AGENDA DIABETES SUBCOMMITTEE OF PTAC

Meeting: 9.00 am – 3:45 pm

11 December 2013

PHARMAC
Level 9
Simpl House
40 Mercer Street
Wellington

9:00am	**Arrival (coffee/tea)**
9.15 am	**Welcome and introductions**
(a)	Declarations of conflicts of interest
(b)	Record of the previous Diabetes Subcommittee meetings
9.45 am	Introduction to Device team
10:00am	Therapeutic group review
11:30 am	**Morning tea (provided)**
11.45 am	Blood glucose meter and strips implementation update
12.30 pm	**Lunch (provided)**
1.00 pm	Insulin pump review
1.30 pm	Insulin pumps for cystic fibrosis
2.00 pm	Insulin pumps and pregnancy
2:30pm	Dapagliflozin for type 2 diabetes
3:00pm	**Afternoon tea (provided)**
3:15pm	Diabetes default dispensing review
3:45 pm	Meeting finish

AGENDA DIABETES SUBCOMMITTEE OF PTAC

Meeting: 9.00 am – 4:30 pm

19 August 2014

PHARMAC
Level 9
Simpl House
40 Mercer Street
Wellington

9:00am	**Arrival (coffee/tea)**
9.15 am	**Welcome and introductions**
(a)	Declarations of conflicts of interest
(b)	Record of the previous Diabetes Subcommittee meetings
9:45 am	Canagliflozin
11:00 am	**Morning tea (provided)**
11.15 am	New Agent review
12.30 pm	**Lunch (provided)**
1.15 pm	Biosimilars discussion
1.45 pm	Insulin pumps workshop on Special Authority
3:00 pm	**Afternoon tea (provided)**
3:15 pm	Insulin pumps continued
4:30 pm	Meeting finish

AGENDA – DIABETES SUBCOMMITTEE OF PTAC

Meeting: 9.00 am 4.15pm

16 April 2015

PHARMAC
Level 9
Simpl House
40 Mercer Street
Wellington

9:00 am **Arrival (coffee/tea)**

9.15 am **Welcome and introductions**

(a) Declarations of conflicts of interest

(b) Record of the previous Diabetes Subcommittee meetings

9. 45 am Therapeutic Group Review (DL=George Laking)

11.00 am **Morning Tea (provided)**

11.15 am Anti-diabetic agents Request for Information (RFI) (DL=Peter Moore)

1.00 pm **Lunch (provided)**

1.30 pm Insujet needleless injection device (DL=Andrea Rooderkerk)

2.30 pm Insulin Pump Panel transition to Special Authority (DL=Nic Crook)

3.30 pm **Afternoon tea (provided)**

3.45 pm Blood Glucose Meters (brief overview of proposed approach to funding)

4.15 pm Meeting finish

DL = Discussion Lead

AGENDA DIABETES SUBCOMMITTEE OF PTAC

Meeting: 9:00 am 2:50 pm

10 October 2016

PHARMAC
Level 9
Simpl House
40 Mercer Street
Wellington

Time	Agenda item	Discussion leader
9:00 am	**Arrival (coffee/tea provided)**	
9:15 am	Welcome and introductions 1. Declarations of conflicts of interest 2 Record of the previous Diabetes Subcommittee meeting	Chair
9:40 am	Factors for Consideration	Lauren B
10:00 am	Therapeutic Group Review	Chair
10:30 am	**Morning tea (provided)**	
10:50 am	Therapeutic Group Review continued	Chair
11:35 am	Matters Arising 1. Insulin needles 2 Antidiabetic agents	
12:35 pm	Diabetes health economics model	
1:05 pm	**Lunch (provided)**	
1:35 pm	Blood glucose meters and strips	
2:35 pm	Any other business	
2:50 pm	**Meeting ends**	

From: Withheld under [mailto:Withheld under section 9(2)]
Sent: Tuesday, September 19, 2017 4:06 PM
To: applications <applications@Pharmac.govt.nz>
Subject: Application to Fund the Abbott Freestyle Libre Interstitial Fluid Glucose Sensor and Reader
Attachments: Interstitial fluid glucose monitor.docx, freestyle libre for glucose monitoring pdf 2285963268047557 pdf

Hi

Attached are the documents I have prepared to support an application to have the Freestyle Libre system funded by Pharmac in NZ

This system is greatly assisting insulin dependent diabetic patients in the European Union, Australia and now NZ to better monitor and control blood glucose levels.

The system has just been approved to be publically funded and available in the UK through the National Health System (NHS). Some European countries are also publically funding the Freestyle Libre

Australia is considering publically funding the system and is currently in a data gathering phase collecting individual patient experiences via a national survey.

