

Technology Assessment Report No.417

Economic Analysis on FreeStyle Libre Flash Glucose Monitoring System - Type 1 diabetes

Last updated June 2020

Summary of Proposal

PROPOSAL OVERVIEW
Pharmaceutical FreeStyle Libre Flash Glucose Monitoring System (FreeStyle Libre)
Supplier Abbot Laboratories NZ Limited
Proposed Indication Patients with Type 1 diabetes
Dosing Each patient requires a new self-adhesive sensor every 14 days to be applied to the back of the upper arm and a Bluetooth™ enabled reader (replaced every 2-years) to periodically check the interstitial glucose level
Pharmaceutical Price Reader Withh (approx.) Retail price from Abbott Australia (~2 year duration) 14 day sensor: Withhel
PTAC PRIORITY Diabetes Subcommittee March 2019 (minutes) <ul style="list-style-type: none">• High priority for a special authority population including type 1 diabetics aged <18 years, pregnant or planning to become pregnant. PTAC Subcommittee May 2019 – no formal recommendation (minutes)
PHARMConnect: link

Executive Summary

This technology assessment report (TAR) assesses the incremental cost effectiveness and budget impact of FreeStyle Libre, a flash glucose monitoring system for people type one diabetics compared to conventional finger prick testing as a method of measuring blood glucose levels.

Summary of Supplier Cost-Utility Analysis

The Supplier included an economic model with their application, suggesting a modelled incremental cost-effectiveness ratio (ICER) of [Withheld] per quality-adjusted life year (QALY; [Withheld] QALYs per \$mil). PHARMAC staff have conducted a preliminary review of this model and compared its findings against several readily available economic models undertaken by international HTA agencies. PHARMAC staff have several concerns with the Supplier model (including the utility increment and validity for patients with unstable diabetes) and suspect that the incremental cost effectiveness of flash glucose monitoring is overestimated.

Summary of PHARMAC Cost-Utility Analysis

A 24-hour model was created to model the cost-effectiveness of flash glucose monitoring (FreeStyle Libre) compared with conventional finger prick testing as a method to measure blood sugar levels. The model did not include consideration of improved blood glucose control as a result of a change in blood glucose measurement method. The analysis considered the cost of the FreeStyle Libre sensor ([Withheld] every two years) and reader ([Withheld] per 14 days) and a net reduction of 3.5 test strips a day on average. The analysis also considered the incremental quality of life gained by using FreeStyle Libre that was comprised of a reduction in daily finger prick testing, a reduced fear of having hypoglycaemic events and a reduction in the amount of time spent in a hypoglycaemic state.

The estimated base case cost effectiveness for flash glucose monitoring compared to conventional finger prick testing was [Withheld] QALYs gained per \$1 million invested. The model was most sensitive to variation in the incremental quality of life gain and the incremental change in test strip usage between the two methods of glucose measurement. The likely cost-effectiveness range of this proposal is [Withheld] QALYs per \$1 million invested, which is informed by the likely variation in the incremental utility gain (incremental utility gain plus or minus 25%). The possible range is [Withheld] QALYs per \$1 million invested based on the possible variation in the incremental utility gain (incremental utility gain plus or minus 50%).

Summary of Budget Impact Analysis

The budget impact analysis estimated that, after uptake, 16,400 type one diabetics will adopt flash glucose monitoring in the first year of listing. This is estimated to increase by year five to 28,600 as a result of both population growth and increased uptake. Given the cost of readers, sensors, and strips (savings), the net cost per patient per year is [Withheld]. This results in a net cost to the CPB and DHB in year one of [Withheld] million and [Withheld] million respectively, increasing to [Withheld] million and [Withheld] million by year 5 of listing. The total 5-

year NPV discounted at 8% annually for this investment is [Withheld] million, of which [Withheld] million is CPB expenditure.

