Diabetes Subcommittee of PTAC
records related to continuous glucose monitoring systems (CGMs)

11 December 2013
4 Therapeutic Group Review

Horizon Scanning
4.17 The Subcommittee considered that there may be a place in therapy for continuous glucose monitoring in the future and would welcome a funding application for this technology.

19 August 2014
4 Matters arising

Continuous Glucose Monitoring
4 6 The Subcommittee noted that two companies were investigating bringing Continuous Glucose Monitors (CGMs) to New Zealand. Members considered that is would be appropriate for any applications to be reviewed by the Diabetes Subcommittee prior to PTAC consideration

4.7 The Subcommittee noted that CGMs studies would likely be easier to interpret than pump studies Members noted that there would be identifiable patient populations who would likely benefit from a CGM

6 April 2015
5 Therapeutic Group and NPPA Review

Horizon scanning
5 10 The Subcommittee noted that there are several brands of continuous glucose monitoring systems available on the market but as yet PHARMAC has not received a funding application.

10 October 2016
1 Therapeutic Group Review

Horizon scanning
1 1 The Subcommittee noted several products for people living with diabetes that had not been reviewed for funding but may be of interest in the future: smart glucose monitoring devices eg. Freestyle Libre supplied by Abbott, continuous glucose monitoring systems (CGMS) and closed loop systems involving insulin pumps and CGMS (also known as artificial pancreas).

19 March 2019
3 FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes

Application

3.1. The Subcommittee reviewed an application from Abbott Laboratories NZ for the funding of the FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals 4 years of age and over with type 1 diabetes

3.2. The Subcommittee took into account, where applicable, PHARMAC's relevant decision-making framework when considering these agenda items

Recommendation

3.3. The Subcommittee **recommended** that the FreeStyle Libre Flash Glucose Monitoring System be funded with **high** priority for certain patients with type 1 diabetes subject to the following Special Authority criteria:

Initial application only from a relevant specialist or nurse practitioner Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis related diabetes; and
2. Either:
   - 2.1. Patient is aged 18 years or under; or
   - 2 2 Patient is aged over 18 years; and
   - 2.3. Any of the following:
     - 2.3.1. Patient has impaired awareness of hypoglycaemia and has been admitted to hospital at least twice in the previous 12 months with hypoglycaemia requiring medical intervention; or
     - 2.3.2. Patient has been admitted to hospital at least twice in the previous 12 months with diabetic ketoacidosis; or
     - 2 3 3 Patient is pregnant, breastfeeding, or actively planning pregnancy

Renewal application – only from a relevant specialist or nurse practitioner.

Approvals valid for 24 months for applications meeting the following criteria:

1. Either:
   - 1.1. Both:
     - 1.1.1 Patient is continuing to derive benefit from flash glucose monitoring by achieving and maintaining a reduction of HbA1c from baseline of 10mmol/mol; and
     - 1.1.2. The number of hypoglycaemic episodes has not increased from baseline; or
   - 1.2. Both:
     - 1.2.1. Patient is continuing to derive benefit from flash glucose monitoring by achieving a 50% reduction from baseline in hypoglycaemic events; and
     - 1.2.2. HbA1c has not increased by more than 5mmol/mol from baseline.

Discussion

3.4. The Subcommittee noted a number of submissions from consumers and clinicians in support of funding for the FreeStyle Libre Flash Glucose Monitoring system

3.5. The Subcommittee noted that type 1 diabetes is a chronic disease resulting from the autoimmune destruction of pancreatic β-cells resulting in insulin deficiency; and considered that there are likely to be approximately 25,000 individuals with type 1 diabetes in New Zealand.

3.6. The Subcommittee considered that while the prevalence of type 1 diabetes is higher in European/Pakeha than Māori and Pacific peoples, Māori and Pacific peoples have poorer long term outcomes Members considered that there was significant data regarding the inequities of outcomes for Māori and Pacific with type 2 diabetes and there was no reason to expect this would differ for type 1 patients.

3.7. The Subcommittee noted that individuals with type 1 diabetes use exogenous insulin to manage blood glucose levels but that maintaining a normal range can be difficult. The Subcommittee considered that to reduce the risk and avoid hypoglycaemia, patients often maintain their blood glucose levels in the mild to moderate hyperglycaemic range, which can result in long term microvascular and macrovascular damage.

3.8. The Subcommittee noted that type 1 diabetes can also have a negative impact on quality of life for affected individuals, particularly regarding physical functioning and wellbeing. The Subcommittee noted that the intensive management requirements, the fear of hypoglycaemia and hyperglycaemia, and the fear of long term consequences, can result in significant stress and anxiety. The Subcommittee noted there is also a significant impact on the family and caregivers of individuals with type 1 diabetes.

3.9. The Subcommittee noted that the current standard of care for glucose monitoring in New Zealand is self-monitoring via a finger-prick blood test and patients are testing on average between four and ten times per day The Subcommittee noted that diagnostic blood glucose test meters and consumables are funded for patients meeting certain eligibility criteria, including individuals receiving insulin.

3.10. The Subcommittee noted that the FreeStyle Libre is a Flash Glucose Monitoring (FGM) system that has three components: a disposable sensor, a reader, and optional software.

3.11. The Subcommittee noted that the sensor is applied usually to the upper arm using a disposable applicator, has a thin filament which is inserted under the skin, and that the sensor records data for up to 14 days with readings updated every minute and data stored every 15 minutes

3.12. The Subcommittee noted that optional software allows monitoring of glucose using a smart phone, use of this software means that data is sent to a cloud based server which can be accessed by the patient's healthcare professional. This data is also able to be accessed by the supplier.

3.13. The Subcommittee noted that the FreeStyle Libre has been registered on the Web Assisted Notification of Devices (WAND) database, which is a mandatory requirement for importers, exporters, and local manufacturers, and the sensor registration (15 January 2018; WAND reference: 180115 WAND 6PM9ZF) states the sensor is 'indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with insulin dependent diabetes mellitus The indication for children (age 4 17) is limited to those who are supervised by a caregiver who is at least 18 years of age'.

3.14. The Subcommittee noted that the FreeStyle Libre does not require calibration, however patients would still be required to measure blood glucose via a finger prick test during times of rapidly changing glucose levels or impending hypoglycaemia (approximately

once every second day) The Subcommittee noted that the supplier indicates blood glucose levels as assessed by finger prick are better at informing treatment decisions in these situations. The Subcommittee noted that the FreeStyle reader could be used as a blood glucose meter; however only FreeStyle brand test strips could be used and these were no longer funded in New Zealand.

3.15. The Subcommittee noted that FreeStyle Libre FGM system differs from continuous glucose monitoring (CGM) systems primarily as it does not integrate with insulin pump devices, or provide continuous glucose monitoring, and does not have a hypoglycaemia alarm function which are features found in CGM technology

3.16. The Subcommittee noted that the primary evidence for the use of FreeStyle Libre for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes is provided by the IMPACT trial (Bolinder et al Lancet 2016;388:2254 2263) The Subcommittee noted that IMPACT was a prospective, non masked, randomised controlled trial which assessed whether FreeStyle Libre or self-monitored glucose testing reduced exposure to hypoglycaemia in 328 adults with well controlled type 1 diabetes The Subcommittee noted that the mean time spent in hypoglycaemia reduced by 1.39 hours per day in the FreeStyle Libre group compared with a reduction of 0.14 hours in the control group (between group difference 1 24; SE 0 239; *P*<0 0001) The Subcommittee noted that no device-related hypoglycaemia or safety concerns were reported. The Subcommittee noted that there was no significant difference in diabetes quality of life score between the groups (adjusted between group difference 0 08; SE 0 039; *P*=0 0524)

3.17. The Subcommittee noted published correspondence to and from the authors of the IMPACT trial regarding concerns about skin adverse reactions (Brahimi et al Lancet 2017. 389:1396; Bolinder et al. Lancet. 2017;389:1396 1397; Aerts et al. Lancet. 2017;390:1644). The Subcommittee considered that there would be a small proportion of patients who would experience adverse reactions to the adhesive used on the FreeStyle Libre sensor. The Subcommittee noted that there would also likely be incidents where the adhesive failed or the sensor was displaced, meaning that patients would require another sensor prior to the 14 day period was up and had the potential to be a fiscal risk Members considered that the supplier appeared to be currently providing replacements sensors in the private market in these circumstances.

