PHARMAC
Pharmaceutical Management Agency

Hot topic Meeting Minutes 27/05/2020

Application: FreeStyle Libre® flash glucose monitoring system for Type 1 diabetes

Key documents relating to this hot topic

Hot topic slides	 2020-05-27 Pre-prioritisation.Hot
Diabetes SC minutes	FreeStyle Libre section (March 2019)
PTAC minutes	Review of Diabetes SC minutes (May 2019)
IMPACT study	Bolinder et al. Lancet. 2016; 388(10057):2254 63
FPGM in NZ	Metcalfe et al. NZMJ. 2014;127(1406): ISSN 1175-8716
SELFY study	Campbell et al. Pediatr Diabetes. 2018;19(7):1294 1301.

Attendees:

Presenter: Tal Sharrock, **HEs**: Eric Matthews, Hayden Spencer, Ben Campbell-Macdonald, **TGMs/FAAs:** Elena Saunders, Danae Staples-Moon, **MDs:** Scott Metcalfe, Greg Evans

Discussion

Context to meeting

Group noted that FreeStyle Libre® flash glucose monitoring was first ranked on the OFI at the December 2019 prioritisation meeting for a defined subgroup of type-1 diabetes mellitus (T1DM) patients who were considered by the Diabetic Subcommittee at the meeting held in March 2019.

PHARMAC staff have subsequently considered that the proposed subpopulation of T1DM patients would be practically challenging to restrict access to as a distinct subpopulation, as opposed to funding FreeStyle Libre® flash glucose monitoring for the entire T1DM community.

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As such, this meeting sought to replace the existing ranked FreeStyle Libre® proposal for the subpopulation of T1DM patients with a new updated proposal for the entire T1DM population.

It was also noted that the health economist who assisted with the original PHARMAC analysis was no longer working for the organisation and as such it was considered appropriate to review the assumptions underpinning our economic evaluation of this proposal.

PICO

Group noted the proposed PICO as presented in the slides. Consensus was reached that the PICO as presented was appropriate except for the outcomes, which needed to account for the benefit that flash glucose monitoring would provide for patients in alleviating to some degree the fear of having a hypoglycaemic event.

The PICO agreed upon at this meeting is outlined in the table below:

Population	Any of: 1. Patient has type-1 diabetes mellitus 2. Patient has undergone pancreatectomy 3 Patient has cystic fibrosis-related diabetes
Intervention	FreeStyle Libre® flash glucose monitoring
Comparator	Finger prick blood glucose monitoring (FPGM)
Outcomes	Health related quality of life (HRQOL) gain from: 1. Reduction in time spent in hypoglycaemia resulting from improved glycaemic monitoring 2 Reduction in finger pricking required for glycaemic monitoring 3. Reduction in fear of hypoglycaemic events

Clinical recommendation for funding

Group discussed the clinical advice recommendation given by the Diabetes Subcommittee at the March 2019 meeting, which has been recorded internally as a low priority recommendation for funding

Action points:

1. TGMs to review documentation around clinical recommendation.
2. Proposal to be ranked with low subcommittee recommendation.

Utility gain-discussion

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The utility values and how they were derived in the original PHARMAC economic analysis was presented for both the base-case, lower sensitivity limit and upper sensitivity limit (see slides for detail)

