PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR PHARMAC BOARD MEETING 27 AUGUST 2024

To:	Pharmac Directors
From:	Chief Executive
Date:	August 2024
Item:	3.1

Proposal to fund continuous glucose monitors, insulin pumps and insulin pump consumables for people with type 1 diabetes

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures, the Board exercise its delegated authority and:

resolve to approve the amendments to the Pharmaceutical Schedule relating to insulin pumps as set out in Appendix One

resolve to list New Zealand Medical and Scientific Ltd's (NZMS) brand of continuous glucose monitors (Dexcom), insulin pump and associated consumables (Tandem) in the Pharmaceutical Schedule as set out in Appendix One

resolve to list Abbott Laboratories NZ Limited's (Abbott) brand of continuous glucose monitors (Freestyle Libre) in the Pharmaceutical Schedule as set out in Appendix One

resolve to list Pharmaco (New Zealand) Ltd's (Pharmaco) brand of insulin pump (YpsoPump) and associated consumables in the Pharmaceutical Schedule as set out in Appendix One

resolve to delist Intermed Medical Limited's (Intermed) brand of insulin pump (Medtronic MiniMed 770G) from the Pharmaceutical Schedule from 1 January 2025 as set out in Appendix One

resolve to approve the agreement dated 2 August 2024 with Pharmaco for the supply of YpsoPump brand insulin pumps and associated consumables

resolve to approve the agreement dated 22 July 2024 with NZMS for the supply of Tandem brand insulin pumps and associated consumables and Dexcom brand continuous glucose monitors

resolve to approve the listing agreement dated 26 July 2024 with Abbott for the supply of Freestyle Libre brand continuous glucose monitors

note the consultation feedback and petition received as set out in the Appendices to the paper and the changes proposed following careful consideration of the feedback, as set out below

resolve that the consultation on this proposal was appropriate, taking into account the significant consultation feedback received and considered by Pharmac and no further consultation is required.

Purpose

This paper seeks a decision from the Board on a proposal to fund a range of continuous glucose monitors (CGMs) for all people with type 1 diabetes and increase access to already funded insulin pumps and insulin pump consumables. The proposal would result in a change to the funded insulin pump options, specifically a delisting of a currently funded insulin pump and listing of a new option.

Why proposal should not be considered under Delegated Authority

The proposal outlined in this Board paper has not been dealt with by the Chief Executive under delegated authority, because the estimated Financial Impact (NPV) of this proposal is more than $10,000,000 of the Pharmaceutical Budget. The Financial Impact (NPV) is calculated on the basis of the net present value of the proposed subsidy (ex-manufacturer exclusive of GST) over five years at a discount rate of 8% to be paid by the funder for the product(s) and the forecast demand, taking into account any effect of the change /decision on that demand, versus the status quo.

Strategic Direction

The proposal to list a range of CGMs, insulin pumps, and insulin pump consumables in the Pharmaceutical Schedule from 1 October 2024. The proposal results from a competitive commercial process. This aligns with our purpose to deliver the best health outcomes from New Zealand's investment in medicines and medical devices by making choices and managing expenditure and supply.

This proposal would help enhance the wellbeing of New Zealanders living with type 1 diabetes.

Our engagement throughout this process with consumer, clinical and sector partners demonstrate our desire to ensure that medicines and medical devices are used 'appropriately, equitably and well' and highlights our role in contributing to an effective and equitable health system.

Executive Summary

We released a consultation in March 2024 on a proposal to fund CGMs, insulin pumps, and insulin pump consumables.

We received a substantial amount of feedback in response to this proposal and identified aspects of the proposal that we needed to consider further.

The magnitude and complexity of the feedback resulted in a delay to the proposed implementation date of 1 July 2024. We know the delay was extremely disappointing for many people but it was important for us to take the extra time to ensure we've listened, understood and considered the issues that were raised to make sure our final proposal is as robust as it could be.

We have met with key stakeholders including consumers, clinicians, suppliers and government agencies, as well as seeking additional expert advice. We have made a number of key amendments to the proposal in response to the feedback and the advice we received.

