財團法人
癌症希望基金會
HOPE FOUNDATION for CANCER CARE

Position Paper for Cancer Treatment Accessibility

2021/9 Version 4

Position Paper for Cancer Treatment Accessibility

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A. Introduction

Cancer has ranked first among the top 10 causes of death in Taiwan for 39 years. Social costs such as reduced productivity due to cancer are beyond measurement, and many families have been caught in this plight as such. Established 20 years ago, the HOPE Foundation for Cancer Care has accompanied over 350 thousand families through the cancer treatment process. During this process, difficulties that many cancer patients face include unavailability of medication, unaffordability of medication, and even the high treatment expenses that many cancer patients have to pay at the cost of their properties. Why are there still so many heart-breaking stories under the umbrella of National Health Insurance? In light of this, the Foundation started to focus its attention on medication for cancer patients and collecting related experiences. Since 2016, we have consulted clinicians and domestic and foreign scholars, held expert meetings and summits, and generated multiple suggestions, and we have proactively communicated with all parties in addition to reviewing restrictions of domestic systems.

The first Position Paper for Cancer Treatment Accessibility that combined research accomplishments was released in 2017, followed by its second and third editions in 2018 and 2019. Proposals such as “more systematic and efficient review and inclusion in coverage of new treatments”, “more reasonable allocation and use of NHI finances”, “improved user-friendliness of clinical trial information”, and “commercial insurance supplementary to HNI coverage” were introduced under the high level of attention and guidance from all parties. The Foundation feels truly honored and pleased.

Between 2019 and 2020, the Foundation continued to communicate the difficulties encountered in out-of-pocket payments for medications by sharing the stories of the patients. Patient forums and communications among experts/scholars, government officials, and patient groups were organized to reach a consensus on NHI reforms. Efforts were made to lobby stakeholders such as legislators and Minister Shih-Chung Chen of Health and Welfare. Commercial insurance seminars were held for two consecutive years to facilitate discussions with related experts of the possibility in innovation of insurance policies. We approached the media and discussed with them the present and future of NHI by releasing multiple papers on NHI policy initiatives through them, by attending media workshops, and by organizing the press conference entitled “NHI Reforms for My Health” where a survey involving a thousand respondents was conducted. We appreciate the positive feedback and communication opportunities from the competent authority and its reference to the proposals introduced by the Foundation in some of its systems.

In mid-2021, the COVID-19 pandemic that had been ongoing for over a year worldwide abruptly hit Taiwan and posed tremendous challenges for the medical settings as a whole, as well as the right to medical care of patients with cancer. Many policies and reforms were put on hold, too. Despite the difficult times, the Foundation continued with data collection, advanced studies, and cross-disciplinary expert visits and discussions in order to find out the best solution for treatment accessibility that centers on patients. It is our hope that it may be considered and discussed by government authorities concerned and we welcome any feedback from all parties.

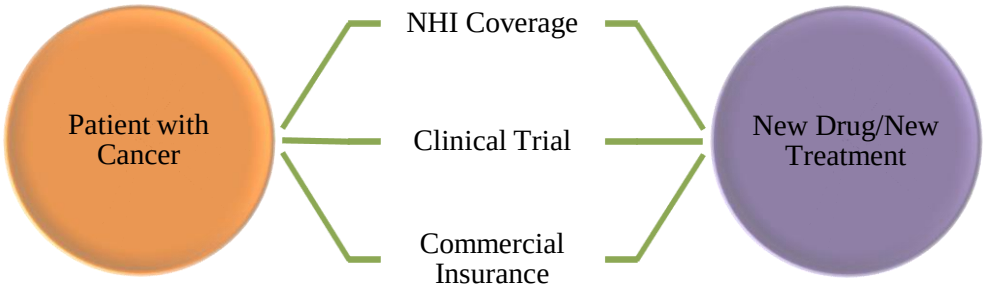

Figure 1: Possible ways for patients with cancer to use new drugs and new treatments

B. Highlights

Analysis of Issues 1 (P9) **NHI Coverage for New Treatments - Lengthy Process**	**Policy recommendation 1 (P10)** **More Systematic and Efficient Review and Inclusion in Coverage of New Drugs**
1. Absence of a reasonable timetable defined for review of new drugs	1. There should be an open and expected reasonable timetable in place for the review of new drugs so that concerned authorities can keep track of the review status and progress to accordingly boost the review efficiency and minimize loopholes.
2. Absence of a prioritized review mechanism for new drugs	2. Establish a prioritized review mechanism for new drugs just like that available at the Food and Drug Administration: Items meeting the criteria are prioritized for review in order to provide more time for patients with cancer.
3. Lack of sufficient emphasis on opinions from patients with cancer	3. Continue to promote diversified patient involvement schemes: The rights of patient group representatives to get involved in the National Health Insurance Committee and in Pharmaceutical Benefit and Reimbursement Scheme Joint Committee to speak proactively shall be protected and the visibility of opinions from patients with cancer shall be reinforced.

Analysis of Issues 2 (P11) **NHI Coverage for New Treatments - Financial Restrictions**	**Policy recommendation 2 (P13)** **More reasonable allocation of NHI finances**
1. Ineffective new drug budget planning and utilization	1. Keep track of medical trends and ensure that budget is used in an efficient way: Horizon scanning is properly utilized to keep track of the treatment trends and their budgets and to facilitate the development of precision medicine. 2. The pilot project of the Cancer Drugs Fund: The Cancer Drugs Fund was created as a transitional measure to pay for new drugs with significant financial impacts and

	undefined efficacy so that they may be provided to the patients early on.
2. Re-evaluation schemes and exit principles non-rigidity	3. Promote the rigid re-assessment scheme to improve coverage: The real world evidence (RWE) is collected to help with periodical evaluation of drug efficacy and benefits from the coverage and effective utilization of NHI resources.
3. Failure to devote rebates from the Managed Entry Agreement (EMA) exclusively to the budget for new drugs	4. Restore rebates from the Managed Entry Agreement (EMA) as the exclusive budget for new drugs: Increase budgeting flexibility for new cancer drugs or make them the funding source for the Cancer Drugs Fund.
4. Failure to live up to the essence of users sharing the payment	5. Restore the flat rate as required by law for the co-payment system, with the co-payment waived for major illnesses and injuries and the maximum number of years defined. (1) Restore the flat rate of co-payment for the general public as defined in laws and regulations on the National Health Insurance. With the current medical expenses combined, co-payment at 20% or more will be collected. (2) Under the premises of the more capable paying more and an upper limit defined, co-payment is waived for patients with major illnesses and injuries. (3) Outpatient and inpatient expenses are combined, with the upper limits of per-occurrence and annual co-payments defined in order to avoid an excessive economic burden on the people.

Analysis of Issues 3 (P17) Difficult-to-Understand and Insufficiently Transparent Clinical Trial Information	**Policy recommendation 3 (P18) Improved User-friendliness of Clinical Trials Information**
1. No official referral mechanism for clinical trials at hospitals	1. Establish an authority to take charge of clinical trial referrals: It is hoped that an exclusive window configured with appropriate manpower and operating funds may be available for official referrals in the future to facilitate the creation of a well-knitted clinical trial network.
2. Low visibility of clinical trial disclosure channels	2. Communicate clinical trial information and make the best of novel communication tools according to the population: Tools such as different portals and the NHI APP are utilized to improve public clinical trial information and correct awareness.
3. Insufficiently integrated database disfavors inclusion efficiency and impact how fast new drugs are introduced	3. Integrate the database to boost clinical trial efficiency and quality: Expedite clinical trial match efficiency under the premise that personal data security is protected to attract international clinical trials and to expedite accessibility of new drugs.

Analysis of Issues 4 (P20) **Insufficient Risk-sharing Benefits of Commercial Insurance**	**Policy recommendation 4 (P21)** **Effectively Supplementary Commercial Insurance**
1. People have insufficient knowledge of insurance	1. Turn around people's knowledge of insurance (1) The essence of insurance is protection: The Financial Supervisory Commission (FSC) shall proactively educate the public and provide them with the incentives to purchase pure protection commodities. (2) Understand the risks and plan properly: Concerned authorities shall be empowered to define the NHI coverage and co-payment for the treatment of cancer in order to help the general public to choose plans appropriately reflective of the stage in their life and their demand.
2. Insurance policy pending innovation	2. Development of modernized insurance (1) Proactively manage early disputes concerning insurance benefits: The FSC shall have the insurance company and its sales representatives communicate how "highly alternative medical treatment" may be paid and have risk properly controlled. (2) Cross-disciplinary collaboration to promote innovative insurance policy: Continue to run the cross-disciplinary team consisting of representatives from the Insurance Bureau and the National Health Insurance Administration and seek that the Ministry of Health and Welfare spearhead the integration of out-of-pocket data at respective hospitals and provide related statistics to facilitate the design of innovative insurance policies with reasonable premiums.