1. Proposal Overview

1.1 Proposal Background

- The funding application was received from Abbot in November 2017 for FreeStyle Libre, flash glucose monitoring system for the self assessment of blood glucose for type 1 diabetes patients.
- The proposal was reviewed by the [Diabetes Subcommittee](#) at their March 2019 meeting. The proposal was given a high priority recommendation for funding in a high health need population of type 1 diabetics as defined by a Special Authority. The special authority population included type 1 diabetics who were aged under the age of 18, those who were planning to become pregnant or those who were pregnant
- The meeting record from the Diabetes Subcommittee was reviewed by [PTAC](#) in May 2019. The Committee considered that it was unable to endorse the recommendation provided by the Subcommittee. The Committee considered they required further evidence to support a benefit, particularly an improvement in quality of life. In addition, the committee considered that the proposal did not fit well into the assessment framework of medicines and was perhaps more appropriate to consider as a device for which the Committee felt they did not have the necessary skills to assess
- The proposal for the Special Authority population proposed by the Diabetes Subcommittee was assessed and ranked on the Options for Investment list in December 2019.
- In June 2020, the proposal was re-prioritised to incorporate all type 1 diabetes patients, as it is considered that the group defined by the Diabetes Subcommittee would be challenging to define in practice and that the group should therefore be widened to include all patients with type 1 diabetes in line with the original supplier application.
- The below TAR reflects the analysis for the proposal to fund flash glucose monitoring for all type 1 diabetics in New Zealand.

1.2 PICO

provides a summary of the patient population; intervention; comparator treatment; and main outcomes of treatment for the assessment of flash glucose monitoring if were to be funded in New Zealand for all type 1 diabetics.

Table 1 below provides a summary of the patient population; intervention; comparator treatment; and main outcomes of treatment for the assessment of flash glucose monitoring if were to be funded in New Zealand for all type 1 diabetics

Table 1: PICO statement for the assessment of FreeStyle Libre for type 1 diabetes

Population	People with type one diabetes
Intervention	Flash glucose monitoring (Freestyle Libre) (determining blood glucose by scanning a device over an arm patch) ¹
Comparator	Self-monitoring using finger prick testing and a blood glucose meter
Outcome	Quality of life gain from: <ul style="list-style-type: none">• A reduction in time spent in hypoglycaemia• Reduced fear of hypoglycaemia events occurring• Reduction in daily finger prick testing

1.3 Disease Description

Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic β cells resulting in insulin deficiency. Insulin deficiency leads to hyperglycaemia and the potential to develop ketoacidosis. Although the etiology of type 1 diabetes has not been fully elucidated, the disease is believed to develop when environmental factors in genetically susceptible individuals trigger T cell activity, resulting in β -cell destruction.

Type 1 diabetes is a life-long disease that is most often diagnosed during childhood or adolescence, with only 25% of cases diagnosed in adults (Source: Subcommittee paper)

1.4 Epidemiology

According to the Ministry of Health Virtual Diabetes Register, there was estimated to be 253,000 individuals with diabetes (type 1 and type 2) in New Zealand in 2018. The general global consensus is that 10% of individuals with diabetes have type 1 diabetes; however, the epidemiology is known to vary widely by geographic location and ethnicity. PHARMAC staff note that 10% may be an overestimation for New Zealand (Source: Subcommittee paper) Type 1 diabetes is more common in Non Māori populations than Māori though the burden of disease experienced by Māori with diabetes is more significant ([Robson et al, 2000-2005, Hauora Māori Standard of Health](#))

1.5 The health need of the person

¹ Note: This TAR does not specifically discuss alternative personal blood glucose monitoring devices that could be used in place of FreeStyle Libre. The majority of these alternative devices rely on continuous blood glucose measurements.

Individuals with type 1 diabetes typically present with polyuria, polydipsia, and weight loss. Approximately 30% of patients also present with signs of diabetic ketoacidosis including fruity-smelling breath, drowsiness, and lethargy. A small proportion of patients are diagnosed prior to the onset of symptoms, typically children who are being monitored because they have close family members with type 1 diabetes.