- Consensus was reached that the baseline health state utilities associated with glucose monitoring devices as reported in the Matza et al 2017 paper were plausible and appropriate to base our economic modelling on. These estimates were:
    - 0.851 for conventional monitoring (FPGM)
    - 0.882 for flash glucose monitoring
- These baseline health state utilities resulted in an incremental HRQOL of 0.031 gained per year for patients using flash glucose monitoring compared to patients using FPGM.
- Group considered that the Matza el al 2017 paper represented the best currently available evidence to inform the HRQOL increment that could realistically be obtained from using flash glucose monitoring vs finger-prick glucose monitoring. The group also acknowledged that there were known limitations with the Matza et al 2017 study design, and that other HTA agencies had considered the evidence constituted low grade evidence.
- The group further noted that there is a considerable body of HRQOL data likely to emerge in the short to medium term, including an EQ-5D study currently being conducted in New Zealand in adolescents with T1DM.
- It was noted that the Matza et al 2017 findings informed the economic modelling for FreeStyle Libre® as undertaken by Healthcare Improvement Scotland and that considerable effort had been undertaken to validate the economic analysis via external peer review conducted at the University of Edinburgh
- It was noted that the original PHARMAC analysis (as informed the original December 2019 ranking) incorporated an improbably high HRQOL value to inform the high possible CUA estimate as currently ranked on the OFI.
    - The group noted that the earlier high possible CUA estimate was based on the upper limit (i e top of the 95% confidence interval) of estimated HRQOL as reported in the Matza et al 2017 paper (0 083)
- The group felt that the gain of less time in hypos and accompanying improvement in HRQOL (as originally estimated in the PHARMAC analysis informing the December 2019 ranking) was reasonable to include in the base case of this updated analysis.
    - The reduction in time spent in hypoglyacaemia due to flash glucose monitoring was informed by the results of the Bolinder et al 2016 paper (reduction of 1 18 hours per day)
- The group felt that it was also appropriate to add the utility gain that would occur as a result of a lower fear of hypo events in general with free style.
    - The group noted the values already presented from TAR68 that living with fear of hypo events has a QOL of 0 995 or a loss of 0 005 from full health
    - The group considered that flash glucose monitoring would not alleviate all of this health loss but assuming a proportion of it would be alleviated was reasonable.

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Action point: HE to add HRQOL gain from reduced fear of hypo events to the base case of the model and consider to what degree this would be reduced by to be reasonable.

- The group discussed that it could be beneficial to check a 3% incremental health gain against previous economic assessments to see if the order of magnitude was reasonable **(ACTION:** HE)
- The group noted that the HRQOL gain is likely greater in children/younger people that adults
- Group agreed that sensitivity analysis around the base-case utility should be conducted using +/ 25% in the likely CUA range and 50% in the possible CUA range.
- Group noted that it was important to note that the decrement of having a hypo was one off and assumed full recover. Considered a reasonable approach to the assessment give the available data and evidence.

Test strip use per day

Consensus was reached at the meeting that the estimated test strip use in each arm of the model should be considered as:

Arm of model	**Base case consumption of test strips**	**Source**
FreeStyle Libre®	0.5 test strips per day	IMPACT study
FPBG	4 test strips per day	Metcalfe et al, 2014.

- Group noted that although the supplier for FreeStyle Libre® has their own branded test strips it was reasonable to assume the test strips in this analysis are the ones we currently fund.
- Group noted an error on the slides that clinical advice should read 4 10 test strips a day not 10-14 as was presented (HE updated this on the slide post meeting)
- Group noted that the model includes an incremental cost of test strips rather than attributing test strips to each arm

Action point: CUA model to be adjusted to reflect test strip consumption in each arm as outlined in the table above.

- Group noted that lancets are not funded by PHARMAC and are purchased by the patient and therefore are not included in the CUA modelling.

Action point: HE to acknowledge lancet self-funding in TAR as a saving that would be incurred by patients if FreeStyle Libre® was to be funded in New Zealand

- Group felt the original estimated incremental reduction in test strip consumption per day of 7 was likely to high
- MD noted and circulated research done in NZ which suggested people used 112 per user per month, which equated to 4 test strips per day (Metcalfe et al, 2014)

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- It was noted that the supplier had considered a median of 6 test strips per day was appropriate to inform the supplier provided CUA modelling. It was noted that this estimate of 6 had been informed by a study conducted in Australia (Miller et al. Diabetes Care. 2013;36(7):2009-14)
- Group considered that that NZ paper was more relevant and up to date.
- Group considered it would be appropriate to use a daily average of 0.5 test strips in the intervention arm as per the IMPACT trial and 4 per day in the comparator arm Group agreed that sensitivity analysis with 6 and 10 daily test strips in the comparator arm only should be modelled.

