Funding of paediatric cancer treatments in New Zealand

Discussion paper on rule 8.1b of the Pharmaceutical Schedule

November 2022

PHARMAC
TE PĀTAKA WHAIORANGA

Executive summary

Te Pātaka Whaioranga - Pharmac is reviewing rule 8.1b of the Pharmaceutical Schedule.

Rule 8.1b provides for exceptions to the usual process for accessing pharmaceuticals, allowing Te Whatu Ora hospitals to give any pharmaceutical to someone being treated in either of New Zealand's two specialist paediatric services for the treatment of cancer. This means children with cancer can access treatments that aren't on the list of publicly funded pharmaceuticals, or treatments for which they don't meet the usual access criteria.

This approach means no time is lost in accessing treatments that aren't yet publicly funded. It also enables participation in clinical trials where access to the pharmaceutical might be a requirement for entry.

In practice, most of the pharmaceutical treatments used for paediatric cancer are listed on the Pharmaceutical Schedule and available to children and young people with cancer. For medicines that are not listed, rule 8.1b bypasses the usual assessment and prioritisation pathways that Pharmac uses to determine whether a pharmaceutical represents a good investment relative to other pharmaceuticals that could be funded. Pharmac's ability to monitor use of rule 8.1b and manage cost growth is therefore limited.

Furthermore, concern has been expressed by some stakeholders that rule 8.1b could be unfair or inequitable, in that other groups of people don't have a similar provision. Treating all groups the same is not, however, always the right thing to do. A focus on fairness and equity can result in groups being treated differently if there are clear reasons to do so. As such, it is important to determine if there are clear reasons to support the ongoing existence of the rule.

In early 2022, the panel reviewing Pharmac considered the funding of paediatric cancer treatments. In the interest of fairness, they recommended they are treated the same way as all other pharmaceuticals.

This leads us to ask whether special measures are needed to access paediatric cancer treatments that aren't on the Pharmaceutical Schedule and, if so, whether the current approach (rule 8.1b) is appropriate.

We need to better understand the difference that rule 8.1b is making to the lives of children with cancer, their family and whānau, and the people working hard to support them. That's why we are undertaking this engagement process to hear people's experiences and views.

This is only the first stage of the review. It is by no means a foregone conclusion that there will be changes to rule 8.1b. If, following this engagement process, it looks like changes are needed, we will engage further before any final decisions are made. If changes are to be made, they will only be implemented after careful consultation, development, and testing so that we can be confident that the new system will work smoothly.

We appreciate that cancer and its treatment can have profound health, emotional, social, educational, and economic impacts on children, their family, and whānau. The prospect of change may be unsettling for many people, including service providers.

We want to assure you that, even if changes are implemented, all publicly funded paediatric cancer treatments that are currently used, irrespective of how they are currently funded, will continue to be available now and in the future.

1 Introduction

1.1 Overview of Te Pātaka Whaioranga - Pharmac's role

Te Pātaka Whaioranga - Pharmac was set up 29 years ago to provide nationally consistent access to pharmaceuticals while limiting the rapid growth in expenditure occurring at the time. Pharmac's purpose, or objective, is to secure, for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment. It must do this within the fixed budget set by government (the Combined Pharmaceutical Budget, referred to throughout this document as the CPB). To achieve its objective, Pharmac manages the Pharmaceutical Schedule of publicly funded medicines that applies consistently within New Zealand. This means the same pharmaceuticals are available wherever someone lives.

In addition, Pharmac is required to be guided by the Health Sector Principles, set out in the Pae Ora (Healthy Futures) Act 2022, when performing its functions and exercising its powers and duties to the extent that is reasonably practicable. Of relevance to this review is Section 7(1)(a), which states that the health sector should be equitable, including ensuring that Māori and other population groups:

(i) have access to services in proportion to their health needs
(ii) receive equitable levels of service
(iii) achieve equitable health outcomes.

1.2 We are committed to upholding te Tiriti o Waitangi

Ōritetanga (equity) for Māori in Aotearoa New Zealand is guaranteed by Article 3 of te Tiriti o Waitangi. Pharmac is committed to upholding the mana of te Tiriti and applying the principles for implementing it identified in the 2019 Hauora report and given effect through the Pae Ora Act.[1]

We have had whakawhanaungatanga with Māori cancer experts and consumer advisors and will be seeking further input, including from whānau Māori, as part of this engagement process.

1.3 Unique funding process for paediatric cancer treatments

Historically, access to cancer treatments was managed by individual District Health Boards (DHBs, now Te Whatu Ora) who each undertook their own assessments, decision-making, and financial management. Following a review by the Ministry of Health and the New Zealand Cancer Treatments Working Party, the Government decided that a more consistent, nationwide approach to the funding of cancer treatments was needed. As a result, Pharmac assumed responsibility for cancer medicines in 2005.

In consultation with DHBs and medical experts, a unique funding process (rule 8.1b of the Pharmaceutical Schedule) was developed for cancer treatments for those treated within a paediatric service. Rule 8.1b of the Pharmaceutical Schedule enables exceptions to the usual process for accessing pharmaceuticals, allowing Te Whatu Ora hospitals to give (and be eligible to receive a subsidy for) any pharmaceutical for use within a paediatric service for the treatment of cancer.

[1] Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry retrieved from https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_152801817/Hauora%20W.pdf on 5 May 2022.

1.4 Our review of rule 8.1b for paediatric cancer treatments

We're reviewing rule 8.1b for paediatric cancer treatments because concerns have been raised around its fairness when compared with other populations and conditions and the growing costs of new cancer medicines.

Work on the review of rule 8.1b began in 2019 but was paused due to the impacts of COVID-19 on Pharmac and the wider health system's priorities and capacity.

We have now resumed the review, mindful of the Government's focus on achieving more equitable health outcomes, the enactment of the Pae Ora (Healthy Futures) Act 2022, and the independent Pharmac Review recommendations that medicines for the treatment of cancer should be considered in the same way as all other medicines.[2]

We want to explore whether special measures are needed to access paediatric cancer treatments that aren't on the Pharmaceutical Schedule and, if so, whether or not the current policy settings are appropriate.

We are seeking to increase our understanding of rule 8.1b and how it contributes to:

- achieving the best health outcomes possible
- ensuring pharmaceutical expenditure is sustainable
- health equity.

The review focusses on access to paediatric cancer treatments through rule 8.1b. Accordingly, paediatric cancer treatments already listed on the Pharmaceutical Schedule are out of scope of this review.

1.5 We will continue to fund existing paediatric cancer treatments

This is only the first stage of the review. It is by no means a foregone conclusion that there will be changes to Rule 8.1b. If, following this first stage, it looks like changes are needed, there will be further engagement before any final decisions are made.

If changes are to be made, they will only be implemented after careful consultation, development, and testing so that we can be confident that the new system will work smoothly.

We appreciate that cancer and its treatment can have profound health, emotional, social, educational, and economic impacts on children, their family, and whānau. The prospect of change may well be unsettling for many people, including service users and service providers. We want to assure you that even if changes are implemented, all publicly funded paediatric cancer treatments that are currently used, irrespective of how they are currently funded, will continue to be available.

[2] Pharmac was recently reviewed by an independent panel. The Panel reported to Government in March 2022. Their final report can be accessed here: https://www.health.govt.nz/system/files/documents/publications/pharmac-review-final-report.pdf

2 Background

2.1 Paediatric cancer is uncommon

Paediatric cancer is uncommon in Aotearoa New Zealand.[3] The number of children diagnosed with paediatric cancer is relatively small in the context of the overall health and disability system.

In Aotearoa New Zealand, the average number of children aged 0 to 14 years diagnosed with cancer each year between 2015 and 2019 was 153. Around 25,000 people are diagnosed with cancer each year, meaning children account for less than 1 percent of all cancer diagnoses.

