AstraZeneca

An Interim Cancer Medicines Fund for New Zealand

Providing earlier, faster, and fairer access to cancer treatments for New Zealand patients

Green Paper

June 2024

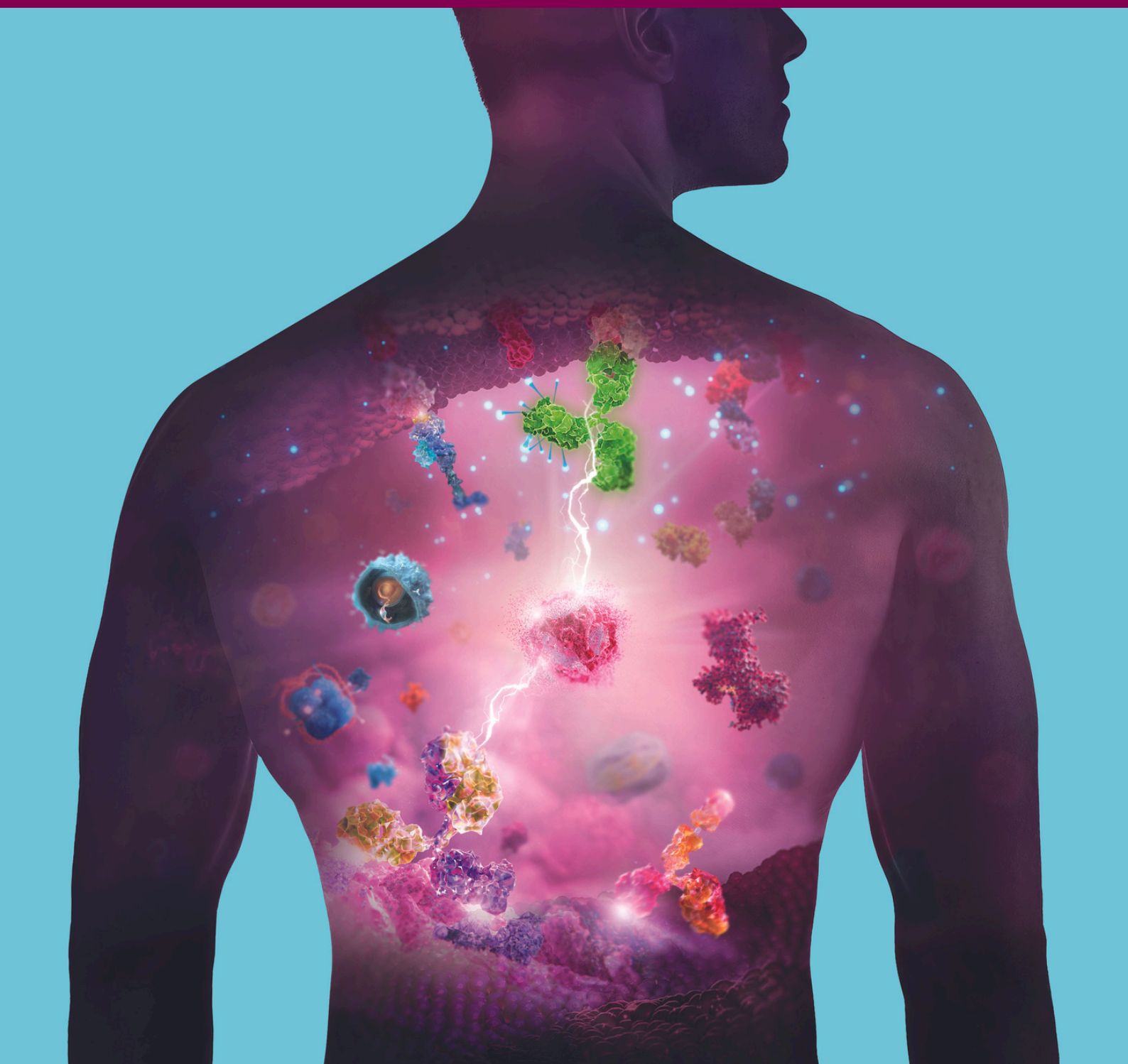

Table of Contents

Executive Summary

Each year, approximately **25,000** people in Aotearoa are diagnosed with cancer[1], and around **9,500** tragically lose their lives.[2] Cancer is the leading cause of death in New Zealand, and accounts for nearly one-third of all deaths.[3]

While cancer survival rates have increased substantially in New Zealand over the past 20 years, survival rates are not improving as quickly as survival rates in comparable countries.[4] For example, in New Zealand the median survival for advanced breast cancer is **16 months**, compared to 32+ months globally.[5] This may be due to delays in new cancer treatments becoming available.

Providing earlier, faster, and fairer access to healthcare and treatments is crucial to improve cancer survival rates.[6] Better cancer outcomes are more likely to be achieved with earlier diagnosis, faster access to new treatments, and more equitable access to effective medicines.

Cancer treatments are changing rapidly, with many new treatments working in different ways to traditional chemotherapy agents and new treatments are being developed at a rapid pace.[7]

> In New Zealand, the average number of days taken for new medicines to be reimbursed by Pharmac after Medsafe registration is 769 days, and 967 days, on average, for new cancer medicines.

