

The logo for PHARMAC, featuring the word "PHARMAC" in a bold, sans-serif font above the Māori name "TE PĀTAKA WHAIORANGA" in a smaller, all-caps font. The logo is contained within a white circle.

PHARMAC
TE PĀTAKA WHAIORANGA

Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes

22/10/2019

Ningxin (Nelson) Ding, Health Economist

In preparation for Full Prioritisation meeting scheduled
December 2019

Disease Description

- Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta-cells resulting in insulin deficiency. This leads to hyperglycaemia and the potential to develop ketoacidosis.
- Type 1 diabetes is a life-long disease that is most often diagnosed during childhood, with only 25% cases diagnosed in adults.
- There are likely to be approximately 25,000 individuals with type 1 diabetes in New Zealand (253,000 diabetes patients in 2018; 10% of them are type 1).
- 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.

Health Need & Current Treatments

- Patients typically present with polyuria, polydipsia, and weight loss.
- Appropriate therapy with exogenous insulin prevents severe hyperglycaemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult.
- Current care for assessing blood glucose is to self-monitor using a blood glucose meter between 4 to 10 times per day (finger-prick).
- Substantial burden to caregivers and families.

Proposal Background

- The funding application was received in November 2017.
- The Subcommittee recommended that the FreeStyle Libre Flash Glucose Monitoring System be funded with high priority for certain patients with type 1 diabetes (2019)

released under the
Official Information Act

PICO

Intervention: Freestyle Libre Flash Glucose Monitoring System

Comparator: self-monitor using a blood glucose meter

The targeted patients are (Initial application):

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.

PICO

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


Patient is continuing to derive benefit from flash glucose monitoring.

- Outcomes: hours in hypo, severe hypo events, costs

Clinical Evidence

- Key evidence by PTAC: IMPACT trial (Bolinder et al. Lancet. 2016;388:2254-2263)
- Hypo hours per day: Free style: 3.38h baseline, 2.03h (end of 6 month)
Control group (finger-prick): 3.44h baseline to 3.27h
Difference in difference: 1.18h (significant)
- Hypo events per day: Free style: 1.81 baseline to 1.32
Control group: 1.67 baseline to 1.69
Difference in difference: 0.47 (significant)
- Hypo events per day: Free style: 1.81 baseline to 1.32
- Pietropaolo et al. : hypo required admission to ED or hospitalization: 0.02-0.5 events per patient per year

Clinical Evidence

- Combined Pietropaolo et al. and Bolinder et al. :
if we assume that the ratio between hypo required admission to ED and hypo events per day is constant, then the number of admission is expected to decrease by 0.004 to 0.11 events per patient per year
- Matza et al. : QoL from EQ5D: free style: 0.882,
conventional (finger prick): 0.851
Problem: population in the trial were not type 1 diabetes patients !!!
- Difference: 0.03 + or – 0.053 (might be 0 or even negative)
 Are there benefits ???

Key Assumptions

- Time Horizon: per day
- A sensor lasts up to 14 days (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).
- A reader would need to be replaced every two years.
- Hypo hours per day (assume severe but no admission to ED or hospitalization) decreases by 1.18h/d.
- Hypo required admission to ED decreases by 0.004 events by year.
- Self-monitor using a blood glucose meter 4 times/d. Hence 4 strips /d.

Model Structure

free style vs
control

```
c_ambulance = 0
c_ED = 326
c_reader = Withheld
c_sensor =
Withheld under
c_strips_day =
Withheld under

disutility_hypo_hour
= 0.0000166
ED_events_day =
0.004/365

other_incre_utility...
= 0

time_decrease_hy...
= 1.18
```

free style

control

Released under the
Official Information Act

Costs & Qol

Parameter	Value
ED admission (DRG)	\$326
Reader per year	Withheld under
Strips per 50	Withheld under section
Sensor (last for 14d)	Withheld under section

Parameter	Value
Fear of hypoglycemic episode	0.995-1
Severe hypoglycemics episodes	0.85
QALYs gain from avoid hypo per hour	$(0.995-0.85)/(365*24)=0.0000166$

Results

	Costs	Incre cost	Incre Eff	ICER
Control	Withheld under			
Free style	Withheld under	Withheld under	0.0000196	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)

released under the
Official Information Act

Sensitivity Analysis

- Add ambulance cost if admission to ED
- QoL from Matza (now includes the disutility from frequent finger pricks)
- 10 Strips per day
- Hypo hours per day increase or decrease by 50%
- ED costs and sensor costs increase or decrease by 50%.
- [Redacted] Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)
[Redacted] Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)
[Redacted] Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j) Retail pricing from Australia suggest the unit cost of each reader is approximately NZD\$100.
- The decrease in hypo events required emergency admission or hospitalization changed to 0.11 per year
- QALYs gain from avoid hypo per hour: min: 0 (only in the possible range)
max: $(1-0.85)/365/24=0.0000171$

Results

- Likely range: Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2) QALYs / \$m (driven by strips and readers)
- Possible range: dominated to Withheld under QALYs / \$m (driven by utility increase)
- In Sweden (FreeStyle Libre, TLV 2017): NZD\$25,900 to \$190,500 per QALY (5.2 to 39.0 QALYs per \$M).

Withheld under section 9(2)(ba)(i) and 9(2)(j)



BIA

- Type 1 Diabetes: 10% of the whole diabetes
- Increase by 5% per year.
- Uptake rate: 0.4 first year, 0.6 second year, then 0.1 increase every year
- May add one more GP visit per year as more available data now GP have

Discussion & Questions

- Low CUA results with wide range
- May suitable for young patients who fear finger prick
- May suitable for patients who have really bad blood sugar control and require frequent tests
- Probably not apply to all type 1 diabetes patients

Thank you

released under the
Official Information Act