3.18. The Subcommittee noted that supporting evidence for the use of FreeStyle Libre in children and young adults is provided by the SELFY study, which was a single arm, open-label study in 76 individuals aged 4 to 17 years with type 1 diabetes (Campbell et al Diabetologia 2017;60 [Suppl 1]:S1 S608 [conference abstract only]) The Subcommittee noted that the time in normoglycemic range (3.9 to 10.0 mmol/L) increased from baseline by a mean of 1.0±2.8 hours per day (P=0.0056), and that HbA1c reduced from baseline by 4 4±5 9 mmol/mol (P<0 0001) The Subcommittee noted that three device-related adverse events were reported, and that there were no device-related serious adverse events.

3.19. The Subcommittee considered that there are a significant number of patients self funding FreeStyle Libre in New Zealand and that this was resulting in further inequities in outcome for patients with type 1 diabetes

3.20. The Subcommittee considered that the frequency with which patients with type 1 diabetes see health care providers is dependent on age and glycaemic control. If FreeStyle Libre were funded, the Subcommittee considered there may be some requirement for additional appointments with health care providers particularly initially and that the time required for patient management would be increased if data from the device were to be utilised. However, there may be a longer term reduction in management requirements if individuals improved glycaemic control and this could be significant if severe hypoglycaemic episodes and DKA were avoided.

3.21. The Subcommittee considered that access to a FGM system such as FreeStyle Libre for patients under the age of four could provide significant benefits but noted that there is currently no data available for this age group and it is outside the WAND registration.

3.22. The Subcommittee considered that if FreeStyle Libre were to be funded, that the uptake would be high, particularly for children and young adults. The Subcommittee considered that the main benefits of FGM appeared to be the convenience of testing, an increasing frequency of glucose testing and an associated flow on effect to improved glycaemic control. However, the Subcommittee considered this appeared to be a time bound effect in many patients.

3.23. The Subcommittee considered that for some patients who are not currently finger prick testing for various reasons, having access to FGM technology could provide the data and motivation for improved glycaemic management

3.24. The Subcommittee considered that approximately half of patients initially provided with FreeStyle Libre would continue using it long-term, either constantly or sporadically.

3.25. The Subcommittee considered that evidence for FGM was still developing and evolving but that this was a promising technology. The Subcommittee considered that the currently available evidence to support the efficacy and safety of FreeStyle Libre is of moderate quality.

3.26. The Subcommittee considered that funded access to an FGM system would benefit all patients with type 1 diabetes and as such there would likely be a significant fiscal impact associated with the funding of FreeStyle Libre. The Subcommittee considered that there are specific populations who have the highest health need for improved glycaemic control and who are likely to receive the most benefit from FreeStyle Libre and that it would be appropriate for funding to be initially targeted to these groups.

3.27. The Subcommittee considered that the highest priority for funding and patients most likely to benefit from FGM systems are children and young adults with type 1 diabetes. The Subcommittee considered other groups who could be targeted based on greater potential to benefit were patients with cystic fibrosis related diabetes; patients with type 1 diabetes who are pregnant, breastfeeding, or actively planning pregnancy; patients with hypoglycaemia unawareness; and patients who have been admitted to hospital at least twice in the previous twelve months due to diabetic ketoacidosis or hypoglycaemia The Subcommittee acknowledged that the population of people who would use FGM system during pregnancy, breastfeeding and those planning pregnancy would represent a very large number of patients and, as had been encountered with insulin pump funding, could be difficult to further define

3.28. The Subcommittee noted that it would be important for ongoing funding criteria to require improvement in HbA1c and/or hypoglycaemic events to be demonstrated and that use should be discontinued where patients were not achieving an improvement in glycaemic control

General Comments regarding CGM and FGM

3.29. The Subcommittee noted that there were several types of glucose monitoring technologies, currently available and under development, including continuous glucose monitoring (CGM) systems, flash glucose monitoring (FGM) systems, sensor- and flash-augmented pump therapy, hybrid closed loop pump therapy, and fully closed loop therapy

3.30. The Subcommittee considered that there were some major differences between CGM and FGM currently Namely, CGM systems available at this time provide continuous data, require 12-hourly blood glucose calibration, have alarms that can be set to detect out of range glucose levels, can be integrated with insulin pumps and some have predictive algorithms to suspend and resume insulin delivery; FGM systems while they do provide glucose level trend arrows to encourage closer monitoring or intervention and are factory calibrated, they currently require the sensor to be manually scanned and are not designed to be integrated with insulin pumps or provide alarm features for predicted hypoglycaemia.

3.31. The Subcommittee noted that some patients are using open source transmitter attachments available on the market for use with FGM systems that allow for continuous glucose readings and alarm functionality (e.g. the MIAOMIAO Smart Reader).

3.32. The Subcommittee considered that this raised several areas of concern that were broader issues for PHARMAC with the use of community devices, particularly given the limited regulatory controls around devices products in New Zealand currently. Members considered that safety for diabetes patients using devices was a significant concern especially where closed loop systems were being used. Members considered that it was unclear whether support from suppliers would be provided for patients using open-source or other “DIY” technology who ran into technical issues, had device failure or experienced adverse events.

3.33. The Subcommittee considered that the use of devices in this way also raised a number of data governance and privacy considerations including: who owned the data generated; how it was shared, accessed and interpreted; appropriately gained consent for its use; and the training and resourcing of health professionals to manage this.

3.34. The Subcommittee considered that the field of glucose monitoring technologies is developing rapidly, in regard to both hardware and software. The Subcommittee considered that as the technology develops additional features will likely include improved sensitivity, reduced requirement for calibration, and closed loop functionality.

3.35. The Subcommittee considered that that given the interlinked nature of insulin pump and CGM technology, any future decisions to fund these devices in the New Zealand market should consider how these technologies integrate with each other. The Subcommittee considered there would be a preference for pump ‘agnostic’ interstitial glucose monitoring technology

3.36. The Subcommittee considered that the fast moving pace of technology development in the devices field, and the complexity of the devices themselves, meant that consideration needed to be given to the availability of appropriate systems and services so that patients and healthcare professionals were adequately supported to use these products. The Subcommittee considered it was particularly important that accurate, reliable and useful information could be accessed easily to troubleshoot any issues that arose

3.37. The Subcommittee considered that the introduction of any CGM or FGM technology would impart a significant burden on health care system due to the resources required to adequately train and educate healthcare professionals, patients, and caregivers on the use of the devices. The Subcommittee considered that the volume of information provided by these technologies would be clinically beneficial but would likely significantly increase the time required for health care professionals to incorporate this into their clinical decision making.

3.38. The Subcommittee considered that it will be critical that appropriate education be provided to health care professionals for any CGM or FGM technology introduced to New Zealand. The Subcommittee considered that it would be important that this is product specific, but also that there is a centrally collated information source with resources available regarding all products and technologies that patients may be using and practical details guiding where further information can be found, and how and where to get replacement products

3.39. The Subcommittee considered it would likely be important for the contractual requirements for suppliers address issues specific to devices such as training, support, data governance as well as terms for discontinuation scenarios and replacement of devices.

3.40. The Subcommittee considered that the quality of evidence available regarding the efficacy and safety of CGM and FGM technologies is affected by the inability to conduct blinded randomised controlled trials, as the intent of the devices is that blood glucose monitoring is visible (in other words, it is not possible to use a ‘sham’ device in an randomised controlled trial setting). The Subcommittee considered that much of the data currently available was based on relatively short follow up of 3-6 months for what was a long-term disease and that data with longer timeframes would be of more interest.