Other offsets

- Group noted that as is the case currently, cost-offsets from a small reduction in hospitalisations was appropriate to include in the base-case
- Group noted that results published in the SELFY study suggested that patients using FreeStyle Libre® were likely to consume a 4% higher insulin daily dose (IDD) compared to patients using FPGM.
    - The group considered that it was difficult to establish whether a 4% higher IDD constituted a clinically significant difference that could be extrapolated to the wider T1DM population.
    - Consensus was reached that it was appropriate to acknowledge the possibility of a marginally higher IDD qualitatively in the TAR, though not to include this uncertain incremental cost in the updated modelling.

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AGENDA

Prioritisation Meeting

To be held at the PHARMAC Office on

Tuesday 2 June 2020

Overall Agenda

1. Overview of meeting process
2 Acknowledgement of proposals funded since the last prioritisation meeting
3 Ranking of proposals on the 'only if cost neutral or cost saving' list
4 Ranking of proposals on the 'recommended for decline' list
5. Miscellaneous changes to proposal status to be acknowledged
6. Prioritisation of new proposals to the *Options for investment* list
7. Re-prioritisation of the proposals on the *Options for investment* list with updated information
8. Consideration and confirmation of al ranked prioritisations lists
9. Budget boundaries

Prioritisation Paper (Supplementary material)

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

- Section 1: Overview of meeting format
- Section 2: Factors for Consideration
- Section 3: Health need
- Section 4: Cost effectiveness
- Section 5: Government health priorities
- Section 6: Proposal summaries

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Proposals to be re prioritised with updated information

Re-ranked items should take 3 - 5 minutes each.

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation

Proposal	Reason	TG M	HE
Freestyle Libre - all Type 1 diabetes	Re-visit old model/BIA	ES	TS
Out of scope			
Out of scope		Out of	
	Out of scope		
Out of scope		Out of	
	Out		

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Prioritisation Meeting

June 2020

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Content

1. Zoom polling
2. Proposals funded since the last meeting
3. Proposals recommend to the ‘cost-neutral/cost-saving’ list
4. Proposals ‘recommend for decline’
5. New items to be ranked on the OFI list
6. Re-rank items to the OFI list
7. Miscellaneous changes

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Zoom polling

- Zoom polling to assist ranking
- Question, should this proposal be moved?
  - Move up
  - Move down
  - Remain in place
- Please ensure you have joined the zoom meeting on your laptop/tablet, to participate in polling.

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Options for Investment – Speaking Order

Therapeutic Group Manager	• Introduces item. • Key therapeutic and commercial issues. • Why is it being prioritised today?
Health Economist	• Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? • Explain the key drivers of the cost-effectiveness result. • Explain the range of cost-effectiveness estimates.
Medical Directorate	Any other relevant clinical issues not yet raised.
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues.
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

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Re-rank items to the OFI list (1)

Proposal	Reason	TGM	HE
Freestyle Libre - all Type 1 diabetes	Re-visit old model/BIA	ES	TS
Out of scope			
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Out of scope	Out of scope	Out of scope	
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Prioritisation Paper

Prioritisation Meeting to be held at the PHARMAC Office on

Tuesday 2 June 2020

Contents

In addition to the Prioritisation meeting agenda document, please refer to the following sections of this paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

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Section 1: Prioritisation meeting format

The quarterly prioritisation meeting is a key step in PHARMAC's decision processes, where each current funding proposal is considered and ranked using the Factors for Consideration.

Formally, PHARMAC's assessment of funding proposals is a 'deliberative process', whereby all relevant different points of view are considered and traded off against one another. This contrasts with systems that use predetermined weights for each criterion

In a deliberative process, it is critical that all perspectives are considered by all people involved in the consensus decision This means that all meeting participants should have good opportunity to make sure that key points are heard and that they hear and understand the points raised from other perspectives.

This document includes only brief summaries of information about each proposal; for full details please refer to the relevant Technology Assessment Report and PTAC minutes.

Below is the protocol to structure the staff discussions during the prioritisation meeting. It builds on a successful process that PHARMAC has developed over many years, while giving it more structure as appropriate to the large group involved in each meeting.