As shown in Table 1, 26 percent of new paediatric cancer diagnoses between 2015 and 2019 involved tamariki Māori. This is generally consistent with the ethnic composition of New Zealand's 0 to 14-year-old population, with tamariki Māori estimated to account for 27 percent, Pacific peoples 10 percent, and Asian 16 percent.[4]

Table 1: Average new paediatric cancer diagnoses per year between 2015 and 2019 by ethnicity[5]

Ethnicity	Average number of new diagnoses	Percent of new diagnoses
NZ European	75	49%
Māori	40	26%
Asian	17	11%
Pacific peoples	17	11%
Other	4	3%
Total	**153**	**100%**

Many children with cancer require several years of treatment, so the number of people receiving treatment each year is greater than the number of new diagnoses. This includes children with cancer recurrence (for example, 21 recurrences were recorded in 2021).[6]

[3] See Appendix 3 for an infographic overview of key childhood cancer incidence data from the National Child Cancer Network.
[4] Te Aho o Te Kahu. 2021. He Pūrongo Mate Pukupuku o Aotearoa 2020, The State of Cancer in New Zealand 2020. Wellington: Te Aho o Te Kahu, Cancer Control Agency.
[5] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.
[6] National Child Cancer Network. 2022. New Zealand Children's Cancer Registry Snapshot 2021.

2.2 Types of paediatric cancer

Children are affected by many types of cancer, as shown in Table 2. Between 2015 and 2019, leukaemia was the most common, accounting for almost a third of all diagnoses. This was followed by central nervous system (CNS) tumours, which accounted for just under a quarter of diagnoses, and Lymphoma, which accounted for 14 percent of paediatric cancer cases.

Table 2: Average new paediatric cancer diagnoses per year between 2015 and 2019 by diagnostic group[7]

Includes:	Cases	Percent
Leukaemias	45	29%
CNS tumours	36	23%
Lymphomas	22	15%
Renal tumours	9	6%
Neuroblastoma	8	5%
Soft tissue sarcomas	9	5%
Bone Tumours	6	4%
Germ cell tumours	7	4%
Retinoblastoma	3	2%
Hepatic tumours	2	1%
Other	6	4%
Total	**153**	**100%**

2.3 Survival rates for children with cancer

Aotearoa New Zealand's overall five-year survival rate for children with cancer has improved considerably over time. Table 3 shows that this rate has improved three-fold over the last 50 years.

Table 3: Changes in overall paediatric cancer five-year survival rates, 1961 to 2019[8]

1961-1970	1990-1993	2005-2014	2010-2019
28%	66%	84%	86%

Current treatments for paediatric cancers deliver positive survival outcomes overall. Table 4 shows that 85 percent of children survive 10 years or more.

[7] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.

[8] Sullivan, M. & Ballantine, K. 2014. The incidence of childhood cancer in New Zealand 2000-2009: The first outcome analysis of the New Zealand Children's Cancer Registry. Auckland: National Child Cancer Network.

Table 4: Paediatric cancer survival rates 2010 to 2019[9]

1 year	3 years	5 years	10 years
93%	87%	86%	85%

From the 2010 to 2019, 89 percent of children diagnosed with leukaemia survived for at least five years, compared with only 6 percent in the 1960s.

As shown in Table 5, outcomes for children with cancer in Aotearoa New Zealand are similar to other countries that we traditionally use as benchmarks for our health sector performance.

Table 5: International comparison of five-year survival rates for all paediatric cancers

Country (time period)	Five-year survival rate
New Zealand (2010-2019)	86%
Australia (2005-2014)	85%
United Kingdom (2012-2016)	84%
Canada (2013-2017)	84%
Germany (2005-2014)	85%
United States (2012-2018)	85%

2.4 Equity of access and outcomes for paediatric cancer

The Crown has an obligation under te Tiriti o Waitangi to achieve equitable health outcomes for Māori (through ōritetanga, the principle of equity, and whakamaru, the principle of active protection). These obligations are further expressed in the Pae Ora Act.

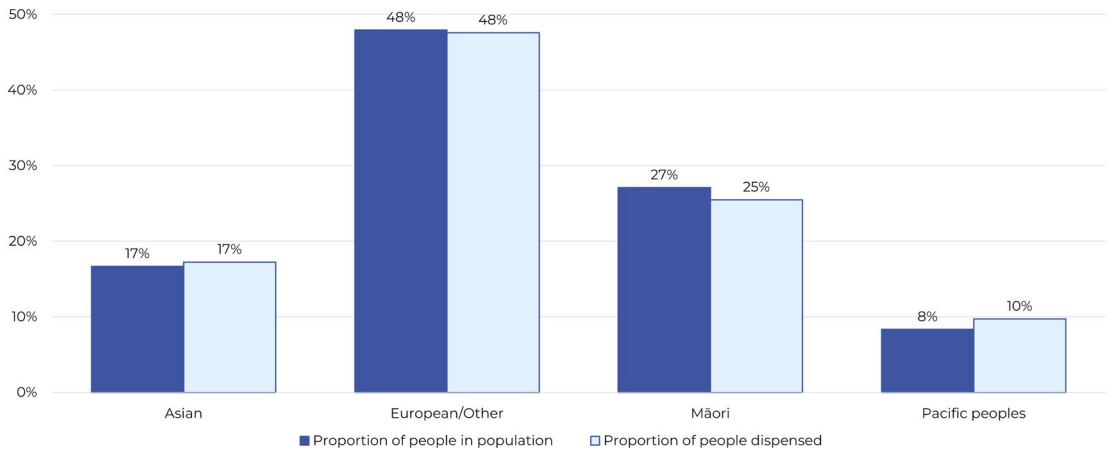
Among the overall population, comprising mainly adults, health inequities occur at all stages and affect a number of specific population groups. For example, Māori are approximately 20 percent more likely to develop cancer than non-Māori and twice as likely to die from cancer. Pacific peoples also experience higher cancer incidence and mortality for a range of cancers compared with non-Pacific.[10] However, children are not exposed to the same environmental and lifestyle factors so their patterns look somewhat different from the overall population.

Access to paediatric cancer treatments appears equitable

Our data, as presented in Figure 1, indicates that access to paediatric cancer treatments through the exceptional circumstances funding pathway (which includes rule 8.1b), when broken down by ethnicity, appears to be proportional on a population basis.

[9] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.
[10] Sullivan, M. & Ballantine, K. 2014. The incidence of childhood cancer in New Zealand 2000-2009: The first outcome analysis of the New Zealand Children's Cancer Registry. Auckland: National Child Cancer Network.

Figure 1: Proportion of children with cancer funded by exceptional circumstances compared to New Zealand's population aged under 25, Year ending June 2021



Note: Data uses Prioritised 1 ethnicity.
Dispensing data is for people aged 25 and under, while the population data is for people aged 24 and under.

How equitable are health outcomes for children with cancer?

Unless otherwise stated, data in this section is drawn from an analysis of New Zealand cancer registration data for children aged 0 to 14 years at diagnosis from 2010 to 2019.[11]

[11] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.

Table 6: Summary of paediatric cancer survival, by prioritised ethnicity, Aotearoa New Zealand, 2010 to 2019 [12] [13]

Prioritised ethnicity	Cases	One-year survival		Three-year survival		Five-year survival	
		%	95% CI	%	95% CI	%	95% CI
Māori	385	89.6	(86.1–92.2)	83.3	(79.2–86.7)	80.9	(76.5–84.6)
Pacific peoples	160	91.8	(86.4–95.2)	84.2	(77.5–89.0)	82.6	(75.6–87.7)
Non-Māori,non-Pacific peoples	977	94.4	(92.8–95.7)	88.9	(86.8–90.7)	87.8	(85.6–89.7)
Overall	1522	92.9	(91.5–94.1)	87	(85.2–88.6)	85.5	(83.6–87.2)

There is a small gap between the five-year cancer survival for both Māori (81 percent) and Pacific peoples (83 percent) when compared to non-Māori, non-Pacific peoples (88 percent) across all childhood cancers. While this is not statistically significant, the consistent pattern of slightly lower survival for Māori and Pacific peoples warrants attention.