3.41. The Subcommittee considered that future review of CGM and FGM funding applications will require data indicating the impact of the technology on blood glucose time in range and haemoglobin A1c (HbA1c) levels, utility in broader patient groups, and long term efficacy and safety data. The Subcommittee considered that it was likely for diabetes patients using CGM technology they would reduce the volume of blood glucose test strips

3.42. Members considered that the impact of this technology was more complex than just changes in HbA1c as it would also provide convenience that would impact on a diabetic patients’ lifestyle and reduce stress associated with managing their condition; and that there may be challenges for translating these kinds of benefits in a health technology assessment

3.43. The Subcommittee considered that real world analyses may provide the most valuable data for glucose monitoring technologies. Members noted that evaluation of CGM in Australia was currently underway and that analysis of 12 month data would likely be available soon Members considered the 6 month data indicated a reduction in hypoglycaemic events and a mild benefit in terms of HbA1c from use of CGM.

3.44. The Subcommittee considered that further data was needed to help inform which populations gained benefit from use of CGM. The Subcommittee considered that the data required would likely need to come from rich and diverse sources and was likely to be different from that traditionally provided to support medicines funding.

3.45. The Subcommittee considered that glucose monitoring systems such as CGM and FGM are likely to provide significant benefit to certain patients who are receptive and responsive to the technology, but that it will be difficult to prospectively identify who these individuals will be. Members considered that based on observations in the private market there were clearly some patients who benefitted and others who did not however, any access criteria needed to be carefully considered so that disparities would not be exacerbated.

MEMO TO DIABETES SUBCOMMITTEE

To: Diabetes Subcommittee

From: Therapeutic Group Manager

Date: March 2019

Continuous glucose monitoring (CGM) and Flash glucose monitoring (FGM) technology – brief overview

QUESTIONS TO SUBCOMMITTEE

Note to members: These questions have been identified by PHARMAC staff as being particularly relevant to the application. Please feel free to provide additional information as appropriate

1. What data or information would the Subcommittee like to see to support consideration of CGM technology?
2. What additional factors or contractual requirements should be considered by PHARMAC with a potential listing of CGM of FGM? (i.e. support, software, warranty etc)
3. How should CGM technology be factored into PHARMAC's approach to the insulin pump market in future?
4. Does the Subcommittee have any other comments or recommendations regarding CGM or FGM technology?

PURPOSE OF THIS PAPER

The purpose of this paper is to provide a brief overview of some of the CGM technology that is available and may be brought to the New Zealand market and seek advice from the Subcommittee regarding the types of data and information that is needed to facilitate consideration of these products.

DISCUSSION

Currently diabetes patients monitor blood glucose levels by fingerpick capillary blood glucose measurement to guide treatment decisions and management of their disease.

More recently there has been an increase in the number of devices and technology aimed at glucose monitoring and help with the management of type 1 diabetes.

This paper provides a brief overview of the types of products available or in development and some of their features. The content is sourced primarily from a NZ Doctor article[1].

[1] https://www.nzdoctor.co.nz/article/news/clinical/current-and-future-technology-management-type-1-diabetes

Continuous glucose monitoring systems

Continuous glucose monitoring (CGM) systems have been in increasing use over the past 10 or 15 years. CGM systems use a small indwelling sensor, placed with a small introducer to the subcutaneous tissue of the arm or abdomen. The sensors generally last from six days to two weeks, depending on the model

Interstitial rather than blood glucose level is measured. This has some limitations, including, currently, a need for eight to 12 hourly blood glucose calibrations (not for some newer systems not currently available in New Zealand), a time lag, and some inaccuracy (±10 per cent) when compared with capillary blood glucose monitoring In addition to a read out of current interstitial glucose, trend arrows are also provided.

The main CGM options currently being used on the private market in New Zealand come from two manufacturers: Dexcom and Medtronic.

The current Dexcom models are the G4 and G5, which provide updated glucose data every five minutes to a receiver or mobile device, or to an accompanying insulin pump. The G5 and the next version the G6 sensors are also approved for making insulin dosing decisions (except for hypoglycaemia) The G6 sensor is factory calibrated meaning reduced finger prick testing.

Medtronic CGM systems (Enlite sensor range) provide similar data with the added strength of being a key component of sensor-augmented pump therapy and hybrid closed loop therapy (see below) when paired with more a compatible insulin pump.

Flash glucose monitoring

Flash glucose monitoring (FGM) is very similar to CGM in that it also measures interstitial glucose. Like the Dexcom G5, it is approved for clinical decision making (not in cluding management of hypoglycaemia), but it does not provide continuous data. FGM sensors are factory calibrated (ie, no routine calibration finger-pricks needed) and the current product has a 14 day sensor life, and are approved for use in children 4 years or older and adults

Sensor-augmented pump therapy

Sensor-augmented pump (SAP) therapy uses a pairing of an insulin pump with simultaneously running CGM systems (ie, user wears a pump and infusion set as well as a CGM sensor).

SAP provides the ability for low-glucose suspend or predictive low-glucose suspend functions where the glucose data are transmitted by Bluetooth to the pump and (where a predictive function exists) the data go through an algorithm to predict the possibility of future hypoglycaemia; if the risk is sufficient, the pump suspends insulin delivery until the glucose returns to safe levels. These systems have been available in some form or other on the private market since the mid to late 2000s

Flash augmented pump therapy

Flash-augmented pump (FAP) therapy is essentially a simpler and cheaper version of SAP, which utilises FGM via the Abbott FreeStyle Libre system While FAP therapy may provide improvements over traditional insulin pump therapy alone, the data for this has not yet been published and the two technologies are not currently integrated in any way (unlike SAP).

Hybrid-closed and closed loop pump therapy

The future of this technology appears to be in hybrid closed loop pump therapy and fully closed loop pump therapy. While not yet available, these technologies would an both increase and decrease insulin rate based on CGM system interstitial glucose readings Currently the hybrid systems require calibration of the CGM system, as well as patients to input additional finger-prick glucose and carbohydrate ingestion data However, it should be noted that the current cost of such systems is likely to be in excess of $15,000 per year. It should also be noted that there appears to be a growing movement of open access closed loop technology and algorithms internationally and in New Zealand.

NEXT STEPS

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

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j) To date, we have received details of products from two suppliers interested in listing products on the Schedule:

Guardian 3 and Guardian Connect (supplied by Medtronic)

- both use consumable sensors (7 days) and separate transmitter (1 year).
- Guardian 3 SAP (for use in conjunction with the Minimed 640G insulin pump), predictive low glucose suspend function and which automatically suspends insulin and will resume once levels recover. Glucose readings updated every 5 minutes on pump screen.
- Guardian Connect for use as a stand alone CGM system for patients not on insulin pump treatment or those using other types of insulin pumps Sends information to the transmitter every 5 minutes, which then sends data via Bluethooth to a smartphone App on the patient's (and caregivers) mobile phone, every 5 minutes, provides a continuous display and the ability to set alarm limits for safety purposes.

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

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

Overview of some CGM and FGM systems and key specifications:

Please note that this information should be treated as commercial in confidence as some has not provided publically to date.

	[redacted]	[redacted]	[redacted]	**Medtronic Guardian 3**	**Abbott Freestyle Libre**
Launch date	[redacted]	[redacted]	[redacted]	2016	2015
Calibration	[redacted]	[redacted]	[redacted]	1 2/day	factory
Use life	[redacted]	[redacted]	[redacted]	7 days	10-14 days
Accuracy (MARD)	[redacted]	[redacted]	[redacted]	10.6%	11.4%
Comments	[redacted]		[redacted]	SAP integration with pump	Calibration free Small size

THE FACTORS FOR CONSIDERATION

Factors are presented here in the order they appear in the paper, 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
- The impact on Government health priorities

HEALTH BENEFITS

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

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

PHARMAC
TE PĀTAKA WHAIORANGA

PHARMACEUTICAL SCHEDULE APPLICATION

To: Diabetes Subcommittee

From: Funding Application Advisor

Date: March 2019

FreeStyle Libre Flash Glucose Monitoring System (FreeStyle Libre) for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes (≥4 years of age)

SUMMARY OF PHARMACEUTICAL			
Brand Name	FreeStyle Libre	**Chemical Name**	N/A
Indications	Type 1 diabetes (≥4 years and older)	**Presentation**	A disposable sensor, a reader, and optional software
Therapeutic Group	Diabetes Management (Alimentary Tract and Metabolism)	**Dosage**	N/A
Supplier	Abbot Laboratories NZ Limited	**Application Date**	Feb 2018
MOH Restrictions	NA	**Proposal type**	New listing
Current Subsidy	NA	**Proposed Restriction**	Special Authority
Proposed Subsidy	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)	**Manufacturer's Surcharge**	Nil
Year	2019	2020	2021
Number of Patients†	Withheld under section 9(2)(b)(ii)	Withheld under section 9(2)(b)(ii)	Withheld under section 9(2)(b)(ii)
Net Cost to Schedule‡	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)
Net Cost to DHBs (5-year NPV, 8%)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)		

DHBs, District health board; MOH, Ministry of Health; NPV, Net Present Value.