C. Review of Progress with Policies between 2019 and 2020

After immune checkpoint inhibitors (IO) and CDK4/6 inhibitors were included in the NHI coverage in 2019, multiple drugs treating breast cancer, lung cancer, medullary thyroid cancer, fallopian tube cancer, primary peritoneal carcinoma, melanoma, lymphoma, prostate cancer, and advanced renal cell carcinoma were included successively throughout 2020, as were antiemetics, leucocyte growth boosters, and peripheral medications treating cancer-related fatigue.

Besides the inclusion of cancer drugs in the NHI coverage, the Foundation has followed up on and examined the reviews of new drugs included in the NHI coverage and the finances as well as policies on clinical trials and commercial insurance over the past two years.

I. Gradually Improved Systems and Efficiency in the Review and Inclusion of New Drugs in National Health Insurance Coverage

(I) Enforced Items:

1. To expedite the review of new drugs, the NHIA has enforced the "New Drug Submission Inspection"[1] scheme since January 1, 2020 to ensure that NHI review begins only after all materials are prepared and to reduce the time wasted on supplementation and re-submission.
2. The NHIA has enforced "face-to-face communication and consultation"[2] since January 1, 2020. Members of the Health Technology Assessment (HTA) group of the Center for Drug Evaluation (CDE) communicated directly areas with concerns with the NHIA and the review experts in order to reduce the possible delay and misunderstandings associated with only written correspondences. Following the communication effort, if the CDE believes that the report needs to be revised, the post-amended HTA report may be submitted after the meeting.
3. Patient Opinions Gradually Gain Prominence
   (1) The CDE already officially included patient opinions in 2020 in the HTA report to facilitate discussions during the Pharmaceutical Benefit and Reimbursement Scheme Joint Committee (the PBRS).
   (2) The CDE consulted the Foundation in 2020 and updated the "New Drug and New Medical Device Patient Opinion Sharing Platform" in August of the same year to make it more friendly for the readers and those trying to provide requested information.
   (3) Since 2020, the PBRS is precedented by pre-meetings held by the CDE where representatives of patient groups can share user experiences of new drugs directly.

[1]「藥品納入全民健康保險給付送審資料檢查表」，2019 年 11 月版
[2]「專家諮詢會議前之面對面溝通諮詢」作業流程

(II) Items Under Preparation:

1. The NHIA authorized the National Health Research Institutes to hold the "NHI Drug Coverage and Payment System Reform Proposal" forum where the "establishment of payment review principles and criteria" was introduced. It is to define the incremental cost-effectiveness ratio (ICER), which will be the reference in the review of new drugs; the ICER may not adequately increased for the minorities.
2. The CDE was already authorized in 2019 by the NHIA to conduct the study on the "review of current NHI coverage benefits applying the health technology reassessment (HTR)".

II. Normalized Finance for More Reasonable Distribution and Utilization in Paying for New Drugs

(I) Enforced Items:

1. The budget for new drugs is climbing on a yearly basis and that for new drugs and new technologies in 2020 and 2021, respectively, was NTD 3.186 billion and NTD 3.671 billion.
2. The Managed Entry Agreement (MEA) was approved in June 2018. The manufacturer must return an amount at a certain ratio to the drug cost as the contribution to global budget of National Health Insurance to hopefully be used exclusively for new drugs treating cancers.
3. The Ministry of Health and Welfare announced an increase in the NHI premium on December 30, 2020. Effective January 1, 2021, the rate would be increased from 4.69% to 5.17% and that for supplementary premium from 1.91% to 2.11% to adequately broaden sources of funds for the National Health Insurance.

(II) Items Under Preparation: The NHIA has announced adjustments of certain co-payments in 2021, focusing on those for drugs and examinations.[3][4] Nevertheless, substantial policies are yet to be seen.

III. Adequate disclosure of clinical trial information:

The CDE continues to enforce its plan to improve the clinical trial information network, including its reader-friendly text and information abundance.

IV. Promotion of the idea of commercial insurance supplementary to NHI coverage

(I) Enforced Items:

1. The FSC defined the threshold for traditional life insurance in June 2019 in order to increase the protection of insurance coverage for the people in Taiwan and to encourage insurance

[3] 健保重大變革//部分負擔 將調整收費，20210223，自由時報
[4] 健保藥品部分負擔 200 元上限不變 一定金額以下擬免收錢，20210311 中國時報

companies to adjust their insurance commodities. It was meant to correct the issue of excessive growths in premium income from the large quantity of savings-oriented policies sold and to return to the protective nature of insurance[5]. The 2020 statistics of the Life Insurance Association show that[6] premium income from traditional life insurance dropped by 37.5% and that from health insurance grew by 7.7%. The developments are headed towards the policy goal.

2. Insurance policies for out-of-pocket genetic testing, targeted treatments, and immune cell treatments are already available on the market from insurance companies.

(II) Items Under Preparation: The Insurance Bureau has authorized scholars to analyze the incidence rates of diseases based on the NHI database for years. The findings are adopted by insurance companies for actuary purpose. The Insurance Business Development Center authorized scholars to conduct cancer-related studies in 2014. The Insurance Bureau invited the chairman of the Foundation and many experts in 2019 to join efforts with the NHIA in starting cross-disciplinary talks and in forming the task force. At present, commercial cancer coverage policies are designed differentially for early-stage, mild, and severe levels of cancer in order to meet the protective demand. Continuous research on the innovation of policies in the future still requires further cross-disciplinary collaboration.

[5] 金管會召開壽險業負責人座談會，20190522，金管會
[6] 2020 年 1~12 月壽險業績統計，2020 年壽險公會

D. Overview of Cancer Treatments in Taiwan

I. Number of People with Cancer Keeps Climbing and Remains as No. 1 Cause of Death among Nationals

According to the 2018 Cancer Registry Report of the Health Promotion Administration, 116,131 people were newly diagnosed with cancer in Taiwan, an increase of 4,447 people from the preceding year and the number of people newly diagnosed with cancer officially broke the threshold of 110,000 sufferers with an incidence of 309.8 out of every 100,000 people. One person was diagnosed with cancer every 4 minutes and 31 seconds on average, which was 9 seconds shorter than the preceding year.

Meanwhile, cancer has ranked first among the top 10 causes of death in Taiwan for 39 years. In 2020 alone, 50,161 people died of cancer, accounting for 29.0% of all deaths; the death rate was 212.7 out of every 100,000 people. In terms of age, 86% of the deaths occurred in sufferers 55 years and above. In terms of the type of cancer, lung cancer remained as the top cause of death, followed by liver cancer and colorectal cancer.

II. Statistics of NHI Premium for Cancer Treatments

The NHIA statistics show that a total of 777,486 patients with cancer were being treated throughout 2020.[7] Among them, the top 10 types of cancer accounted for up to 75% of these cases, with the number of people seeking medical attention shown in Figure 2 below.

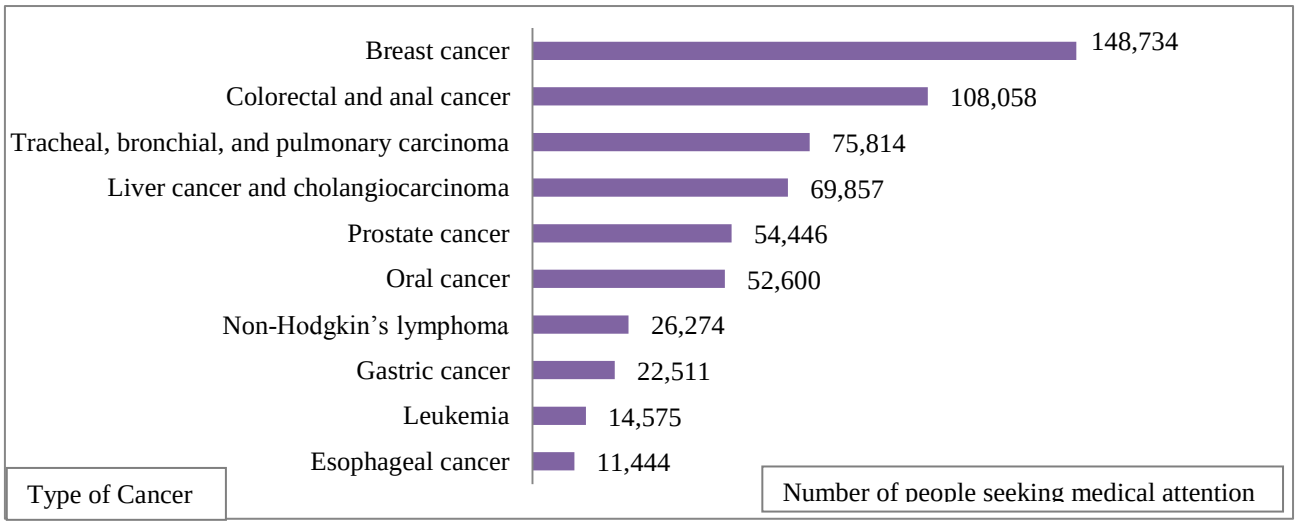

Figure 2 Statistics of people seeking medical care for top 10 cancers in 2020
(Source: National Health Insurance Administration)

[7] 2020 年各類癌症健保前 10 大醫療支出統計(健保署，2021.06.09)

NHIA statistics show that the total medical expenses on the treatment of cancer throughout 2020 was approximately NTD 121.2 billion.[8] That is, every 1 out of 5.5 NT dollars as the NHI premium was spent on the treatment of cancer. The overall cancer treatment cost (including painkillers and anti-emetics), in particular, was climbing each year and broke the threshold of NTD 40 billion in 2018, and was NTD 49.06 billion in 2020. The margin of growth was 8.48% on average over the past yearly five years. Regarding the climbing cancer cost each year, much of the cost was due to the increased number of cancer cases and the elevated cost of medical care. Many new drugs and new treatments are yet to be included in the NHI coverage or are payable under strict conditions. Many obstacles remain in terms of the accessibility of new drugs.