This presents a significant challenge to New Zealand's current pharmaceutical funding mechanism, which is resulting in fewer new cancer treatments receiving public funding, when compared to comparable countries with similar health systems.[8]

As a result, there is an increasingly strong drive to improve patient access to potentially life-saving cancer treatments. As the number of innovative medicines in industry research pipelines continues to increase, existing models for medicines funding need to evolve to ensure timely and equitable access to new cancer treatments.

1 Cancer Control Agency, Cancer in numbers in Aotearoa New Zealand (Webpage 2024) https://teaho.govt.nz/cancer-numbers
2 Cancer Control Agency, What are our common causes of cancer death? (Webpage 2024) https://teaho.govt.nz/cancer-numbers/cancer-deaths
3 Ministry of Health, New Zealand Cancer Action Plan 2019-2029, 4
4 Cancer Control Agency, State of Cancer in New Zealand 2020 Report revised March 2021, 7
5 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 5
6 Lichtenburg F. R., Measuring the Impact of Pharmaceutical Innovation in Australia 1998-2018 (2019).
7 Cancer Control Agency, Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa, 2022, 1
8 Ibid

Currently, New Zealand cancer patients face a significant time lag when it comes to accessing new medicines, with a 967 day wait on average, between a new cancer medicine receiving approval by Medsafe, and that medicine being made available with funding by Pharmac.[9] This is twice as long as comparable countries with similar health systems.[10]

An **Interim Cancer Medicines Fund** could bridge this lengthy delay, providing an opportunity to reframe and reinvigorate New Zealand's approach to funding advanced health technologies. An Interim Cancer Medicines Fund would allow rapid access to new cancer treatments while further evaluation and assessment is being undertaken by Pharmac prior to permanent government reimbursement being provided. A Fund would involve risk-sharing arrangements between Government and pharmaceutical companies, and would be governed by eligibility criteria, ensuring political independence is maintained.

> An Interim Cancer Medicines Fund presents an opportunity to address the gap between regulatory and reimbursement approvals, and better support the medicines access needs of New Zealand cancer patients.

This Green Paper considers and evaluates the implementation of an Interim Cancer Medicines Fund in New Zealand. It also explores existing models for interim or provisional government-reimbursed access arrangements in the United Kingdom, Germany, Canada, and Italy, to derive insights into potential approaches the New Zealand Government may pursue.

This Paper notes that the methodology for interim pricing agreements and negotiation requires consideration. Furthermore, this Paper encourages the consideration of fit-for-purpose evidence requirements for cancer medicines to enable timely access for patients.

9 IQVIA, Access to Medicines (A to M 4) January 2011 to June 2023, 2023, 2
10 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 3

Rationale

Currently in New Zealand, patients are waiting far too long to access new cancer medicines. It takes **967 days**, on average, for a new cancer medicine to be made available on the Pharmaceutical Schedule once it has been approved by the Medsafe, which is **424 days longer than Australia**.[11] There are 131 modern medicines available through public funding in Australia that are not publicly funded in New Zealand,[12] and unfortunately, many patients will die whilst waiting for access. When compared to OECD countries, New Zealand ranks last for market access to modern medicines, whilst Australia ranks 18th out of 32 OECD countries.[13]

New Zealand has a capped medicines budget, enshrined in legislation. This budget has not kept pace with population growth or inflation.[14] There are currently 31 cancer medicines across 62 indications on Pharmac's Options for Investment List (OFI List),[15] and applications for funding have been with Pharmac for **6.07 years** on average.[16] Many medicines on this list are already funded and have become a standard of care in other countries.

Between 2012 and 2021, New Zealand only funded 7% of the 460 new medicines launched in the OECD, where the OECD average was 29%.[17] New Zealand ranks last for market access to new medicines, coming in behind countries such as Hungary, Estonia, Lithuania, Mexico Turkey and Latvia.[18] At 0.4% of GDP, New Zealand's total investment in medicines is well below the OECD average of 1.4%, and even non-OECD countries like Mexico and Colombia are investing more in medicines than New Zealand.[19]

When cancer treatments with high-added therapeutic value (HATV) and high unmet clinical need are deemed safe and fit for purpose by the rigorous MedSafe approval process, rapid access to those treatments is critical for New Zealand cancer patients, who may otherwise have limited treatment options. Some patients will die while they are waiting for treatments to be funded through Pharmac. Others crowdfund to meet private treatment costs. Some must seek treatment in Australia and other countries.

Conditional approval for reimbursement is a widely utilised international approach to manage the uncertainty associated with funding emerging health technologies,[20] however there are no such pathways in New Zealand. Instead, Pharmac uses its Named Patient Pharmaceutical Assessment (NPPA) process to consider whether to fund a treatment for an individual patient whose clinical circumstances are exceptional. The purpose of the NPPA policy is to consider those patients whose needs can't feasibly be met by the Pharmaceutical Schedule process.