There are many insulin dependent diabetics and care givers of insulin dependent diabetics who are hanging out to adopt this technology but can't afford to self-fund. My observation is that this technology is a "game changer" in the diabetes management arena and as such the NZ Health System needs to be on board.

Thankyou

Withhe

Withheld under
Withheld under
Withheld under
Withheld under
Withheld under

Application for changes to the Pharmaceutical Schedule

A guide to help people, clinicians, clinical groups and consumer groups prepare funding applications to PHARMAC

Foreword

PHARMAC is the government agency that decides, on the behalf of District Health Boards, which pharmaceuticals should be publicly fund in New Zealand For more information on the process PHARMAC uses to make its funding decisions and how we determine if a proposal to fund a treatment would help us achieve our Statutory Objective, please visit the PHARMAC website

PHARMAC's objective is "to secure, for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

Each year, PHARMAC receives a large number of applications that contain proposals either to fund new pharmaceuticals or to widen access to pharmaceuticals that we already fund. As PHARMAC must work within a fixed budget, we need to make difficult choices about which applications we should progress to a funding decision at any given time. This involves assessing large amounts of often complex information, to identify those proposals that would provide the best health outcomes.

We have written this funding application form for people, clinicians, clinical groups and consumer groups to use. We recognise that some individuals and groups won't have the same resource as pharmaceutical suppliers to prepare applications. This form is to help you provide the right information in order to progress the application.

This form is a guide you don't have to follow it in detail, or at all, but it will make processing your application much easier and may reduce the time involved If you don't know some information, please feel free to leave those sections blank; however the form does outline the general information that we need to assess a funding application. Having your application address these points may reduce follow-up questions to you, and could speed up how quickly we consider it.

The *Guidelines for Funding Applications to PHARMAC*, updated in 2015, set out the full information that we need to progress any funding application. We expect pharmaceutical suppliers to follow the full *Guidelines for Funding Applications to PHARMAC* when submitting a funding application. However, as an applicant, please feel free to view them should you wish to have more detailed information on submitting an application.

Send your applications to us at:

Email: **applications@pharmac.govt.nz**

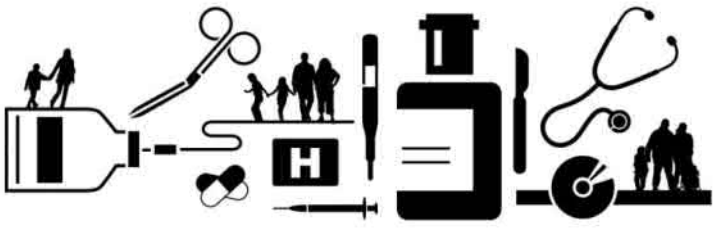
Post: **PO Box 10254**
The Terrace
Wellington 6143

You may also find it beneficial to talk to the relevant Therapeutic Group Manager at PHARMAC before you make a formal funding application. Please email us as above, and we will contact you.

We will keep you informed of progress. We publish and regularly update a record of all current funding applications via the Application Tracker on our website (**www.pharmac.govt.nz**), which details the current status of applications and relevant PTAC and subcommittee minutes.

Please note:

- We need you to supply copies of referenced articles that support the application, wherever possible. Have them referenced in the relevant section of the application form, and clearly say which (if any) cited publications you cannot provide.
- We prefer funding applications related to medicines that have been registered by Medsafe While we can consider funding applications for unregistered medicines or unregistered indications, this is determined on a case–by-case basis
- We may decide to defer our assessment of your application until we receive a full funding application from the supplier, which they would need to prepare in accordance with the full *Guidelines*



PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Changes to the Pharmaceutical Schedule

Application

Applicant

Name

[redacted]

Department & DHB, practice or organisation

Consumer/End User/Patient

Email address

[redacted]

Phone or pager

[redacted]

Are you making this application on behalf of a wider group (department, society, special interest group)? If so, who?

Yes. All insulin dependent diabetics (or caregivers of insulin dependent diabetics) in NZ who want to better manage blood glucose levels to reduce/eliminate diabetic complications

Is there anyone else that we should contact if we have questions about specific parts of this application?

No. I can research any questions raised and provide required answers.

Proposed pharmaceutical

Chemical

Interstitial fluid glucose monitor

Presentations and strengths

14day sensor

Brand name(s)

Abbott Freestyle Libre

Suppliers (eg pharmaceutical companies, wholesalers)

Mediray, 53-55 Paul Matthews Road, Albany, Auckland 0632, New Zealand (See www.freestylelibre.co.nz)

Price

$102.94 (ncluding shipping and GST) $85.16 before shipping and GST

Is it registered by Medsafe?

Yes. As a medical device. Refer Medsafe WAND database.

Describe the indication(s) that funding is being sought for.