Speaking order

Therapeutic Group Manager	Introduces item. Key therapeutic and commercial issues. Why is it being prioritised today?
Health Economist	Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? Explain the key drivers of the cost-effectiveness result. Explain the range of cost effectiveness estimates
Medical Directorate	Any other relevant clinical issues not yet raised
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

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Section 2: Factors for consideration

Factors are presented here in the order they are listed in decision papers, without implying any ranking or relative importance.

Need

- The health need of the person
- The availability and suitability of existing medicines, medical devices and treatments
- The health need of family, whānau, and wider society
- The impact on the Māori health areas of focus and Māori health outcomes
- The impact on the health outcomes of population groups experiencing health disparities
- Government Health Condition Priorities

Health Benefits

- The health benefit to the person
- The health benefit to family, whānau and wider society
- Consequences for the health system
- Government Health System Priorities

Suitability

- The features of the medicine or medical device that impact on use by the person
- The features of the medicine or medical device that impact on use by family, whānau and wider society
- The features of the medicine or medical device that impact on use by the health workforce

Costs and Savings

- Health related costs and savings to the person
- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system

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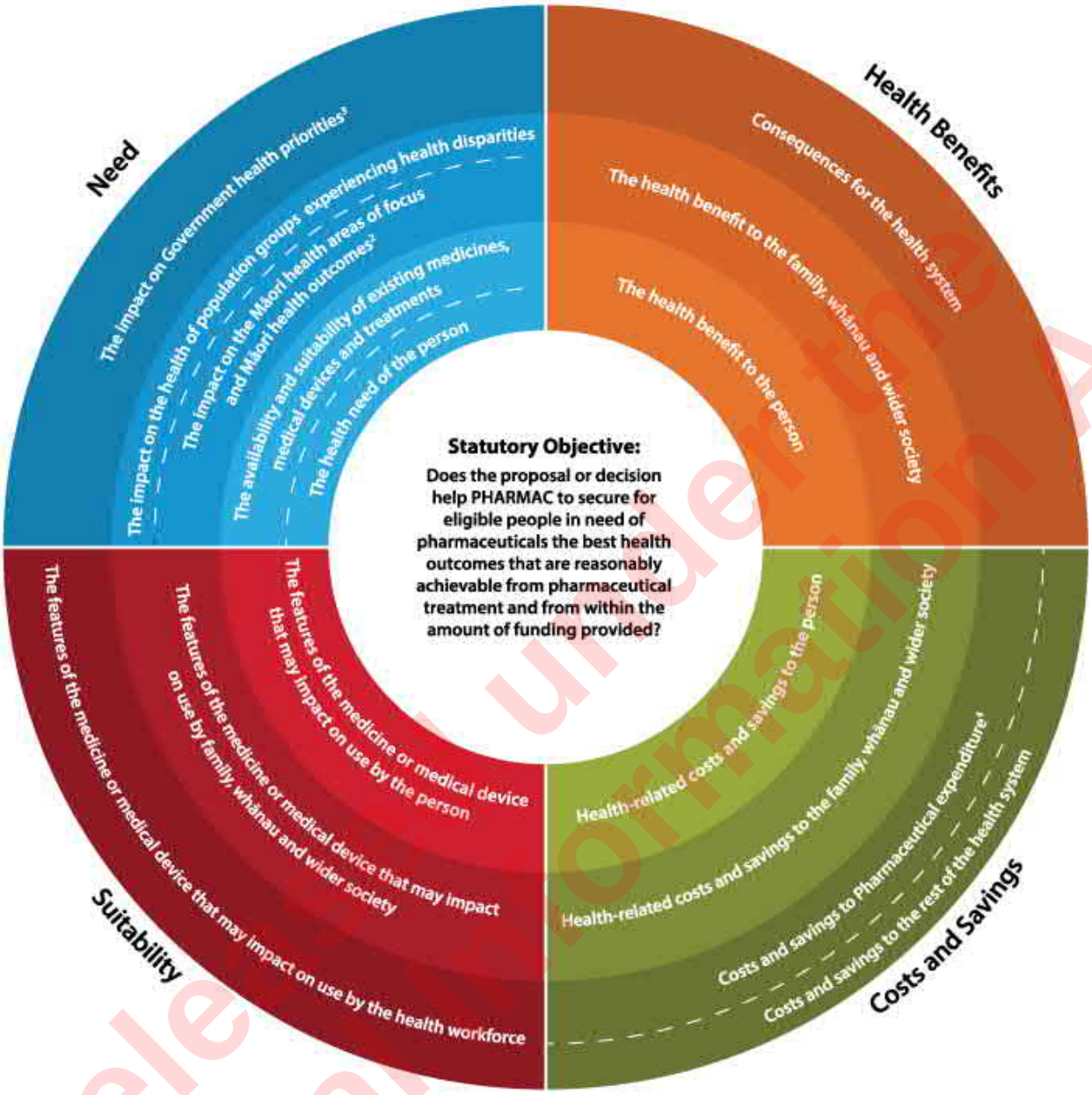
Figure 1: PHARMAC Factors for Consideration