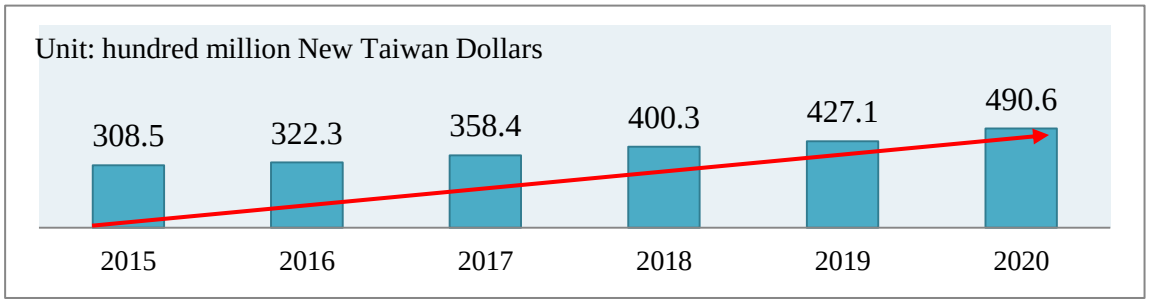

Figure 3 Statistics of overall cancer treatment costs

(Source: National Health Insurance Administration)

III. Trends in the Use of Cancer Drugs

Of the medicinal products solely treating cancer (including targeted drugs, chemotherapy drugs, hormones, immunomodulators, immune checkpoint inhibitor (IO), and radiopharmaceuticals), targeted drugs remain as the mainstream in the treatment of cancer. In April 2019, immune checkpoint inhibitors (IO) were included in the NHI coverage with NTD 800 million allocated. In 2020, coverage increased to NTD 1.08 billion. The ratio of targeted drugs to other cancer treatments dropped slightly in 2019 and climbed again in 2020.

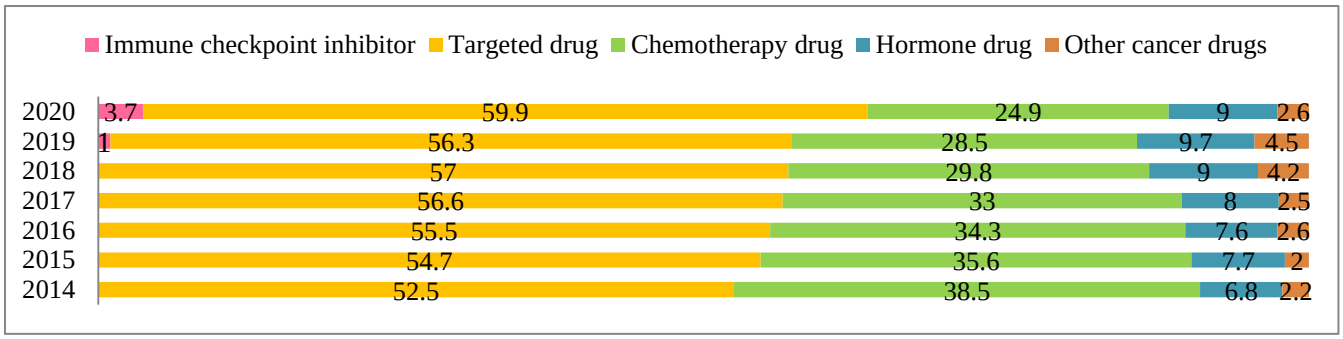

Figure 4 Percentages of costs of drugs for respective cancers

(Source: National Health Insurance Administration)

[8] 每 5.5 元有 1 元用在治癌，健保如何精準給付？ (康健雜誌，2021.09.17)

E. Improved NHI Review and Allocation of Resources

Ms. A: The doctor says that the new drug works for me but I am not qualified for NHI coverage. With chemotherapy, I will be too weak to make money and support my family. It is impossible for my parents to take care of me, either. To remain working and maintain the current family life, I can only choose to use the new drug paying out of my own pocket.

Mr. B: The new drug can keep the tumor under control but each regimen costs NTD 100 thousand. I clearly tell my family that I will only use the new drug up to the end of benefits available from my insurance coverage; I do not want to spend any of my family's money.

Cancer treatments are being introduced one after another. During the lengthy process for them to be included in the NHI coverage, however, many patients with cancer choose to give up on treatment because of the unaffordable out-of-pocket cost or hang on despite the high cost and subsequently have their quality of life seriously impacted. The strict restrictions over payment criteria of the NHI led to the compromised efficacy of new drugs for many cancer patients by the time these treatments are used. This situation is possibly due to prior treatments that have already made the patient's physical condition suboptimal, or due to the limited period when the new drug is covered by the NHI and thus continued use requiring payment out-of-pocket even though the new drug remains effective. The Foundation hopes to take care of both the rights of patients with cancer and the sustainability of NHI resources and bring forth the following policy recommendations to reduce the time needed to have NHI coverage, to enhance the NHI payment efficacy, and to accordingly rescue the valuable lives of more patients with cancer.

Analysis of Issues 1: NHI Coverage for New Treatments - Lengthy Process

1. Absence of a reasonable timetable defined for review of new drugs

The NHIA only specified that the HTA group needs to produce a complete HTA report within 42 calendar days as part of the review timetable for new drugs to be covered by the NHI but did not specify the regulations governing subsequent submission timetables, such as the submission deadline for manufacturers and the timing for it to be included in the review during the PBRS. This lack of clarity usually makes it impossible to precisely keep track of the review progress and once gave rise to concerns about international data quoted in the HTA being outdated. This disfavors the overall quality and efficiency of the review of new drugs.

2. Absence of a prioritized review mechanism for new drugs

Besides the absence of a defined reasonable timetable for the review of new drugs as mentioned above, the Prioritized Review Mechanism upon Registration of New Drugs that is available at the Food and Drug Administration (hereinafter referred to as the TFDA) is lacking at the National Health Insurance Administration; a prioritized review mechanism is yet to be established for indications of new drugs that treat seriously life-threatening conditions and new drugs with medically advantageous clinical purposes and those capable of meeting urgent medical needs. As a result, new cancer drugs having met the above-mentioned criteria are pending as general drugs and may take longer to be approved. According to the statistics provided by Chao-Chih (Janice) Chen, the chairperson of the PBRS, the median number of days from submission by the manufacturer for review by the NHIA to the effective date when novel cancer drugs are included is 555, which is nearly twice that of new non-cancer drugs, which is 304 days[9]. Cancer is a life-threatening disease and, for the patients who are racing against time, the lack of a prioritized review mechanism is unreasonable.

3. Lack of sufficient emphasis on opinions from patients with cancer

(1) The criteria and procedure by which members of the National Health Insurance Committee screen patient groups are not fair nor sufficiently transparent.

According to the Information on the Composition and Employment of Members of the National Health Insurance Committee[10], the screening of patient groups consists of two stages. Stage 1 is the submission of prepared materials based on which groups are categorized, scored, ranked, and circled by external screening members reflective of their respective characteristics.

[9]新藥生效分析，陳昭姿，2020/10

[10]全民健康保險會委員組成及聘任說明，健保會 2011 年版

Only circled groups can take part in Stage 2 for lot drawing. External screening members, however, are not completely aware of the nature of each group. Hence, the categorical rating may not reflect the actual functionality of the group. The ultimate scores and circled status are not released; the procedural transparency leaves room for improvement.

(2) Patient group representatives unable to speak in the PBRS

In 2019, the Ministry of Health and Welfare revised Article 4 of the Regulations Governing the Joint Establishment of National Health Insurance Drug Dispensing Items and Fee Schedule by adding two representatives of patient groups to be seated in the meeting who may only speak during a roll call by the chairperson. Two years have passed and little progress has been made in the speaking rights sought for by patient groups.

(3) Collection through the patient opinion platform limited to drugs applying for indications for the first time

At present, the NHIA only collects user experiences from patients using new drugs that are submitted for the first time. The addition of indications of many targeted new drugs in the NHI coverage has been applied for recently. An expansion in indications means that the specific drug may benefit more patients with cancer; nevertheless, it also means greater impacts on NHI finances. As such, user experiences of patients become even more important. Unfortunately, user experiences are yet to be collected through the platform from patients with expanded indications. Patients hence miss the opportunity to have their voices heard regarding the protection of their right to treatment.