Monitoring of blood glucose levels in insulin dependent diabetics

If this pharmaceutical has been registered by Medsafe, is it licenced for these indications? If not, is it licenced for these indications overseas? Please provide details

Yes Licenced in NZ and overseas (Australia and European Union)

How many people in New Zealand do you expect would receive the pharmaceutical?

Initially 5000. This would rise in number as the benefits of the technology to reduce/eliminate diabetic complications were recognised by prescribing medical professionals.

What is the expected dosing?

At a minimum 1 sensor per month Ideally 2 sensors per month to provide the option of continuous monitoring

What is the likely duration of treatment, if patients respond to treatment?

Depends on patient. Some patients (or caregivers of patients) will want to adopt continuous monitoring, others will be happy to use the technology as a means to fine tune blood glucose management and as such may not require sensors on a regular basis.

Describe the setting that this pharmaceutical would be used in. Is the need for this this treatment limited to a hospital setting, or is it also required in the community? If in hospital, is it theatre only, on medical wards, or in outpatient clinics?

Worn by the insulin dependent diabetic in daily life.

If this is a new pharmaceutical, are there likely to be other uses for it?

No not new Has been available in the EU/UK for over 2 years and Australia for nearly a year No other uses than interstitial fluid glucose level monitoring.

Treatment initiation

Is treatment with the pharmaceutical started empirically? If so, please describe the symptoms, signs or other features necessary to initiate therapy

No. Treatment is not dependent on symptoms as the device is a monitor used to indicate glucose levels in the fluid in interstitial tissue.

Are there any specific tests needed to confirm diagnosis? If so, please name these tests, and say whether these are currently performed routinely, where they take place, and whether they are funded.

The standard tests used to make a diagnosis that the patient requires insulin replacement (or insulin addition) therapy to treat Diabetes Miletus

Should other therapies have been used prior to starting treatment with this pharmaceutical? If so, which?

No not necessarily There may be some argument to support a greater need of use in patients with poorly controlled blood glucose levels.

Treatment continuation

How would treatment success be defined or measured?

Some to significant reduction in the 3monthly, 6monthly and yearly Glycosylated Haemoglobin (HBA1C) measurement values and reduction in the frequency, amplitude & duration of postprandial blood glucose peaks in patients

What is the average length of treatment required before determining treatment response?

Depends on the patient. Some patients will be able to use the data from the sensor soon after placement to make immediate improvements to blood glucose management. Others will take longer.

What other interventions would be needed in the event of treatment-related adverse events?

The only adverse reactions to treatment known at this time are discomfort generated (short term pain & minor bleeding) from applying the sensor and allergic epidermal reactions to the adhesive used to secure the sensor. These adverse reaction types only appear to affect a very small number of patients and both can be mitigated relatively easily. Short term pain and bleeding is random and is related to sensor placement. Adverse skin reactions can be averted by applying thin hyper allergenic tape to the skin and then installing the sensor over the top of this tape.

Prescribing and dispensing

Should initiation of this therapy be limited to certain prescriber types? If so, please explain why.

No. As the Abbott Freestyle Libre sensor is a medical device Specialist Medical Doctor, Medical Doctor, Registered Nurse and Phamacist prescriber types should be able to prescribe.

If starting this therapy was limited to certain prescriber types, would it be appropriate for ongoing prescribing to be managed by a wider group of prescribers? If so, who?

Yes. All applicable prescriber types.

Are there any other issues that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or safety issues?

No The manufacturer supplies adequate patient information included with the product packaging in this regard

Health need

Health need

Please include full citation details of supporting evidence (eg randomised controlled trials) and attach copies of any cited publications.

What is the health need of people with the indication(s) for which funding is sought? Please include details of whether reduced life expectancy could be expected or details of potential loss of quality of life including the cause of this loss.

Insulin dependent Diabetes Miletus

Is there an unmet health need in the populations that may potentially receive benefit from this treatment? If so, please explain.

Yes Insufficient data is available from current testing methods (Caresens blood glucose meters) for most insulin dependent diabetics to be able to make informed qualitative management decisions of their blood glucose levels over time

Are there sub-populations within these populations that have a higher health need?

It could be argued that children/adolescents and some non European ethnic communities would have the most to gain. My opinion is that all insulin dependent diabetics that want to take up the technology would significantly benefit

What are the treatments that patients with these indications currently receive, if any? Please describe the dose, duration of treatment, along with the risks and benefits associated with this treatment

Pharmac subsidised blood glucose meter (currently Caresens) once every 5 years and blood glucose test strips (currently Caresens) as needed refreshed at 3 monthly intervals

Are there any issues regarding the availability or suitability of existing treatments for this indication?