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Section 3: Health Need.

These graphs show estimates of the health loss experienced by an average or typical patient in the relevant cohort with currently funded treatments for treatments on the current prioritisation list They do not reflect the effect of the new products under consideration Each bar starts at the average age of onset of the specific disorder in question. Absolute values are shown in a separate table.

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Out of scope

Freestyle Libre Flash Glucose	Type 1 diabetes	

Out of scope

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Table 1: Lifetime Health Need associated with conditions

Drug	Indication	Lifetime QALYs lost
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Freestyle Libre Flash Glucose Monitoring System	Type 1 diabetes	18
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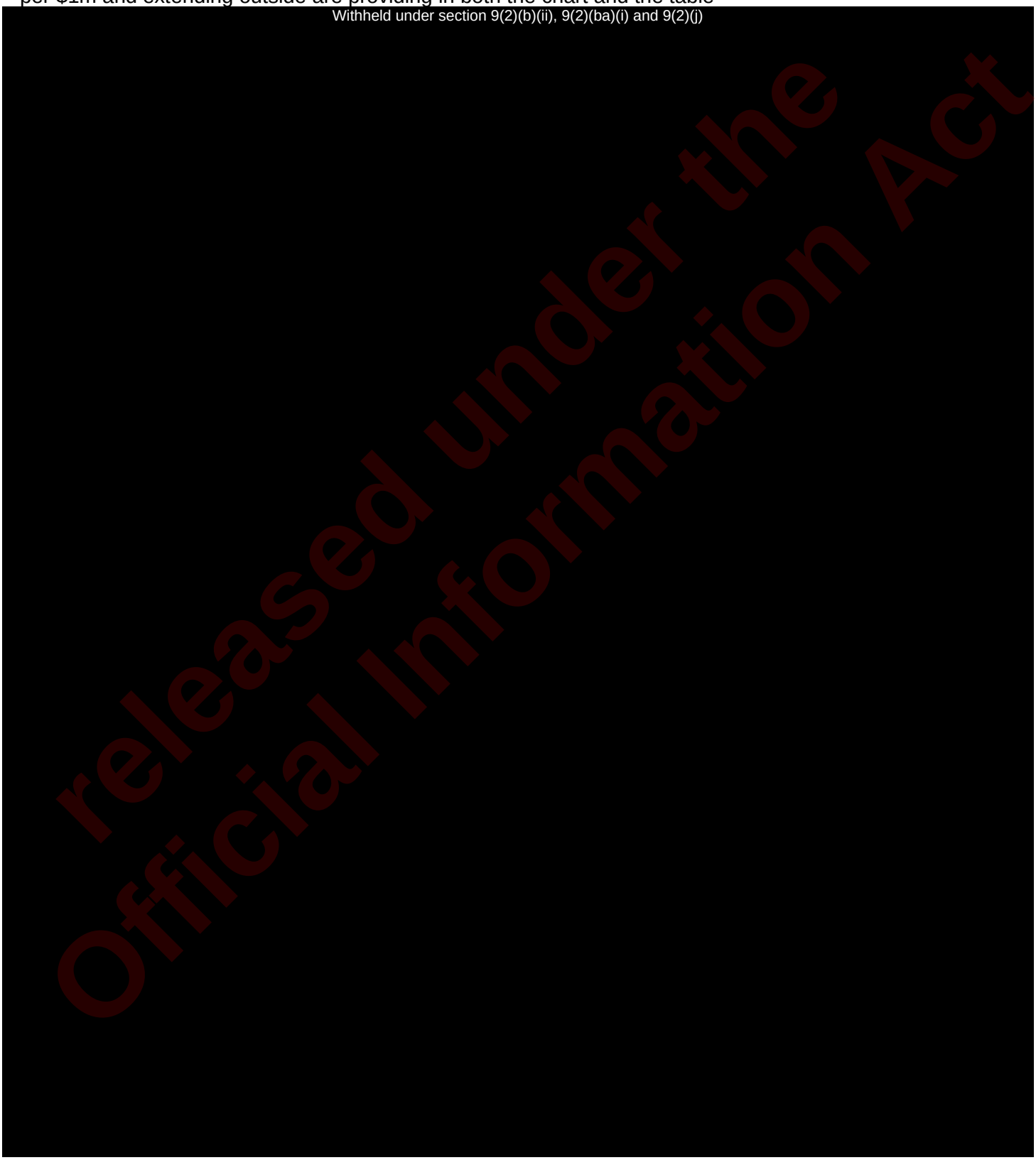
Section 4: Cost effectiveness