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

† Supplier estimate.

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

Withheld under section 9(2)(b)

QUESTIONS TO SUBCOMMITTEE

Need

1. Is the health need of patients with type 1 diabetes appropriately described in this paper?
2. Is the Subcommittee aware of any additional information or evidence regarding the epidemiology or differential outcomes for Māori and non Māori with type 1 diabetes?

Health benefit

3 Does FreeStyle Libre provide any additional health benefit or create any additional risks compared with funded glucose monitoring options?

4. What is the Subcommittee's opinion regarding the advantages and disadvantages of flash glucose monitoring systems compared with continuous glucose monitoring systems?

5 Do the draft Special Authority criteria adequately describe the patients who would receive the most benefit from FreeStyle Libre? If not, how should the criteria be amended?

5.1. Is it appropriate to restrict access to patients with well controlled diabetes (≤58 mmol/mol)?

5.2. Are the initial application and renewal application time periods appropriate?

5.3. Should access to FreeStyle Libre be restricted by Special Authority criteria or would Subsidy by Endorsement be more appropriate (as used currently for blood glucose diagnostic test meters)?

6 What is the strength and quality of evidence, including its relevance to NZ, for health benefits that may be gained from FreeStyle Libre?

7 Would the funding of FreeStyle Libre address any equity issues regarding the management of type 1 diabetes in New Zealand?

8 Should FreeStyle Libre be funded, are there any consequences to the health system that have not been noted in the application?

9 If FreeStyle Libre were to be funded, what support and training would be required for prescribers and patients?

Suitability

10 Are there any non clinical features of the FreeStyle Libre that may impact on use, either by the patient, by family, or by healthcare workers, that have not been considered in the application?

Costs and savings

11. Would the use of FreeStyle Libre create any significant changes in health-sector expenditure other than for direct treatment costs?

Cost Utility Analysis

12. Does the Subcommittee consider that the suppliers estimate of patient number is appropriate (n = 26,291 with type 1 diabetes in 2019)?

13. Does the Subcommittee consider that patients would be likely to use more than Wit FreeStyle Libre sensors per year?

14. Does the Subcommittee consider the forecasted uptake rates of FreeStyle Libre are reasonable? Why, or why not?

15 Is the Subcommittee aware of any evidence which suggests FreeStyle Libre is superior to self monitoring of blood glucose via test strips in reducing HbA1c levels or reducing health care utilisation (e g ED attendance, admissions, outpatient care, ambulance call outs)?

16 How often would an average patient with type 1 diabetes see a GP for ongoing management of their diabetes, and would this be expected to change if FreeStyle Libre was funded?

17. How often would an average patient with type 1 diabetes see a nurse practitioner or an endocrinologist, and would this be expected to change if FreeStyle Libre was funded?

Recommendations

18. Should FreeStyle Libre be listed in the Pharmaceutical Schedule?

19 If listing is recommended, what priority rating would you give to this proposal [low / medium / high / only if cost-neutral]?

20. Does the Subcommittee consider that the proposed Special Authority criteria are appropriate? If not, how should they be amended?

21. Does the Subcommittee have any comments or recommendations additional to the application?

PURPOSE OF THIS PAPER

The purpose of this paper is to seek advice from the Subcommittee regarding an application from Abbot Laboratories NZ Limited for the use of the FreeStyle Libre Flash Glucose Monitoring System (FreeStyle Libre) for the continuous measurement of interstitial fluid glucose levels in individuals with type 1 diabetes (≥4 years of age).

PHARMAC has also received five applications from consumers and one application from a clinician for the FreeStyle Libre, and several letters of support from consumers. One of the consumer applications was for all patients with insulin dependent diabetes, including individuals with type 2 diabetes. This application also specified the use of FreeStyle Libre in conjunction with the MaioMaio Smart Reader, which uses Bluetooth to transmit data directly to smart phone applications designed to purpose.

DISCUSSION

BACKGROUND

Previous consideration of continuous or flash glucose monitoring systems

PHARMAC has not previously considered any funding applications for flash glucose monitoring systems. An application for the Withheld under continuous glucose monitor was received from a consumer in September 2017, but this could not be progressed without further information from the supplier. An application for the Guardian 3 and Guardian Connect continuous glucose monitoring systems was also submitted to PHARMAC by a supplier in late February; however, this application was received after the agenda for the Diabetes Subcommittee was finalised and is therefore not being considered at this meeting

Previous consideration of FreeStyle Libre

PHARMAC has not previously considered any funding applications for FreeStyle Libre.

Need

Description of the disease

Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic β cells resulting in insulin deficiency. This 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

Epidemiology

According to the Ministry of Health Virtual Diabetes Register, there was estimated to be 245,680 individuals with diabetes (type 1 and type 2) in New Zealand in 2017 [1] 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.

[1] Ministry of Health Virtual Diabetes Register (VDR) Available at: https://www health govt nz/our work/diseases-and-conditions/diabetes/about-diabetes/virtual-diabetes-register-vdr. Accessed on 13 February 2019

The health need of the person

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.

The availability and suitability of existing medicines, medical devices and treatments

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.

The health need of family, whānau, and wider society

Caring for an individual with type 1 diabetes places a substantial burden on family and whānau. Management requires daily responsibilities and coordination of care between specialists, primary care, and day-care/school Families of children with type 1 diabetes report having to restrict work hours, spending significant time caring/coordinating care, and experience significant financial burden Families and caregivers may also experience social impacts and emotional distress.

The impact on the Māori health areas of focus and Māori health outcomes

Type 1 diabetes is more prevalent in European/Pākehā than Māori. PHARMAC staff were unable to identify any specific epidemiological data or information regarding differential outcomes for Māori and non Māori patients with type 1 diabetes.

> *Is the Subcommittee aware of any additional information or evidence regarding the epidemiology or differential outcomes for Māori and non Māori with type 1 diabetes?*

The impact on the health outcomes of population groups experiencing health disparities

PHARMAC staff could not identify any New Zealand specific data regarding population groups experiencing health disparities associated with type 1 diabetes; however, international studies indicate that low socioeconomic status is associated with higher levels of morbidity and mortality for individuals with type 1 diabetes

The impact on Government health priorities

The prevention, intervention, rehabilitation, and wellbeing of people with long term conditions such as type 1 diabetes is one of the ten Government health priorities

Health Benefit

Details of the pharmaceutical under consideration

Clinical Pharmacology and Mechanism of Action

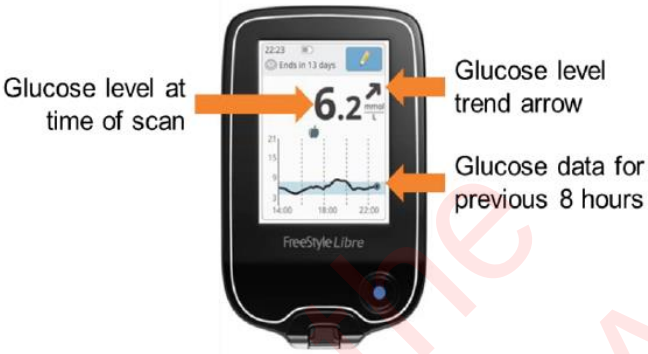
The FreeStyle Libre system has three components: a disposable sensor, a reader, and optional software.