We have not been able to address all of the issues raised. In particular, we are not proposing to fund Medtronic's brand of CGMs and insulin pumps (with a small number of exceptions as outlined below), which was requested by many consultation responders. However we are confident the proposal is the best outcome we could have achieved within the amount of budget available.

The proposal would result in the funding of:

- two brands of CGMs, providing a choice of five different models of CGMs for people to choose from. The options include standalone CGMs and pump compatible CGMs
- two brands of insulin pumps and the associated pump consumables and software for people to choose from.

We expect the proposal would result in approximately 12,000 people receiving CGMs in year 1, increasing to over 18,000 after five years. We expect the number of people who could access funded insulin pumps would increase from 4800 (current funding) to nearly 10,000 over 5 years.

s 9(2)(j)

s 9(2)(j)

Impact on health outcomes for populations with the highest needs

Diabetes is a government area of health priority. Pharmac staff consider that the progression of this proposal would have a positive impact for Māori. While type 1 diabetes is more common in non-Māori and non-Pacific populations, Māori with type 1 diabetes are more likely to experience both acute (i.e. diabetic ketoacidosis) and long-term diabetic complications (i.e. cardiovascular disease). There is evidence that access to diabetes technologies could disproportionately improve health outcomes for Māori with type 1 diabetes.

Pharmac staff are aware that Māori and Pacific people receive insulin pumps at a lower rate than non-Māori and non-Pacific people and are less likely to be continued on insulin pump therapy once initiated. We are proposing amendments to the current insulin pump criteria to help to address these access barriers. Similarly, we have ensured that the proposed CGM eligibility criteria contribute to equity of access.

External Māori representation was part of our evaluation committee to ensure the voice of Māori was included when the product were evaluated. As this was a competitive procurement process, we requested that suppliers detail how they would support improving access for groups experiencing health inequities in New Zealand, specifically for Māori. The ability of suppliers to contribute to addressing these inequities was a feature when Pharmac's Evaluation Committee evaluated the proposals received. Suppliers provided limited initiatives in respect of how they would support improving access for Māori and other groups, mainly around working with a range of community groups.

Budget Impact Summary

The financial implications of this proposal are outlined in the Cost and Savings discussion under the 'Factors for Consideration' assessment of the proposal in Appendix Seven and in more detail in the Summary Budget Impact Assessments for the individual medicines in Appendix Two. The overall multiproduct proposal budget impact assessment is outlined below.

Table 1 Overall Budgetary Impact Assessment of combined CGMs and Insulin Pumps proposal

SUMMARY OF PROPOSAL						
Market data	**Year ending**	**30 Jun 2025**	**30 Jun 2026**	**30 Jun 2027**	**30 Jun 2028**	**30 Jun 2029**
Estimated number of people affected by proposal		12,386	13,790	15,334	17,036	18,921
Estimated number of Māori or Pacific peoples affected by proposal		1,598	1,779	1,978	2,198	2,441
Estimated number of people who would access new technology from proposal		12,386	13,790	15,334	17,036	18,921
Reimbursed Pharmaceutical Expenditure	Expenditure (gross)	$55,854,000	$69,340,000	$70,613,000	$79,006,000	$84,310,000
	Expenditure (net)	s 9(2)(b)(ii), s 9(2)(j)				
	Net cost of the proposal					
	Net present value (NPV)					
TOTAL - Combined Pharmaceutical Budget	Net cost to CPB					
	Net present value (NPV)					
	Net distribution costs	$2,234,000	$2,774,000	$2,825,000	$3,160,000	$3,372,000

Other (Non-Pharmaceutical) Health Sector Costs	Other (non-pharmaceutical) Health Sector costs	($1,089,000)	($1,618,000)	($1,798,000)	($1,997,000)	(2,218,000)
	Total net other Health Sector costs	$1,145,000	$1,156,000	$1,027,000	$1,163,000	$1,154,000
	Net present value (NPV)	$4,867,000				
Total - Pharmaceutical and Health Sector Costs	Total cost (savings) to Health Sector including CPB cost	s 9(2)(b)(ii), s 9(2)(j)				
	Net present value (NPV)					

Notes:

1. Expenditure (gross) = forecast of spending at the proposed subsidies
2. Expenditure (net) = forecast gross expenditure less rebates and savings due to anticipated reduction in use of blood glucose test strips.
3. Net cost of the proposal = forecast incremental cost of the proposal
4. Hospital pharmaceutical expenditure is not included as this is expected to be negligible
5. Other (non-pharmaceutical) health sector costs = any additional costs/savings the pharmaceutical is expected to generate in other health budgets, including the costs of all health service use covered by Vote Health. This proposal includes savings to the health sector from a reduction in hospitalisations for hypoglycaemic events.
6. Net cost to CPB/Health Sector = forecast of change in spending compared with status quo
7. All pharmaceutical costs are ex-manufacturer, excluding GST
8. NPV is calculated over 5 years using an annual discount rate of 8%
9. Calculations are in A1817440

The Proposal

The proposal is to:

- fund two brands of CGMs from 1 October 2024, with 5 different models for people to choose from:
    - everyone with type 1 diabetes, or pancreatogenic[1] diabetes, would be able to choose either a Dexcom One+, or Freestyle Libre 2 CGM
    - people with type 1 diabetes, or pancreatogenic diabetes who would benefit from using a CGM in conjunction with an insulin pump (an automated insulin delivery system) would be able to choose either a Dexcom G6, Dexcom G7 or a Freestyle Libre 3+ CGM
- fund two brands of insulin pumps, and the associated pump consumables, from 1 October 2024, for people who meet the eligibility criteria. People would be able to choose from either the NZMS Tandem t:slim X2 pump or the Pharmaco YPSO pump
- widen access to insulin pumps so that access is extended to the wider type 1 population.
- delist the MiniMed 770G insulin pump from the Pharmaceutical Schedule from 1 October 2024 and delist the compatible insulin pump consumables from 1 October 2026. Insulin pumps last can last up to 5 years. The proposed delisting date for the consumables would enable people with a MiniMed insulin pump funded before 1 October 2024, up to 2 years to transition to one of the other funded options.

Details of the proposed listings and relevant dates including dual supply periods are detailed in Appendix Three.

The proposal incorporates a number of amendments from the proposal originally consulted on. These have been informed by the consultation feedback we received, our subsequent engagement with various stakeholders, and expert clinical advice.

We expect that this proposal could have a significant impact on the health system given the number of people who would benefit from access to these technologies. The advice we received indicates that the longer transition time of two years for insulin pumps would provide specialist diabetes units with a greater ability to prioritise their resources. We have engaged with Health New Zealand, interested clinicians and other sector representatives to help ensure

[1] Pancreatogenic diabetes covers people with Type 3c / monogenic and permanent neonatal diabetes who would derive benefit from the CGM technology

that the service delivery aspects of the proposal could be met. We would continue to work with key stakeholders as part of the implementation workstream to ensure the successful delivery of this proposal.

Background

Insulin pumps have been funded by Pharmac since 2012. There are currently 2 funded brands of insulin pump: the Medtronic MiniMed 770G supplied by InterMed and the Tandem t-slim X2 supplied by NZMS

Some insulin pumps can communicate with compatible CGMs via software and automatically adjust insulin doses based on glucose readings from the CGM. These systems are known as Automated Insulin Delivery (AID) or hybrid closed-loop systems.

Pharmac first received a funding application for the Abbott Freestyle Libre 1 Flash Glucose Monitor(FGM) in 2018. Since then, the Diabetes Advisory Committee considered additional funding applications for CGM (or flash monitoring devices), in 2019 and 2021.

The advice we have received from our clinical advisors is that funding CGMs would substantially reduce the short and long-term burden of disease for all people with type 1 diabetes, given the central importance of glycaemic control in reducing the risk of complications from diabetes and the onerous nature of finger prick blood glucose testing. Our advisors also told us that all CGMs provide a similar health benefit.

s 9(2)(j)

[redacted]

Commercial strategy

s 9(2)(b)(ii), s 9(2)(j)

[redacted]

Procurement process

Pharmac released a request for proposals (RFP) on 11 July 2023 for the supply of CGM and insulin pump devices for people with type 1 diabetes (and pancreatogenic diabetes).

The primary objective of the RFP was to determine whether the funding of CGMs for all people with type 1 diabetes was possible from the available funding from Pharmac's fixed budget.