Yes. The Caresens meters are proven unreliable and the technology they are based on is at least 20years old now. Freestyle Libre is recent technology (just over 2 years on market). A significant number of insulin dependent diabetics do not finger prick test on a regular basis owing primarily to the difficulties of actually doing the test and of being able to repeatedly do the test pain-free.

Would the pharmaceutical replace or complement these existing treatments? Please explain.

Effectively replace finger prick testing for most insulin dependent diabetics. Finger prick testing using blood glucose test strips would still occasionally be needed. The reason for this is as follows. The Freestyle Libre sensor measures glucose level in interstitial fluid, there is around a 10 -15minute lag in actual blood glucose value. If the blood glucose value is changing rapidly (rising – hyperglycaemia, falling hypoglycaemia) the Freestyle Libre sensor does not effectively track this in real time It does however indicate (by an arrow on the display) that there is a rapid change in blood glucose value. In the event of a rapid rise or a rapid fall the patient can still use the meter and test strips to do a finger prick test to verify the value and then take corrective action if need be. Excepting the limitation of the lag in tracking of rapid changes in blood glucose values, the Freestyle Libre sensor provides a very accurate glucose profile. Information provided is effectively equivalent to doing a finger prick test every 15minutes over the course of 24hrs every day the sensor is active (nominally 14days)

Does this indication disproportionately affect any populations that may already be experiencing a health disparity?

No

Is there an unmet health need in other people due to the indication, such as in people who care for or live with those with the indication, or from spread of disease?

Yes. Caregivers will benefit as they will be able to more effectively monitor the blood glucose levels of those under their care.

Health benefits and risks in the indication(s) for which funding is sought

Please include full citation details of supporting evidence (eg randomised controlled trials) and attach copies of any cited publications.

Discuss the potential benefits from treatment with the pharmaceutical compared with current treatment options (if any).

Ability to see the previous 8 hours of blood glucose values displayed as a continuous line graph on the reader display from one swipe of the reader over the sensor.

Discuss the potential risks from treatment with the pharmaceutical compared with current treatment options (if any).

Not aware of any

Are there sub-populations that have higher potential benefits or risks? If so, please describe

Children and adolescents will most probably benefit the most, although all insulin dependent diabetics have the opportunity to improve control with this technology

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?

Yes. Peace of mind, less mental & physical stress for patients, care givers and whanau.

Health benefits and risks in the indication(s) for which funding is sought

How would funding the pharmaceutical result in other measurable benefits or risks to the health sector, eg changes in number of surgeries, hospitalisations, nursing time, diagnostic tests?

Reduction in blood tests associated with Diabetes Miletus management (i.e. HBA1C) as the software calculates values for the patient.

Allow Medical Professionals to have better conversations with patients regarding interventions needed to better manage Diabetes Miletus

Reduced hospitalisations owing to fewer complications needing hospital level interventions.

Suitability

Please include full citation details of supporting evidence (eg randomised controlled trials) and attach copies of any cited publications

Are there any features of the treatment that may impact on its use (eg method of delivery, size, shape, taste)? If so, please explain.

Please see attached PDF "freestyle-libre-for-glucose-monitoring-pdf-2285963268047557.pdf" generated by the National Institute for Health & Care Excellence (NICE) in the United Kingdom.

Costs and savings

Please include full citation details of supporting evidence (eg randomised controlled trials) and attach copies of any cited publications

Would the funding of this treatment create any costs or savings to the health system (eg would treatment require increased monitoring, or would it free up clinician time)?

Yes. Significant savings in the cost of treatment directly related to Diabetes Miletus complications in the Public and Private Health Systems in NZ While there is data available yet in NZ (the Freestyle Libre soluiton has only been on the market in NZ for a few months) to support evidence that use of the Freestyle Libre system results in lower HBA1C scores, anecdotal evidence from overseas use indicates that it does. There is significant evidence worldwide that patients who maintain low HBA1C scores are a reduced cost on the health system. In addition reduced HBA1C scores relate directly to improved quality of life (i.e. less complications) for patients who manage to achieve this.

A number of patients report using less insulin and significantly less test strips once starting on the Freestyle Libre system i e while there is a cost to adopting the Abbott Freestle Libre system in having to purchase the reader and sensors, this can be offset to some extent by the cost savings generated from needing less insulin and less test strips.

As the sensor and associated reader provides a glucose profile over 8 hours in the form of an easy to view and interpret graph on the reader display, the patient can perform self-monitoring and make interventions in the treatment of blood glucose levels as needed The sensor takes a reading every minute and stores 8 hours of data broken down into 15minute time slots. The reader will download this data from the sensor. Using a personal computer application the patient can upload 24hours of data from the reader to a laptop or desktop device. The application can be used to generate graphs and statistics that can be shared with Medical Professionals. This gives Medical Professionals the opportunity to review and analyse significantly more data than is available from manual finger prick records maintained by the patient or by blood glucose test meter downloads

Please see attached PDF "freestyle-libre-for-glucose-monitoring-pdf-2285963268047557.pdf" generated by the National Institute for Health & Care Excellence (NICE) in the United Kingdom.