Policy recommendation 1:
More Systematic and Efficient Review and Inclusion in Coverage of New Drugs

1. There should be an open and expected reasonable timetable in place for the review of new drugs

The NHIA may set up an open and reasonable timetable that includes the announcement of the submission status (such as initial submission and missing information, etc.), inclusion of drugs in NHI review. This is so that concerned authorities can keep track of the drug review status and can be aware whether the review is delayed because of issues encountered in the submission or due to a backlog in scheduling. Such a system would also allow for the ability to boost the review efficiency, to minimize loopholes, and to avoid a time interval that is too large between the output of an HTA report and entry into NHI review and a resulting loss of HTA report time-effectiveness.

2. Establish a prioritized review mechanism for new drugs just like that available at the Food and Drug Administration

Cancer is a life-threatening condition. Some of the new drugs included in the NHI coverage are meant to meet urgent medical needs. The Prioritized Review Mechanism upon Registration of New Drugs of the **Food and Drug Administration** should be referred to. As long as new drugs treating cancer meet the criteria for prioritized review, they shall be entered for prioritized review so that patients with cancer can have access to adequate treatment with minimal delays.

3. Continue to promote diversified patient involvement schemes

(1) Open and transparent member screening process for the National Health Insurance Committee

- Groups with the intention to run for membership shall be given the opportunity to select their own category; this is to prevent the difficulties of sharing fair opportunities because of the non-conforming nature of the group.
- The rating records shall be released so that participating groups know why their candidates were not elected.

(2) Ensure the rights of representatives of patient groups in the PBRS

Diversified participation is emphasized in the second-generation NHI. Efforts shall be made to ensure that representatives of patient groups have rights equal to those of the representatives of other groups in the PBRS. Patient groups are no longer simple audience members in the PBRS; they are now official representatives who actively speak up and consolidate the essence of patient involvement in the NHI decision-making process. It is

advised that the NHIA periodically hold relevant training courses, help representatives of patient groups gain basic knowledge about the PBRS and NHI review so that patient groups can express opinions more professionally and more effectively to facilitate subsequent communications.

(3) Reinforced visibility of patient opinions

To address possibly imbalanced financial impacts during NHI review, patient user experiences on expanded indications of new drugs should be collected to signify the value and benefits of the drug. Meanwhile, the NHIA should make use of social media such as Facebook to improve the visibility of the "New Drug and New Medical Device Patient Opinion Sharing Platform" so that more patients have the opportunity to express their opinions.

Analysis of Issues 2: NHI Coverage for New Treatments - Financial Restrictions

1. Ineffective new drug budget planning and utilization

NHI expenditure only accounts for 3.3% of the GDP of Taiwan, less than that of any country with social security systems,[11] indicating that government investments in the NHI are insufficient. Furthermore, most of the large molecular biologics (that is, biologics) that have been introduced to the market one after another for the past few years are drugs for unmet medical needs, such as those treating cancer, rare diseases, and rheumatism and immune disorders. Although they are good news for the patients, they tend to be expensive and precise medication requires prior genetic testing. Such pricey costs impact the finances of national healthcare insurance systems significantly. It is, however, not an issue encountered only in Taiwan. The financial burden brought about by new medical technologies is also mind-wrenching in other countries around the world.

Over the past five years, the budget for NHI-covered new drugs multiplied. Progress has been made on including new drugs under NHI coverage. Since the additional budget for new drugs is decided by the estimated budget inferred for the coming two years after the replacement rate of new drugs is removed from the declared mean value of the costs of new drugs included over the past five years, the retroactive appropriation approach often led to the budget value failing to reflect the developments of medical technologies or very strict payment criteria as a result. Common ones included a restricted number of years of use and medication eligibility, which are not all reasonable[12]. Large molecule drugs only account for around 16% of the NHI covered drugs, which is far below the 34% in advanced countries,[13] indicating that medication in Taiwan has yet to keep up with the developments of cancer drugs and there is still room for growth in the future.

2. Re-evaluation schemes and exit principles non-rigidity

For drugs that are currently covered by the NHI, there are no substantial re-evaluation schemes and exit principles available. Covered items with low treatment efficacy, on the other hand, they are withdrawn only when they have not been used for a long time. This disfavors the efficacy in the utilization of NHI resources. The discontinued coverage of the eight immune checkpoint inhibitors (IO) in 2019 by the NHIA after they were found to have undesirable efficacy when compared in advanced liver cancer and gastric cancer versus another six types of cancer, however, triggered debates[14]. The main cause was the absence of rigid and consistent re-evaluation schemes

[11] 葉旭霖／以國際脈絡、統計檢視，台灣醫療支出和健保真的花太多錢嗎？ (報導者，2020.10.07)
[12] 醫病平台／健保癌症用藥給付的合理起跑點(聯合報元氣網, 2020.08.21)
[13] 「全民健康保險藥品給付及支付制度改革」論壇第三次會議(2020.03.13)
[14] 參考胃腺癌及晚期肝癌 不再給付免疫新藥(聯合報 2020.03.30)、健保會委員關切胃腺癌及晚期肝細胞癌病人使用癌症免疫藥品之權益(全民健康保險會 2020.06.12)

and exit principles defined by the NHIA. With rigid re-evaluation schemes and exit principles lacking and the limited growth in the funding source for the NHI, it is inevitable that the introduction of innovative drugs would be delayed, undermining the rights of cancer patients to receive adequate treatment in a timely manner.

Although the NHIA already outsourced the study on the "review of current NHI coverage benefits applying the health technology reassessment (HTR)" to be conducted by the CDE in 2019, a consensus or implementation of substantial policies has yet to be seen to this date. The NHIA can hopefully take this seriously and expedite consolidation of policies.

3. Failure to devote rebates from the Managed Entry Agreement (EMA) exclusively to the budget for new drugs

The Managed Entry Agreement (EMA) was officially approved by the NHIA in 2018. It enables the NHIA to enter into price negotiation agreements and enforce repayment plans with manufacturers on expensive drugs treating cancer that may significantly impact finances. For the time being, however, the repayment will be returned to the NHI global budget, which is not helping much with regard to the overall budget for new drugs.

4. Failure to live up to the essence of users sharing the payment

(1) Co-payment for the general public in medical care

In countries or regions where universal health coverage is available, the cost of medical care is relatively low. As such, over-consumption of healthcare services can be a concern. In light of this, a fixed amount or a certain ratio will be collected as the co-payment reflective of the financial capability of each patient. With users knowing that medical care is provided at a cost, it helps to adequately reduce waste and low-efficacy medical care (In Japan, for example, the co-payment collected accounts for 30% in general and 10% for low-income elderly people aged 70 and above. In Australia, on the other hand, the co-payment collected for a single drug is AUD 41.3 and only AUD 6.6 for patients relatively disadvantaged within the safety net[15]).

(2) Co-payment for patients with major illnesses and injuries

The waiver of co-payment for patients with major illnesses and injuries such as cancer is unique of Taiwan (even in Korea where the co-payment for major illnesses and injuries is relatively low, it is 5%). The waiver was adopted for the NHI in the beginning to prevent poverty due to illness since many patients must discontinue their work to get medical attention, and frequent visits to the doctor are needed in the case of major illness and injury. This preferred treatment has now triggered a debate over its fairness since the co-payment is waived

[15] About the PBS(https://www.pbs.gov.au/info/about-the-pbs#What_are_the_current_patient_fees_and_charges)

based on the type of disease instead of financial capability; it is believed that the policy goes against the initial considerations for the waiver.

Policy recommendation 2: More reasonable allocation of NHI finances

1. Keep track of medical trends and ensure that budget is used in an efficient way

The financial burden brought about by new drugs is mind-wrenching in countries around the world. In order to define the response plans early on, horizon scanning is adopted in countries with different healthcare systems[16]. The different roles and functions of new health technologies being developed are monitored and data are collected for analysis purpose in order to caution early possible impacts on the health, social, and medical care service systems in the future. The NHIA started to enforce horizon scanning in November 2020 and set up the Prospective New Drug and New Coverage Budget Estimation Registry and Platform. Manufacturers are asked to periodically report the costs and indications of drugs that may be available on the market in the coming two to three years. Those costs would serve as the baseline for appropriating the budget. It is the Foundation's hope that horizon scanning helps correct the significant gaps between the budget set aside retrospectively and the actual costs of new drugs that were found in the past which make it impossible to include new drugs in the NHI coverage. The NHIA shall apply horizon scanning as part of advance deployment taking advantage of the growth in the global budget after the NHI premium is slightly raised in 2021 and make patient-centered rolling correction to keep track of trends with new drugs with the goal of more reasonable planning.

In boosting cost-effectiveness and cutting expenses, we hope that pharmaceutical companies can introduce more outcome-based approaches in payments for new drugs and improve the payment value. However, in terms of the substitute policy enforced in other countries over the past few years (such as a reduction in price by 30% and 25%[17], respectively, in Korea and in Australia after the patents of drugs have expired to facilitate the introduction of generic drugs and biosimilars), the Foundation is happy to see the increase of the NHIA in the use of generic drugs and biosimilars as it helps preserve the budget for drugs and the budget may be used to introduce more new drugs. While implementing the substitute policy, however, the government shall strictly safeguard the quality of the substitutes (safety and efficacy) to ensure that the rights of patients to medication are not undermined as such.