It was proposed that there would be up to two suppliers of CGMs and up to two suppliers of insulin pumps. s 9(2)(b)(ii), s 9(2)(j)

Given the level of competition and rate of change with respect to diabetes technologies, suppliers were encouraged to provide information on their pipeline products that would likely be available during the dual supply period.

s 9(2)(j)

Evaluation Process

External advisors (technical and consumer) were present on the Technical and Consumer Evaluation Committee (TECEC) to provide insight and advice on the non-price aspects of the RFP submissions. This was followed by an internal Pharmac Evaluation Committee meeting, where the advice from the first evaluation meeting was considered alongside all of the Factors for Consideration (including costs and savings).

The TECEC consisted of Diabetes Advisory Committee members, other clinical experts, consumer experts, and health sector representatives. Members were selected in consultation with the New Zealand Society for the Study of Diabetes (NZSSD), Diabetes NZ and Health New Zealand. The Committee provided specific advice on the suitability, health benefits and implementation aspects of the proposals, as well as more general advice for Pharmac to consider when making its final decision. The record of this meeting is included as Appendix Five.

s 9(2)(b)(ii), s 9(2)(j) However, it was acknowledged that would require existing patients to change from one of the currently funded brands of insulin pumps (MiniMed 770G). The proposed funding scenario is outlined in Figure 1, below.

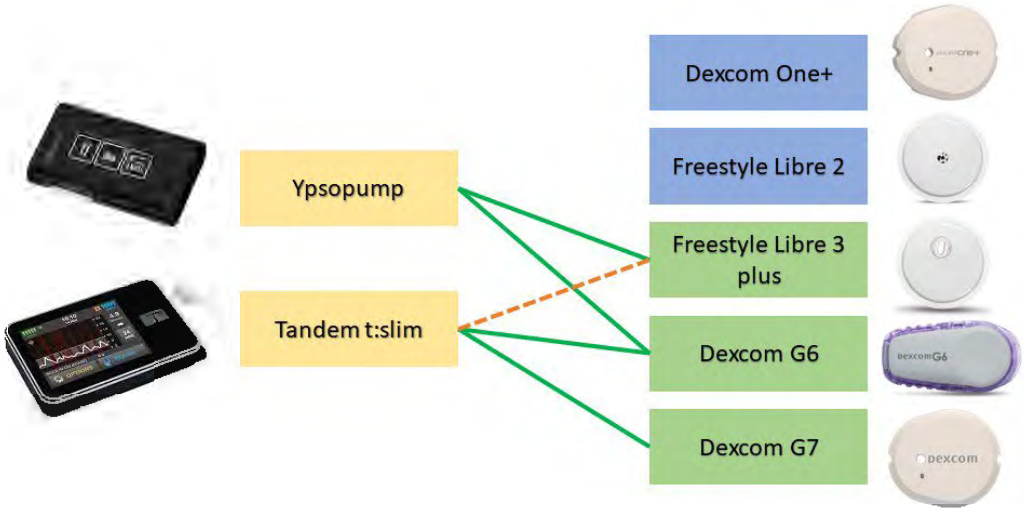

Figure 1. Interoperability of preferred funding scenario. The standalone CGMs are indicated in blue, the compatible CGMs are indicated in green and the insulin pumps are indicated in yellow. Interoperability is indicated in a green line and the orange dashed line indicates that interoperability is not yet available (expected no later than 1 July 2025)

Contract terms

s 9(2)(b)(ii), s 9(2)(j)

[redacted]

[2] Copies of the agreements can be made available to any Board member on request.

s 9(2)(b)(ii), s 9(2)(j)

[redacted]

Implementation

Pharmac has developed a comprehensive implementation plan (Appendix Six) to support a successful onboarding and a transition from the currently funded insulin pumps.

We have worked with the suppliers, NZSSD, and Diabetes New Zealand, as well as Health Pathways, Healthify, and stakeholders such as General Practice New Zealand (GPNZ), and Pharmaceutical Society of New Zealand (PSNZ) to ensure that implementation activities are coordinated and appropriately targeted to the various stakeholder types, and to ensure that the wider health sector is prepared for the additional users of CGMs, insulin pumps and AID systems that are expected to access funding as a result of this proposal.