The NICE document referenced above includes reference to a number of peer reviewed studies and references a number of ongoing studies. Some of the documents referenced are:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4649725/ "The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System"

https://www.ncbi.nlm.nih.gov/pubmed/27634581 "Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial."

https://www ncbi nlm nih gov/pubmed/28137708 "An alternative sensor based method for glucose monitoring in children and young people with diabetes "

https://www.ncbi.nlm.nih.gov/pubmed/28401454 "Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes."

From: April-Mae Marshall **On Behalf Of** applications
Sent: Wednesday, 20 September 2017 3:50 pm
To: '[redacted]' <[redacted]>
Subject: RE: Application to Fund the Abbott Freestyle Libre Interstitial Fluid Glucose Sensor and Reader

Dear [redacted]

Thank you for the funding application for Interstitial fluid glucose monitor from Abbott Freestyle Libre for treatment of diabetes we are pleased to have the opportunity to consider this product for funding

We will look to include this application on the next Pharmacology and Therapeutics Advisory Committee (PTAC) agenda or the next meeting of the Diabetes Subcommittee of PTAC. We will be in touch once PHARMAC staff have reviewed the application.

Regards
April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt nz

From: Nobes, Michael S [mailto: Withheld under section 9(2)(a)]
Sent: 31 January 2018 14:03
To: Danae Staples-Moon < Withheld under section 9(2)(a) >
Cc: Chalikias, Peter < Withheld under section 9(2)(a) >; Alexander Rodgers < Withheld under section 9(2)(a) >
Subject: Abbott Diabetes Care PTAC Application for FreeStyle Libre

Dear Danae,

As discussed at our meeting last year on the 9th of November, I'd like to confirm that we'll be submitting a PTAC application for FreeStyle Libre

The application will be sent on Friday 2nd of February to arrive at PHARMAC on Monday the 5th of February as originally promised.

In addition, the PTAC Secretary will be sent two New Zealand spec samples of the FreeStyle Libre glucose monitoring system (both sensor and reader kits) as a separate delivery from our current NZ distributor, Mediray

To assist with the evaluation, I'll send a FreeStyle Libre demonstration kit (identical to the one we featured at our November meeting) from our Melbourne office to the PTAC Secretary as another separate delivery.

We look forward to working with you to progress the application for FreeStyle Libre funding on the Pharmaceutical Schedule

Kind regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under Withheld under section 9(2)

From: Danae Staples-Moon
Sent: Wednesday, 31 January 2018 2:47 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>; Alexander Rodgers <Withheld under section 9(2)(a)>
Subject: RE: Abbott Diabetes Care PTAC Application for FreeStyle Libre

Dear Michael,

Thanks for the update regarding submitting a funding application for the May PTAC deadline and other deliveries to expect I can confirm that the samples from Mediray were received today The PTAC secretary will be able to confirm receipt of your submission and other delivery once received.

Kind regard
Danae

Danae Staples-Moon | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

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

PTAC Secretary
PHARMAC
Level 9
40 Mercer Street
WELLINGTON 6011
NEW ZEALAND

2nd February 2018

Dear PTAC Secretary,

Please find attached the submission for FreeStyle Libre on behalf of Abbott Laboratories NZ Limited (trading as Abbott Diabetes Care).

In accordance with your guidelines, please find attached three copies of the submission separated into three volumes as discussed with April-Mae Marshall, within the PTAC Secretary Office. The three volumes are –

- Synopsis of the Submission
- Complete Submission
- Attachments requiring printing

Also included is a USB containing one electronic version of the submission including the above volumes and the additional attachments, endnote files, checklists and WAND information.

If you have any questions regarding the above, please do not hesitate to contact either Withheld under section 9(2)(ba)(i) on Withheld under section 9(2)(a) (email – Withheld under section 9(2)(a)) or Michael Nobes from Abbott Diabetes Care on Withheld under section 9(2)(a) (email – Withheld under section 9(2)(a))

Yours sincerely,

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

From: April-Mae Marshall
Sent: Monday, 5 February 2018 1:59 pm
To: '[redacted]' <[redacted]>
Subject: Freestyle Libre Application

Dear [redacted]

Thank you for submitting the funding application for FreeStyle Libre

We are pleased to have the opportunity to consider this product for funding.