Table 7 compares five-year survival rates by prioritised ethnicity and age group. Survival rates are similar across ethnic groups of children aged 0 to 9 years across all types of childhood cancer. There is a clear equity gap between Māori and non-Māori, non-Pacific peoples aged 10 to 14 years at diagnosis.

Table 7: Summary of five-year paediatric cancer survival, by prioritised ethnicity and age group, Aotearoa New Zealand, 2010 to 2019 [14]

Prioritised ethnicity	One-year survival		Three-year survival		Five-year survival	
	%	95% CI	%	95% CI	%	95% CI
Māori	81.4	(74.5–86.6)	85.0	(76.9–90.4)	74.9	(64.7–82.6)
Pacific peoples	84.6	(73.2–91.4)	81.8	(67.8–90.1)	80.6	(64.8–89.8)
Non-Māori non-Pacific peoples	86.8	(73.2–91.4)	88.0	(82.9–91.7)	89.5	(85.0–92.6)

Further analysis of survival outcomes by ethnicity and type of cancer is limited due to the small population size. However, survival equity is reported for the three main types of childhood cancers (leukaemia, CNS tumours and lymphoma), which comprise approximately two thirds of all cases.

[12] 'Prioritised ethnicity' means that people are allocated to single ethnic group in an order of priority even if they identify with more than one ethnicity. The priority order used in Aotearoa is Māori, Pacific Peoples, NZ European, and Other. For example, if someone identifies as Māori and Tongan, they're reported as Māori only.

[13] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.

[14] National Child Cancer Network. 2022. Childhood cancer incidence in Aotearoa, New Zealand 2015-2019. Auckland: National Child Cancer Network.

Survival rates are not influenced by where children live, who they are treated by, or their socioeconomic status

The National Child Cancer Network (NCCN) has previously analysed three-year survival rates among a group of 764 children in New Zealand diagnosed with cancer from 2010 to 2014 with follow-up to 31 December 2017 (see Table 8). The purpose of the analysis was to understand if children with cancer receive the same quality of care, irrespective of their socioeconomic background or whether they live near one of the national paediatric cancer specialist services located in Auckland or Christchurch (refer to section 2.5 for more information about the system of care).

Table 8: Three-year survival rates by socio-economic status, place of residence, and treatment centre, 2010 to 2014[15]

	One-year survival	Three-year survival	95% CI
Deprivation index			
Most deprived	205	83.2	77.2 – 87.7
Average	282	88.6	84.2 – 91.8
Least deprived	276	83.9	78.9 – 87.8
Place of residence			
Auckland or Christchurch	363	86.4	82.4 – 89.6
Outside of Auckland or Christchurch	401	84.6	80.6 – 87.8
Treatment centre			
Starship Blood and Cancer Centre	498	85.6	82.2 – 89.5
Children's Haematology Oncology Centre	266	85.4	80.5 – 89.2

The analysis showed there was no statistical difference in survival rates by either socioeconomic status or place of residence. The analysis of residence suggests that children living outside Auckland and Christchurch, where the national paediatric cancer specialist services are located, are served well through nationally consistent and supportive care guidelines and co-ordinated shared-care arrangements with their local hospitals.

[15] https://childcancernetwork.org.nz/wp-content/uploads/2018/12/SIOP-Nov-2018-Quality-of-care-poster_-Skeen-J..pdf

2.5 Paediatric cancer treatment: the system of care

The need for a specialist approach to paediatric cancer treatment

Paediatric cancers are qualitatively different from adult cancers. Cancers occurring in children differ from cancers in adults in their incidence and characteristics. Unlike many cancers in adults, childhood cancers are not strongly linked to lifestyle or environmental risk factors. Furthermore, the methods and medicines used to treat adults are not always directly transferrable to children.

There are two specialist paediatric cancer services

The two specialist treatment services for children with cancer are located in the Starship Blood and Cancer Centre in Auckland and the Children's Haematology and Oncology Centre in Christchurch. The two centres work closely together and respectively treated 75 and 25 percent of the 159 children diagnosed with cancer in 2021.

All children are initially seen at Starship or Christchurch hospital. Children are referred back to their regional care centre to be supported closer to home when it is safe to do so. For those children living outside Auckland and Christchurch, ongoing care is provided by the 14 shared-care centres across the country.

The National Child Cancer Network (NCCN)

The NCCN is a contracted provider of Te Aho o Te Kahu, the Cancer Control Agency. The NCCN brings together health professionals, carers, and relevant organisations to work collaboratively and provides governance across child cancer services in Aotearoa New Zealand.

The NCCN has a range of activities to support the ongoing delivery of child cancer services. These include maintaining over 200 supportive care guidelines (developed by Starship and Christchurch hospitals) and 14 service level agreements with regional shared-care centres. These guidelines and service level agreements promote good practice and drive consistency of care across the country.

The NCCN governs the New Zealand Child Cancer Registry (NZCCR), which reports childhood cancer incidence, treatment, and outcomes. Data captured by the NZCCR is cross referenced with the New Zealand Cancer Registry (NZCR), regularly reported on, and is available for research activity.

2.6 Participation in clinical trials

Paediatric cancer specialists have told us that they could not practise effectively without access to, or participation in, a clinical trial network. Clinical trials are seen by clinicians as the standard of care for the treatment of children with cancer, which is fundamentally a collaborative, research-based model of care.

The ability to offer clinical trial participation is an expectation of a high-quality paediatric cancer service.[16] This is because paediatric cancer involves a much smaller number of people with greater diversity of diagnoses and variations in disease morphology than adult cancer where there is a larger number of people and usually a greater evidence base to support treatment protocols.

Clinical trials are undertaken for all types and stages of paediatric cancer. Due to the small numbers in this highly specialised field and the high financial costs, clinical trial participation is usually via international collaborative groups, such as the Children's Oncology Group (COG) and Australia and New Zealand Children's Haematology Oncology Group

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Participation in clinical trials is important to continually improve the standard of care for children with cancer. Clinical trials are designed to complement each other and decisions on new therapies are made using information built through successive trials. Significant amounts of information sharing occur within these oncology groups that comes with being involved in and contributing to them. This ultimately results in new protocols that become the new standard of care. It is an iterative process that is quite different to the treatment in many fields of adult oncology.

[16] https://starship.org.nz/health-professionals/starship-blood-and-cancer-centre/

[17] Additionally, there are a small number of industry-sponsored trials run at Starship. Other research projects include a clinical trial funded by the Child Cancer Foundation and Cure Kids which aims to find a treatment for difficult-to-detect and relapsing cancers using genetic samples.

Many trials focus on researching new treatments to learn if they are more effective or safer than existing treatments or standards of care. These types of studies evaluate new paediatric cancer treatments, different combinations of existing treatments, new approaches to radiation therapy or surgery, and new treatment protocols. Many explore new ways of diagnosing or monitoring cancers. It is common for trials to incorporate a number of these aims. There are also clinical trials that focus on supportive care and psychosocial assessment, and some trials are focused on reducing the immediate and long-term side effects of therapy without compromising survival outcomes.

Participation in clinical trials offers many benefits to the people receiving treatment and the system. Trials may provide access to the latest research, treatment protocols, and guidelines, which are updated frequently. Participation in clinical trials also provides paediatric oncologists and haematologists with access to international networks, training opportunities, and the external review of their clinical activity. COG requires performance monitoring and periodic auditing to review members adherence to performance standards.

