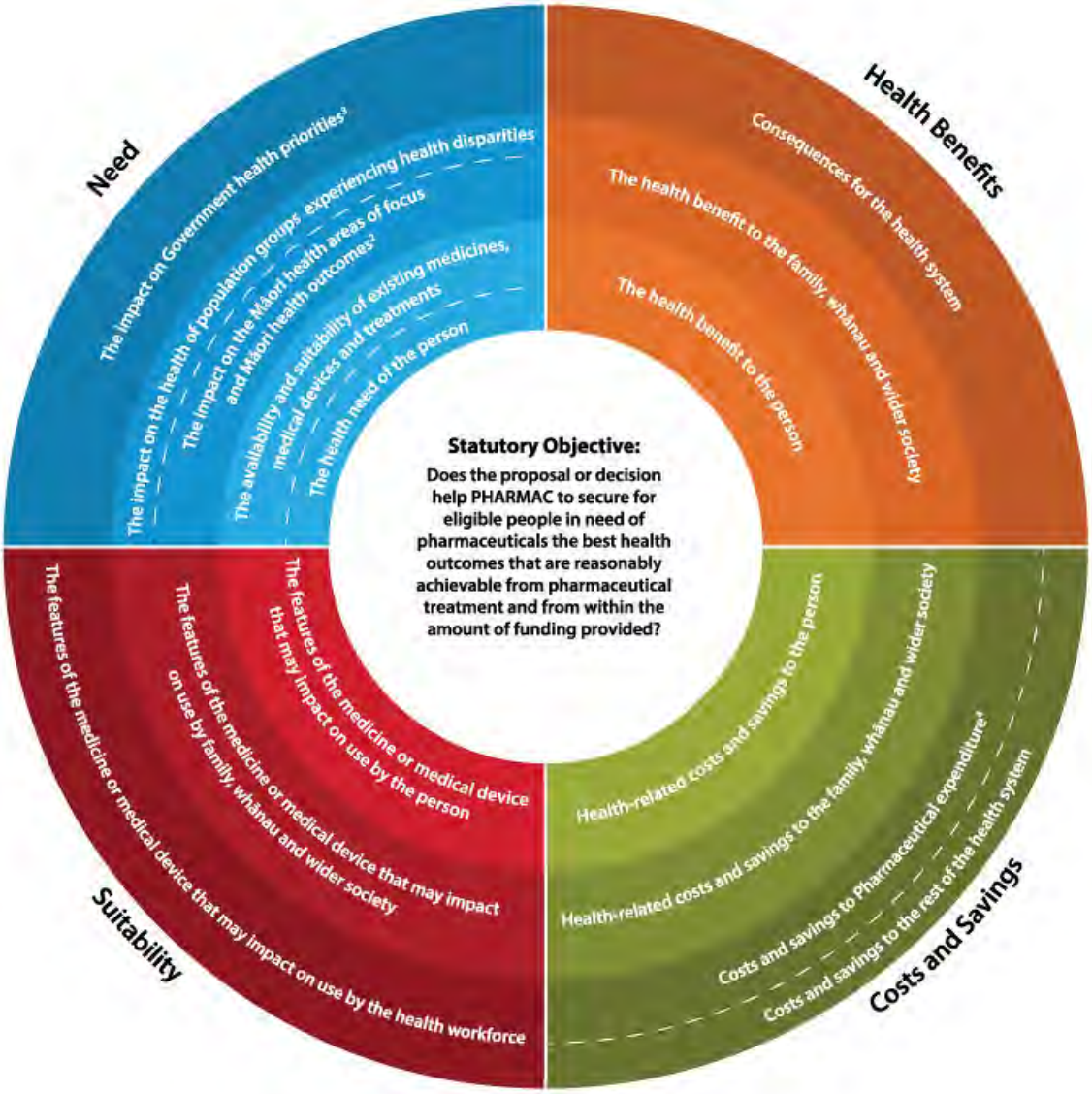
Appendix Seven

Factors for Consideration

This section of the paper sets out Pharmac staff's assessment of the proposal using the 'Factors for Consideration' in the Operating Policies and Procedures. Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Board is not bound to accept Pharmac staff's assessment of the proposal under the 'Factors for Consideration' and may attribute different significance to each of the Factors from that attributed by Pharmac staff.



Footnotes

[1] The person receiving the medicine or medical device must be an eligible person.
[2] The current Māori health areas of focus are set out in Pharmac's Te Whaioranga Strategy.
[3] Government health priorities are currently communicated to Pharmac by the Minister of Health's Letter of Expectations.
[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB).
[5] Please note Pharmac's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.

Health need

Disease/illness

Type 1 Diabetes

Type 1 diabetes is a chronic condition that happens when the pancreas does not produce any insulin – this affects blood sugar control. The only treatment for type 1 diabetes is the injection of insulin guided by blood sugar levels.

It's important for people with type 1 diabetes to regularly check their blood sugar levels. A person with type 1 diabetes may fall into a diabetic coma if their blood sugar levels are too low (hypoglycaemia). If a person's blood sugar levels are too high (hyperglycaemia), then they may experience a life-threatening condition called diabetic ketoacidosis.