We will consider this application for inclusion on the agenda for the May 2018 PTAC meeting and will confirm this closer to the time

Regards
April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

20 February 2018

Withheld under section 9(2)(a)(ii)
Withheld under section 9(2)(a)(ii)

via email: Withheld under section 9(2)(a)

Dear Withheld under

Funding Application FreeStyle Libre

Thank you for the funding applications for FreeStyle Libre glucose monitoring system. We are pleased to have the opportunity to consider this product for funding for treatment of type 1 diabetes.

PHARMAC staff have reviewed the application with reference to the Guidelines for Funding Applications to PHARMAC and are planning to initially seek clinical advice Diabetes Subcommittee at their next meeting We will keep you informed regarding the application's progress.

We would like to give you the opportunity to make a presentation of your application to PHARMAC staff. Danae Staples Moon is the therapeutic group manager responsible for the diabetes therapeutic group Danae can be reached at Withheld under section 9(2)(a) or by emailing Withheld under section 9(2)(a).

We look forward to evaluating your application and providing you with the record of the Subcommittee's recommendations to PHARMAC.

Yours sincerely

April-Mae Marshall

April Mae Marshall
PTAC Secretary

CC: Michael Nobes, Market Access Director, Abbott Laboratories NZ Limited (trading as Abbott Diabetes Care) , Withheld under section 9(2)(a)

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Tuesday, 13 March 2018 4:33 pm
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Subject: [SPAM]? Offer by PHARMAC for Abbott Diabetes Care to present on the FreeStyle Libre submission

Dear Danae,

Thank you for PHARMAC's correspondence, dated 20 February 2018, offering Abbott Diabetes Care to present on the FreeStyle Libre application.

As outlined in my phone message, I'd like to touch base with you regarding the logistics for the presentation

An understanding of potential dates, audience and format would be helpful for planning purposes.

I look forward to connecting with you on this matter and seeing you again to discuss FreeStyle Libre

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

The information contained in this communication is confidential, may be subject to legal privileges, may constitute inside information, and is intended only for the use of the addressee. It is the property of Abbott Laboratories or its relevant affiliate. Unauthorized use, disclosure or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify Abbott Laboratories immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.

From: Withheld under section 9(2)(a)
Sent: Thursday, April 5, 2018 7:50 AM
To: Diabetes Feedback <diabetesfeedback@pharmac.govt.nz>
Subject: CGM use could improve HbA1c and reduce distress in adolescents with type 1 diabetes

https://www.diabetes.co.uk/news/2018/apr/cgm-use-could-improve-hba1c-and-reduce-distress-in-adolescents-with-type_1_diabetes_98217280.html?utm_source=Communicator&utm_medium=Email&utm_content=Untitled22&utm_campaign=Poor+outcomes+spark+urges+for+NHS+foot+care+improvement&utm_dispatch%20ID=6825252&utm_email%20name=DCUK+NL+-+03%2f04%2f18

As a parent of a now [redacted] year old with type 1 and depression, please consider this article in the light of the current application for funding of the libre freestyle blood glucose scanning technology.

Kind regards, [redacted]

From: Nobes, Michael S [mailto: [redacted]]
Sent: 26 April 2018 13:26
To: Danae Staples-Moon <[redacted]>
Cc: Prakash, Deepak <[redacted]>; Chalikias, Peter <[redacted]>
Subject: [SPAM]? Request for a progress update on the Diabetes Subcommittee meeting date

Dear Danae,

With respect to our February funding application for FreeStyle Libre, can you please provide an update on whether our application will be reviewed by the Diabetes Subcommittee and, if so, what the meeting date will be?

Also, can you please confirm when applications are added to the PHARMAC application tracker website since FreeStyle Libre is yet to appear on this list as a 'received application' even though the page was updated on 21 March 2018.

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: [redacted]
F: +61 3 9855-8020
M: [redacted]

The information contained in this communication is confidential, may be subject to legal privileges, may constitute inside information, and is intended only for the use of the addressee. It is the property of Abbott Laboratories or its relevant affiliate. Unauthorized use, disclosure or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify Abbott Laboratories immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.

From: Danae Staples Moon
Sent: Tuesday, 1 May 2018 12:12 pm
To: 'Nobes, Michael S' <[redacted]>
Cc: Prakash, Deepak <[redacted]>; Chalikias, Peter <[redacted]>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

Thanks for your email. Yes, I can confirm that the intention is for advice to be sought in the first instance from the Diabetes Subcommittee. While a date has yet to be set, we are currently considering the optimal time for this to be scheduled and I am expecting this will likely be before the end of the year. I will let you know once a date and agenda has been confirmed.

I have updated the Application tracker so it should now show receipt of your application. Apologies for the delay in this happening.