Clinical trials, which have brought forward advancements in treatments, are considered to have been a major reason for the significant progress in the prognosis and survival rate of children with cancer over the past decades.[18]

2.7 Link between participation in clinical trials and rule 8.1b

Participation in clinical trials may be conditional on being able to access medicines used in the trial. We understand that rule 8.1b makes this possible, as Pharmac funds medicines that would not otherwise be available. For example, we've been told that without rule 8.1b, paediatric haematologists would not have been able to access clinical trial networks involving the use blinatumomab or inotuzumab, medicines used to treat relapsed or refractory B-cell acute lymphoblastic leukaemia.

In 2021, 42 children were enrolled in international therapeutic clinical trials (26 percent of children diagnosed that year). We understand that there are a further cohort who, while not technically enrolled in a clinical trial, will be receiving treatment informed by protocols developed in a clinical trial setting.

In addition, children are often enrolled in other non-therapeutic research studies, such as tumour biology studies. In 2020, for example, 55 children were enrolled in such studies.[19]

[18] Bond MC, Pritchard S. Understanding clinical trials in childhood cancer. Paediatrics & Child Health. 2006;11(3):148-150.
[19] National Child Cancer Network - New Zealand Children's Cancer Registry Snapshot 2021

Difference in medicines access for clinical trials between paediatric and adult settings

The Pharmaceutical Schedule outlines situations where a medicine is eligible for a subsidy and/or when a medicine can be used in a Te Whatu Ora hospital. In general, a Te Whatu Ora hospital may not give an unlisted medicine – such as those generally used in clinical trials.

There is an exception to this rule for medicines used in a clinical trial. Under rule 8.1b of the Pharmaceutical Schedule, Te Whatu Ora hospitals may give any pharmaceutical that is funded by an entity other than Pharmac when it is being used as part of a clinical trial or for ongoing treatment following the end of such a clinical trial.

In practice, this means that medicines provided in other clinical trials, such as adult cancer, must be funded by a third party, which is often a pharmaceutical company or charitable institution. This is different to paediatric cancer clinical trials where rule 8.1b applies – meaning that funding is via the CPB.

2.8 The interface between treatment of children and adolescents/ young people with cancer[20]

Cancer treatment for adolescents and young adults with cancer (AYA) has been described as the 'interface of paediatric and adult oncology'.[21] There can be marked similarities and differences between children with cancer and AYA.

A distinct range of cancers affect AYA. The spectrum of AYA cancers includes some paediatric cancers, such as acute lymphoblastic leukaemia, while malignant bone tumours peak in the teenage years. Thyroid cancer, Hodgkin lymphoma, and testicular cancer become increasingly common in this age group.

In addition to the range of cancers that affect AYA, the psychosocial care needs of AYA with cancer tend to be broader in scope and intensity than children or older adults due to emotional, developmental, and social changes occurring during this life stage.

Approximately 165 AYA aged 15 to 24 years are diagnosed with cancer each year, with more than half of these aged 20 to 24 years. This number has remained relatively stable over the past decade.[22]

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20 Unless stated in otherwise all data in this section is drawn from Ballantine, K., Moss.R & Watson, H. (2020). Adolescent & Young Adult Cancer Incidence and survival in Aotearoa 2008-2017. Auckland: Adolescent and Young Adult Cancer Network Aotearoa.

21 In New Zealand, AYA is currently defined as 12-24 years (which overlaps with the paediatric definition of 0-14 years). However, there is no universally defined AYA age range. For example, the Canadian Cancer Society define AYA as 15-29 years, Australia uses both 15-24 and 15-29 years, while the Journal of Adolescent and Young Adult Oncology uses 15-39 years.

22 If those aged 25-29 were also included in New Zealand's AYA range, the annual total would increase to 325.

The overall five-year survival rate for AYA aged 15 to 24 years is currently 84 percent. While this is a 4 percent increase in the last decade, the survival rate remains behind the 89 percent seen in Australia.

There is also a gap between five-year survival rates for AYA by ethnicity. Five-year survival for AYA aged 15 to 24 years was 78 percent for Māori and 81 percent for Pacific peoples, compared to 87 percent for non-Māori, non-Pacific peoples. We have been told by paediatric and AYA cancer specialists that there is an equity issue at the boundary between the 0 to 14 year age group and AYA older than 15 years of age.

While some AYA receive treatment in specialist paediatric cancer services, AYA with cancer are generally treated in adult oncology services. They are therefore ineligible to receive cancer treatments through rule 8.1b.

Paediatric and AYA cancer specialists have told us that this is inequitable given AYA with cancer can have paediatric-type cancers from a biological perspective. In this sense, age is an arbitrary distinction. Moreover, Pharmac's Named Patient Pharmaceutical Assessment (NPPA) process is unlikely to be available for AYA with cancer who need access to cancer treatments not listed on the Pharmaceutical Schedule. (Refer to section 3.2 for more information about the NPPA process.)

Access to cancer treatments through rule 8.1b is not dependent on a person's age. It depends on whether or not they are treated in a paediatric cancer service – at Starship or Christchurch hospitals. Any changes to rule 8.1b to ensure consistency of access to cancer treatments for AYA with paediatric-type cancers wouldn't impact access to paediatric cancer services. However, we do not know the number or proportion of AYA with paediatric-type cancers being treated in adult cancer services rather than paediatric services in Aotearoa New Zealand.

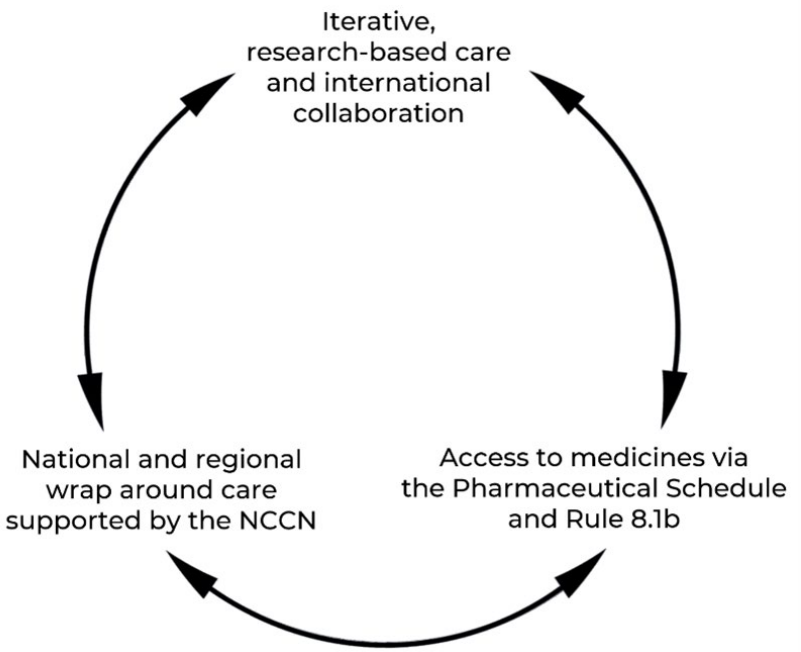
An extension of rule 8.1b to include AYA with paediatric-type cancers may reduce medicines access equity issues, depending on the definition of AYA used, but it might also significantly increase the use of rule 8.1b and place pressure on the national CPB for all funded medicines (particularly when factoring in considerations such as weight-based dosing).

2.6 Participation in clinical trials

In summary, we understand that the system of care is based on access to and participation in clinical trial networks – a collaborative, research-based model of care – for people with paediatric cancers. This is seen as the standard of care for the treatment of children with cancer. Figure 2 illustrates this system of care.