Precision medicine is a current trend in the development of medical care and that emphasizes the right medicine for the right condition. Many cancer drugs need to be used in patients carrying certain specific genes to render the best treatment benefits. The NHI coverage for EGFR and ALK genetic testing for lung cancer that has successively become available and has not only relaxed the financial burden for the patients but also reduced ineffective medical expenses. This change is worth

[16]台灣執行前瞻性評估(Horizon Scanning)之作法與現況。 醫藥品查驗中心,2020.04.30
[17]國家衛生研究院「全民健康保險藥品給付及支付制度改革」論壇第三次會議資料, 2020.03.13

recognition. In order for NHI resources to be utilized in an efficient way, the NHI coverage should be made available as a package for the corresponding new drugs and testing of specific genes in the future to maximize the efficacy of NHI resources.

2. The pilot project of the Cancer Drugs Fund

The Cancer Drugs Fund (CDF) is available in the UK (refer to Page 23 for details) for new drugs that are urgently needed for clinical use, with highly undefined efficacy, and high financial impact. The National Institute for Health and Care Excellence (NICE) will submit the Health Technology Proposal for each application for a new cancer drug within 90 days to confirm if transitional payments will be made out of the CDF and to provide the drug to cancer patients in need under national coverage as early as possible. Such transitional payments may last a maximum of two years. During this period, pharmaceutical companies are asked to collect information on the actual medication and user experiences of patients and re-submit it for review. With proven efficacy, the drug may be included for normal coverage. On the other hand, the drug will be withdrawn and no longer payable. The drug, however, will continue to be provided by the manufacturer in order to protect the right of patients currently using the drug. Since the CDF became available for the first time in 2011, despite bankruptcy and reformation, among other changes that it has gone through, its accomplishments have been widely recognized. The UK government even promises that the fund will be expanded and become the Innovative Medicines Fund (IMF) so that patients who do not have cancer can also use the drugs and benefit from them early on[18].

It is advised that the NHIA can run the Cancer Drugs Fund like that in the UK while simultaneously collecting information on the outcome of medicine used by the patients and the patients' experience (RWE) in addition to auxiliary measures such as the re-evaluation scheme. They may serve as a reference during the decision-making process over whether to include a certain drug in the NHI coverage. Examples include immune checkpoint inhibitors that may only be included in the coverage over a period of five years. With the CDF available as the auxiliary scheme, it may expedite inclusion in coverage. For the auxiliary funding source, tobacco surcharge,[19] charity lottery, and[20] EMA rebates for cancer drugs may be considered. If transfer of funding sources is restricted by law, it may be considered to set up funds with contributions from the general public or enterprises, too. Management shall still be the responsibility of the NHIA. Suitable systems and budget shall be available to keep the funds operable so that patients can have access to suitable treatments as early as

[18]英國創新藥物基金奠基在癌症藥物基金的成功操作模式，楊雯雯，2021/08/02
[19]菸品健康福利捐，衛生福利部國民健康署
[20]公益彩券盈餘分配比率，台灣彩券股份有限公司

possible to reduce unnecessary consumption of medical care. This will fall in line with the policy of the Ministry of Health and Welfare to "invest in health."

3. Promote the rigid re-assessment scheme to improve the coverage

Re-assessment of health technologies has become one of the approaches to improve the quality of care and stabilizing finances that was adopted by health insurance authorities in countries around the world over the past nearly ten years. It covers two concepts, namely obsolescence and health technology disinvestment[21] and has been enforced in the UK, Spain, Australia, and many EU states.

It is advised that the NHIA refer to the international approaches mentioned above while introducing a complete re-assessment scheme for items already covered by the NHI. It is also advised that the NHIA collect real world evidence, periodically evaluate the benefits payable on the efficacy of drugs for the same type of disease, and define the objective criteria for comparing treatment efficacy across different types of cancer that is reflective of the actual usage among patients. In case of undefined efficacy or a treatment falling short of expectations, the specific drug is withdrawn based on consistent criteria with patients' right to medication being protected. Resources saved with the re-assessment scheme may be devoted to paying for new drugs and new technologies to enhance the efficacy in the configuration of NHI resources; it also avoids recurrence of disputes such as discontinued payments for IOs treating advanced liver cancer and gastric cancer.

4. Restore rebates from the Managed Entry Agreement (EMA) as the exclusive budget for new drugs:

The MEA rebates, when returned to being part of the NHI global budget, help minimally given that the NHI global budget is worth nearly NTD 800 billion. MEA rebates may render more substantial effects on the budget for new drugs that totals over NTD 3 billion. Furthermore, since the rebates are derived from the MEAs for respective drugs, they shall be used exclusively for the specified purpose. It is advised to contribute MEA rebates exclusively to the budget for new drugs to add to the flexibility of the budget for novel cancer drugs or to make them one of the sources for the Cancer Drugs Fund. It helps boost the accessibility of new cancer drugs with highly undefined efficacy.

[21] 淺談醫療科技再評估(當代醫藥法規月刊 99,2019.01.10)

5. Restore the flat rate as required by law for the co-payment system, with the co-payment waived for major illnesses and injuries and the maximum number of years defined

By adjusting the co-payment, it reminds patients that medical care is provided at a cost and that they should utilize medical care with caution to reduce unnecessary waste of the NHI on low-efficacy medical care. This allows the NHI to be more reasonably distributed and to utilize surplus funds. The extent of adjustment, on the other hand, is considered primarily on the basis of the financial capability of the patient.

(1) Restore the flat rate of co-payment for the general public as defined in laws and regulations on the National Health Insurance

Article 43 of the current National Health Insurance Act stipulates that without referrals, a co-payment of 50%, 40%, and 30%, respectively, is collected at a medical center, a regional hospital, and a local hospital. With referrals, on the other hand, 20% of the medical care charge is collected as the co-payment. The current practice, however, is that a fixed amount as announced is collected (NTD 420 at a medical center, NTD 240 at a regional hospital, NTD 80 at a local hospital, and NTD 50 at a clinic). In other words, the co-payment that should have been paid by people seeking medical attention is transferred to be payable out of the NHI global budget, which makes NHI finances even worse. As such, it is advised that co-payment shall be collected at a flat rate as defined under the National Health Insurance Act in honor of the essence that users share the payment.

(2) Adjust the waiver of co-payment for patients with major illnesses and injuries

The Foundation believes that whether a patient is entitled to a waiver of co-payment shall be determined by his/her "financial capability" instead of disease. In light of fairness and reasonable configuration of NHI resources, the waiver of co-payment for major illnesses and injuries shall be gradually canceled. Considering the financial burden for patients with major illnesses and injuries from medical care over the long term, however, a lower ratio of co-payment than that for the general public may be applied, such as 10% in Japan or 5% in Korea. This avoids the risk of ethical abuse. For low-income patients, however, a complete waiver of co-payment and auxiliary measures such subsidies from the government need to be available.

As for the assertion that cancer patients and the NHIA share the payment for new cancer drugs at different ratios (such as 10%-30% for the patient and 70%-90% for the NHIA), at first glance, it seems that patients can have access to the new drugs more promptly to reduce their burden; the uncertain gray area associated with the efficacy of new drugs that is to be addressed by the patients, however, is a hidden concern. Patients who are unable to afford the medication will be the first to be sacrificed. It opens the door to hierarchical medical care.

Suppose that the costs of drugs come to NTD 1 million a year. Patients may need to afford NTD 100,000 to NTD 300,000 to afford such costs. The 2019 Family Income Survey Report[22] shows that the disposable median income per person was NTD 302,887. In other words, with the above-mentioned co-payment for new cancer drugs, nearly half of the patients will lose their right to such medicines. The NHI shoulders the liability over the efficacy of covered drugs. This proposal will, however, create additional burden for the patients because of the required professional judgment and co-payment, which is obviously against the essence of the National Health Insurance.

(3) Set the upper limit of co-payment

At present, the NHIA only sets the upper limit of co-payment for hospitalization throughout the year[23]. The Foundation believes, however, that outpatients and inpatients shall be combined while the upper limit of all co-payments throughout the year and that of each co-payment are being set. For co-payments throughout the year, it is advised to adopt one-tenth of the per-capita GDP as the baseline and make proper adjustments reflective of the insured salary of each person. For the upper limit of co-payment for each outpatient visit, on the other hand, it may be considered to be set at NTD 1,000 to NTD 2,000. For special subjects, such as low-income earners and near-poverty people, their affordability and auxiliary measures may be evaluated separately.

[22] 2019 年家庭收支調查報告，主計處，2019

[23] 獨／明年住院自付額天花板再調高，單次最多付 4.3 萬元，聯合報，2021.09.12

F. Improved Efficacy and Friendliness of Clinical Trials

Patient C: I have heard in patient groups that there are clinical trials at other hospitals that I can take part. I really want to try but I do not where to get further information. I dare not ask my doctor, either, because I am afraid that he will no longer treat me as such.