11 IQVIA, Access to Medicines (A to M 4) January 2011 to June 2023, 2023, 6
12 Ibid, 2
13 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 9
14 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 2
15 Pharmac, Options for Investment List, (Webpage, as at 7 June 2024) https://connect.pharmac.govt.nz/apptracker/s/ranking-lists-for-funding-applications?reportType=OFI
16 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 9
17 Ibid, 9
18 Ibid, 8
19 Medicines New Zealand, Budget 2024 Medicines Investment: Broken Hearts and a Third World Position, Media Release 31 May 2024, https://www.medicinesnz.co.nz/resources/media-releases/media-releases-single/budget-2024-medicines-investment-broken-hearts-and-a-third-world-position
20 Health Technology Assessment Policy and Methods Review Reference Committee, Health Technology Assessment Policy and Methods Review Consultation Options Paper (Report, 2024) 12

Prescribers are encouraged to use NPPA if a person has an urgent clinical need or their clinical circumstances are unusual. Pharmac will consider whether funding this person will have an implication for the wider patient population. Treatments funded through NPPA must be “end of spectrum”. This means that there are no other clinically suitable funded options for the person, and the patient must have tried all suitable funded options before seeking funding for a treatment through NPPA.

NPPA cannot be used to undermine the Pharmaceutical Schedule by providing a competing pathway to access funded treatment and has significant limitations in terms of paperwork and resources required to administer individual NPPA requests.

To solve this problem and give patients access to the treatments they need, an evidence-based access scheme in the form of an Interim Cancer Medicines Fund in New Zealand would ensure timely access to treatment options expected to provide a substantial and clinically relevant improvement to patient outcomes over existing therapies. This finite fund would deem medicines eligible for interim funding during the time period between when they receive Medsafe approval and Pharmac reimbursement. This scheme would help patients to gain earlier access to cancer medicines that may save or significantly extent their life, whilst further economic data is being collected for Pharmac to make an assessment on need, health benefits, costs and savings, and suitability, as per its existing assessment framework.

The Fund could be administered by Pharmac, or by another body such as the Ministry of Health or Cancer Control Agency. It would have a dedicated budgetary allocation, and would be governed by eligibility criteria, ensuring political independence is maintained. It could target specific cancer patients who may not have any other treatment options available, to receive earlier access to new medicines.

Economic Benefit and Potential Savings to the Health System

Investing in new cancer treatments as soon as the regulator approves them would deliver substantial social and economic benefits for New Zealand – such as higher workforce productivity, improved health equity, and a reduced need for government-funded support services, whilst also giving patients more time with their loved ones and the opportunity to contribute to their community.

> Between 1995-2012, Canada saw a 23% decline in hospital days for cancer patients as a result of pharmaceutical innovation.

For every $1 invested in cancer treatments in New Zealand, there is $1 saved in the New Zealand health system.[21] Funding one cancer medicine in New Zealand reduces mortality by 5%, and reduces hospitalisation by 5.6%,[22] whilst societal benefits of pharmaceutical innovation have been seen to reduce the number of people unable to go to work or school by 4.5% on average.[23] In Canada between 1995-2012, pharmaceutical innovation resulted in a 23% decline in hospital days for cancer patients.[24]

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$1

invested in cancer treatments in New Zealand,

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is saved in the New Zealand health system.

21 Medicines New Zealand, New Zealand's Medicines Landscape 2023-24, 10
22 Ibid
23 Ibid
24 Ibid

An Interim Cancer Medicines Fund in New Zealand

Purpose

The purpose of an Interim Cancer Medicines Fund is to provide patients with access to new cancer treatments that may save or significantly extend their lives, prior to these treatments receiving funding through Pharmac. The Fund would expedite access to innovative treatments for these cancer patients to provide equitable access regardless of a patient's ability to pay before reimbursement. An interim fund with specific criteria provides consistent and predictable funding for these medicines, reducing disparities in access for clinicians and their patients. Ultimately, it demonstrates a commitment to improving cancer care and aligns with public health goals of providing fair and equitable access to medicines for all cancer patients.

Assessment Criteria for Interim Funding

The criteria governing the implementation of an Interim Cancer Medicines Fund should be clear, transparent, and balanced to address the expectations of various stakeholders. Crucially, eligibility requirements should be conducive to patient uptake and positive patient benefit.

Medicines eligible for reimbursement may be identified as high-priority medicines, namely:

- The medicine addresses a high and urgent unmet clinical need; and
- The medicine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

Compatible criteria for interim funding could also be developed based on:

- Agreed requirements for evidence development within a set time period to further inform cost-effectiveness evaluation, including any ongoing clinical trials, progression-free survival, real world evidence reporting by patients, clinicians and sponsors, and, where possible, overall survival;
- Agreed processes for price reviews and/or rebates based on outcomes;
- An agreed maximum number of patients the medicine is administered to per annum;
- An agreed limit on the total financial exposure for the Government;
- An agreed system for continuous evaluation of an Interim Cancer Medicines Fund;
- Agreed requirements for disclosure before prescribing eligible medicines to patients; and
- Community, consumer and clinician engagement in development and implementation.

'Innovative medicines' may already be registered and reimbursed for other cancer indications.