We would like to deepen our understanding of this system of care, how strong the interdependencies are between each part of the system, and the sensitivity of the system to changes in rule 8.1b.

Figure 2: System of care for paediatric cancer



3 Funding paediatric cancer treatments

3.1 Pharmac's core functions and processes: the Pharmaceutical Schedule

Section 69(1) of the Pae Ora (Healthy Futures) Act 2022 sets out several functions to be carried out by Pharmac. Two functions are central to this review.

(a) To maintain and manage a Pharmaceutical Schedule that applies consistently throughout Aotearoa New Zealand, including determining eligibility and criteria for the provision of subsidies.
(b) To manage incidental matters arising out of paragraph (a), including providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule in exceptional circumstances.

In short, Pharmac is the government agency that decides which medicines and related products are subsidised for use in the community and Te Whatu Ora hospitals. The Pharmaceutical Schedule lists what Pharmac has approved for funding from the CPB and the criteria for accessing each medicine. Pharmac also determines when to fund medicines for people with exceptional circumstances, where the medicines they need are not available to them on the Pharmaceutical Schedule.

Making decisions about what is funded, and what is not, is complex. In line with these core functions, Pharmac has developed a process for all medicine funding applications to ensure it treats them fairly and equitably. Pharmac undertakes a robust assessment and decision-making process (see Appendix 1 for more detail). To support fairness and consistency, Pharmac has examined available research evidence and developed a standardised set of Factors for Consideration to inform decision-making (see Appendix 2 for more detail).

Each application for a new medicine to be funded is assessed against the Factors for Consideration. This involves technical assessments of a medicine's efficacy for certain populations and conditions, and considerations of who benefits and how much. We also consider appropriateness, suitability, and health inequalities. We compare all applications and determine which ones will get the best health outcomes within the CPB set by government.

Medicines we have approved for funding are listed on the Pharmaceutical Schedule. These medicines are then available to all eligible people who meet related funding criteria (if any) in Te Whatu Ora hospitals, inpatient and outpatient, and community settings. The Pharmaceutical Schedule also includes a section on the general rules and restrictions that apply to subsidies for funded medicines.

Some medicines listed on the Pharmaceutical Schedule have a Special Authority designation. For these medicines, funding requires an approved application for a named individual who meets the criteria specified in the Pharmaceutical Schedule.

3.2 The Exceptional Circumstances Framework

Named Patient Pharmaceutical Assessment policy

Pharmac's Exceptional Circumstances Framework provides alternative pathways for people whose circumstances cannot be met through the Pharmaceutical Schedule at a given point in time. The Framework outlines the process by which funding decisions for exceptional circumstances are made.[23]

The Named Patient Pharmaceutical Asssessment (NPPA) policy sets out the criteria for funding a medicine for an individual whose clinical circumstances are exceptional. The NPPA policy is intended to complement the Pharmaceutical Schedule, as there are situations in which consideration of an application for a treatment for a someone with exceptional circumstances is warranted. The core principles underpinning the NPPA policy are outlined below.

1 **A person must have exceptional clinical circumstances.** The person must have an urgent clinical need and unusual clinical circumstances, for which the medicine is not ordinarily available through the Pharmaceutical Schedule. This takes into consideration how the particular person's needs differ from others, and what the implications of funding the medicines would be on the system.

2 **A person must have tried all existing funded alternative treatments.** The person must have tried all suitable funded options that are available before seeking funding for treatments via the NPPA policy. Other currently funded options must have been found to be clinically unsuitable for the individual before a NPPA application will be considered.

3 **The treatment must not have been considered for funding via the Pharmaceutical Schedule previously for the same indication.** If the person's clinical circumstances are different to those indications that have already been considered by Pharmac, funding the treatment under the NPPA policy will be considered.

[23] Find out more about the Exceptional Circumstances Framwork on Pharmac's website: https://pharmac.govt.nz/exceptional-circumstances-framework-including-the-named-patient-pharmaceutical-assessment-policy/

Once a NPPA application has been approved, it sets a policy precedent. Future applications on the same grounds are also likely to be approved without requiring detailed reassessment.

Special access medicines – specialist panels

For certain high-cost medicines, Pharmac has established and administered specialist panels, for example the former Gaucher Panel. A specialist panel's role is to assess whether a person meets the access criteria established by Pharmac and is eligible for funding.

A specialist panel is established where:

a. the eligibility criteria are too complex to fit into the electronic Special Authority framework or
b. there is a significant risk that people who do not meet the agreed access criteria would slip through.

3.3 Rule 8.1b of the Pharmaceutical Schedule

Rule 8.1b sits outside Pharmac's regular Pharmaceutical Schedule and NPPA funding processes.

Rule 8.1b was developed for cancer treatments for people who are treated in a paediatric cancer service. It addressed some of the underlying complexities that made regular listing of paediatric cancer treatments difficult. These complexities included:

- the research-based model of care for children with cancer, including participation in clinical trials
- the small number of people requiring treatment each year for most indications
- that many of these treatments and indications were not approved or would not be likely to be approved for use by Medsafe or other international regulatory authorities.

Rule 8.1b allows Te Whatu Ora hospitals to give (and be eligible to receive a subsidy for) any pharmaceutical for use within a paediatric cancer service. Pharmac manages an administrative process to approve access to a subsidy from the CPB in accordance with rule 8.1b. Approvals allow claiming for the full cost of the paediatric cancer treatment, excluding supportive care treatments. They are generally granted for a five-year period and may be extended on application.

Paediatric cancer treatments accessed through rule 8.1b are based on a clinical decision made by the person's treating clinicians. This often involves a multi-disciplinary team, and we understand they do consider the financial cost associated with treatment.

Pharmac currently has no oversight of the decision-making processes that occur beyond what medicines are used and the cost of those medicines. We appreciate that there is oversight, but this largely sits within the paediatric cancer centres. This means that, for some paediatric cancer treatments, there is no assessment against Pharmac's Factors for Consideration or prioritisation against all the other medicines Pharmac would like to fund.

3.4 Data on pharmaceutical cancer treatments used in a paediatric service

Pharmac does not have exact data on the cost or number of people dispensed medicine under rule 8.1b. Therefore, dispensing data for paediatric cancers presented in this paper was extracted using the following criteria.

a. Medicines dispensed to people aged 25 and younger only. This will capture people treated within a paediatric service that had medicines dispensed under rule 8.1b.
b. Medicines which are pharmaceutical cancer treatments; identified using subsidy claims made by Te Whatu Ora hospitals. The chemicals infliximab, tocilizumab, ivacaftor, and palivizumab have been removed from this data as they are not used to treat cancer. Rituximab has been kept in the data as some indications are used for cancer.

Both criteria above are expected to overestimate dispensings under rule 8.1b. This is a deliberate choice to ensure that people dispensed medicines under rule 8.1b are fully included in the data presented. However, this means that some people who were not dispensed medicines under rule 8.1b will also be included in the data.