Clinical trials are one of the ways that patients with cancer can have access to new drugs. It is common, however, that the patients do not know where clinical trials are available or that doctors or pharmaceutical companies have no means to recruit the needed subjects; the supply end and the demand end cannot be linked successfully. Patients need transparent and public clinical trial resources networks so that they can get in contact with healthcare professionals. Furthermore, it is the Foundation's hope that related systems and manpower may be perfected and an attractive clinical trial setting may be created so that patients with needs can have access to adequate treatments and new treatments early on.

Analysis of Issues:
Difficult-to-Understand and Insufficiently Transparent Clinical Trial Information

1. No official referral mechanism for clinical trials at hospitals

The Taiwan Clinical Trial Consortium (TCTC), which became operative in 2011, currently consists of 14 clinical trials targeting specific diseases (including liver disease, lung cancer, breast cancer, and cell therapy), including nearly 300 clinicians and Principal Investigators. The respective hospitals, however, are enrolled voluntarily. It is not an official governmental organization and is not responsible for the management and promotion of clinical trials, either. Without an official referral system, it is hard for the good-intentioned consortium to exercise a function and it doubles the effort for half the result in the implementation of clinical trials.

2. Low visibility of clinical trial disclosure channels

The awareness of clinical trials among the general public other than healthcare professionals is low. They tend to think of people attending clinical trials as guinea pigs, and rarely obtain recruiting information of clinical trials. As a result, the Taiwan Clinical Trials Information Platform and the Taiwan Drug Clinical Trial Information Network are quite strangers to them, which is a pity.

Information about clinical trials, however, is available on either the Taiwan Clinical Trials Information Platform or the Taiwan Drug Clinical Trial Information Network. These two websites are highly overlapping and do not have well-defined target populations. As a result, information may be decentralized, and it is even more challenging to define the difficulty or level of case suitable for the target population. It weakens the usefulness of the websites and patients who wish to gain more information do not know where to begin.

3. Insufficiently integrated database disfavors inclusion efficiency and impact how fast new drugs are introduced

For the clinical trials conducted in Taiwan, it is often practically impossible to locate suitable patients precisely and quickly. One of the key factors is that the NHI database in Taiwan is only available for academic purpose in light of the security of personal data, not for commercial purposes. Completed data of genetic testing and out-of-pocket medical care are decentralized in respective hospitals or testing laboratories. As a result, the data is not sorted out which disfavors the location of subjects for clinical trials and further leads to the impossibility of Taiwan being a prioritized choice in the developments of international clinical trials. It also indirectly undermines the opportunities of cancer patients to have access to new drugs.

Policy recommendation: Improved User-friendliness of Clinical Trials Information

1. Establish an authority to take charge of clinical trial referrals

Taiwan is known for its outstanding soft capabilities in clinical trials. Hopefully, the government can choose a responsible authority to serve as a window into these capabilities and take charge of the management of applicable laws and regulations on clinical trials. Certain manpower and budgets shall be in place, and more hospitals and healthcare professionals are invited to join in the TCTC and remain functional. A tight clinical trial network is created as such for improved referral efficiency to facilitate early entry of novel treatments into Taiwan.

In addition, the COVID-19 Vaccine Clinical Trial Intention Registry may be followed for the registration of those willing to take part in clinical trials through tools such as Easy NHI APP. Once registered, people will receive notifications whenever suitable clinical trials are available to boost the recruiting efficiency.

2. Communicate clinical trial information and make the best of novel communication tools according to the population

Considering that the applicable populations vary and that information shall be updated concurrently, it is advised to integrate related information on one web page, with different portals set up and the contents and orientation clearly defined so that populations such as the government, hospitals, the sponsor, and patients who need to receive the information can search for correct and friendly clinical trial information in real time through suitable channels.

In mid-May this year (2021), the number of confirmed COVID-19 cases climbed quickly. While local vaccines are being proactively developed and the general public is being educated to boost their willingness to explore and know clinical trials further, it is advised that government authorities such as the Food and Drug Administration keep track of opportunities and provide relevant health education information regarding clinical trials to reinforce accurate knowledge about clinical trials among the general public. Information may be broadcast through social media (such as FACEBOOK) or in public places (such as MRT train cars) for extensive exposure.

3. Integrate the database to boost clinical trial efficiency and quality

With the treatment of cancer becoming more personalized and precision-oriented, many drugs are no longer focused on a specific type of cancer but on a specific genotype. It is foreseeable that combining NHI and genetic testing databases will be a future trend. In October, 2019, the Ministry of Health and Welfare established the National Biobank Consortium of Taiwan (NBCT)[24]. It combines

[24] 人體生物資料庫整合運作，增進產官學研資源共享共榮(國家衛生研究院，2020.10.12)

more than a hundred domestic databases such as the NHI database, the cancer database, and the mortality database as well as multiple biological databases. Besides continuing to support the steady growth of the platform so that more thorough data on genetic testing of patients may be collected, it is advised to also form a centralized managing authority. The Korea Ko-NECT office may be followed.[25] Ko-NECT is a non-profit organization sponsored by the MOHW of Korea that provides the latest reliable information about clinical trials (such as the location and the investigator) and integrates relevant information needed for conducting clinical trials. Taiwan can refer to the Korean model by authorizing suitable authorities to properly manage and utilize databases and boost the match-making efficiency of clinical trials under the premise of protecting personal data security so that suitable patients may be found more quickly. Only when a model suitable for Taiwan is developed can it attract international clinical trials and expedite the accessibility of new drugs.

[25] KoNECT (Korea National Enterprise for Clinical Trials)

G. Promote commercial insurance supplementary to HNI coverage

Family D: When I was applying for insurance benefits for my family, I found that out-of-pocket drugs were not covered. Despite the claimed protection for life, it does not seem to help much.

Many people only find out that the coverage available under policies purchased in the early days is far from being sufficient to meet the current demand when they are urgently needing insurance benefits for their cancer. That there are far less benefits available than actually needed may be the result of the insufficient knowledge of the general public about insurance and the costs of medical care for major illnesses as well as the failure to periodically update the insured scope. The supplementary effect of commercial insurance falling short of expectations may also be the result of the changing medical technologies each day, the constantly introduced new cancer treatments, and the gap between the developments of commercial insurance and the progress made in medical technologies. We expect that commercial insurance will honor its protective essence by adequately and properly supplementing what is insufficient of the NHI to become the most helpful pal of patients with cancer while they are fighting against cancer.

Analysis of Issues: Insufficient Risk-sharing of Commercial Insurance

1. **People have insufficient knowledge of insurance**

(1) Insurance is to get the money paid back.

People often believe that it is waste of money if insurance is not used since so much premium is paid each year. Therefore, savings or investment-oriented repayment commodities have mushroomed. Before 2019, the premium for savings-oriented insurance accounted for 97% of overall life insurance. After the threshold ratio of traditional life insurance was set by the FSC in 2019, the percentage dropped significantly; nevertheless, investment-oriented insurance hit a record high over the past 13 years[26] in June 2021, which shows that people still tend to use insurance as a wealth management tool. Because of the repayment of the principal and interest associated with savings and investment-oriented commodities, however, the coverage available for medical care remains low.

(2) All insurance is the same.

The scope of benefits under the NHI of Taiwan is extensive. It usually does not cost much with ordinary illnesses. As such, people who have not been treated for cancer often are unaware of the costs of medical care for critical conditions such as cancer; therefore, the insured amount tends to be low. Statistics of the Life Insurance Association show that nearly 50% (46%) of the benefits available for invoice-based reimbursements of insurance on out-of-pocket cancers are below NTD 100,000, which, for the cost of cancer treatment which can easily reach NTD 1 million a year, offer little help. On the other hand, for the insurance on major illnesses that have to do with the benefits available for cancer, the number of the insured as of the end of 2019 only accounted for around 30% of that for personal health insurance and personal injury insurance, indicating that the insured rate for personal major illnesses still leaves room for growth[27].

2. **Insurance policy pending innovation**

(1) Lagging coverage with existing policies

Once the insurance contract sustains, benefits will be paid according to the terms and conditions included in the policy in the future. The coverage available with life-time policies purchased in the early days is no longer sufficient to meet the current needs given the developments of medical technologies; as a result, circumstances such as unfulfilled reimbursement criteria or seriously insufficient benefits to cover the cost of treatment occur. In the case of chemotherapy for cancers, with the advancement in medical technologies, it is

[26] 擋不住投資狂潮 壽險 5 月業績近 6 成來自投資型保單，工商時報, 2021.06.15
[27] 我國健康險商品之市場概況，壽險公會, http://www.lia-roc.org.tw/index03/heath.pdf

common that outpatient chemotherapy replaces hospitalized chemotherapy, which makes the daily hospitalization benefits available for policies purchased in the early days useless.