If a person's blood sugar levels are not controlled over an extended period of time, they are more likely to experience, cardiovascular disease, neuropathy, diabetic nephropathy, and diabetic retinopathy and a reduced life expectancy in poorly managed disease.

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.

Pancreatogenic diabetes is otherwise known as Type 3c diabetes and is diabetes secondary to other factors such as chronic pancreatitis, pancreatic surgery (eg pancreatectomy) of pancreatic tumours.

Availability and suitability of existing treatments

Appropriate therapy with injectable insulin administered multiple times a day helps to prevent complications from type 1 diabetes, however maintaining glucose levels within the normal range remains a difficult task. In New Zealand, the available funded options require people with type 1 diabetes to measure their blood sugar levels with finger-prick testing using a blood glucose monitor. This requires significant cognitive load (to remember to test at several points throughout the day) and results in significant physical discomfort. We understand this is unsuitable and can prevent people from testing their blood sugar levels as often as guidelines recommend.

In New Zealand, insulin pumps, medical devices that continuously deliver a baseline level of insulin are funded for eligible people. They are an alternative to manually injecting insulin multiple times a day. They also allow for bolus doses of insulin to be delivered around mealtimes.

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 (meaning x) or continuous glucose monitoring (CGM) systems funded for use within New Zealand. However, a number of individuals have accessed funding via the Health New Zealand Carer support scheme or via the WINZ disability allowance (child) which provides a supporting payment to allow self-funding of CGMs, however there remains significant financial shortfall and substantial inequity in access to CGMs.

Health need of others

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.

Impact on Māori health areas of focus and health outcomes

Although the prevalence of type 1 diabetes is lower in non-European New Zealanders compared to European New Zealanders, Māori experience a disproportionate burden of diabetes-related adverse outcomes compared to other ethnicities. While Māori comprised 10.1% of individuals with type 1 diabetes in 2021 (Wheeler et al. NZMJ. 2019;132: 1491), in the year 2018/9, Māori comprised 23.1% of publicly funded discharges for type 1 diabetes-related complications (Ministry of Health. National Minimum Dataset. 2021).

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

Pacific peoples experience a disproportionate burden of diabetes-related adverse outcomes compared to other ethnicities. In 2021, Pacific peoples comprised 4.5% of individuals with type 1 diabetes (Wheeler et al. NZMJ. 2019;132: 1491), however in the year 2018/19, Pacific peoples comprised 6.6% of publicly funded discharges for type 1 diabetes-related complications (Ministry of Health. National Minimum Dataset. 2021). Further, the rate of moderate or severe hypoglycaemia events was greater among Pacific peoples compared European individuals (24.8 per 100 person-years compared to 14.9 per 100 person-years, p=0.03) (Carter et al. Diabetologica. 2008;51: 1835-184).

The impact on Government health priorities

Diabetes is one of five non-communicable disease areas of focus covered under the Government Policy Statement on Health 2024-27.

Health Benefit

Health benefits to the person

Continuous Glucose Monitors (CGMs)

CGMs consist of a sensor which sits just underneath the skin and a transmitter that regularly sends information to a compatible device (eg. smartphone, tablet or reader device). Some CGMs allow a user's clinicians, carers, family or friends to "follow" these readings, which can help with diabetes management, particularly for younger children. In some newer CGM models, the sensor and transmitter are available as a single component.

CGMs measure interstitial sugar levels (the sugar levels in the fluid between cells), to estimate an individual's blood sugar levels. CGMs allow people with type 1 diabetes to receive glucose measurements in real-time without the burden of finger-prick testing. Some CGMs can be set up with alarms to alert the user or follower when sugar levels are rising too high or dropping too low. This allows users to respond and manage rapid changes in their sugar levels and help prevent the development of hypoglycaemic events.

Our advisors have told us that insulin pumps are not suitable for everyone but that CGMs would provide benefit to all people with type 1 diabetes whether used in an automated insulin delivery system or as a standalone device.

Our advisors have told us that CGMs, when used as a stand-alone device, are associated with a reduction in hypoglycaemic events, a reduction in anxiety associated with hypoglycaemic events, improvement in blood sugar control, as measured by HbA1c, and a reduction in the disutility associated with finger pricking for blood glucose tests.

Automated Insulin Delivery Systems / Insulin Pumps

CGMs can also be paired with an insulin pump to create an automated insulin delivery (AID) system, where an algorithm uses the readings from the CGM to increase the insulin dose if blood sugar levels rise too high and to reduce the insulin dose or temporarily pause insulin delivery if blood sugar levels drop too low. This enables an individual to adopt a more hands-off approach to their diabetes management, however such systems still require an individual to monitor their carbohydrate intake and make allowance for things like exercise.

Our advisors have told us that the time spent in the recommended glycaemic range is further improved when a CGM is connected to a pump as an AID system. While our advisors considered that the algorithmic approaches used by AID systems do differ, they noted that evidence suggests very similar clinical outcomes in terms of HbA1c improvements, time spent in the recommended glycaemic range, reductions in the number of hypoglycaemic and ketoacidosis events.

