PHARMAC
Pharmaceutical Management Agency

Hot Topic Minutes
23rd October 2019

Application: FreeStyle libre for T1DM

Application tracker link

Presentation Objective Link:

Attendees:

Presenter: Ningxin Ding (Nelson)

HE Minute: Hayden Spencer & Tal Sharrock

TGMs/FAAs: Elena Saunders

MDs: Tristan (x), Gregory Evans

Discussion

Background

Meeting noted the estimated prevalence of T1DM in New Zealand and the daily burden of current management.

Current treatment paradigm

Patients currently managed with test strips.

PICO

- P: Type 1 DM (with special authority restrictions)
- I: Freestyle libre
- C: Self monitor using a blood glucose meter
- O: Hours in hypoglycaemia / severe hypo events

Application history

Funding application received 2 years ago; SC high clinical recommendation provided in 2019.

Key evidence

IMPACT trial data discussed (Bolinder et al Lacent 2016;388:2254 2263)

Meeting noted the key outcome measures from this trial included:

1. Hypo hours per day
2. Hypo events per day

Matza et al HR QoL from EQ-5D

Limitations with this study noted

1 Population in trial noted not to be type 1 diabetes patients
2. Trial was conducted by the supplier

Difference of 0.03 noted between treatment arms of the study (within realms of possibility)

Model

Model horizon was one day
Sensor last 14 days (base case)
Reader lasts 2 years
Self monitoring with blood glucose test strips; currently 4 test strips in base case; recommended to change to average of current usage (noted to be between 4 10 test strips)

Action Points

Requirement of test strips in interventional arm of model.
Adjust average daily number of test strips in comparator arm of model from 4 to 7 daily.

Transitional probabilities

Proportion of hypo hours per day
Proportion of hypo events per day

Costs

Included costs:

1. ED admission
2 Reader per year
3. Strips per 50
4. Sensor cost

It was noted that there was a confidential rebate to test strips that still required to be factored in.

Action Point

- **Review SGLT2 / GLP1 inhibitor TARs for rebated price of test strips.**

HR QOL

Noted that utility parameters included

1 Fear of hypoglycaemic events
2. Severe hypoglycaemia episodes
3. QALY gain from hypo per avoided hypo

It was noted that the base case utility of T1DM as previously modelled would be more appropriate for modelling, though retaining the same incremental benefit as proposed (therefore, no effect on the final results presented at this meeting though better reflected prior analysis.

Action Point

Review earlier TARs / HR QOL database for base utility of T1DM patients to inform this model

- **Retain differential as calculated in Mazta et al paper and apply accordingly to the base utility.**

CUA results

Meeting noted that the FreeStyle libre model returned a base case result of W QALYs per $1m. Likely range Withheld QALYs / $m (driven by strips and readers).

Multiple one-way sensitivity analyses have been undertaken. Final ranges to be determined as revisions to utility values required, though likely to reach low teens in possible range.

Model noted to be most sensitive to decrease in hypoglycaemia hours and utility gain from using the free style systems (includes disutility from finger prick).

BIA

Significant budget impact is noted with the projected uptake of this proposal.

Update based on high uptake of total T1DM prevalence

Uptake requires more work based on current SA access criteria

Action Point

Additional work required estimating the probable uptake rate in the defined target population as indicated in the SA criteria.

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Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes

22/11/2019

Ningxin (Nelson) Ding, Health Economist

In preparation for Full Prioritisation meeting scheduled December 2019

Disease Description

- Type 1 diabetes mellitus is a chronic disease leads to hyperglycaemia and the potential to develop ketoacidosis.

- Most often diagnosed during childhood.

- 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 than Māori and Pacific peoples, Māori and Pacific peoples have worse long-term outcomes.

Health Need & Current Treatments

- Patients typically present with polyuria, polydipsia, and weight loss.
- Insulin is used to prevent 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).

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)

PICO

Intervention: Freestyle Libre Flash Glucose Monitoring System

Comparator: self-monitor using a blood glucose meter

The targeted patients are (Initial application): 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.

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)

- Pietropaolo et al. : hypo required admission to ED or hospitalization: 0.02-0.5 events per patient per year
- 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

Clinical Evidence

- Matza et al. : QoL from EQ5D: free style: 0.882,
  conventional (finger prick): 0.851

Problem: (1) population in the trial were not type 1 diabetes patients

(2) The trial was conducted by the supplier (should we trust them?)