(2) Absence of out-of-pocket data as the actuary basis for innovative policies

Related healthcare policies in Taiwan are designed with standardized disease definitions. The NHI is the impartial third party; that is, benefits are available for items covered by the NHI. This helps protect the consumers against different reimbursement criteria for the same conditions but it also restricts the benefits available for out-of-pocket medical care that is not covered by the NHI. Despite the invoice-based reimbursements of insurance that are available for out-of-pocket items now, the absence of out-of-pocket medical care data to allow careful calculation of a fair price leads to incomplete reflection of actual circumstances in Taiwan. If the risk is overestimated, the premium will appear high. Due to the lack of statistics of out-of-pocket items and amounts for patients in Taiwan, insurance companies can hardly obtain data on the current trends in the development of medical technologies and actual clinical conditions. As a result, they find it difficult to carefully decide and design policies meant to supplement the current gap in medical economics.

Policy recommendation: Effectively Supplementary Commercial Insurance

1. Turn around people's knowledge of insurance

(1) The essence of insurance is protection.

The FSC shall proactively and actively promote public education that helps communicate the correct idea about insurance: Insurance is meant to protect against and to transfer unknown risks, instead of being just a wealth management instrument. Meanwhile, the efforts made by the Insurance Bureau, the Taiwan Insurance Institute, the Life Insurance Association, the Non-life Insurance Association, and insurance companies to promote educational films or courses shall be reinforced. Policies shall be applied as well to guide the general public to know insurance and further provide them with incentives, such as higher tax deductibles for those purchasing pure protection-oriented insurance.

(2) Understand the risks and plan properly

Statistics of the NHIA show that the medical costs of Top 10 cancers of 2020 were between NTD 100,000 and NTD 400,000,[28] excluding out-of-pocket items. It costs up to NTD 1 million a year to afford many cancer drugs and hence the actual treatment costs of cancers are often several times that listed in the governmental statistics. According to the survey conducted by the Foundation and Cigna in 2020, a main source of financial burden among 50% of the interviewed cancer patients was drugs, which are also currently minimally covered by commercial insurance. The medical care data of the insured included in the NHI database for the time being are meant primarily for use in academic research. The government did not collect and systematically analyze the out-of-pocket items and amounts. Hopefully, the government can have qualified authorities collect information about out-of-pocket items and amounts for cancers and periodically announce the treatment costs of cancers (such as the treatment costs of the top 10 cancers, including NHI covered and out-of-pocket ones) as well as provide complete and up-to-date information for people to reference while they prepare their insurance policies properly.

In the planning of insurance policies, on the other hand, long-term and short-term/fixed-term coverages shall be equally emphasized. Hopefully, the FSC can guide and educate people on correct ideas about insurance planning and on the proper use of long-term insurance for hedging purpose and the flexibility associated with fixed-term insurance so that they may purchase insurance commodities reflective of their needs in different stages of life and make the best of limited budget for optimal benefits of decentralizing risks through insurance.

[28] 2020 年各類癌症健保前 10 大醫療支出統計(健保署，2021.06.09)

2. Develop of modernized insurance

(1) Proactively manage early disputes concerning insurance benefits

Although the FSC issued multiple official letters between 2010 and 2018 requesting that insurance companies determine the benefits available for "highly alternative medical treatment" on broader terms (such as inpatient chemotherapy to be replaced by outpatient chemotherapy), most policy holders did not receive any relevant information. It was not until the recent surge in the confirmed cases of COVID-19 overburdened the medical system, made it impossible for hospitals to receive inpatients and forced patients to receive the treatment at the outpatient department when that the news about relaxation in the available benefits was widely known. In other words, the FSC must proactively solve the issue that items payable under policies purchased in the early days no longer reflect the current medical situation and that service provided by sales representatives shall be reinforced. When appropriate, the required assistance for the insured shall be proactively provided so that the rights of the insured and the risk control of the company may be taken care of at the same time.

(2) Cross-disciplinary collaboration to promote innovative insurance policy

It is advised to continue to run the cross-disciplinary team consisting of representatives from the Insurance Bureau and the NHIA that will deliberate on the possibility of adequately allowing access to the NHI database under the premise that personal data security is free of concern. Since the scope of operation of the NHIA does not include the collection of information about out-of-pocket items and amounts of patients, it is hoped that the Ministry of Health and Welfare can spearhead the integration of out-of-pocket data of patients at respective healthcare facilities, and with personal data protected, periodically announce important information. On the one hand, this provides the nationals with a range of medical costs for reference. On the other hand, insurance companies may be asked to keep track of the actuary bases and be urged to apply local data while designing insurance policies with more reasonable rates so that insurance policies in the future can better reflect the developments of medical technologies in our country and exercise the supplementary function to the NHI.

H. International experience: UK Cancer Drugs Fund

The Cancer Drugs Fund (CDF) was established in 2011 in the United Kingdom. Its first generation was established as a temporary solution prior to the National Health Service (NHS) adopting value-based pricing for cancer drugs. It was meant to increase the accessibility of new drugs for cancer patients and to improve cancer care as part of the NHS. At its inception, £200 million was provided each year to pay for innovative cancer drugs. Due to the lack of clear criteria for how and when drugs should exit the scheme, the CDF exceeded its budget and spent £340 million. Thus, urgent change is needed to be financially sustainable for the future CDF.

Starting from 29 July 2016, the new Cancer Drugs Fund became operational with a new managed access scheme of clear entry and exit criteria. The NHS England and the National Institute for Health and Care Excellence (NICE) launched a full public consultation on proposals for reforming the CDF, partnered with the pharmaceutical industry, work together to address uncertainties involved in the efficacy of new cancer treatments by collecting more data while paying for the drugs through the CDF. The additionally collected data will help the NICE decide whether a new therapy should be included as part of routine coverage or not.

1. The new CDF is designed to achieve three key objectives

(1) To provide patients with faster access to the most promising new cancer treatments.

(2) To drive stronger value for money for taxpayers in drugs expenditure.

(3) To provide expedited access to promising drugs of pharmaceutical companies that are willing to set reasonable prices by expediting the NICE review process and managing drugs included in the CDF.

2. The new CDF consists of four pillars

(1) A modified appraisal process: The NICE appraisal process starts before a drug/indication receives its marketing authorization.

(2) To enable patients to have access to new drugs as early as possible through transitional payments.

(3) A Managed Access Agreement to resolve uncertainty: The agreement needs to occur between the pharmaceutical company and NHS England and must include a data collection arrangement and a CDF Commercial Agreement.

(4) Financial control by overall CDF budget.

To expedite the review of new drugs and help patients have access to new drugs as early as possible; the drug review system designed in the UK is very forward-looking. The second-generation CDF in the UK combines the NICE technology rating procedure and also the idea of concurrent

review. That is, while the drug is being reviewed for a permit to be issued, the NICE holds review meetings and provides the technology assessment preliminary review proposal. Once the permit is obtained, when the feedback from preliminary review is positive, transitional payments may be made out of the CDF and patients can use the new drug as early as possible before the rating is finalized. Within 90 days after the permit is issued, the NICE needs to complete the final technology assessment proposal. If it is advised to be included in normal coverage, payments will be switched to be made out of the NHS. For new drugs that are promising yet have undefined clinical efficacy, if it is considered that collecting the clinical medication data or clinical trial data will help improve the uncertainty associated with clinical efficacy and accordingly the uncertainty associated with cost-effectiveness, the NICE will advise that payments be derived from CDF. The pharmaceutical company can now decide whether to accept the preliminary review feedback from the NICE and begin the CDF payment plan. Pharmaceutical companies that agree on CDF payments will deliberate on the feedback from the NICE with the NHS and jointly sign the management agreement on the collection of clinical data and payment finances and will be subject to the financial expenditure control plan for the CDF global budget. During the period payable under the CDF, pharmaceutical companies need to provide the NICE with subsequent clinical data collected within two years following initiation of CDF payments according to the contents of the Clinical Data Collection Agreement so that the final advice from the review may be provided.