Risk-Sharing Arrangements

An appropriate risk-sharing arrangement between the pharmaceutical company and the Government is imperative to the success of an interim access mechanism. Risk-sharing agreements are intended to help maintain the appropriateness and cost-effectiveness of listed medicines.

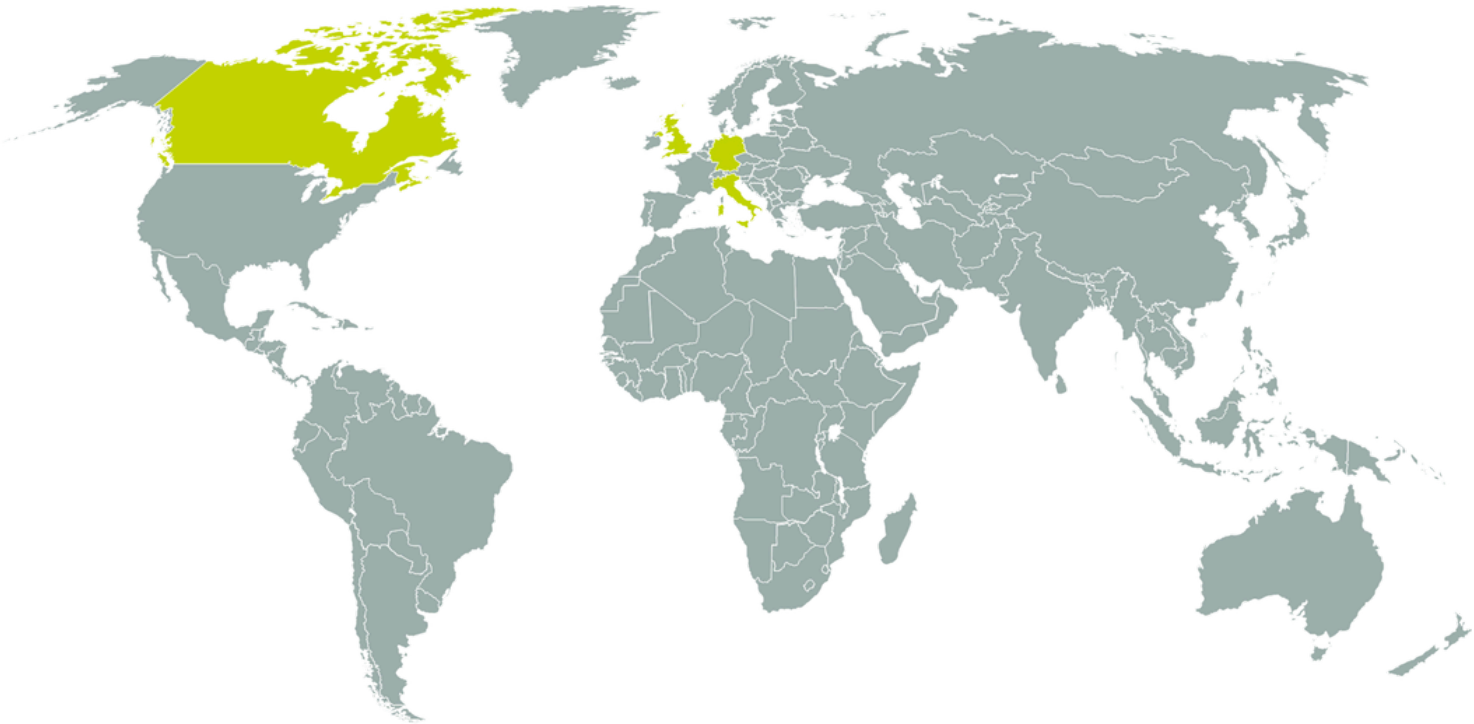
For example, managed entry agreements (MEAs) are strategic arrangements between payers and sponsors (governments and companies), employed to ensure timely patient access to advanced healthcare treatments, particularly when there is uncertainty about their clinical or cost-effectiveness. MEAs are designed to address the inherent uncertainties surrounding the value, uptake and performance of emerging technologies through conditional or managed reimbursement. MEAs between payers and sponsors are used internationally to facilitate timely patient access to advanced healthcare treatments, particularly when there is uncertainty about their clinical or cost-effectiveness. Industry and government should work together to identify opportunities to streamline this process.

International Approaches

Numerous Organisation for Economic Co-operation and Development (OECD) governments have implemented interim access to cancer medicines.[25] It is imperative to extract insights from international approaches to reimbursement.

International Health Technology Market Approval, Funding and Assessment Pathways (2023) was commissioned by the Australian Government Department of Health and Aged Care to inform the Health Technology Assessment Policy and Methods Review.[26] It offers a highly comprehensive assessment of international HTA processes.

Outlined below are **four case studies** (the United Kingdom, Germany, Canada and Italy) that illustrate the application of reimbursement pathways and varying frameworks that facilitate them.