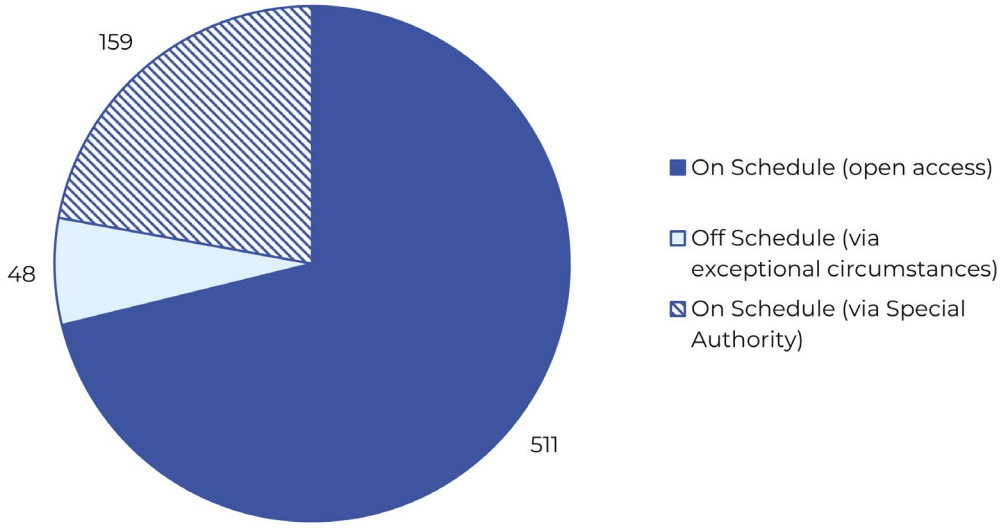
3.5 Most paediatric cancer treatments are listed on the Pharmaceutical Schedule

As shown in Figure 3, in 2020/21, 93 percent of people with paediatric cancers were prescribed medicines listed on the Pharmaceutical Schedule.[24] The remaining 7 percent accessed medicines that were accessed via rule 8.1b.

While some medicines listed on the Pharmaceutical Schedule are not indicated for paediatric populations and are therefore not automatically funded for children, they can be accessed via rule 8.1b if the responsible clinician determines this is appropriate.

[24] Note that individuals may be 'double counted' if, in the course of their treatment, they accessed both listed and unlisted medicines.

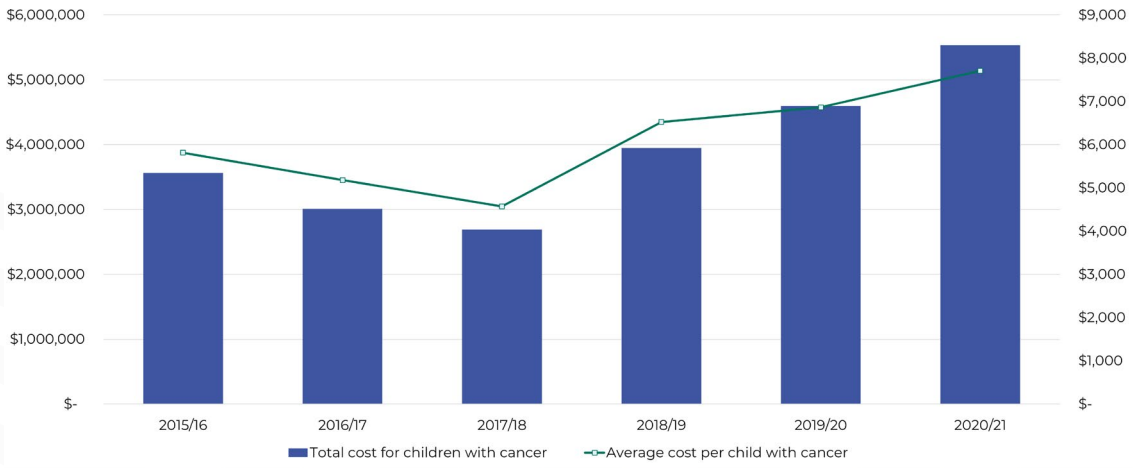
Figure 3: Number of children dispensed medicine, by funding path, Year ending June 2021



3.6 Total cost of paediatric cancer treatments

According to our annual expenditure data, the total cost of all paediatric cancer treatments used to treat people aged 25 and under in the 2020/21 financial year was approximately $5.5 million. In absolute terms, this represents a small proportion of the CPB of less than 1 percent.

Figure 4: Total gross cost and average cost per child for cancer treatment (excl GST), 2015/16 to 2020/21 (Financial year ending 30 June)

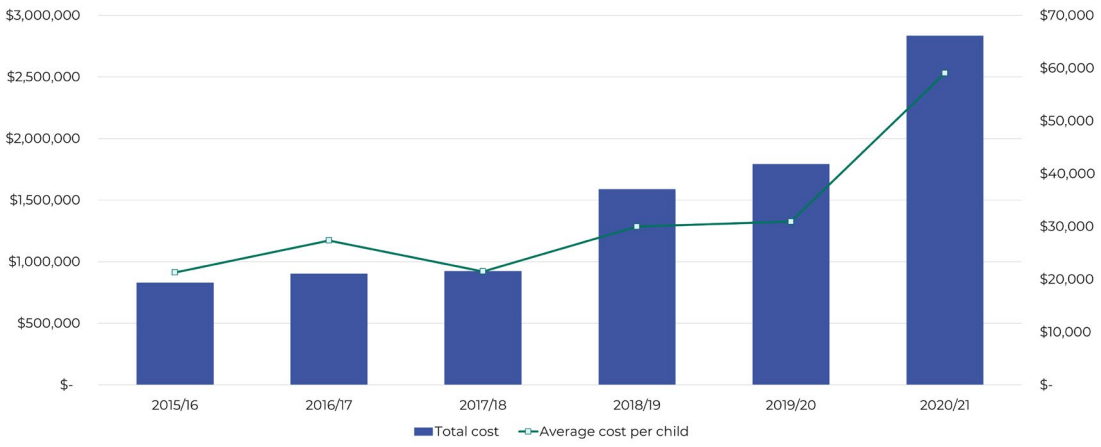


3.7 Cost of paediatric cancer treatments accessed through rule 8.1b

According to our annual expenditure data, paediatric cancer treatments accessed through rule 8.1b for people aged 25 and under in the 2020/2021 financial year was approximately $2.8 million. This is about half of the total expenditure spent on paediatric cancer treatments in 2020/21.

As shown in Figure 5, the cost of paediatric cancer treatments via rule 8.1b has been steadily increasing in recent years and we consider it is likely to continue to increase. The increases in expenditure via rule 8.1b are primarily driven by a few newer medicines that are not listed on the Pharmaceutical Schedule, such as blinatumomab, L-aspariginase and pegaspargase, and new agents such as Chimeric Antigen Receptor (CAR) T-cell therapy. There is a risk that this growth could place increasing pressure on the CPB.

Figure 5: Total gross cost and average cost per child for cancer treatment funded via exceptional circumstances (excl GST), 2015/16 to 2020/21 (Financial year ending 30 June)



[24] Note that individuals may be 'double counted' if, in the course of their treatment, they accessed both listed and unlisted medicines.

4 Considerations for the review

To help us better understand the complex issues in respect to funding access to paediatric cancer treatments, we are seeking your input into this review. Key issues and focus questions are outlined in this section.

4.1 How well do we understand child cancer and the system of care?

Aotearoa New Zealand's overall five-year survival rate for children with cancer has improved considerably over time. In the period from 2010 to 2019, 89 percent of children diagnosed with leukaemia survived for at least five years, compared with only 6 percent in the 1960s. Outcomes for children with cancer in Aotearoa New Zealand are similar to other countries that we traditionally use as benchmarks for our health sector performance.

Question 1

Is our understanding of the overall health outcomes being achieved for children with cancer, correct? If not, please provide any further information or context.

Paediatric cancer specialists have told us that they could not practise effectively without access to, or participation in a clinical trial network. Clinical trials are seen as the standard of care for the treatment of children with cancer, which is fundamentally a collaborative, research-based model of care. Access to currently unfunded medicine through rule 8.1b may also be a pre-condition for participation in some clinical trials.

Question 2

In what other clinical contexts is participation in clinical trials the standard of care?

Question 3

To what extent is access to paediatric cancer clinical trials dependent on access to medicines through rule 8.1b?

Question 4

How sensitive is this system of care to changes to rule 8.1b?