The sensor has a thin, sterile filament which is 0 4 mm wide and inserted approximately 5 mm under the skin. This is attached to a small disc (35 mm × 5 mm). 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

A reader will be supplied directly by Abbot Diabetes Care for each patient. 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.

Figure 1: FreeStyle Libre components (supplier provided image)

Sensor (compared with €2 coin≅ 2 NZD coin is the same diameter	Reader
	

It should be noted that the FreeStyle Libre is described by the supplier as a flash glucose monitoring system This differs from a continuous glucose monitoring (CGM) system in that it does not require calibration, it does not integrate with insulin pump devices, and it does not provide a continual display of interstitial glucose (the scanner must be moved over the sensor to prompt a result to be displayed). Furthermore, FreeStyle Libre does not provide a hypoglycaemia alarm, as is found with some CGM devices

Patients using both Freestyle libre and CGM are recommended to retain a personal supply of finger prick blood testing strips and blood glucose meter. Flash monitoring of interstitial fluid glucose levels during times of rapidly changing glucose levels or impending hypoglycaemia is not considered appropriate by the supplier. Blood glucose levels as assessed by finger prick, are better at informing treatment decisions in these situations.

> *What is the Subcommittees opinion regarding the advantages and disadvantages of flash glucose monitoring systems compared with continuous glucose monitoring systems?*

New Zealand Regulatory Approval

There is no approval system for medical devices under the Medicines Act 1981 and there is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplier in New Zealand FreeStyle Libre has been registered on the Web Assisted Notification of Devices (WAND) database, which is a mandatory requirement for importers, exporters, and local manufacturers

According to the supplier, the most recent registration (15 January 2018; WAND reference: 180115-WAND-6PM9ZF) included the paediatric indication with the intended purpose as shown below

> The sensor is a component of the FreeStyle Libre Flash Glucose Monitoring System and is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with insulin dependent diabetes mellitus. The indication for children (age 4 17) is limited to those who are supervised by a caregiver who is at least 18 years of age

In addition, the Reader was registered on the WAND on 7 July 2017 (WAND reference: 170421 WAND 6O0MOY) with the intended purpose as shown below

> Glucose meter reader to assist in the determination of interstitial-fluid glucose levels in human specimens.

Proposed Treatment Paradigm

The supplier has indicated that FreeStyle Libre is designed to largely replace self monitoring of blood glucose in people with insulin dependent type 1 diabetes. The supplier has noted that patients would still self monitor blood glucose using a finger prick test approximately once every second day (to test during periods of rapidly rising or falling blood glucose).

Proposed Special Authority Criteria

The supplier has indicated that access to FreeStyle Libre should be restricted to patients with type 1 diabetes (adults and children). PHARMAC staff have drafted the following proposed Special Authority criteria which is consistent with standard Special Authority criteria language and incorporates aspects of the Australian and UK criteria described below:

Special Authority for Subsidy

Initial application – (type 1 diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2 Patient must be four years of age or older; and
3 Patient has well controlled diabetes (≤58 mmol/mol); and
4. Any of the following:
    4.1. Patient is pregnant, breastfeeding, or actively planning pregnancy; or
    4.2. Patient undertakes intensive self-monitoring of blood glucose, defined as monitoring at least eight times daily; or
    4 3 Patient meets the funding criteria for insulin pump therapy where a successful trial of FreeStyle Libre may avoid the need for pump therapy; or
    4.4. Patient has recently developed impaired awareness of hypoglycaemia; or
    4 5 Patient has been admitted to hospital at least twice in the previous 12 months with diabetic ketoacidosis or hypoglycaemia; or
    4.6. Patient requires a third party to carry out monitoring and where conventional blood testing is not possible.

Renewal application – (type 1 diabetes) only from a relevant specialist or nurse practitioner Approvals valid for 24 months for applications meeting the following criteria:
All of the following:

1. Patient is continuing to derive benefit from flash glucose monitoring.

Does the Subcommittee consider that the Special Authority criteria proposed are appropriate? If not, how should they be amended?

Do these criteria adequately describe the subpopulation who would gain the most benefit from FreeStyle Libre?

Is it appropriate to restrict access to patients with well controlled diabetes (≤58 mmol/mol)?

Are the initial application and renewal application time periods appropriate?

Should access to FreeStyle Libre be restricted by Special Authority criteria or would Subsidy by Endorsement be more appropriate (as used for blood glucose diagnostic test meters)?

International Recommendations

PHARMAC staff were unable to find any evidence of funding applications having been submitted to PBAC (Australia), CADTH (Canada), SMC (Scotland), or NICE (United Kingdom) Below is the information that could be identified regarding the funding of FreeStyle Libre in the four countries identified above (note that no information could be identified for Canada or Scotland)

Australia: As of 1 March 2019, FreeStyle Libre will be included on the list of available continuous glucose monitoring (CGM) products subsidised under the CGM initiative for individuals meeting certain eligibility criteria, subject to price negotiations with the product sponsor Eligible patients will include:

- women with type 1 diabetes who are pregnant, breastfeeding or actively planning pregnancy
- people with type 1 diabetes aged 21 years or older who have concessional status (e.g., older people, people with disability, low-income earners), and who have a high clinical need such as experiencing recurrent severe hypoglycaemia events
- children and young people with conditions similar to type 1 diabetes who require insulin This includes a range of conditions such as cystic fibrosis related diabetes or neonatal diabetes.

England: As of April 2019, FreeStyle Libre will be funded for people with type 1 diabetes in England via the NHS who fit the following criteria (Regional Medicines Optimisation Committee position statement; Appendix 1):

1. Patients who undertake intensive monitoring >8 times daily.
2 Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8 5% [69 4 mmol/mol] or disabling hypoglycaemia as described in NICE TA151) where a successful trial of FreeStyle Libre may avoid the need for pump therapy

3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and FreeStyle Libre does not have that function.
4. Frequent admissions (>2 per year) with diabetic ketoacidosis or hypoglycaemia.
5 Those who required third parties to carry out monitoring and where conventional blood testing is not possible. In addition, all patients (or carers) must be willing to undertake training in the use of FreeStyle Libre and commit to ongoing regular follow up and monitoring (including remote follow up where this is offered). Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.

A NICE Medtech innovative briefing regarding FreeStyle Libre for glucose monitoring was also published in July 2017 (Appendix 1). The briefing noted that the resource impact of FreeStyle Libre is uncertain and depends upon the extent to which improved glucose control translates into fewer complications, reduced admissions, and less use of glucose test strips.

The health benefits to the person, family, whānau and wider society

Evidence Summary

The supplier has identified that the primary evidence for the health benefits of FreeStyle Libre is provided by the IMPACT trial. The supplier has also indicated that supporting information is provided by the SELFY study A summary of the pivotal publications for these studies is provided in the table below (Table 1).

The supplier also identified a number of conference abstracts that provide supporting information regarding FreeStyle Libre. These are available in Appendix 3.

Table 1: Summary of evidence for FreeStyle Libre (full texts available in Appendix 2)

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
IMPACT	Multicentre, prospective, non-masked, randomised controlled trial	Adults with well controlled T1DM	N = 328	FreeStyle Libre vs SMBG with capillary strips	6 months	• 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 • 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	• 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 discontinued due to AEs vs 1 patient (<1%) in the SMBG group	Bolinder et al. Lancet. 2016;388:2254-2263.
IMPACT (letter to editor)	Correspondence	N/A	N/A	N/A	N/A	• N/A	• Raised concerns regarding skin AEs • 13 cutaneous AEs in 10 patients related to the device were reported in IMPACT (3 mild, 4 moderate, 6 severe) • The management of these AEs during the study remains unclear and not proportional to severity	Brahimi et al. Lancet 2017. 389:1396.

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
							• It would be helpful for practitioners and patients to know what type of device-related skin AEs require treatment or discontinuation	
IMPACT (author reply)	Correspondence	N/A	N/A	N/A	N/A	N/A	• The number and type of events in IMPACT are similar to those seen for other devices worn on the skin for a period of time • Sensor-related symptoms were recorded as AEs if the effects were severe and lasted for more than 7 days or if required prescription medication to resolve • Skin symptoms were treated by use of barrier products (e.g. cavilon spray) or drug therapy (e.g. zinc ointment, fenistil gel, hydrocortisone cream) or by relocating the device • Since the conclusion of IMPACT design changes have been made to improve breathability and to facilitate exclusion of moisture between the sensor-skin interface	Bolinder et al. Lancet. 2017;389:1396-1397.