25 Deloitte Access Economics, *A Collaborative Assessment of Access to Cancer Medicines in Australia* (Report, May 2017) 44.
26 Laka M., Carter D., Gao Y., Tamblyn D. & Merlin T., *Australian Health Technology Assessmenty Methods and Policy Review – Paper 1 – International Health Technology Market Approval, Funding and Assessment Pathways* (Draft Paper, 2023) 2.

The United Kingdom

As noted in **Funding and purchasing decisions and managing uncertainty**, a Paper commissioned by the Australian Government Department of Health and Aged Care to inform the Health Technology Assessment Policy and Methods Review in 2023, *"The Cancer Drugs Fund serves as an exemplar of a CED scheme integrated within a national HTA process, ensuring that patients have access to promising cancer drugs while generating additional evidence to address uncertain clinical effectiveness."*[27]

The **Cancer Drugs Fund (CDF)** was established in 2010 in the United Kingdom in response to criticism over the timeliness of access to new cancer medicines, which were not appraised by the National Institute for Health and Care Excellence (NICE) or had not been recommended for routine commissioning.

According to NHS England, the CDF provides:

- *"An early funding source, via Interim Funding Agreements (IFA), for treatments that receive a provisional positive recommendation from the National Institute for Health and Care Excellence (NICE), without them having to wait for NICE final guidance to be published and subsequent entry into the routine commissioning system.*

- *A source of funding, via Managed Access Agreements (MAA), for treatments that show clinical promise and where further data collection is needed to resolve uncertainty around their effectiveness."*[28]

Initially established in 2010, the Cancer Drugs Fund was redesigned in 2016 to ensure longer-term sustainability following higher than anticipated expenditure in its first years of operation. Key to the success of this reform was bringing the CDF under the remit of NICE.

Under this redesign, if NICE believes a medicine is promising but there is not yet enough evidence on its benefits and value for money, NICE can approve the medicine for a limited time (often around two years) and have it paid for via the CDF while more evidence is gathered.[29]

NICE then makes a final decision, often using evidence of any benefit the drug has provided to NHS patients to help inform that decision.[30]

The **Innovative Medicines Fund (IMF)** was established in 2021 to extend funded managed access to non-cancer conditions, separately.

27 University of Technology Sydney, *Australian Health Technology Assessment Methods and Policy Review – Paper 6 – Funding and purchasing decisions and Managing Uncertainty* (Draft Paper, 2023) 156.
28 'Cancer Drugs Fund activity update Q2 2023-24', NHS England (Web Page, 2023) <https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/>.
29 Cancer Research UK, The new Cancer Drugs Fund has quietly reached a significant milestone (Webpage 2024) <https://news.cancerresearchuk.org/2018/12/14/the-new-cancer-drugs-fund-has-quietly-reached-a-significant-milestone/>
30 Ibid

The CDF and IMF both operate on a fixed budget under an expenditure control mechanism. **The total CDF Budget for 2023-24 is £340m**.[31] The total IMF Budget is also £340m. Expenditure is managed using a combination of confidential discounts in commercial agreements; and rebates across the entire fund at the end of the year if the budget cap is exceeded.[32]

> The CDF accounts for less than 2% of the overall medicines, appliances and medical devices budget in the United Kingdom.

The CDF accounts **for less than 2% of the overall NHS medicines, appliances, and medical devices budget**. The total cost to NHS commissioners for medicines, appliances, and medicines devices in 2022/2023 was **£18.5bn**. (This figure[33] includes a deduction of £674m for central rebates, including those negotiated to commission treatments in the CDF and in routine commissioning. Without central rebates, the total cost was **£19.2bn**.)[34]

NHS England and NICE work in partnership with pharmaceutical companies to address uncertainty about the effectiveness of new cancer treatments. This involves collecting additional data during a managed access period, including real world evidence (RWE) and data from ongoing clinical trials. Data collection is designed to address key areas of uncertainty highlighted by NICE in a preliminary appraisal and is then utilised in full appraisal for routine commissioning.[35] The additional data helps NICE to decide whether a new treatment should be routinely funded.[36]

Since the United Kingdom's new approach to funding cancer drugs began in July 2016 (as of 21 December 2023),

~21,000

Patients have benefited from earlier access to treatments through Interim Funding Agreements.