Previously ranked proposals are shown in existing priority order New proposals are placed roughly within the list as a starting point only. Cost-effectiveness ranges (0 to 70 QALYs per $1m) may extend off the chart; proposals that are completely off the chart or cost saving/cost neutral are detailed in the table on the next page; proposals with ranges within 0 to 70 QALYs per $1m and extending outside are providing in both the chart and the table

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)



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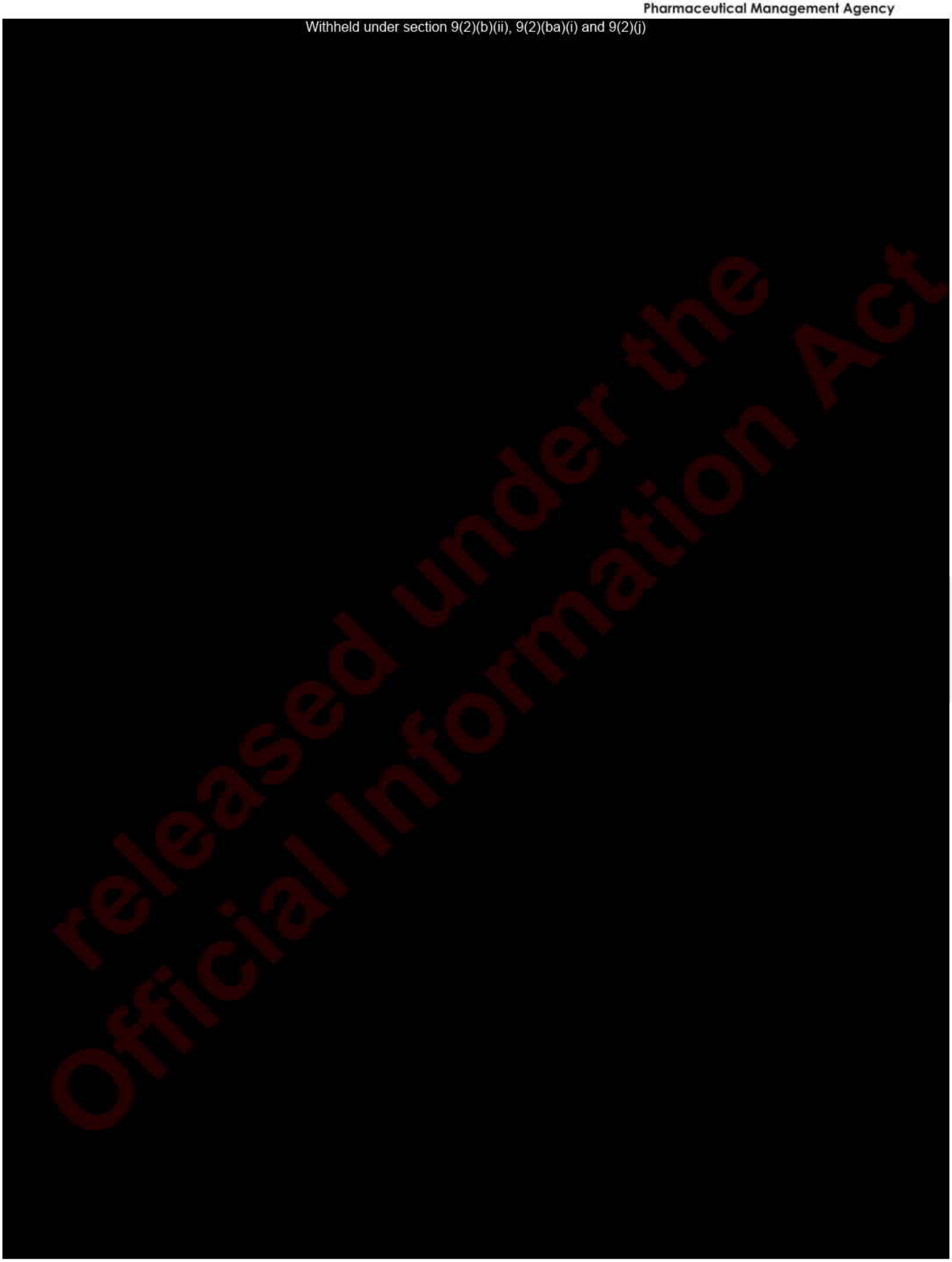