We note that Pharmac's agreements require the suppliers to lead the development of educational and training materials with both patients and clinicians in mind.

Factors for Consideration

The proposal has been assessed using the 'Factors for Consideration'. Detail about the assessment under each Factor for Consideration is available in Appendix Seven.

Consultation and Comments from Interested Parties

Section 70 of the Pae Ora (Healthy Futures) Act 2022 (the Act) requires Pharmac to consult, when it considers appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of Pharmac, may be affected by decisions on those matters.

Accordingly, a consultation letter was circulated to the sector on 28 March 2024. Approximately 1300 unique consultation responses were received, including from consumers, clinicians, patient support groups and industry. The consultation letter, distribution list and all responses received by 26 April 2024, are attached as Appendix Eight.

A wide range of consultation feedback was received. The majority of responders were very supportive and acknowledged the significant benefit that this proposal would have on improving health outcomes for all people with type 1 diabetes.

A petition was received (Appendix Eight F) signed by approximately 10,000 people requesting that the Medtronic Minimed 780G and the Guardian 4 CGM are part of the funding proposal. A subsequent meeting was held between Pharmac staff and the petition organiser.

Some responders were supportive provided there was a longer transition period to change from currently funded Medtronic pumps, and some responders were not supportive at all. Responders who were not supportive were primarily not supportive due to the fact that Medtronic CGMs and insulin pumps were not part of the proposal and this included a petition urging Pharmac to reconsider its delisting of the MiniMed insulin pump.

Wider concerns were also raised about the ability of the health system to implement the proposal, possible impact on funding that some people had sourced from other government agencies for CGMs and a number of respondents requested funding beyond treatment of type 1 diabetes.

As a result of the feedback, progression of the proposal to a decision was delayed, to ensure that all feedback had been fully considered and issues resolved to the extent possible. A meeting was held with the Diabetes Specialist Advisory Committee on 21 June 2024 to specifically address the clinical issues raised in the consultation feedback and to define the parameters for the exceptional circumstances process. A detailed summary of what Pharmac

staff believe are the significant matters raised in these responses and our response to them is provided in Appendix Nine.

Key Themes raised in the consultation feedback included:

- Support for the Medtronic AID system for niche population groups
- Concerns over the limiting nature of the Dual Supply approach
- Concerns regarding product usability / suitability of different products
- The procurement process possibly not selecting the best technology
- Transition period being too short to enable an orderly transition
- A desire for a less complex special authority application process
- Requests for eligibility for additional patient groups ie patients with Type 2 diabetes
- Concerns regarding the implementation process and resource constraints in the health system
- The need for high quality educational material and training resources
- Concerns regarding privacy and data management
- Concerns regarding the impact on funding provided by other Government agencies for CGMs
- Requests for clarity regarding access how to access a funded to alternative brand, and in which scenarios this would be possible

Key changes to the proposal following consideration of consultation feedback

After carefully considering this feedback, meeting with key clinical and consumer stakeholders, and taking additional clinical advice, we have made the following changes to the proposal:

- provided a 2-year transition period for those individuals currently accessing a Medtronic MiniMed insulin pump
- modified the proposed eligibility criteria for CGMs and Insulin pumps to include individuals with forms of diabetes similar in impact to type 1 diabetes (eg monogenic/Type 3c)
- simplified the proposed eligibility criteria to remove requirements for insulin pump and CGM renewal to demonstrate objective evidence of maintained improvement in glycaemic control.
- extended approval periods for insulin pump consumables from 3 months to 6 months to better align with onboarding practices.
- removed the requirement in the initial approval for AID compatible CGMs and Insulin pumps to demonstrate severe unexplained hypoglycaemia requiring assistance; or impaired awareness of hypoglycaemia, including those with severe unexplained nocturnal hypoglycaemia.
- increased the amount of funded insulin pump consumables where required to ensure people have adequate supplies and enabled three monthly dispensing of the devices from their pharmacies (currently people only receive one month at a time).