Kind regards
Danae

Danae Staples-Moon | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S [mailto: Withheld under section 9(2)(a)]
Sent: 08 June 2018 17:57
To: Danae Staples Moon < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date
Importance: High

Hi Danae,

Is there any clarity on a date for the Diabetes Subcommittee yet to consider the FreeStyle Libre application – even if Q3 or Q4 2018?

Any update would be useful since we're getting many queries from the public about the anticipated PHARMAC process and timing.

Cheers,
Michael

Abbott
Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Danae Staples-Moon
Sent: Monday, 11 June 2018 8:14 am

To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>; Brockwell, Glenn <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Apologies for not having replied before now. There is not yet a confirmed date. We are currently considering dates in Q4 however, as there are a number of factors that go into determining meeting dates we may need to consider alternative timings.

Kind regards
Danae

Danae Staples-Moon | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S [mailto:Withheld under section 9(2)(a)]
Sent: 12 June 2018 16:30
To: Danae Staples Moon <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>; Brockwell, Glenn <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thanks for the update, Danae.

Is PHARMAC conducting or planning to conduct any HTA or product evaluations on FreeStyle Libre in the lead up to a future subcommittee meeting?

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under Withheld under section 9(2)

From: Danae Staples Moon
Sent: Friday, 15 June 2018 3:22 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter

< Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

There may be some HTA work done in order to provide information for clinical advisors However, generally HTA work is undertaken once clinical advice has been received so that the advice can be incorporated into our analysis.

Kind regards
Danae

Danae Staples-Moon | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S
Sent: Tuesday, 7 August 2018 3:14 PM
To: Danae Staples-Moon < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

Has there been any movement with regards to the Diabetes Subcommittee meeting date?

On another related query, how far in advance do the Diabetes Subcommittee members receive the FreeStyle Libre application?

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: Nobes, Michael S < Withheld under section 9(2)(a) >
Sent: 21 September 2018 17:32
To: Danae Staples Moon < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >

Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date
Importance: High

Hi Danae,

Is a Diabetes Subcommittee meeting still anticipated by year end as previously communicated?

If not, is there another timeframe or date?

On another related query, how far in advance do the Diabetes Subcommittee members receive the FreeStyle Libre application?

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Danae Staples-Moon
Sent: Monday, 24 September 2018 9:00 am
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

At this stage it is unlikely that a Diabetes Subcommittee meeting will be held before the end of the year. I am currently looking at dates in Q1 next year and will let you know once a date has been confirmed.

Generally, the material for consideration at a meeting (including the applications) is sent about a month in advance to members for their consideration.

Kind regards
Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: 18 February 2019 18:57
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date
Importance: High

Dear Danae,

Based on your last email in September 2018, a Diabetes Subcommittee meeting was anticipated for Q1 2019

Is this still the timeframe?

We are deeply concerned about the lack of any progress given that the FreeStyle Libre application was now submitted over 12 months ago (on 5th of February 2018)

On this note, the current application tracker only notes that the application was received in Feb '18 rather than also stating that advice is being sought from a sub committee (i.e. "Referred to Committee")

We have received numerous queries from people living with diabetes and HCPs specifically on the progress of the application and why Pharmac has not yet reviewed it.

We trust that our application will be given a level of priority commensurate with the high clinical unmet needs in the New Zealand type 1 population that can be addressed by the FreeStyle Libre system

Regards,
Michael

Abbott
Michael Nobes, Ph.D.
Market Access Director
ANZ
Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia
O: Withheld under
F: +61 3 9855 8020
M: Withheld under Withheld under section 9(2)

From: Danae Staples Moon
Sent: Tuesday, 19 February 2019 3:48 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Thanks for your email. I can confirm that the Diabetes Subcommittee is meeting in March 2019 and the funding of Freestyle Libre will be considered at this meeting. I have also updated the App Tracker to reflect that the application has been referred to the subcommittee for advice.

Kind regards
Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Tuesday, 19 February 2019 4:03 pm
To: Danae Staples Moon <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date
Attachments: 2018-02-20 Freestyle Libre Supplier May PTAC.PDF

Thank you, Danae.

That is good news.

Has a specific date been set for the March meeting?

PHARMAC has previously offered Abbott the opportunity to make a presentation of our application to PHARMAC staff, as attached.

As such, we'd suggest that this presentation be best scheduled prior to the Diabetes subcommittee meeting and time may be short if early March.

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under Withheld under section 9(2)

From: Danae Staples-Moon
Sent: Wednesday, 27 February 2019 4:02 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

Yes, the meeting will be on March 19 and I agree it would be best for your presentation to occur prior to the Subcommittee meeting. Therefore, would need to look at a date either next week or in the week starting the 11th?
Let me know if there is a date/time that would suit you and I will see what fits in diaries.