Appropriate therapy with exogenous insulin prevents severe hyperglycaemia and ketoacidosis from occurring but maintaining glucose levels within the normal range is difficult. Overtreatment results in hypoglycaemia, which can range from mild and uncomfortable to life-threatening. To avoid hypoglycaemia, patients are more likely to maintain blood glucose levels in the mild to-moderate hyperglycaemic range, which over the long term can cause microvascular and macrovascular damage. Chronic complications of type 1 diabetes include cardiovascular disease, neuropathy, diabetes nephropathy, and diabetic retinopathy.

Type 1 diabetes also has a significant negative impact on quality of life for affected individuals, particularly regarding physical functioning and wellbeing. The intensive nature of disease management, fear of hyperglycaemia or hypoglycaemia, and fear of long term complications can result in significant stress and anxiety.

1.3 Current Treatment

The current standard of care for assessing blood glucose for patients with type 1 diabetes levels is to self-monitor using a blood glucose meter between four and ten times per day. This involves pricking a finger with a lancet, applying the blood to a test strip, and inserting the test strip into the meter. In New Zealand, diagnostic blood glucose test meters and consumables are funded for patients meeting certain eligibility criteria, including individuals receiving insulin. Currently, there are no flash or continuous glucose monitoring systems funded for use within New Zealand.

1.2 Intervention

The FreeStyle Libre system has three components: a disposable sensor, a reader, and optional software. The sensor has a thin, sterile filament which is 0.4 mm wide and inserted approximately 5 mm under the skin. The filament is attached to a small disc (35 mm × 5 mm) the size of a two-dollar coin. Medical grade adhesive is used to keep the sensor in place on top of the skin once applied to the back of the upper arm. The sensor continuously records data for up to 14 days; readings are updated every minute and data is stored every 15 minutes.

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

Withheld App and software options are also available, including:

- The FreeStyle LibreLink app which is available for iPhone and Android and allows glucose to be monitored using your phone
- The FreeStyle LibreLinkUp app allows monitoring of data from individuals using the FreeStyle LibreLink app (for parents/caregivers)
- LibreView computer software which allows an individual to sync data from the LibreLink app or upload data from the FreeStyle Libre reader

Patients using either Freestyle libre or a continuous glucose monitoring device are recommended to retain a personal supply of finger prick blood testing strips and blood glucose meter for use during rapidly changing glucose levels or emergency situations by the Supplier. The Freestyle libre reader has a built-in test strip port, however this port is unable to accommodate the publicly funded CareSens test strips available in New Zealand

released under the
Official Information Act

2. Health Benefits

Table 2 below outlines the two key pieces of published evidence that were used in the health economic assessment of FreeStyle Libre. The evidence was reviewed by the Diabetes Subcommittee in March 2019 ([minutes](#)).

Table 2: Summary of key clinical evidence used in the health economic assessment of FreeStyle Libre

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
IMPA CT	Multicentre, prospective, non-masked, randomised controlled trial	Adults with well controlled T1DM	N = 328	FreeStyle Libre vs SMBG with capillary strips	6 months	<ul style="list-style-type: none"> • Mean time in hypoglycaemia (<3.9 mmol/L) in the FreeStyle Libre group changed from 3.38 h/day to 2.03 h/day at 6 months (baseline adjusted mean change -1.39) vs 3.44 h/day to 3.27 h/day in the SGMB group (baseline adjusted mean change -0.14); • Between group difference -1.24 (SE 0.239; $P < 0.0001$), equating to a 38% reduction in time in hypoglycaemia in FreeStyle Libre group 	<ul style="list-style-type: none"> • No device-related hypoglycaemia or safety issues reported • 276 AEs in 124 participants • 10 SAEs (5 in each group); none were device related • 13 AEs related to the sensor were reported by 10 participants (allergy events, insertion site symptoms, erythema, and oedema) • 6 patients (5%) in the FreeStyle Libre group 	Bolinder et al. Lancet. 2016;388:2254-2263.