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
							• The authors acknowledge that some individuals will be intolerant to medical-grade adhesive	
IMPACT (response to author's response)	Correspondence	N/A	N/A	N/A	N/A	N/A	• The authors of IMPACT indicated that the skin symptoms were related to contact irritation rather than contact allergy • Isobornyl acrylate, which is present in FreeStyle Libre is a skin sensitiser provoking allergic contact • Allergic spreading reaction occurred in some patients, whereas contact irritation is strictly confined to the application site • The fact that some patients discontinued use indicates that bandages and barrier sprays did not provide relief	Aerts et al. Lancet. 2017;390:1644.
IMPACT & REPLACE driving	Short report. Retrospective analysis of blood glucose results from IMPACT and REPLACE trials	Adults with T1DM and T2DM	N = 465	FreeStyle Libre vs SMBG	N/A	• Within 4 hours of a capillary blood glucose result ≥5 mmol/l a sensor glucose result of <3.9 mmol/l occurred on 22.0% of occasions for those with T1DM and 8.4% for those with T2DM ○ Within 2 hours: 13.8% vs 4.4% ○ Within 1.5 hours: 10.0% vs 3.1%	• N/A	Rayman et al. Diabet Med. 2018;35:491-494.

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy	Safety	Citation
						• Sensor-based glucose monitoring has the potential to support assessment of safe glucose levels for driving		
SELFY (abstract only)	Single-arm, open-label study	Patients aged 4-17 years with T1DM	N = 76	FreeStyle Libre	10-week	• Time in range (3.9 to 10.0 mmol/L) improved from baseline by 1.0 hours/day (SD 2.8; *P*=0.0056) • HbA1c improved vs baseline (-4.4±5.9 mmol/mol; *P*<0.0001) • Time in hyperglycaemia reduced vs baseline (-1.2±3.3 hours/day; *P*=0.0038) • No signfiicant change in time in hypoglycaemia (1.1±1.2 hours/day) • Total daily insulin dose increased by 1.4±3.5 units (*P*=0.0010) • Diabetes Treatment Satisfaction Questionnaire showed increased overall treatment satisfaction	• 96 mild of moderate sensor insertion site symptoms from 42 patients • 3 device-related AEs reported by 3 patients (all mild; dry collection, dry flaky skin, redness) • No device-related SAEs reported	Campbell et al. Diabetologia. 2017;60 (Suppl 1):S1-S608.
N/A	Prospective study, single-arm, open-label study	Patients aged 13-19 years with T1DM	N = 47	FreeStyle Libre	3 months	• Improvement from baseline was noted for fear of hypoglycaemia (*P*=0.0001), worry (*P*=0.0001), QoL (*P*=0.002), HbA1c level (*P*=0.008), and hypoglycaemia (*P*=0.023) • Use of FreeStyle Libre reduced the frequency of hypoglycaemia, HbA1c level, and worry, and increased behaviour and QoL	• None reported.	Al Hayek et al. Clin Med Insights Endocrinol Diabetes. 2017;10: 1179551417 746957

AEs, adverse events; QoL, quality of life; SMBG, self-monitoring of blood glucose; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

Literature Search

PHARMAC staff conducted a PubMed search (search terms: FreeStyle Libre filtered by Clinical Trial) and identified five relevant publications regarding the use of FreeStyle Libre for type 1 diabetes:

- Bailey et al. Diabetes Technol Ther. 2015;17:787-94. Evaluated the performance and usability of the FreeStyle Libre system for interstitial glucose monitoring compared with capillary blood glucose in patients with type 1 and type 2 diabetes. The overall mean absolute difference was 11.4%. The authors concluded that the FreeStyle Libre system was accurate compared with capillary blood glucose reference values, with accuracy remaining stable over 14 days of wear.
- Edge et al. Arch Dis Child. 2017;102:543 549. Investigated the accuracy, safety, and acceptability of FreeStyle Libre in the 89 children with type 1 diabetes The results demonstrated the accuracy, safety, and user acceptability of the FreeStyle Libre, with accuracy unaffected by subject characteristics.
- Massa et al. Horm Res Paediatr. 2018;89:189 199. Investigated the accuracy and usability of FreeStyle Libre in 67 children with type 1 diabetes The results identified reasonable agreement between FreeStyle Libre readings and capillary blood glucose measurements, but noted large interindividual variability
- Reddy et al. Diabet Med. 2018;35:483-490. Assessed the impact of continuous glucose monitoring (Dexcom G5) or flash glucose monitoring (FreeStyle Libre) over 8 weeks in 40 adults with type 1 diabetes. The results indicated that continuous glucose monitoring reduced time spent in hypoglycaemia and impaired awareness of hypoglycaemia compared with FreeStyle Libre.
- Szadkowska et al Diabetes Technol Ther 2018;20:17 24 Evaluated the clinical accuracy of FreeStyle Libre among 79 children with type 1 diabetes in a real world summer camp setting. The results indicated that FreeStyle Libre was accurate, but that results flagged by the rapid fall flag and “trend undetermined” should be verified by blood glucose management

PHARMAC staff note that there are also a large number of additional publications regarding FreeStyle Libre and 65 clinical trials involving FreeStyle Libre registered on clinicaltrials gov

Consequences for the health system

The supplier has noted that poor diabetes management and the resulting complications places a significant burden on the health system, and that better management of diabetes may lessen some of this burden.

The supplier has indicated that an additional GP visit would be required at the time a patient is initiated onto FreeStyle Libre in order to familiarise the patient with the system and its functionality.

> *If FreeStyle Libre were to be funded, what support and training would be required for prescribers and patients?*

The supplier has suggested that the use of FreeStyle Libre will result in a reduction in hypoglycaemic episodes, which will consequently reduce the utilisation of ambulance,

emergency department, and hospital resource. PHARMAC staff could not identify any data indicating that the use of FreeStyle Libre specifically results in reduced healthcare utilisation

Suitability

The features of the medicine or medical device that impact on use

The FreeStyle Libre system has three components: a disposable sensor, a reader (provided by the supplier), and optional software. Each sensor kit contains one sensor, one sensor applicator, and an alcohol wipe. The sensor is applied using the applicator to the back of the upper arm and is held in place with medical grade adhesive. Application is marketed as being painless. The sensor remains in place for 14 days. The sensor is water-resistant up to one meter for up to 30 minutes. The supplier has indicated that the reader should be replaced every two years

Device-related adverse events identified in the IMPACT trial included allergy events, itching, rash, insertion site symptoms, erythema, and oedema (Bolinder et al Lancet 2016;388:2254 2263). Published correspondence queried both the management of these issues in the trial (Brahimi et al Lancet 2017 389:1396) and also the potential for an allergic response to a component of the adhesive (Aerts et al. Lancet. 2017;390:1644). The authors of IMPACT indicated that tolerability would be an issue for some patients

The supplier recommends that individuals take care not to bump into objects; avoid touching, pushing, or pulling the sensor; take extra care when getting dressed and bathing; and avoid contact sports

The supplier has also indicated that a finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels. PHARMAC staff are therefore uncertain whether the accuracy of interstitial glucose measurement is acceptable for clinical use

Costs and Savings

Costs and savings to pharmaceutical expenditure

Cost per patient

The supplier suggests that at the proposed unit pricing (Withheld for each sensor) the annual cost per patient is Withheld. This cost includes the use of one self monitoring test strip every second day for use with existing blood glucose monitors Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and

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

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

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

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2) Retail pricing from Australia suggest the unit cost of each reader is approximately NZD$100

Estimated Incremental Total Cost of Listing

The Supplier has provided an estimated incremental total cost of listing Freestyle Libre in New Zealand over the next five years. This is shown presented in Table 2 below. PHARMAC staff have reviewed the full calculations and assumptions underpinning this estimate as suggested by the supplier to relate to the New Zealand context (see page 7 21, 'Financials' A1114378). PHARMAC staff broadly agree with the supplier's assumptions regarding the management and associated costings of type 1 diabetes within the New Zealand context; however, PHARMAC staff consider that the proposed prevalence of type 1 diabetes within New Zealand might be overestimated (see section on 'Epidemiology' above), resulting in an overestimated budgetary impact. PHARMAC staff also note that the supplier has assumed that patients will require approximately Wit sensors per year, but that this does not take into account any usage for less than 14 days (e.g. if a sensor was removed, accidentally knocked off, or damaged within 14 days) It should also be noted that the budget impact analysis would not be relevant if access to the FreeStyle Libre was restricted to the patients described in the draft Special Authority criteria

Table 2: Supplier provided usage and estimated overall net cost to Government health budgets due to funding of FreeStyle Libre.