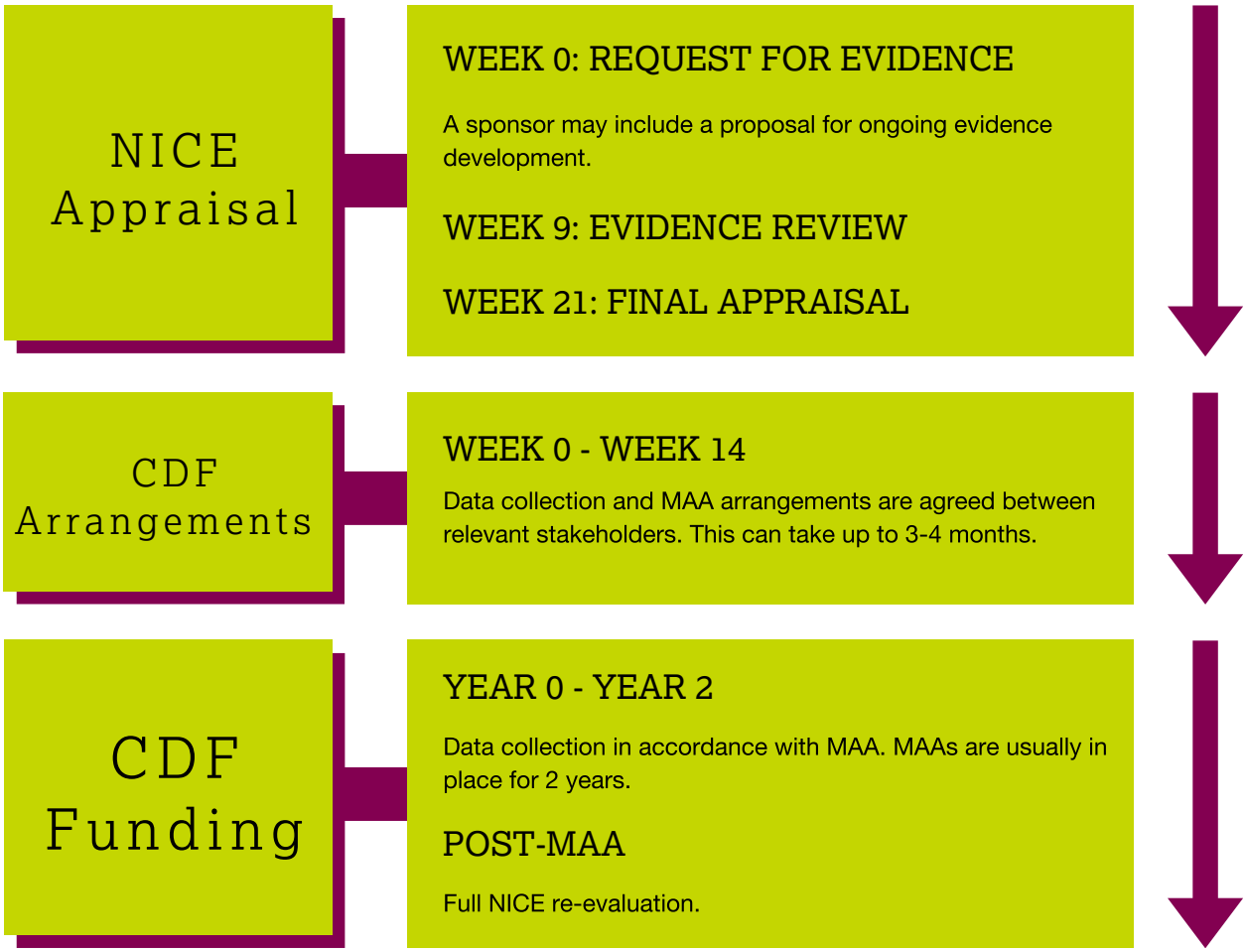
~59,500

Patients have been able to access new treatments because of negotiated Managed Access Agreements.

31 'Cancer Drugs Fund', NHS England (Web Page) <https://www.england.nhs.uk/cancer/cdf/>.
32 Medicines Australia, Funding Innovative Medicines (White Paper, 2023) 37.
33 'Prescribing Costs in Hospitals and the Community', NHS Business Services Authority (Web Page, 2023) < https://nhsbsa-opendata.s3.eu-west-2.amazonaws.com/pchc/pchc-2022-2023-narrative-v001.html>
34 Ibid.
35 Medicines Australia, Funding Innovative Medicines (White Paper, 2023) 37.
36 'Cancer Drugs Fund activity update Q2 2023-24', NHS England (Web Page, 2023) < https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/ >.

As of 21 December 2023, “Since the new approach to funding cancer drugs began in July 2016, approximately 96,100 patients have been registered to receive treatment with 103 drugs treating 261 different cancer indications. Of these patients, over 21,300 have benefited from earlier access to treatments through Interim Funding Agreements (IFA). In addition, over 59,500 patients have been able to access new treatments because of MAA [NHS England has] negotiated with companies, at significantly discounted prices to the NHS, whilst further data is collected. This data informs a future NICE technology appraisal.”[37]

Figure 1: Overview of the Cancer Drugs Fund (CDF) Listing Process[38]



37 ‘‘Cancer Drugs Fund activity update Q2 2023-24’, NHS England (Web Page, 2023) < https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/ >.
38 Medicines Australia, *Funding Innovative Medicines* (White Paper, 2023) 37.

Germany

In Germany, legislation regulating the reimbursement of new, innovative medicines (new therapeutic entities) within the statutory healthcare system (Arzneimittelmarkt-Neuordnungsgesetz, 'AMNOG') was introduced on 1 January 2011.[39]

The AMNOG process affords German patients rapid, reimbursed access to new therapies.