4.2 How effective is rule 8.1b in terms of achieving the best health outcomes?

Overall, Aotearoa New Zealand achieves good outcomes for children with cancer. It is not clear if these good outcomes are dependent on making paediatric cancer treatments available through rule 8.1b. As discussed the vast majority of cancer treatments accessed by children with cancer are already listed on the Pharmaceutical Schedule. We can be confident that rule 8.1b facilitates timely access to new paediatric cancer treatments.

It is worth noting that most cancer treatments used for children are intended to be curative – that is, a child administered a course of treatment will be fully cured if it is successful and will go on to have a near normal life expectancy.
2020/21

Question 5

To what extent are good health outcomes for children with cancer in New Zealand dependent on making paediatric cancer treatments available through rule 8.1b?

Question 6

Is timely access to paediatric cancer treatments more important than timely access to other medicines or for other populations? If so, why?

4.3 Does the current policy support sustainable use of available resources?

Question 7

Is our understanding of how rule 8.1 operates in practice correct? What else should we know?

Expenditure on paediatric cancer treatments through rule 8.1b has not been a major concern in the past as the vast majority of medicines are accessed through the Pharmaceutical Schedule, as well as the relatively small overall budgetary impact on the CPB. However, we see an increasing risk with new cancer medicines, such as CAR T-cell therapy, which could cost more than $1 million to treat one person. For example, while only a small portion of paediatric cancers used rule 8.1b in 2020 (7 percent), this accounted for half of the total cost.

[24] Note that individuals may be 'double counted' if, in the course of their treatment, they accessed both listed and unlisted medicines.

There are a number of other factors contributing to cost concerns for cancer treatments.

- Rising pharmaceutical prices in the global market, largely driven by personalised medicines and biological treatments, are raising costs here in New Zealand.
- Rapid growth in the number of new cancer therapies increases the pool of medicines for health funders to consider and the time required to research and assess new and emerging medicines.
- Regulatory changes in overseas markets mean new cancer medicines are coming to the market faster but with less evidence to support the claimed health outcomes. This makes it harder for funders to establish a timely case for investment that balances public demand for access with medical effectiveness and cost effectiveness.
- Unlike the Pharmaceutical Schedule or the NPPA policy, there is no national oversight by Pharmac of use or expenditure for paediatric cancer treatments funded through rule 8.1b. With more expensive treatments becoming available and without a mechanism for Pharmac to manage impacts on the overall CPB, reduced access to other medicines, which could deliver more benefits, might be an unintended consequence.

Question 8

How much increase in the use of rule 8.1b do you think will happen as a result of the growing range of new paediatric cancer treatments?

Question 9

Do you see the costs of paediatric cancer treatments accessed through rule 8.1b increasing significantly in the foreseeable future?

Question 10

How could we assess what value paediatric cancer treatments provide against other medicines that could be funded with the same money?

4.4 Does the current policy support health equity?

Pharmac's objective is to achieve the best possible outcomes for all eligible people requiring pharmaceutical treatment from within its fixed budget. We are committed to upholding te Tiriti and making the maximum contribution possible to achieving equitable health outcomes for Māori, Pacific peoples and other groups of people experiencing inequitable health outcomes.

The main way we ensure equity is by applying criteria consistently to our funding decisions and being transparent about how we do this. While we can make exceptions, such as via the NPPA policy on a case-by-case basis, consistency and transparency remain central to the process.

While rule 8.1b is an anomaly in our system for funding access to medicines, it is not necessarily inequitable. Treating a group differently is sometimes necessary to achieve equitable health outcomes. For example, we recently decided to fund empagliflozin for all Māori and Pacific people with high-risk type 2 diabetes, recognising that these groups experience barriers in accessing medicines despite being more likely to experience heart and kidney complications.

We need to consider whether there is a case for placing access to medicines for people with paediatric cancers ahead of access to medicines for other groups, such as:

- other paediatric populations
- Māori and other groups experiencing inequitable health outcomes.
- adolescent and young adults with cancer
- adults with cancer

The recent independent review of Pharmac recommended that cancer medicines be considered on the same basis as all other medicines, and that the emphasis needs to be on severity of disease, clinical alternatives, and what the benefits are relative to cost.

Question 11

What should Pharmac take into account when considering equity issues with respect to rule 8.1b of the Pharmaceutical Schedule?

Other children and rare paediatric disorders

Rule 8.1b appears to be inequitable with respect to other children. For example, rule 8.1b was cited in a complaint to the Human Rights Commission. It was suggested that having rule 8.1b for paediatric cancer treatments was inconsistent and unfair, and should be addressed.

One way to address this would be to extend rule 8.1b to fund treatments for other conditions that affect children, such as rare disorders, conditions that rely heavily on clinical trials, and those that have major and/or long-term impacts on someone's quality of life.

Question 12

Do you consider rule 8.1b to be inequitable from the perspective of other children or those with rare disorders? Why?

Equitable health outcomes for Māori

The data seems to suggest that, overall, tamariki Māori aged 0 to 14 years are experiencing an equity gap when compared to non-Māori, non-Pacific peoples.

However, when broken down to smaller age groups, survival equity is apparent for tamariki Māori aged 0 to 9 years across all types of childhood cancer. The equity gap between Māori and non-Māori, non-Pacific peoples is observed for children aged 10 to 14 years at diagnosis.

We need to be sure that any changes to the current policy settings do not adversely affect tamariki Māori and whānau.

From a wider health perspective, there are te Tiriti and Pae Ora obligations and compelling needs-based arguments to prioritise expenditure on Māori and other population groups experiencing inequitable health outcomes. We are already beginning to do this and are developing tools that will enable us to be more effective in delivering equitable health outcomes.

Question 13

To what extent do the current policy settings, including rule 8.1b, contribute to the health outcomes achieved for tamariki Māori and Pacific children with cancer?

Adolescent and young adults with cancer

We have been told by paediatric and AYA cancer specialists that there is an equity issue at the boundary between those younger than 14 and people older than 15 years of age.

While some AYAs receive treatment in specialist paediatric cancer services at Starship or Christchurch hospitals, AYA are generally treated in adult cancer services. When treated in adult cancer services, they are ineligible to receive cancer treatments through rule 8.1b.

An extension of rule 8.1b to include AYA with paediatric-type cancers may reduce equity issues for medicine access, depending on the definition of AYA used. However, it might also significantly increase use of rule 8.1b, thereby placing pressure on the CPB and causing other inequities.

Question 14

Do you consider rule 8.1b to be inequitable from the perspective of adolescent and young adults with cancer? Why?

Equity with other groups of people

One option that would improve equity for children with other conditions, those with rare disorders, adolescents and young adults with cancer, or anyone else for whom rule 8.1b might seem to be inequitable, is to widen eligibility to rule 8.1b. As noted, there is a risk though that this will place considerable pressure on the CPB and cause inequities with other conditions.

Question 15

How might we address equity and fairness concerns related to paediatric cancer medicines through rule 8.1b and access to medicines for other groups

4.5 Other information or thoughts?

Question 16

Is there anything else we need to know to inform this review? If so, please let us know.

5 Providing feedback

Provide feedback by 5pm Tuesday 31 January 2023.

We encourage you to use the online submission form so we have the best chance of capturing your views: **pharmac.govt.nz/feedback**

You can also email your submissions to: **consult@pharmac.govt.nz**

Privacy and confidentiality

Feedback we receive is subject to the Official Information Act 1982 (OIA). Please be aware that we may need to share your feedback, including your identity, in response to an OIA request. This applies to anyone providing feedback, whether they are providing feedback themselves or for an organisation, in a personal or professional capacity.