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
						<ul style="list-style-type: none"> Time spent in hyperglycaemia (>13.3 mmol/L) was reduced in the FreeStyle Libre group ($P=0.0247$) Diabetes QoL score did not favour either group in the full analysis set ($P=0.0524$), but was significantly improved in the per-protocol set 	discontinued due to AEs vs 1 patient (<1%) in the SMBG group	
HR-QOL study	Time trade-off interviews using identical descriptions of diabetes and insulin treatment, only the method of measuring glucose was different	Members from the general public in UK	N = 209	FreeStyle Libre vs SMBG with capillary strips	n/a	<ul style="list-style-type: none"> Mean utility of 0.851 ± 0.140 for conventional monitoring Mean utility of 0.882 ± 0.121 for flash glucose monitoring Statistically significant difference between mean utilities. 37.3% of the 209 patients rated flash monitoring higher, 61.7% had the same utility values for both. 	n/a	Matza et al. Value Health. 2017 Mar;20(3):507-511.

3. PHARMAC Cost Utility Analysis

3.1 Economic model

A 24 hour model was constructed to compare the cost-effectiveness of the flash glucose monitoring system, FreeStyle Libre with conventional finger prick testing as methods to measure blood glucose level in type one diabetics. Measurement of blood glucose level is necessary to inform insulin dosage and ultimately maintain blood sugar levels within the necessary range. Due to the uncertainty concerning if insulin usage and blood sugar level control is different between the two methods of measuring blood sugar levels, this economic assessment only considers the cost effectiveness of the measurement method itself.

Intervention

The intervention, flash glucose monitoring, in this analysis was based on the Freestyle libre product. FreeStyle Libre requires the use of an electronic reader which needs to be replaced every two years and a sensor patch which needs to be replaced on the individuals arm every 14 days. Swiping the reader over the sensor patch allows the reader to display the concentration of blood sugar in the blood.

Comparator

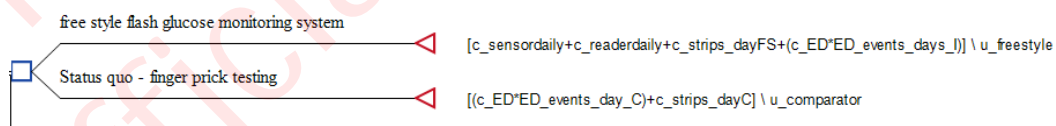
The comparator in this analysis is conventional finger prick testing. Conventional finger prick testing involves pricking the finger with a lancet to draw blood that is then inserted into a meter using a test strip which returns the concentration of blood sugar in the blood.

The model

A 24 hour model was constructed to compare the incremental quality of life and costs of monitoring blood sugar levels using FreeStyle Libre or conventional finger prick testing.

The structure of the model is shown in Figure 1 below.

Figure 1: Model structure



3.2 Key Assumptions and Inputs

Volume of test strips

The model considers that on average four test strips per day would be used by type one diabetics using conventional finger prick testing. This value was informed by a New Zealand study by Metcalfe et al, 2014 ([Metcalfe et al, N Z Med J, 2014 Nov 28;127\(1406\):48-62](#)) which looked at the dispensing data of approximately 183,000 people in New Zealand who were dispensed diabetes medicine or blood glucose test strips in 2011. The study found that for patients on insulin only, 112 test strips per month were dispensed on average, resulting in a daily average per person of four.

The model considers that on average 0.5 test strips per day would be used by type one diabetics using FreeStyle Libre. This value was informed by the IMPACT study ([Bolinder et al, Lancet 2016; 388: 2254–63](#)) which found that the mean number of finger prick glucose monitoring tests done per day was 5.5 in the status quo group and 0.5 in the FreeStyle Libre arm.