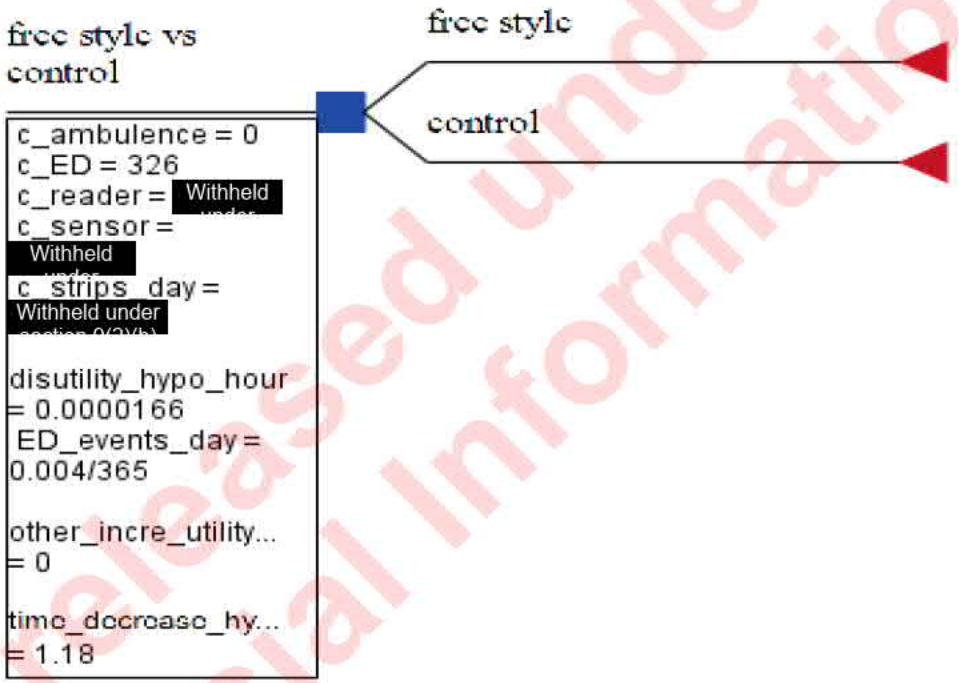
- Difference: 0.03 + or – 0.053 (might be 0 or even negative)

  → Were 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 per year.
- Self-monitor using a blood glucose meter 7 times/d. Hence 7 strips /d.

Model Structure



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 epidose	0.995 to 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)(i)