We can only keep feedback confidential as allowed under the OIA and other related laws. If you want any part of your feedback treated as confidential, you need to tell us. Please let us know if you want to keep part of your feedback confidential, and why. Is it commercially sensitive, confidential or proprietary, or personal information? Clearly state this and tell us which parts of your feedback you want to keep confidential for these reasons. We will consider your request under our OIA requirements.

Pharmac's full privacy statement can be read online:
pharmac.govt.nz/privacy-statement/

List of questions

How well do we understand child cancer and the system of care?

1. Is our understanding of the overall health outcomes being achieved for children with cancer correct? If not, please provide any further information or context.
2. In what other clinical contexts is participation in clinical trials the 'standard of care'?
3. To what extent is access to paediatric cancer clinical trials dependent on access to medicines through rule 8.1b?
4. How sensitive is this system of care to changes to rule 8.1b?

How well do we understand child cancer and the system of care?

5. To what extent are good health outcomes for children with cancer in New Zealand dependent on making paediatric cancer treatments available through rule 8.1b?
6. Is timely access to paediatric cancer treatments more important than timely access to other medicines or for other populations? If so, why?

Does the current policy support efficient and sustainable use of available resources?

7. Is our understanding of how rule 8.1 operates in practice correct? What else should we know?
8. How much increase in the use of rule 8.1b do you think will happen as a result of the growing range of new paediatric cancer treatments?
9. Do you see the costs of paediatric cancer treatments accessed through rule 8.1b increasing significantly in the foreseeable future?
10. How could we assess what value paediatric cancer treatments provide against other medicines that could be funded with the same money?

Does the current policy support equity?

11. What should Pharmac take into account when considering equity issues with respect to rule 8.1b of the Pharmaceutical Schedule?
12. Do you consider rule 8.1b to be inequitable from the perspective of other children or those with rare disorders? Why?
13. To what extent do the current policy settings including rule 8.1b contribute to the health outcomes achieved for tamariki Māori and Pacific children with cancer?
14. Do you consider rule 8.1b to be inequitable from the perspective of adolescent and young adults with cancer? Why?
15. How might we address equity and fairness concerns related to paediatric cancer medicines through rule 8.1b and access to medicines for other groups?

Other information or thoughts?

16. Is there anything else we need to know to inform the review? If so, please add your information of thoughts here.

The journey of a funding application

Anyone can apply for a medicine or related product to be funded. This is the general process applications go through. It's not always linear or this simple, but our Factors for Consideration are used throughout to make sure we are getting the best health outcomes for New Zealand.

1. Apply

A supplier, health professional, or anyone else can submit an application with our online Application Tracker.

2. Review

We review and evaluate applications before putting them to our expert advisory committees.

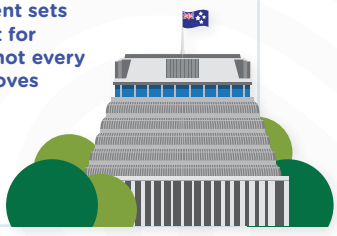
3. Assess

Our committees give us expert clinical and consumer advice. This helps us conduct a thorough assessment of an application using the Factors for Consideration.

4. Prioritise

We decide what applications to progress by comparing applications against others on our Priority Lists. Those we want to take forward are ranked on the Options for Investment list.

The Government sets a fixed budget for medicines so not every application moves forward.



5. Negotiate

We negotiate a price with suppliers that's within our budget, working hard to get some of the best deals with pharmaceutical companies for medicines in the world.

6. Agree

Once we have a provisional agreement with the supplier, we can move the application forward.

7. Consult

We ask New Zealanders what they think. Their submissions help us address issues and adapt proposals based on feedback.

8. Funding decision

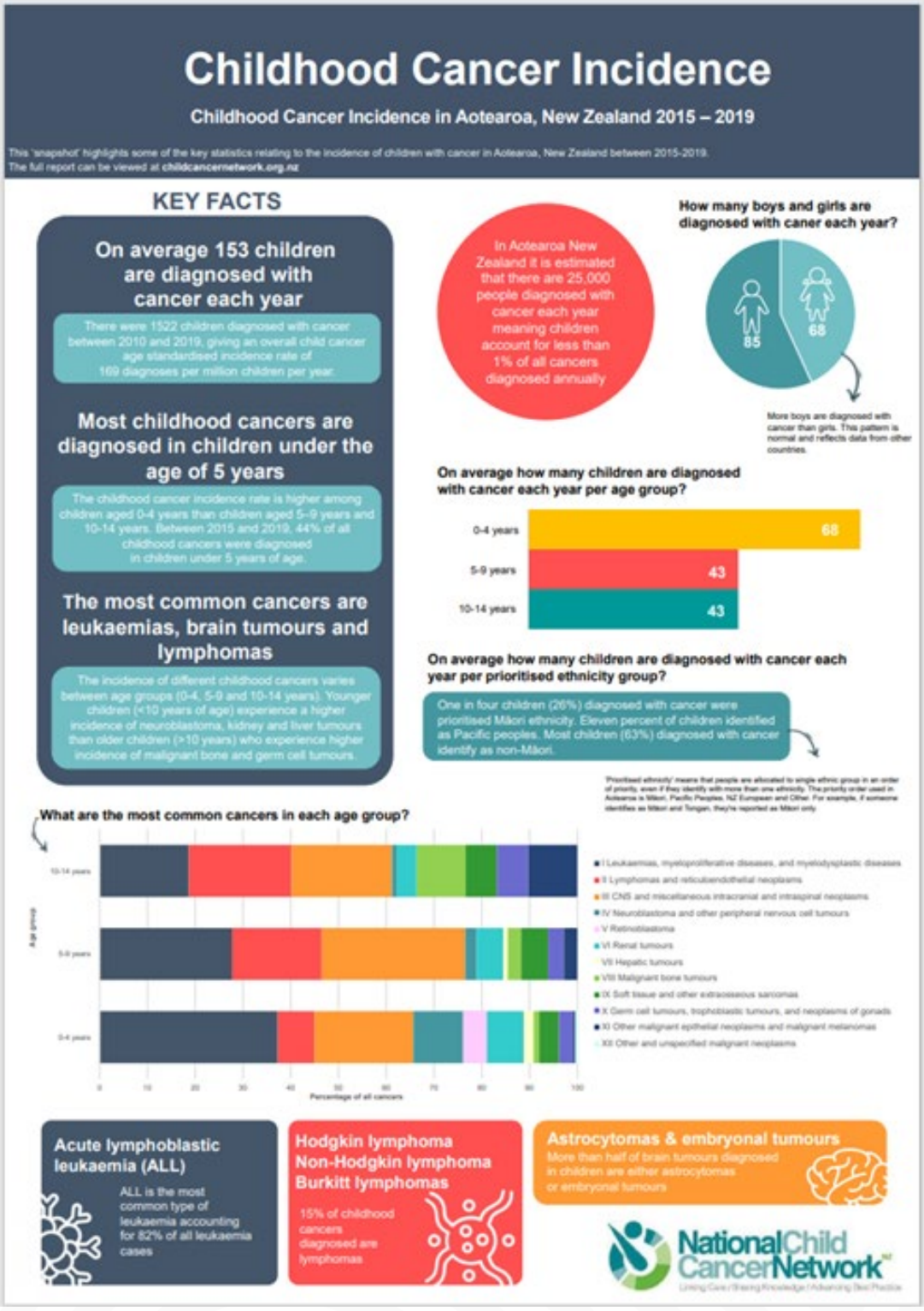
The Pharmac board or delegate makes the final decision. We then notify health professionals and the public.

9. List

The medicine or related product is listed on the Pharmaceutical Schedule and becomes available to New Zealanders.

Appendix 2: Pharmac's factors for consideration framework

Appendix 3: Childhood Cancer Incidence snapshot from National Child Cancer Network



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