PHARMAC consider there is reasonable variability in the average number of test strips used daily in current practice. Internal peer review in May 2020 (A1393385) identified several sources of information to inform this input including:

- clinical advice sought from the Diabetes Subcommittee in March 2019 ([minutes](#)) that stated that it would be reasonable to assume that 4-10 test strips would be used daily in current clinical practice
- an Australian based study that was noted by the Supplier that suggesting a median of 6 test strips a day was reasonable ([Miller et al. Diabetes Care. 2013;36\(7\):2009-14](#))
- IMPACT study which suggested an average of 5.5 daily would be reasonable ([Bolinder et al, Lancet 2016; 388: 2254–63](#))

PHARMAC staff considered that the study by Metcalfe et al, 2014 conducted in a New Zealand setting would be most appropriate to consider in the base-case of this economic assessment. Acknowledging the uncertainty in this parameter, sensitivity analyses were conducted where the average daily volume of test strips used in the comparator arm of the model was varied from six to 10 test strips.

Note: Lancets that are required to use to prick the finger to get a drop of blood for the blood glucose tests are not funded by PHARMAC but are acquired and paid for by a patient. As per the [PFPA](#), this is a patient cost, it was therefore not included in this analysis. It was noted however, that patients on FreeStyle Libre flash glucose monitoring would incur a personal saving outside of VoteHealth as a result of reduced blood glucose testing frequency.

Time spent in hypoglycaemia

The IMPACT study ([Bolinder et al, Lancet 2016; 388: 2254–63](#)) reported that the mean time spent in hypoglycaemia changed from 3.38 hours a day to 2.03 hours per day (a reduction of 1.35 hours a day) in the intervention group and from 3.44 hours a day to 3.27 hours per day in the comparator arm (a reduction of 0.17 hours per day). Therefore,

compared with patients using the conventional finger prick testing, mean time in hypoglycaemia was reduced by 1.18 hours per day for patients on freestyle.

Reduction in emergency department time

Pedersen Bjergaard et al 2017 ([Curr Diab Rep. 2017 Oct 28;17\(12\):131](#)) reports a incidence rate of severe hypoglycaemia requiring parenteral therapy or need for admission to an emergency unit/hospitalisation ranges in the literature between 0.02-0.5 events per patient per year.

In the IMPACT study ([Bolinder et al, Lancet 2016; 388: 2254–63](#)) reported that there was two hypoglycaemia related serious adverse events (requiring hospitalisation or third party intervention) in the flash glucose monitoring group vs four in the control group

To calculate the reduction in emergency department usage, this analysis assumes the incidence rate of hypoglycaemia hospitalisation is the mid-point of the incidence range presented above and that as a result of flash glucose monitoring, the incidence rate is halved (i.e. incidence rate of 0.26 events per patient per year for flash glucose monitoring vs 0.13 events per year for flash glucose monitoring). The incidence rate of 0.02 and 0.5 were used in the sensitivity analysis.

The rate and severity of hypoglycaemia is assumed to be the same every day.

To note:

It was noted that the evidence suggested that patients on FreeStyle Libre have slightly increased insulin usage. Due to the uncertainty of whether this was a clinically meaningful difference and its generalisability, a decision was made not to include this possible additional cost in the model. In the IMPACT trial, no differences in total daily doses of insulin was observed between the study groups at the end of the study period ([Bolinder et al, Lancet 2016; 388: 2254–63](#)).

3.3 Costs

Table 3 below outlines the costs used in the economic model.

The intervention arm of the model incurs the daily cost of having the FreeStyle Libre sensor and reader in addition to 0.5 test strips. The comparator arm incurs the cost of using four test strips a day and the incremental cost of ED admissions for severe hypoglycaemic events that would have otherwise been avoided if the patient was treated with flash glucose monitoring. The latter was calculated by multiplying the cost of an emergency department admission by the incremental reduction in ED events as described in 3.2 section above.

Table 3: Modelled costs

Item	Cost	24-hour cost per patient	Source
Cost of an emergency department admission	\$370 per admission	\$0.26 Comparison \$0.13 Intervention	2018 Cost Resource Manual
Cost of reader	With per 2-year	With	Supplier application
Cost of sensor	With per 14 days	With	Supplier application
Cost of test strips	With per pack of 50 strips (net price after confidential rebate) With per test strip	With comparator arm (assuming 4 test strips a day on average) With intervention arm (assuming 0.5 test strips a day on average)	PHARMAC

3.4 Health-Related Quality of Life

The incremental quality of life gained using flash glucose monitoring to measure blood glucose levels instead of conventional finger prick testing was estimated by PHARMAC staff as outlined below to incorporate the quality of life gain of reducing the number of times a day a patient has to conduct finger prick testing, a reduction in time spent in a hypoglycaemic state and a reduced fear of having hypoglycaemic events.