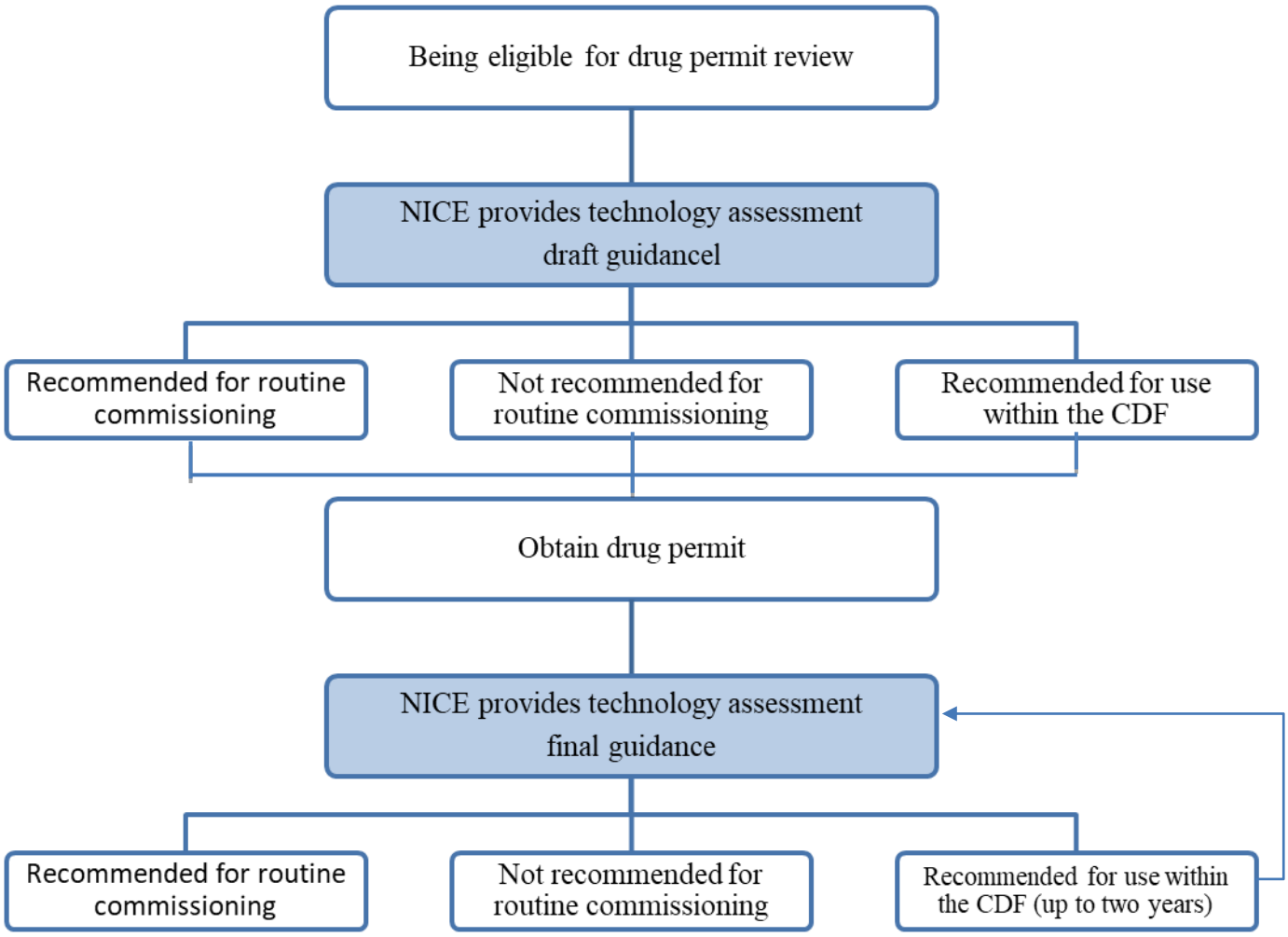

Figure 5 UK NHS new cancer drug evaluation and payment programs

For the second-generation CDF introduced in 2016, the global system is adopted, and the planned annual budget came to GBP 340 million. Conditional premature payments are available for new drugs to meet urgent medical needs and the payment duration is two years at maximum. All the new drugs included in the CDF budget are subject to a proportional rebate mechanism. Prior to the end of each fiscal year, a joint NHS England / NICE CDF Investment Group will determine if and when the rebate mechanism needs to be applied in the event of an overspend. The rebate will be shared by all pharmaceutical companies according to their market share and will be paid back to the CDF.

I. Conclusions and Acknowledgments

The NHI is the pride of Taiwan yet it is at a critical moment pending reforms. Just like what Minister Shih-Chung Chen said in an interview, the NHI is 26 years old now and is faced with issues that are not just about finances but also about its soundness. The overall issues about the NHI and medical care shall be looked at from the perspective of "investment in health": "No investment, No health!"

This Position Paper for Cancer Treatment Accessibility from the Foundation is meant to realize cancer therapy accessibility in honor of the essence of sustainable management of the NHI through reasonable distribution of resources along with commercial insurance supplementary to the NHI while at the same time answering to the care goal "provide timely and adequate cancer treatments to help patients survive successfully" of the Union for International Cancer Control (UICC) - Treatment for All initiative.

We are pleased to see that the Ministry of Health and Welfare is considering NHI reforms applying the idea of "investment in health" and we hope that international experiences may be referred to effectively in the future and resources be devoted to the stipulation of an NHI plan for the coming ten years while the whole nation welcomes a healthy life. The Foundation knows clearly that it takes time for a reform to be enforced and fulfilled. Despite the thorny and challenging path to reforms, with the patients, the government, and the industry working hand in hand, once the gear starts turning, growths towards the better are expected in the future and the whole nation will be entitled to better medical care.

We are indebted to experts and scholars in respective fields for their unreserved guidance on the contents of the Position Paper for Cancer Treatment Accessibility of the fourth edition, including Director Chui-Wen Kuo at Taipei City Hospital, Professor Chih-Hua Chiao at the Department of Financial Engineering and Actuarial Mathematics, Soochow University, and the Taiwan Clinical Research Association that provided professional and insightful advice and Secretary-General Wen-Wen Yang of the Health Outcomes and Technology Teaching and Education Alliance, who advised on the revisions made to the descriptions about the UK Cancer Drugs Fund so that this Position Paper could be as thorough as it is. The Foundation will continue to work with the public sector while jointly building a more systematic, transparent, and reasonable mechanism with the hope for our healthcare system to protect the health of people in Taiwan sustainably.

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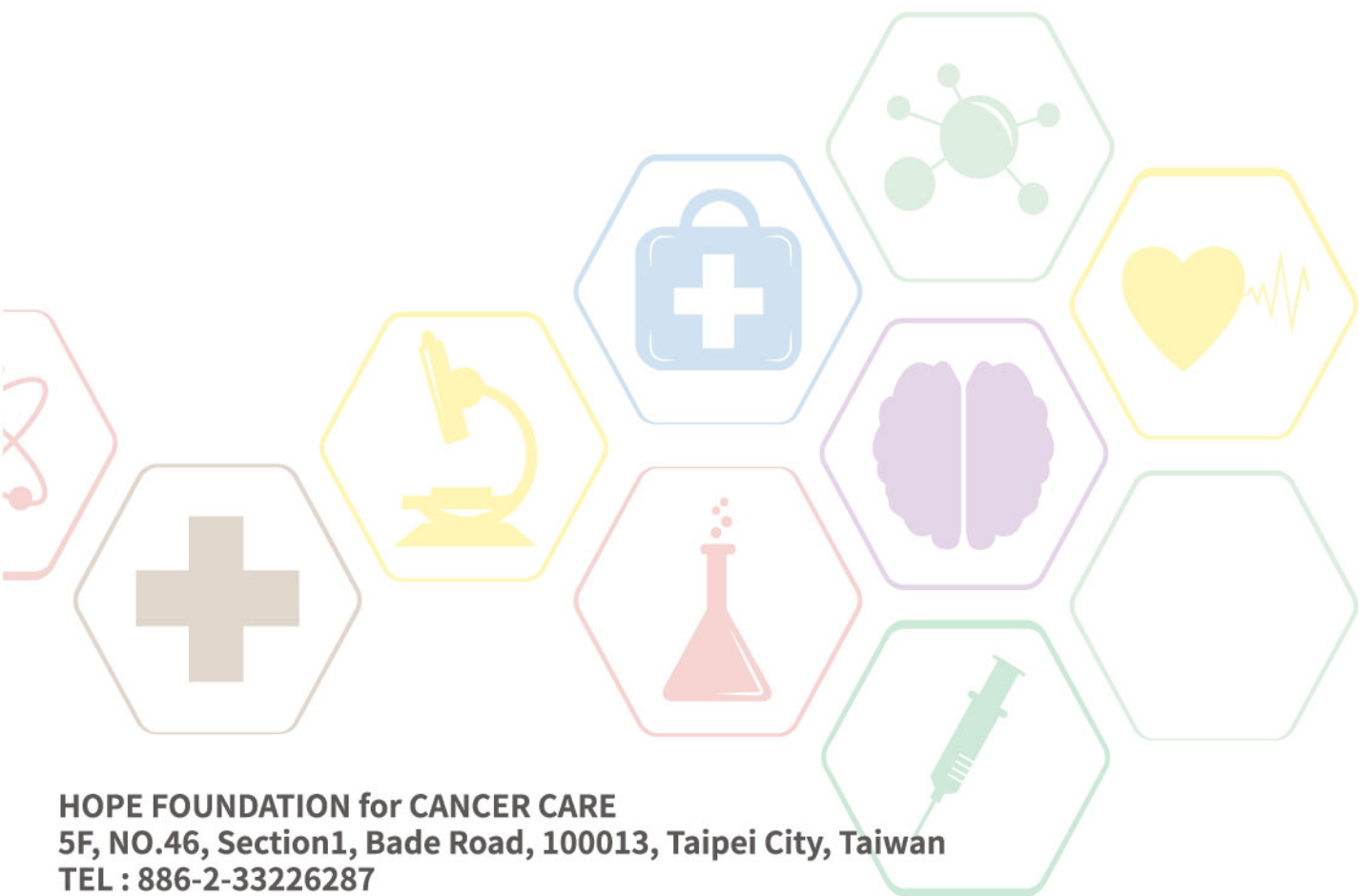

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