The German process enables automatic listing of new therapies, following receipt of marketing authorisation from the European Medicines Agency (EMA) and while HTA and pricing negotiations are completed. Newly authorised active pharmaceutical ingredients can be prescribed immediately upon market launch and are thus available to patients right away.[40]

Upon market entry, the Federal Joint Committee, or Gemeinsamer Bundesausschuss (G-BA) commences an early benefit assessment. The early benefit assessment must be completed within six months after it is launched.[41] The G-BA's subsequent benefit decision is also guided by the Institute for Quality and Efficiency in Healthcare (IQWiG) which independently assesses the medicine. The IQWiG submits an evidence-based expert report to the G-BA, with a recommendation regarding the additional patient-relevant benefit of the medicine.[42]

The medicine is paid at the list price during the first year of assessment and negotiations. The reimbursement price is determined in the second year of launch. It is determined depending on the outcome of the benefit decision. If the medicine has an additional benefit, the reimbursement price is determined by compulsory rebate negotiations between the National Association of Statutory Health Insurance Funds, or GKV-Spitzenverband (GKV-SV) and pharmaceutical companies. If the medicine has no additional benefit, it is assigned a reference price, which is continually reviewed by the GKV-SV.[43]

According to the Commonwealth Fund, *"Manufacturers can withdraw their product from the German market if the resulting price is so low as to undermine prices that can be charged elsewhere. In practice, manufacturers continue to see the German market as important and financially attractive and have not withdrawn any drugs that were shown to offer incremental clinical benefit over their closest comparators."* [44]

Additionally, the G-BA may remove a medicine from reimbursement or restrict the medicine's reimbursed status.[45]

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39 Gandjour A., Schüßler S., Hammerschmidt T. & Dintsios C., Predictors of negotiated prices for new drugs in Germany. *The European Journal of Health Economics* (2020) 21 1049.
40 Gemeinsamer Bundesausschuss, *Information brochure of the Federal Joint Committee* (Brochure, 2022) <https://www.g-ba.de/downloads/17-98-3768/2022-09-30_G-BA-Infobroschuere_EN_bf.pdf> 17.
41 Ibid.
42 Theidel U. & von der Schulenburg J., Benefit assessment in Germany: implications for price discounts. *Health Economics Review* (2016) 6 4.
43 Medicines Australia, Submission No 141 to House of Representatives Standing Committee, Parliament of Australia, Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia (2020) 54.
44 Robinson J., Ex P & Panteli D., 'How Drug Prices are Negotiated in Germany' (*The Commonwealth Fund*, Web Page, 2019) <https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany>.
45 Medicines Australia, Submission No 141 to House of Representatives Standing Committee, Parliament of Australia, Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia (2020) 54.

The New Frontiers Report noted that the German model for provisional access drew support during consultation. The following excerpt from New Frontiers briefly evaluates the German model:

"[Better Access] claimed that 'the German reimbursement process does not come at the cost of a rigorous value assessment,' it merely means that 'the negotiation of prices does not… stand in the way of access for patients.' It did however concede that the system 'has faced fiscal challenges with some companies overpricing and failure of the system to clawback excess from use beyond indication, or failure to achieve health outcomes in real world application versus clinical trials.' It argued that: Australia's experience in the utilisation of Risk Share Arrangements and improving data accessibility through electronic health records places us well to modify a system with suitable 'carrots and sticks' to get the balance of access, affordability and transparency right." [46]

Figure 2: Overview of the German approach to negotiating prices for new medicines [47]

46 House of Representatives Standing Committee on Health, Aged Care and Sport (Cth), The New Frontier – Delivering better health for all Australians (Report, 2021) 133 at 6.77.
47 Medicines Australia, Funding Innovative Medicines (White Paper, 2023) 36.

Canada

To separate the evaluation of cancer medicines from the common drug review process, the pan-Canadian Oncology Drug Review (pCODR) was established by the provincial and territorial Ministries of Health in 2007. In 2014, it was integrated into Canada's Drug and Health Technology Agency's (CADTH).

As part of CADTH's reimbursement review process, the pCODR Expert Review Committee (pERC) makes reimbursement recommendations for oncology medicines to the participating federal, provincial, and territorial publicly funded drug programs.[48] Committee meetings are held 12 times a year.

In Canada, if the medicine demonstrates added comparative clinical benefit, but the cost-effectiveness is not at an acceptable level, the medicine may be reimbursed on the condition that there is a price reduction.[49]

pERC's well-defined deliberative framework is evidence-based. The Committee considers a variety of criteria, including medical and scientific knowledge, current clinical practice, economics, ethical considerations, and patient and public impact.[50]

Deloitte Access Economics, in partnership with Medicines Australia, described the Canadian system in their 2017 report, **Collaborative Assessment of Access to Cancer Medicines in Australia**:

"The purpose of the pCODR process is to bring consistency and clarity to the assessment of cancer drugs. Following approval by the national regulator, Health Canada, pCODR makes recommendations on the reimbursement of cancer medicines. Similar to Australia, a parallel regulatory and reimbursement submission process is available to sponsors to shorten the time between decisions.