The foundational utilities in this model are derived from Matza et al ([Matza et al, Value Health 2017 Mar;20\(3\):507-511](#)) Matza et al reported a utility weight for conventional glucose monitoring of 0.851 and 0.882 for flash glucose monitoring resulting in an incremental gain of 0.031 per year for those patients using flash glucose monitoring systems like FreeStyle Libre.

Internal peer review in May 2020 (A1393385) noted that this utility gain was representative of the utility gain resulting from less finger prick testing and that it would be reasonable to add a utility gain to represent the health gain from both a reduction in fear of hypoglycaemia events and less time spent in a hypoglycaemic state.

The health utility of fear of having hypoglycaemia was 0.995 or a reduction of 0.005 per year from a state of perfect health ([TAR 68 Insulin Glargine](#)). Internal peer review in May 2020 (A1393385) considered that it was unreasonable to assume flash glucose monitoring systems such as FreeStyle Libre will completely dissipate the fear of hypoglycaemic events but considered that it was reasonable to assume, in the absence of other information, that the fear would reduce by 50%. Consequently, a utility gain of 0.0025 per year was added to the Matza et al. (2017) reported utility for flash glucose monitoring of 0.882 per year.

The health utility of being in a hypoglycaemia state was modelled to be 0.85 ([TAR 68 Insulin Glargine](#)). Assuming a base health state of 0.995 as a result of having a fear of going into a hypoglycaemic state, the disutility of going into a hypo state is 0.145 a year (0.995-0.85) or 0.0000166 per hour. Bolinder et al ([Bolinder et al, Lancet 2016; 388: 2254-63](#)) reported a reduction in hypoglycaemic hours between FreeStyle Libre flash glucose monitoring and conventional finger prick testing of 1.18 hours resulting in a utility gain in the free-style libre arm as a result of time in a hypoglycaemic state avoided of 0.0000195 per day.

Taking the above into account, the final utility for patients on flash glucose monitoring is 0.0024 per day (0.8845 per year) compared to 0.0023 per day with conventional finger prick testing (0.851).

Table 4: Health-Related Quality of Life

Health State	Utility
Flash glucose monitoring	0.885
Conventional finger prick testing	0.851

3.7 Results of Economic Analysis

The results of the analysis indicate that the ICER is [Withheld] / QALYs, which is equivalent to [Withheld] QALYs gained per \$1 million invested

The likely cost-effectiveness range of this proposal is [Withheld] QALYs per million which is informed by the likely variation in the incremental utility gain and the possible range is [Withheld] QALYs per million based by the possible variation in the incremental utility gain. See section 3.8 for more detail.

Table 5: Baseline Results

Strategy	Costs	Incremental cost	Incremental QALY	ICER	QALYs gain per \$1 million
Conventional finger prick testing	[Withheld]	[Withheld]	0.00233	[Withheld]	[Withheld]
FreeStyle Libre	[Withheld]		0.00244		

3.8 Sensitivity Analysis

Table 6 and Figure 2 below summaries the results of various sensitivity analyses that were conducted. The cost-effectiveness of FreeStyle libre compared to conventional finger prick testing is most sensitive to the incremental decrease in daily test strip usage and the incremental utility gain.

Multiple one way sensitivity analyses were conducted on the number of test strips used in the comparator arm. When the incremental decrease in daily test strip usage was changed to be 9.5 from 3.5 in the base-case the cost effectiveness changed to [Withheld] QALYs per \$million from the base case of [Withheld] QALYs per \$million.