PTAC and Diabetes Advisory Committee view

Advice on funding applications

Pharmac has received and assessed several funding applications for CGMs and associated AID systems. Various CGMs (Freestyle Libre, Dexcom G6 and Medtronic Guardian 3) have been considered for funding by our Committees, all of which have been recommended for funding. The MiniMed 780G System (includes CGM + insulin pump) was also recommended for funding.

Advice regarding planned procurement activity

In April 2023, advice was sought from the Diabetes Advisory Committee about the possibility of running a competitive process that could potentially result in a change in funded brands of insulin pumps and consumables and listing of CGMs on the Pharmaceutical Schedule. This advice helped inform the design of the request for proposals (RFP) and what was considered to be important in the outcome of any RFP. The Committee considered that:

- in general, all people with type 1 diabetes would benefit from using a CGM device, and that for many patients the available CGMs would provide similar health benefits.
- it would be appropriate to fund one standalone CGM device provided it was funded alongside at least one CGM device capable of hybrid closed-loop interoperability.
- some people would decide to privately fund CGMs which are not publicly funded and that clinicians would still need to be familiar with these products.
- s 9(2)(j)
- suppliers should also provide clinician training and that this training needs to be flexible i.e. options for in-person or online training.
- while the products do differ in design, the health benefits are relatively similar across the currently available products.
- if Pharmac were to fund more than one CGM device, at least one must come with a standalone reader device that does not require a smartphone to operate.
- some newer devices do not require fingerprick testing for calibration and this a significant suitability advantage over devices that require calibration.
- it is important to consider where the data is stored and that that it would be helpful if suppliers provided clinicians with written information that they could provide their patients to explain where the data goes, how it is used and how it is kept private.
- evaluation of bids as a result of a commercial process for CGMs, and insulin pumps should include clinical expert and consumer groups.
- there would need to be supplier provided implementation support in the form of training and education and ongoing support for both people with diabetes and healthcare professionals if there was to be a change.

Advice after consultation

In June 2024 Diabetes Advisory Committee considered a range of issues that were raised during the public consultation. This meeting included considerations of amendments to eligibility criteria, consideration of access to the alternative brand allowance and issues raised during consultation as they related to implementation. The Committee remained supportive of the proposal, indicating that it would result in significant benefit to many people, acknowledging that some existing insulin pump users would have to move to a different product. This advice informed the relevant changes to this proposal outlined in various sections in this paper. The record of this meeting can be found in Appendix Four.

Advisor Conflicts of Interest

All declared conflict(s) of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflict(s), are recorded in the relevant records.

Suitability

Continuous glucose monitors

Advice provided to Pharmac has noted that CGM technologies are likely to provide meaningful health related quality of life benefits to people with type 1 diabetes, particularly with regards to a reduction in the burden associated with finger prick testing, reducing the fear and worry associated with hypoglycaemic events.

The proposed CGMs were considered by the Technical and Consumer Evaluation Committee (TECEC) to be highly suitable options and considered that the proposed Dexcom and Abbott CGMs are easy to apply, had a long wear-time, are calibration free and between them, offered genuine choice for consumers, and had strong evidence supporting their accuracy. The TECEC also considered that both brands had combined transmitter and sensor options, which would be preferable.

AID systems

When paired with an insulin pump and the associated software, the advice we have received indicates that AID systems can further reduce the 'decision' burden associated with type 1 diabetes. As the insulin pump responds to real-time glucose readings by adjusting the rate and dose of insulin delivery, AID systems reduce the fear and worry associated with hypoglycaemic events and chronic hyperglycaemia. The TECEC also considered that interoperable systems, where the pump can be used with multiple CGMs, enable patients a greater degree of choice and flexibility.

Both proposed pumps would be able to be used with the proposed suppliers' compatible CGMs (note that the Tandem pump would only be able to integrate with the Dexcom CGMs at the proposed list date but it is expected that these pumps would be compatible with the Abbott Freestyle Libre 3 Plus CGMs no later than July 2025).

Costs and Savings

A budgetary impact assessment for the individual components of this proposal (CGMs and insulin pumps, including consumables) is located in Appendix Two of this board paper.

Cost and savings to Pharmaceutical expenditure

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

Health related costs and savings for family, whānau and wider community

Pharmac staff have not identified any health-related costs and savings experienced by an individual's family, whānau or wider community because of this proposal.

Costs and savings to the rest of the health system

There would be savings to the health system of approximately s 9(2)(b)(ii), s 9(2)(j) as a result of a reduction in the frequency of hospital admissions due to hypoglycaemic events.

There would be distribution costs related to pharmacy markups on the devices, which are paid by Health New Zealand as part of their contracts with pharmacies. s 9(2)(b)(ii), s 9(2)(j) . This is calculated as s 9(2)(j) of the value of pharmaceutical (in this case medical device).

Cost-Effectiveness

The cost-effectiveness of this proposal for CGMs for people with type 1 diabetes is estimated to be s 9(2)(j) QALYs per $1 million net health sector costs invested. s 9(2)(j)

The full Technology Assessment Report(s) can be made available to Board members on request.