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Section 5: Government health priorities

The impact on government health priorities

This factor asks whether the disease, condition, or illness is a Government health priority.

Last updated: 15 May 2020

Priority or specific health condition	Interpretation for FFC
Priority 1	
Child wellbeing	PHARMAC's decisions will help improve child wellbeing and support children to have a healthy start in life.
Priority 2	
Mental wellbeing	PHARMAC's decisions will help improve mental wellbeing. For PHARMAC, this includes treatment for alcohol and drug addiction.
Priority 3	
Prevention	PHARMAC's decisions will improve wellbeing by preventing health conditions This includes issues such as: • smoking cessation • immunising against infectious diseases • antimicrobial stewardship • sexual health.
Priority 4	
Health equity	PHARMAC's decisions will support better population outcomes, supported by a strong and equitable public health and disability system We are focused on achieving equity in health outcomes and enhancing equitable access to medicines This includes a specific focus on achieving pae ora (healthy futures) for Māori as Te Tiriti partners. Read more about Te Whaioranga ***PHARMAC's equity priorities*** • Priority populations: Māori, Pacific people, low socio-economic status, refugees, rural populations. • Priority health conditions: cardiovascular disease, diabetes, asthma, COPD, gout
Priority 5	
Primary health care	PHARMAC's decisions will support better population health and outcomes supported by primary care We are focused on strengthening primary care through making medicines available and accessible in primary care settings
Specific health conditions	
Rare diseases	This covers conditions that meet PHARMAC's definition of a rare disease (1:50,000 population).
Cancer	We consider that this includes all cancer conditions. However, note that some specific cancers (lung and breast) have a particular focus for PHARMAC under the Hauora Arotahi Māori health areas of focus

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Long-term conditions	We consider that long term conditions includes (but is not limited to): • diabetes • cardiovascular disease • chronic respiratory disease • neurological diseases (such as dementia)
Infectious diseases	We consider that this covers both treatments for and immunisation to prevent infectious diseases We will also continue to promote the responsible use of antimicrobials (including antibiotics) – antimicrobial stewardship

Hauora Arotahi

PHARMAC's Hauora Arotahi (Māori health areas of focus) are:

- mental health
- diabetes
- heart health
- respiratory health
- cancer (lung and breast).

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Section: 6: Proposal Summaries

This section has a dossier for each proposal on the Options for Investment list Where multiple proposals are represented by one item, please refer to the name of the item.