Interestingly, Canada has also established a systematic approach to clinician-led submissions in addition to manufacturer-led submissions. This is a novel approach to the challenge of market failures arising from the challenges of data collection for less common cancers." [51]

Moreover, the pCODR framework incorporates clinical advisory input. In assessing a medicine's value, the pCODR considers evidence from various sources, including patient groups, drug manufacturers, clinician-based tumour groups, and the pCODR Provincial Advisory Group.[52] Clinical guidance panels consider outcomes broader than overall survival (OS), such as including Progression-Free Survival (PFS) and ease of symptom burden.[53]

48 'The pCODR Expert Review Committee (pERC)', Canada's Drug and Health Technology Agency (Web Page, 2024) <https://www.cadth.ca/pcodr-expert-review-committee-perc-0>.
49 Laka M., Carter D., Gao Y., Tamblyn D. & Merlin T., *Australian Health Technology Assessment Methods and Policy Review – Paper 1 – International Health Technology Market Approval, Funding and Assessment Pathways* (Draft Paper, 2023) 94.
50 'The pCODR Expert Review Committee (pERC)', Canada's Drug and Health Technology Agency (Web Page, 2024) <https://www.cadth.ca/pcodr-expert-review-committee-perc-0>.
51 Deloitte Access Economics, *A Collaborative Assessment of Access to Cancer Medicines in Australia* (Report, May 2017) 46.
52 Ibid 49.
53 Ibid.

Italy

Italy's value-based pricing framework and reimbursement pathway is a notable case study in **Paper 6 – Funding and purchasing decisions and Managing Uncertainty**:

"In 2017, Italy introduced the assessment of 'innovation status' for medicinal products as part of the pricing and reimbursement (PR) decision process. As outlined in the 2017 Budget Law, applications are made for innovation status according to **specific criteria of unmet need, added clinical value and the robustness of available clinical evidence.**

[Agenzia Italiana del Farmaco] AIFA evaluates the therapeutic indication and rates it on a five-point innovation scale. This assessment is based on criteria considering clinical need and added therapeutic value to determine a score from 'no innovation' to 'high innovation.' Additionally, a four-point 'GRADE' score for the quality of evidence is used to ascribe temporary/conditional or 'fully innovative' status.

Benefits of the 'fully innovative' status include:

- *Recognition and differentiation: The assessment of innovation status allows for the identification and recognition of innovative medicinal products. This helps distinguish these products from conventional therapies and highlights their potential to bring significant advancements in patient care.*
- *Improved patient access: Innovative medicinal products recognised as innovative gain enhanced access to the market. They are included in a dedicated cancer or other innovative medicinal product fund, each amounting to a total of €500 million. Inclusion facilitates patient access by providing funding support and ensuring availability on regional therapeutic formularies. The duration of innovation status is set at maximum of 36 months, providing a significant period for treatments to have a sustained period for access and reimbursement."* [54]

"Overall, AIFA and its registries play a vital and increasing role in pharmaceutical regulation and reimbursement in Italy. Efforts are being made to address challenges related to administrative burden, data quality and patient access, with a focus on implementing innovative approaches that leverage RWE and value-based pricing." [55]

International approaches to interim funding demonstrate the need for robust and transparent criteria to ensure timely patient access and sustainable policy. The assessment of the value and productivity of cancer medicine should be dynamic and adapt to information that may better inform its use. As innovation becomes more nuanced, the methods for defining and valuing innovation have evolved.

54 University of Technology Sydney, *Australian Health Technology Assessment Methods and Policy Review – Paper 6 – Funding and purchasing decisions and Managing Uncertainty* (Draft Paper, 2023) 158 – 159.
55 Ibid, 161.

Next Steps

New Zealand patients with no other treatment options must wait, on average, **967 days** between a potentially life-changing cancer medicine receiving Medsafe approval, and that medicine being made available through Pharmac.[56] For these patients, time is of the essence.

Government, patients, clinicians and pharmaceutical companies must collaborate to effectively deliver earlier, faster and fairer access to priority medicines for New Zealanders by establishing an Interim Cancer Medicines Fund.

This Green Paper aims to launch a more comprehensive consultation and evaluation of an Interim Cancer Medicines Fund in New Zealand.

Going forward, industry and government stakeholders should consider alignment on:

- Development of a potential funding mechanism/model, including risk-sharing arrangements between pharmaceutical companies and the government.
- Practical implementation of an interim access fund, and how it would operate in collaboration with the current Pharmac system, including co-design for potential legislation.
- Development of criteria for access.
- The relevance and desirability of international interim funding mechanisms, including lessons to be learned from other jurisdictional approaches.

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56 IQVIA, Access to Medicines (A to M 4) January 2011 to June 2023, 2023, 6

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Cancer Control Agency, Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa, 2022

Cancer Control Agency, What are our common causes of cancer death? (Webpage 2024) https://teaho.govt.nz/cancer-numbers/cancer-deaths

'Cancer Drugs Fund activity update Q2 2023-24', NHS England (Web Page, 2023) < https://www.england.nhs.uk/long-read/cancer-drugs-fund-activity-update-q2-2023-24/>

Cancer Research UK, The new Cancer Drugs Fund has quietly reached a significant milestone (Webpage 2024) https://news.cancerresearchuk.org/2018/12/14/the-new-cancer-drugs-fund-has-quietly-reached-a-significant-milestone/

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