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

Does the Subcommittee consider that the suppliers estimate of patient numbers with type 1 diabetes in New Zealand is appropriate?

Does the Subcommittee consider that patients would be likely to use more than Wit *FreeStyle Libre sensors per year?*

PHARMAC staff are also cautious as to whether the proposed uptake of FreeStyle Libre might be conservative given the novel nature of the device, as this would have a considerable impact on the forecasted budgetary impact. PHARMAC staff also note that there is likely to be a substantial private market already using FreeStyle Libre, and that these patients would be likely to transition to funded FreeStyle Libre immediately, which may increase initial uptake rates

Table 3: Supplier estimated uptake of FreeStyle Libre within New Zealand over the next five years.

Age range	2019	2020	2021	2022	2023
0 20	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
21 39	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
40 59	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
60+	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Weighted avg.	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				

Does the Subcommittee consider the supplier's forecasted uptake rates of FreeStyle Libre seem reasonable if there were no restrictions on access? Why, or why not?

PHARMAC staff have used the estimated expenditure provided by the supplier to extrapolate the net impact on the combined pharmaceutical budget that funding FreeStyle Libre would have in New Zealand. This is based on the supplier's estimated uptake of FreeStyle Libre and the prevalence of type 1 diabetes in New Zealand Cost savings resulting from the reduction in expenditure on glucose test strips have been incorporated into the net impact. The five-year impact, forecasted uptake, and net present value are shown in Table 4 below

Table 4: PHARMAC estimated net pharmaceutical expenditure on funding of FreeStyle Libre 2019 23 (based on uptake and prevalence assumptions provided in Supplier's application)

	2019	2020	2021	2022	2023
Uptake (avg.)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Net impact on pharmaceutical budget	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Discounted 8%	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
5 year NPV					Withheld
5 year NPV discounted					Withheld

Note: Yearly forecasted impacts may not total to 5 yearly NPV due to rounding.

International Prices

Limited information on unit cost of FreeStyle Libre was available internationally. Two international unit costs are provided in Table 5 below

Table 5: International prices of FreeStyle Libre

Country	Source	Local Price	Exchange Rate ([Source/date])	Price ($NZ)
New Zealand	Abbot	Withheld	N/A	Withhel
Ireland	HTAG	€59 90	1 65	$99 10
USA	Walmart	$35.99USD	1.46	$51.09

Costs and savings to the rest of the health system

As discussed above, the funding of FreeStyle Libre would result in a considerable cost to the pharmaceutical budget, driven by the ongoing requirement for a new sensor every 14 days. A small cost offset is anticipated by the supplier due to a reduction of the quantity of blood glucose test strips required by patients with type 1 diabetes. Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)

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

Withheld under section 9(2)

The supplier also suggests cost savings to the health system because of reduced medical management of hypoglycaemic events. PHARMAC staff note however, that the Supplier has not incorporated an incremental cost difference in health care utilisation in their detailed analyses following funding of FreeStyle Libre (see worksheet 'FreeStyle Libre Financials'

A1114380). This appears to be in line with the findings of the primary clinical trial their analyses are based on (IMPACT), which did not show a statistical difference in the quantity of ambulance call outs or hospitalisations between patients using FreeStyle Libre or patients using self monitoring. No other articles demonstrating an effect on health care utilisation could be identified by PHARMAC staff

Conceivably, improved glycaemic control would translate into a reduction of late onset diabetic related comorbidity, and consequently a decrease in related health service utilisation; however, the IMPACT trial did not find a statistical difference in HbA1c levels at six months follow up between patients randomised to FreeStyle Libre versus patients using self monitoring (52.4 mmol/mol vs 52.4 mmol/mol, *P* = 0.9543; Bolinder et al. Lancet. 2016;388:2254 2263) This likely reflects the selection criteria adopted by the supplier for this study, in that participants were required to have well controlled diabetes prior to entry (HbA1c ≤58 mmol/mol). No other randomised controlled trials demonstrating an effect on HbA1c were identified by PHARMAC staff, although the supplier has provided several poster abstracts in support of a positive finding.

> *Is the Subcommittee aware of any evidence which suggests FreeStyle Libre is superior to self monitoring via test strips in reducing the amount of health care resources utilised (e g ED attendance, admissions, outpatient care, ambulance call outs) or HbA1c levels?*

Cost Effectiveness (combining the Health Benefits and Costs quadrants)

The Supplier has included an economic model with their application, suggesting a modelled incremental cost effectiveness ratio (ICER) of Withheld per quality-adjusted life year (QALY; Withhel 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 and suspect that the incremental cost effectiveness of Freestyle Libre is overestimated.

Several aspects of the model and how well they relate to the New Zealand context are uncertain. Of these, the method by which the supplier has quantified a clinically meaningful outcome, and therefore effectiveness of the intervention, is a primary concern The model supplied appears to address the current lack of evidence on improved outcomes by drawing considerably upon the suggested improvement in quality of life (known as 'utility') experienced by patients using FreeStyle Libre. This improved quality of life was derived from a sponsored study in participants drawn from a general UK population, without requirement for having diabetes (Matza et al. Value Health. 2017;20:507-511; Appendix 4)[2].

PHARMAC staff have concerns regarding the methodology and validity of this quality of life study that acts as the primary driver of the model Sharing these concerns, a health technology assessment agency in Sweden has probed the supplier model by undertaking a sensitivity analysis on the incremental utility used (FreeStyle Libre, TLV 2017) This highlighted a dramatic change in cost per QALY dependant on the value of the incremental utility

[2] The methodology of the time trade off (TTO) study included 209 participants drawn from the general population in London, UK. The only requirement of these participants was that they were over the age of 18; no clinical criterion was set, such as having existing diabetes. Furthermore, the clinical vignettes used during the TTO interviews have not been published, limiting critical appraisal.

incorporated, ranging from NZD$25,900 to $190,500 per QALY (5.2 to 39.0 QALYs per $mil). Consequently, PHARMAC staff have concerns regarding the current lack of valid outcome data in being able to develop an informative economic model relevant to the New Zealand context.