We have also sought to ensure:

- availability of supplier provided phones for those who need this and want to use the Pharmaco supplied insulin pump.
- availability of technical support for users of technologies at all times for Pharmaco and NZMS, and 10 hours a day seven days a week for Abbott
- that there is a pathway for those who are unable to transition to one of the funded options to access another brand, through Pharmac's Exceptional Circumstances, with criteria informed by our clinical advisors
- availability of the Freestyle Libre 3 plus and interoperability with proposed insulin pumps. Confirmed a date for interoperability between all funded options. Outstanding interoperability

between Freestyle Libre 3 plus and the Tandem control-IQ insulin pump, no later than 1 July 2025

- continued availability of alternative funding streams with other government agencies (Ministry for Social Development and Health NZ).

Issues raised in consultation feedback that are not able to be addressed

We have not been able to address the following key issues as a result of the feedback received:

- funding of the Intermed (Medtronic) supplied insulin pump, insulin pump consumables or compatible CGM. As we have run an open, fair, transparent competitive process, it was not considered possible to renegotiate with the incumbent supplier to enable an alternative supply arrangement, which was different to the terms of the RFP. This would have required recommencing the RFP under different terms. To do this we would need to design and run a new commercial process. It is uncertain how long this would take, but likely at least 12 months and such a delay would have an unreasonable impact on those people with a currently unmet health need. We consider we have addressed much of this concern by extending the transition period on insulin pumps to 24 months. Further information regarding the considerations of TECEC when evaluating all proposals is available in Appendix Five.

s 9(2)(b)(ii), s 9(2)(j)

[redacted]

Legal Advice

Where necessary, management will obtain legal advice on issues such as whether any proposal is consistent with Pharmac's legislative and public law obligations, including those which may have specific relevance to the particular proposal e.g. human rights implications of a proposal. If the Board considers that further legal advice is required on any issue, this should be communicated to management in advance of the Board meeting. Management will then obtain the required advice.

Legal Advisors' View

Confidential and Legally Privileged Advice from Pharmac's Principal Legal Counsel and General Counsel

Summary

s 9(2)(h)

[redacted]

s 9(2)(h)

s 9(2)(h)

Implementation and Communication

Section 70(b) of the Act requires Pharmac to take measures to inform the public, groups and individuals of Pharmac's decisions concerning the Pharmaceutical Schedule. Accordingly, if the recommendations contained in this paper are adopted, Pharmac staff would notify all parties on the consultation distribution list and all responders to the consultation including:

- all pharmaceutical companies;
- PTAC and relevant Specialist Advisory Committee members; and
- special interest groups and interested clinicians (including Diabetes NZ, NZSSD, Health NZ hospital pharmacists, community pharmacists, Health Pathways, PSNZ, GPNZ)

A stakeholder engagement plan would be developed to communicate the outcome of this funding decision. This plan would identify key stakeholders and what they need to know when. The key focus of communication would be to inform of the decision, relevant timeframes for the changes to occur, and signal the availability of resources and support. Key messages developed would:

- be easily accessible and understandable for the target audience (including consumers)
- be reassuring and informative
- signal availability of consumer resources.

An implementation plan has been developed to support this proposal. Details of the proposed implementation activities can be found in Appendix Six.

Pharmac would, in an ongoing manner:

- maintain open lines of communication with sector agencies (e.g. Medsafe and CARM) throughout the transition period to ensure an aligned sector approach
- monitor uptake of CGMs and insulin pumps and feedback from the sector and adjust our implementation response as necessary, especially for populations with highest health need.
- work with the health sector to measure the direct impact on the wider sector.

Appendices

Appendix One	Resolutions.
Appendix Two	Individual BIA (Insulin Pumps / CGMs)
Appendix Three	Summary of Listing Dates
Appendix Four	Record of Diabetes Committee Meeting (21 June 2024)
Appendix Five	Summary of the Technical Evaluation Committee Meeting.
Appendix Six	Implementation Plan
Appendix Seven	Factors for Consideration
Appendix Eight	Consultation Feedback Compiled:
	Appendix Eight A – CGM Consultation Letter
	Appendix Eight B – Compiled Feedback – Supportive no additional info
	Appendix Eight C - Compiled Feedback – Supportive additional info
	Appendix Eight D - Compiled Feedback – Not Supportive
	Appendix Eight E – Responses to Delay Notification
	Appendix Eight F – Petition Signatures CGM
Appendix Nine	Summary Consultation - Themes