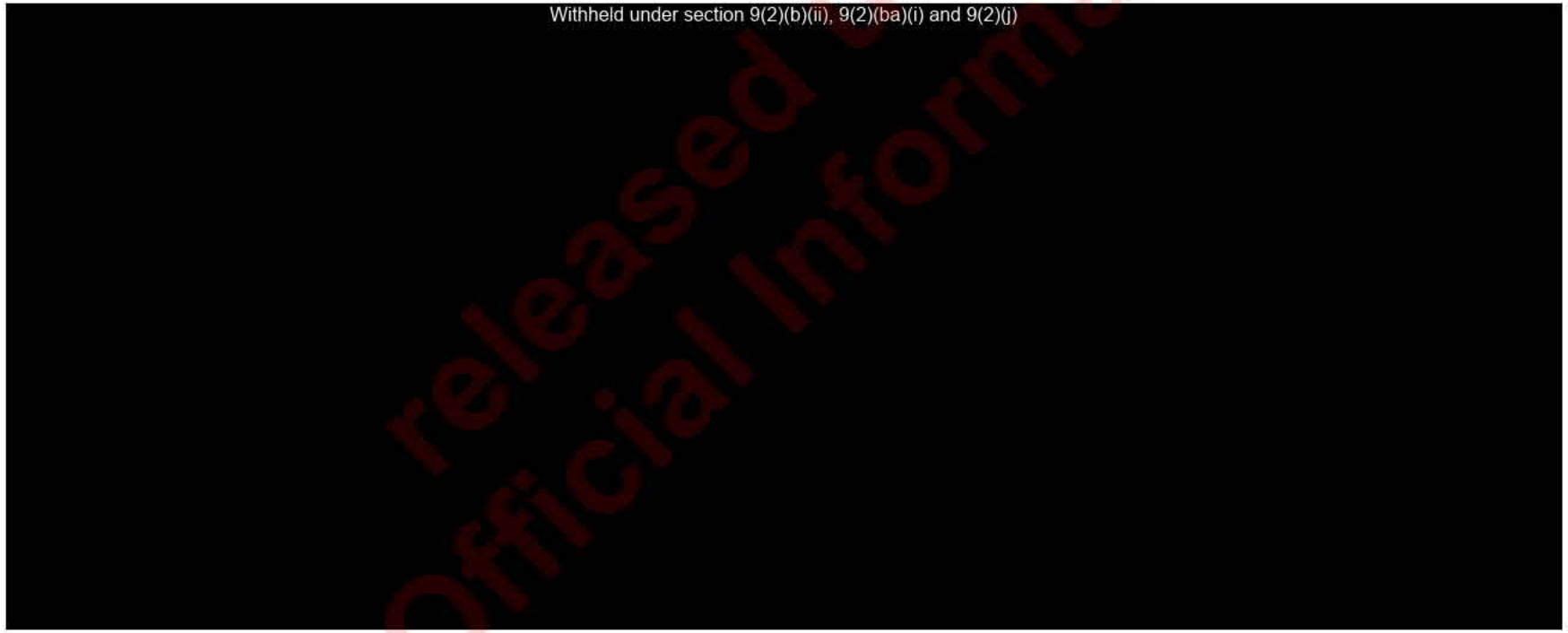
Sensitivity Analysis

- Add ambulance cost if admission to ED
- QoL from Matza (now includes the disutility from frequent finger pricks)
- Strips per day increase or decrease by 50% (3.5 to 10.5/d).
- Hypo hours per day increase or decrease by 50%
- ED costs and sensor costs increase or decrease by 50%.
- Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)
  Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i)
  Withheld under section 9(2)(b)(ii), 9(2)(ba)(i), and 9(2)(i) 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: max: (1-0.85)/365/24=0.0000171

  min: decrease by 50%

Results

- Likely range: Withheld under section 9(2)(b) QALYs / $m (driven by strips and readers)
- Possible range: Withheld under section 9(2)(b) QALYs / $m (driven by QoL gain)
- In Sweden (FreeStyle Libre, TLV 2017): NZD$25,900 to $190,500 per QALY (5.2 to 39.0 QALYs per $M). They account for the decrease in the diabetic complications over 50 years using CORE model.



BIA

- Type 1 Diabetes: 10% of the whole diabetes.
- Increase by 5% per year.
- Aged below 18: 25%.
- Age below 18 + female between 18 and 35: 35%.
- 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.

BIA

Year	1	2	3	4	5	NPV
N of Type 1 Patients	25,300	26,565	27,893	29,288	30,752	
Under 18 or meet the special authority (excluding those actively planning pregnancy; 25% of the total type 1 patents)	6,325	6,641	6,973	7,322	7,688	
Uptake	0.4	0.6	0.7	0.8	0.9	
N of patients on Free style	2,530	3,985	4,881	5,858	6,919	
Total costs to DHB ($)	Withheld under section 9(2)(b)(ii),	Withheld under section 9(2)(b)(ii),	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)

BIA

Year	1	2	3	4	5	NPV
N of Type 1 Patients	25,300	26,565	27,893	29,288	30,752	
Under 18 or meet the special authority (including those actively planning pregnancy; 35% of the whole type 1 patients)	8,855	9,298	9,723	10,251	10,763	
Uptake	0.4	0.6	0.7	0.8	0.9	
N of patients on Free style	3,542	5,579	6,834	8,201	9,687	
Total costs to DHB ($)	Withheld under section 9(2)(b)(ii),	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)

Discussion & Questions

- Low CUA results with a wide possible 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

Thank you

Pre prioritisation Meeting Minutes 22/11/2019

Attendees

- Andrew Oliver
- Karen Jacobs Grant
- Sandy Bhawan
- Ben Campbell Macdonald
- Erica Deverall
- Nelson (Ningxin) Ding
- Nathan Fox
- Tal Sharrock
- Elena Saunders
- Greg Evans
- Scott Metcalfe
- Danae Staples Moon
- Caro DeLuca

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Freestyle Libre for ty

Free style libre for type 1 diabetes '

HE: Nelson
Minute taker: Tal

- A description of type 1 diabetes and the health need of the population was noted by the group
- Diabetes Subcommittee gave a high priority
- Group noted PICO
- Group noted IMPACT clinical trial as key evidence hypo hours per day, hypo events and hypo hospitalisations
- Group noted that the quality of life provided by supplier small benefit to not pricking decrement with hypo event
- The group noted the key assumptions in the model outlined in the presentation
    - Allowance made for test strips being used in intervention arm as well as comparator
- Group noted W QALYs a million as a base case and that various sensitivity analyses were conducted and resulted in a likely range of Withh (driven by strips and readers) and Withheld possible range (driven by QOL range).
- The group discussed that the base-case doesn't include a decrement of QOL due to pricking – agreed that this should be included in the base-case
- HE to update this and the ranges around it **(ACTION)**
- Budget impact group noted assumptions group challenged uptake assumptions Noted they are based on the supplier application but are likely low Suggested amending uptake to 60% Y1, 80% Y@ and 90% year 3 onwards **(ACTION)**
- Health need – put in more re the suitability of current treatment