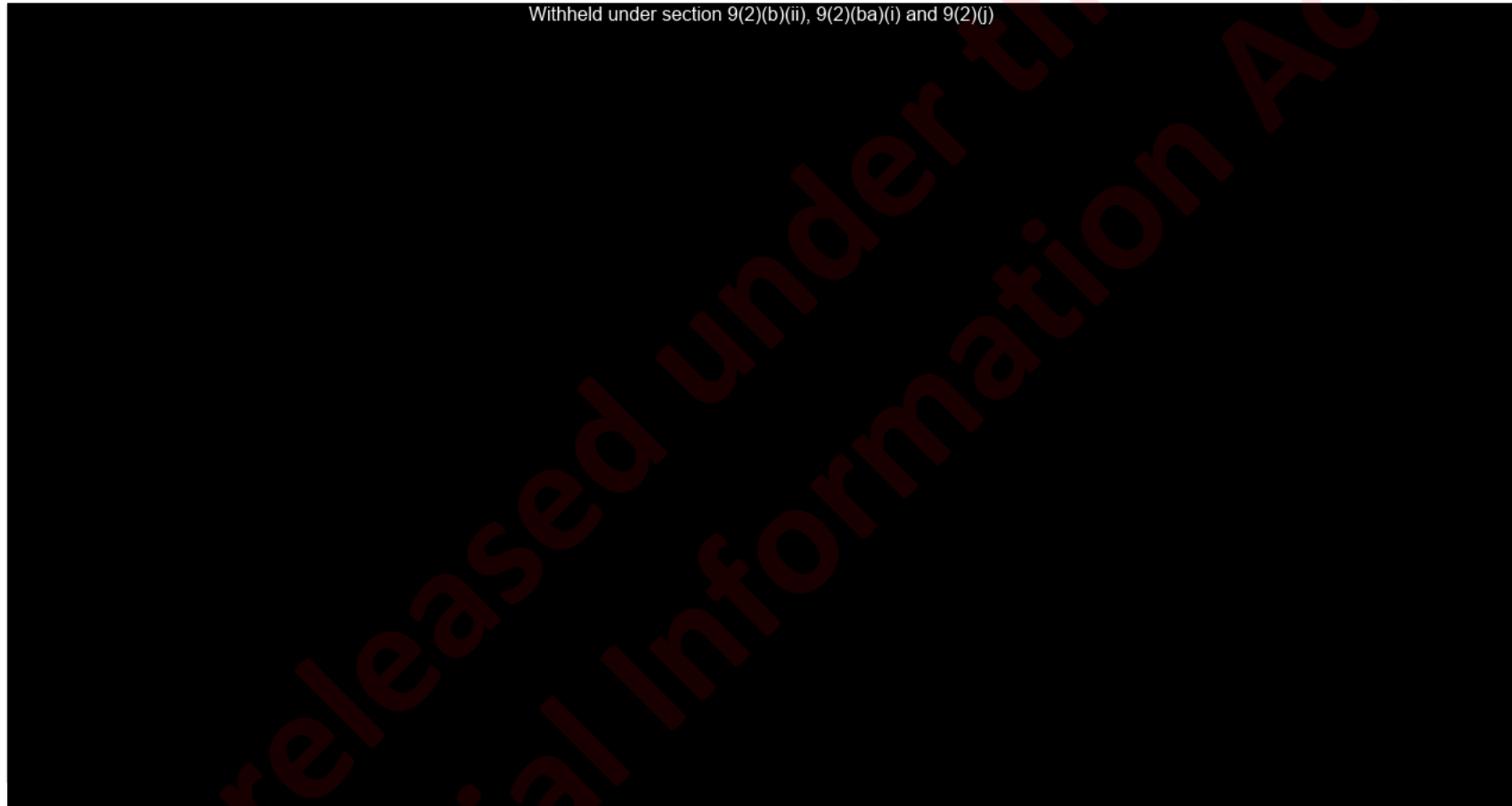
Adjusting the incremental utility gain in the model to be 25% more and 25% less than the base-case resulted in a cost-effectiveness range of [Withheld] to [Withheld] QALYs per \$million. Increasing this variability in the incremental utility gain to be 50% more and 50% less than the incremental change in the base case resulting in a cost effectiveness range of [Withheld] QALYs per \$million

The cost of sensors was increased to reflect that due to issues with adhering the patch to the skin, noting that some patches may need to be replaced more frequently than the recommended 14 day period. A modest reduction in the cost-effectiveness was observed, as expected with a 25% increase in sensor cost, resulting in a cost-effectiveness of [Withheld] QALYs per \$million. Sensitivities on parameters relating to emergency department usage or cost did not materially influence the cost-effectiveness

Table 6: Table of cost-effectiveness results from various sensitivity analysis.