PHARMAC staff are also uncertain as to how valid the economic model is for patients with unstable diabetic control, as it is based on data from patients with an HbA1c <58 mmol/mol (eligibility criteria of the IMPACT study)

A search beyond the core commonwealth Health Technology Agencies (HTA) agencies identified assessments of Freestyle Libre undertaken by PHARMAC equivalent organisations in Sweden, Norway, Wales, Ireland, and EUnetHTA. These are summarised below:

Table 6: Summary of health-technology assessments from international HTAs

Agency	Type of assessment	Conclusions
HTAG, Ireland (2017)	Critical appraisal + BIA	Some evidence to suggest FGM facilitates better glycaemic control and reduce the need for finger prick testing in the order of 1 2000 times per year Insufficient evidence to demonstrate FGM leads to a reduction on ambulance, ED visits or admissions; disputes the Supplier claim that FGM will lead to health sector savings. Recommended a one-year trial of FGM in Ireland to better assess costs, savings and uptake.
TLV, Sweden (2017)	CUA	Base case cost per QALY NZD$61,615; Supplier provided base cost per QALY NZD$46,096; difference primarily driven by utility and number of test strips used Several concerns regarding the implicit assumptions within the model. No firm recommendation was made.
NIPH, Norway (2017)	Critical appraisal + BIA	Raised several concerns with the current evidence base (of generally poor quality) and the subsequent Supplier generated economic modelling No specific recommendation was made for funding of FreeStyle Libre
HTW, Wales (2018)	Critical appraisal	Concluded that the cost effectiveness of FreeStyle libre would be difficult to determine with an acceptable level of confidence. Recommended re review if pivotal new evidence becomes available in the future
RMOC, North England (2017)	Position statement	Significant limitations in available clinical trial data and economic analysis Recommended FreeStyle libre funding restricted only to T1DM patients using MDI or insulin pump therapy, meeting the follow criteria

Agency	Type of assessment	Conclusions
		1 Patients undertaking intensive monitoring ≥8 times daily 2. Meet criteria for insulin pump therapy (HbA1c >64 9 mmol / mol) where FreeStyle may avoid need for pump 3 Patients with recent impaired awareness of hypoglycaemia 4. Frequent admissions (>2 per year) with DKA or hypoglycaemia 5. Those requiring third parties to carry out monitoring and where conventional blood testing is not possible
HAS, France (2016)	Critical appraisal	Recommended funding for patients with either T1DM or T2DM aged >4 years being treated with intensified insulin therapy (external pump or ≥3 injections per day) and performing multiple self monitoring of blood glucose (≥3 / d) (Note limited ability to translate French)
EUnetHTA, EU (2018)	Systematic review + critical appraisal	Available evidence base is comprised of studies that include/contain important risk of biases and moderate to very low certainty of evidence. These studies suggest that FGM associated with reduction of hypo- and hyperglycaemic outcomes and improved treatment satisfaction No firm recommendations made regarding funding (though note this is a supranational organisation)

APPENDICES

Appendix 1: NHS England Regional Medicines Optimisation Committee Flash Glucose Monitoring systems Position Statement.

NICE FreeStyle Libre for glucose monitoring Medtech innovation briefing

Appendix 2: Pivotal publications provided by supplier

- Bolinder et al. Lancet. 2016;388:2254 2263.
- Brahimi et al. Lancet 2017. 389:1396.
- Bolinder et al Lancet 2017;389:1396 1397.
- Aerts et al. Lancet. 2017;390:1644.
- Rayman et al. Diabet Med. 2018;35:491-494.
- Campbell et al Diabetologia 2017;60 (Suppl 1):S1 S608
- Al Hayek et al. Clin Med Insights Endocrinol Diabetes. 2017;10: 1179551417746957

Appendix 3: Abstracts provided by supplier

- Bolinder et al (2016) Using Novel Flash Glucose Sensing Technology Reduces Hypoglycemia in Individuals with Type 1 Diabetes: 868-P. American Diabetes Association's 76th Scientific Sessions. New Orleans.
- Bolinder et. al (2016) Using Novel Flash Glucose Sensing Technology for 6 Months Results in a High Rate of Concordance by Young Adults with Type 1 Diabetes. ePoster #873. EASD Virtual Meeting. Virtual, EASD.
- Campbell et al (2016). Clinical accuracy evaluation of freestyle libre flash glucose monitoring system when used by children and young people with diabetes Diabetes Technology and Therapeutics 18: A29
- Cardona-Hernandez & Suarez Ortega (2017). Comparison of estimated HbA1c assessed through Abbott freestyle libre software and siemens DCA Vintage HbA1c in a sample of children and adolescents with type 1 diabetes Pediatric Diabetes 18(Supplement 25): 78
- Dover et al (2016). Flash Glucose Monitoring Improves Outcomes in a Type 1 Diabetes Clinic Journal of Diabetes Science and Technology Note: hard copy published in 2017.
- Holcombe et al (2017). Trial of FreeStyle Libre in a local service: Impact on diabetes outcomes. Diabetic Medicine 34: 160.
- Löndahl et al (2017). Effect of Flash Glucose monitoring on metabolic control and self esteem treatment satisfaction in people with T1 DM Diabetes Technology and Therapeutics. 2017;19(S1):A-81.
- Löndahl et al (2016) Flash glucose monitoring improves metabolic control and treatment satisfaction in people with type 1 diabetes. Diabetologia 59 (1 Supplement 1): S419

- Mentesidou et al (2017). Flash monitoring system and adverse reactions Pediatric Diabetes 18(Supplement 25): 47
- Mitsuishi (2017). The efficacy of novel glucose monitoring system (flash glucose monitoring) on mental well-being and treatment satisfaction in Japanese people with diabetes. Diabetes 66: A234.
- Pintus & Ng (2017). FreeStyle Libre Flash glucose monitoring (Flash GM) system improves glycaemic control and patient quality of life measures in children with type 1 diabetes with appropriate provision of Flash GM education and support by healthcare professionals. Pediatric Diabetes 18(Supplement 25): 48
- Rayman et al (2016) Can FreeStyle LibreTM sensor-based glucose data support decisions for safe driving? Diabetologia 59(1 Supplement 1): S421
- Scorsone et al. (2017). Glucose control and quality of life in type 1 diabetic subjects under flash glucose monitoring and self monitored glucose testing (SMBG). Presented at the 10th International Conference on Advanced Technologies & Treatments for Diabetes, 15 18 February 2017, Paris, France. [Poster].
- Tirelli et al (2017) Flash Glucose Monitoring in noncompliant children and adolescents with type 1 diabetes. Diabetes Technology and Therapeutics 19(S1): A-1-A 133
- Walton Betancourth & Amin (2017). A clinic based study of the impact of flash glucose sensing technology on glycaemic control and selfmonitoring of blood glucose in children and young people with type 1 diabetes. Pediatric Diabetes 18(Supplement 25): 47 48
- Wijnands et al (2017). The freestyle flash glucose monitoring system has limited effect on the metabolic control of children and adolescents with type 1 diabetes mellitus. Pediatric Diabetes 18(Supplement 25): 38.
- Xatzipsalti et al (2017). Flash glucose monitoring system improves glycemic control. Pediatric Diabetes 18(Supplement 25): 78

Appendix 4: Matza et al. Value Health. 2017;20:507-511

THE FACTORS FOR CONSIDERATION

Factors are presented here in the order they appear in the paper, 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
- The impact on Government health priorities

HEALTH BENEFITS

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

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

PHARMAC
Pharmaceutical Management Agency

FILE NOTE

Subject:	Consumer voice for the development of primary care resources
Event Type:	Meeting
Author:	Bronwyn Locke
Attendees:	Janet Mackay and Bronwyn Locke (PHARMAC) Heather Verry and Ruby McGill (Diabetes New Zealand - DNZ)
Location:	DNZ, Murphy Street, Wellington
Date event took place:	26 September 2018

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)
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3. BL noted that the Freestyle Libre application had been received but had not been progressed to the point of receiving clinical advice. HV asked what need to happen to progress this further. JM explained that ultimately, there is an assessment process to be followed for applications including seeking clinical advice.

Action Points

- Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)
- BL to inform DNZ if the current applications for glucose monitoring are specifically for the Freestyle Libre or for 'generic' glucose monitoring devices.

PHARMAC
TE PĀTAKA WHAIORANGA

FILE NOTE

Subject:	Relationship meeting with Diabetes New Zealand
Event Type:	Meeting
Author:	Janet Mackay
Attendees:	Heather Verry; Liz Dutton (DNZ); Elena Saunders; Janet Mackay (PHARMAC)
Location:	DNZ offices, Murphy Street, Wellington
Date event took place:	12 December 2019 – 2 – 3pm

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

CGM and FGM

DNZ had submitted a petition to Parliament/Health Select Committee about funding of CGM/Freestyle Libre. DNZ considered they should be funded for all people with Type 1 and should not be age restricted. ES informed DNZ that the Freestyle Libre had gone to the Diabetes Subcommittee in March, and then PTAC looked at the subcommittee's recommendation in August. PTAC was unable to provide a recommendation/agreement with the subcommittee's recommendation (which was high). This was likely because there wasn't any long-term outcome data about the clinical impacts of the device.

[redacted]

[redacted]

[redacted]

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

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

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