When data are not given for a Factor, the following terms are used:

No difference: Evidence found that shows no material difference or effect.
None identified: Staff searched for relevant evidence and found none
Not reviewed: Staff did not seek information on this Factor

For more information on any proposal, refer to the Technology Assessment Report, to the relevant Objective file, or to the proposal's records in PharSight

If you are reading this document on screen, select the Word menu option **View | Navigation Pane** Click on the dossier's name to jump to the page

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Freestyle Libre Flash Glucose Monitoring System-Type 1 diabetes

Latest Clinical Recommendation: No Formal Recommendation from PTAC, 23/05/2019

Comparator: Finger prick blood glucose (FPBG) monitoring via a blood glucose meter.

NEED

Condition: Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta cells resulting in insulin deficiency. Loss of endogenous insulin can lead to hyperglycemia and life threatening ketoacidosis

Health need of the person: 18

Insulin is used to prevent severe hyperglycemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult Over treatment results in hypoglycemia, which can range from mild and uncomfortable to life threatening

Health Need Of Family Whānau and Others: Evidence is emerging of significant caregiver stress among parents of children and adolescents with type-1 diabetes (Grover et al. Perspect Clin Res. 2016;7(1):32-39). The evidence is unclear regarding whether increased monitoring using the newer technology increases or reduces caregiver stress.

Availability of existing alternatives: Self monitor using a blood glucose meter between 4 to 10 times per day (finger-prick).

Māori Health Areas of Focus: Yes

Māori health need: Disease burden among Māori more severe

Impact on population groups experiencing disparities: None identified

Government condition priorities: Yes. Long term condition

HEALTH BENEFITS

Health benefit to the person: Freestyle libre flash glucose monitoring system has been shown to decrease the amount of time a patient spends within the hypoglycaemic range per day, the number of severe hypoglycemia events per day. Some evidence has been provided to suggest an improvement in quality of life compared to FPBG monitoring

Health benefit to family, whanau: Probable reduction in caregiver stress resulting from remote monitoring of blood glucose levels via the Freestyle device. This is likely to be even more so overnight when the current method requires waking a child and undertaking a finger prick. Furthermore, the device may allow carers more freedom to leave the patient in the care of others. Conversely, some data indicates that the increased granularity of data available can increase the burden of stress to carers

Health benefit to others: Probable reduction in stress for teachers / teacher aides who are involved in the daily care of children and adolescents whilst they are at school.

Consequences for health system: Freestyle libre flash glucose monitoring system could conceivably reduce the number of required emergency department admissions, and the number of diabetes related complications requiring treatment via the health system The exact impact is unknown

Government system priorities: Health equity

COSTS AND SAVINGS (Lifetime NPV @3.5%).

Health costs to the person: A $5 prescription co-pay will apply every three months.

Health costs to family, whanau, others: Not relevant.

Pharmaceutical costs per person: Net cost per person of Withheld per person per year

Costs to rest of health sector, per person: 4% net distribution costs will apply to this device. Note, no gross pricing has been provided by the supplier in their proposal.

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SUITABILITY

Impact on use by the person: Freestyle libre flash glucose monitoring system involves application once every 14 days, involving one small prick. This compares to the current SMBG method, which can involve up to 10 pricks per day F'style provides near continuous data readings.

Impact on use by others: Device enables remote monitoring of blood glucose via bluetooth uplink to multiple smart mobile devices

Impact on health workforce: Additional data availability may impact on clinical services, increasing the clinic time required to train individual on the use of the device as well as finger prick testing (which will still be required) and for the interpretation of a larger volu data.

COST EFFECTIVENESS

Point estimate = Wit QALYs per $1m.

Likely range Withheld QALYs per $1m

Possible range Withheld QALYs per $1m.

BUDGET IMPACT

Year	1	2	3	4	5
Patients	16,400	22,700	26,500	27,500	28,600
Pharmaceutical costs	Withheld	Withheld	Withheld	Withheld	Withheld
Other health sector costs	$0 99m	$1 38m	$1 62m	$1 68m	$1 74m
Total Health Sector Budget Impact	Withheld	Withheld	Withheld	Withheld	Withheld

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