cost effectiveness because only short-term phase II trial results were available. NICE's independent appraisal committee considered there was plausible potential for osimertinib to be cost effective and identified that an ongoing phase III trial would provide longer-term data addressing the key uncertainties.

CONCLUSIONS:

An integrated approach between payer and HTA decision-maker has significantly changed how cancer

treatments in England are appraised. This collaborative way of working heralds a more sustainable approach to introducing promising cancer treatments.

REFERENCE:

1. Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer. NICE technology appraisal guidance 416. Published 26 October 2016.

OP03 Trends In The National Institute For Health And Care Excellence (NICE) Cancer Drugs Fund Reconsiderations

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INTRODUCTION:

As of July 2016, funding from England's Cancer Drugs Fund (CDF) is dispensed based on the results of National Institute for Health and Care Excellence (NICE) technology appraisal guidances instead of independent CDF appraisals (1). As part of this transition, NICE is reconsidering drugs previously funded through the CDF (2). This analysis examines CDF reconsiderations conducted between the inception of the new process in July and the end of 2016 to identify any possible trends.

METHODS:

We collected all NICE final technology appraisal guidances (3) completed before the end of 2016 and noted whether each drug was a CDF reconsideration, what the final decision was, and which factors impacted the decisions.

RESULTS:

We identified twenty-one NICE oncology reviews competed between July 2016 and the end of 2016.

Of these reviews, eight were reconsiderations of drugs previously funded through the old CDF; the rest were new reviews. Only one drug evaluated in the reconsiderations received a negative decision. All the reconsiderations included confidential manufacturer discounts and all noted updated clinical data. End of life (EOL) criteria expanded the acceptable incremental cost-effectiveness ratio (ICER) range for some of the CDF reconsiderations.

CONCLUSIONS:

All the reconsiderations included updated clinical data and analyses, though it does not appear that updated clinical data were sufficient to bring ICERs to acceptable levels. This is to be expected as the old CDF process served as an alternate funding source for many drugs that did not or were unlikely to fare well under NICE's evaluations. The updated clinical data may have at least increased NICE's confidence in the accuracy of the ICERs. All of the reconsiderations included confidential manufacturer discounts to reach acceptable ICER ranges. The results of this first round of reconsiderations suggest that manufacturers prefer offering their drugs at lower prices to potentially losing National Health Service (NHS) reimbursement entirely.

REFERENCES:

1. "Cancer? Cancer Drugs Fund." Accessed January 11, 2017. <https://www.england.nhs.uk/cancer/cdf/>.
2. "Cancer Drugs Fund | NICE Technology Appraisal Guidance | NICE Guidance | Our Programmes | What We Do | About | NICE." CorporatePage. Accessed January 11, 2017. <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund>.
3. "Published | Guidance | NICE." Accessed January 11, 2017. <https://www.nice.org.uk/guidance/published?type=ta>.

OP04 Lessons Learnt When Implementing A Health Technology Assessment Institution In Costa Rica

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INTRODUCTION:

Faced with increasing financial challenges to the single-payer social security system and constitutional challenges supporting all citizen's right to health, Costa Rica has endeavored to introduce Health Technology Assessment (HTA) to ensure sustainability and promote the timely introduction of technology innovations in the health system. The Ministry of Health initiated a process to establish an independent, external institution providing leadership in the process of HTA.

METHODS:

Based on a survey developed by REDETSA/PAHO (HTA Network of the Americas/Pan American Health Organization), an inclusive method of stakeholders participation was used to analyze the strengths, weaknesses, opportunities and threats regarding the implementation of an HTA entity. This was combined with qualitative research methods, market access situation analysis and the review of coverage and provision processes to define the elements for the new HTA institution. The "in-depth" interviews extended to manufacturers, ministry representatives, services providers, purchasers, patients and citizens representatives, judiciary court, professional colleges, academia and non-governmental organizations (NGOs). Analysis of the professional competencies required for the HTA institution was carried out based on best practice analysis of international HTA institutions.

RESULTS:

The implementation of an HTA unit in Costa Rica was identified by all the actors as crucial to ensuring the