Scenario	Incremental cost	Incremental utility	QALYs per \$million
Base case	With	0.00011	Wi
Test strips comparator – 5 (IMPACT trial)	With	0.00011	Wi
Test strips comparator – W (Supplier application)	With	0.00011	Wi
Test strips comparator – W (Supplier application)	With	0.00011	Wi
Test strips comparator -10 (upper daily limit clinical advice)	With	0.00011	Wi
Incremental utility gain +50%	With	0.00016	Wi
Incremental utility gain – 50%	With	0.00006	Wi
Incremental utility gain +25%	With	0.00013	Wi
Incremental utility gain – 25%	With	0.00009	Wi
Zero cost for reader	With	0.00011	Wi
Sensor cost +25% (overuse of sensors)	With	0.00011	Wi
Sensor cost +50% (overuse of sensors)	With	0.00011	Wi
Cost of emergency department use x2	With	0.00011	Wi
Rate of emergency department admittance 0.02 (lower incidence range)	With	0.00011	Wi
Rate of emergency department admittance 0.5 (lower incidence range)	With	0.00011	Wi

Figure 2: Graph of sensitivity analysis



Note: Black horizontal line indicates the base-case value.

The light blue box represents the likely cost-effectiveness range. The dark blue box represents the possible cost-effectiveness range

4. Budget Impact Analysis

4.1 Population

In 2018, Ministry of Health Virtual Diabetes Register estimated there were 253,000 patients living with diabetes in New Zealand. 10% of these patients are thought to be type 1 diabetics. Therefore, the prevalence of type 1 diabetes is estimated to be 25,300. If we assume that patient population are growing at a constant rate every year (4% per annum), the number of the type 1 diabetes patient in 2020 will be 27,300 increasing to 31,800 in year 5

4.2 Budget Impact

Costs included in the budget impact analysis are the costs of readers, sensors, and strips (savings). Other costs such ambulance costs and costs of emergency department admissions are not included because they are considered negligible, given the very low rate of hypoglycemia required emergency department or hospital admissions

Table 7 outlines the estimated budget impact of funding FreeStyle libre compared to conventional glucose monitoring for all type one diabetics in New Zealand. The analysis considers the patient numbers outlined in Section 4.1 and includes the cost of the reader, sensor and the incremental saving from a change in daily test strip use using the costs and values described above in the cost utility analysis. The cost the DHB reflects the net cost attributed the products pharmacy margins.

Given the cost of readers, sensors, and strips (savings), the cost per patient per year are **Withhel**. This results in a net cost to the CPB and DHB in year one of **Withhel** million and **Withhel** million respectively, increasing to **Withhel** million and **Withhel** million by year 5. The total 5-year NPV discounted at 8% annually for this investment is **Withheld** million, of which **Withheld** million is CPB expenditure.

Table 7: Estimated budget impact for the funding of FreeStyle libre.

	2020	2021	2022	2023	2024	5 Year NPV *
Number of type 1 diabetics	27,325	28,371	29,457	30,584	31,755	-
Uptake	0.6	0.8	0.9	0.9	0.9	
Total number on freestyle	16,395	22,697	26,511	27,526	28,579	-
Net CPB (\$million)	Withh	Withh	Withh	Withh	Withh	Withheld
Net DHB (3%) (\$million)	Withh	Withhe	Withh	Withhel	Withh	Withh
Total	Withhel	Withhel	Withhel	Withhel	Withhel	Withheld

*8% discount rate annually