Kind regards
Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: 27 February 2019 17:45
To: Danae Staples Moon <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thank you, Danae

Can you please advise on available dates for Wed 13th or Thur 14th?

The preference would be morning or early afternoon.

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Danae Staples-Moon [mailto: Withheld under section 9(2)(a)]
Sent: Wednesday, 27 February 2019 4:27 PM
To: Nobes, Michael S < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Wednesday 1.30pm 2.30
Thursday – 9am-10, 1pm-2 or 2-3pm

Hopefully one of these is suitable, if not let me know alternatives.

Kind regards
Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S
Sent: Friday, 1 March 2019 1:41 PM
To: 'Danae Staples Moon' < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

Please book us in for Wednesday 13th 1.30pm-2.30pm.

We look forward to presenting FreeStyle Libre evidence base and a productive discussion.

Cheers,
Michael

Abbott
Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: 01 March 2019 16:32
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

We've just booked flights – the only option is a 3:50pm departure for Melbourne.

Is there any possibility to start earlier on Wednesday?

If not, we'll need to ensure a stop at or close to 2:30pm just in case

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Danae Staples Moon [mailto:Withheld under section 9(2)(a)]
Sent: Monday, 4 March 2019 6:36 AM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Our diaries are pretty tight that day However, I think that we could juggle things to start at 1pm but would need to finish up at 2pm. One hour should be sufficient time to cover the key points and this would give you a bit more breathing space to make the flight.

Kind regards
Danae

Danae Staples-Moon | Senior Therapeutic Group Manager
PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Monday, 4 March 2019 10:45 am
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>; Mitchell, Melissa <melissa.mitchell@abbott.com>
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thanks Danae,

That would be perfect and we'll ensure a 2pm hard stop.

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under Withheld under section 9(2)

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Friday, 15 March 2019 10:31 pm
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: Requested information for FreeStyle Libre #1
Attachments: Withheld under section 9(2)(ba)(i)
Withheld under section 9(2)(ba)(i)
Withheld under

Dear Danae,

Please find attached the requested information on the Withheld under section 9(2)(ba)(i)
Withheld under section since the FreeStyle Libre application was lodged

Also attached is the Withheld under section 9(2)(ba)(i)
Withheld under section 9(2)(ba)(i)

I will also send all of the Withheld under section 9(2)(ba)(i) as a 2nd email

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Friday, 15 March 2019 10:35 pm
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: Requested information for FreeStyle Libre #2
Attachments: Withheld under section 9(2)(ba)(i)

Dear Danae,

As promised, I've attached the Withheld under section 9(2)(ba)(i).

Please reach out with any queries you may have.

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under Withheld under section 9(2)

The information contained in this communication is confidential, may be subject to legal privileges, may constitute inside information, and is intended only for the use of the addressee. It is the property of Abbott Laboratories or its relevant affiliate. Unauthorized use, disclosure or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify Abbott Laboratories immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.

AGENDA
DIABETES SUBCOMMITTEE OF PTAC

Tuesday 19 March 2019
9.00 am – 3.30 pm

PHARMAC, Tait Room, Level 9,
40 Mercer Street, Wellington

Time	Agenda item	Discussion leader
9:00 am	**Arrival (coffee/tea provided)**	
9.05 am	Welcome and introductions	Chair
9.10 am	Declarations of conflicts of interest	Chair /All
9 15 am	Action points	Chair /All
9.20 am	Minutes review • Record of the previous Diabetes Subcommittee meeting, 10 October 2016 • Review of relevant diabetes minutes from PTAC since previous Diabetes Subcommittee meeting	Chair /All
9:35 am	Correspondence and Matters Arising • Letter from NZSSD • Insulin priming • Insulin glargine long acting (Toujeo)	Chair /All
9 45 am	1. Therapeutic Group Review	Chair /All
10.30 am	**Morning tea (provided)**	
11.00 am	Therapeutic Group Review continued	Chair /All
12.00 pm	**Lunch (provided)**	
12.30 pm	CGM and FGM technology overview and Freestyle Libre Flash Glucose Monitoring application	Main: Nic Crook 2nd: Esko Wiltshire (paediatric view)
1 15 pm	Antidiabetic Agents Discussion including updated data for cardiovascular benefit and access criteria discussion	Bruce Small
2 00 pm	**Afternoon tea (provided)**	
2.30 pm	Glucose solution (Hypopak)	Helen Lunt
3.15 pm	Any other business	Chair /All
3 30 pm	**Meeting ends**	

From: Withheld under section 9(2)(a)
Sent: Monday, 1 April 2019 11:48 AM
To: applications <applications@Pharmac.govt.nz>
Subject: Application for funding of Freestyle Libreville and Dexcom CGM

To whom it may concern

Please refer to the relevant Pharmac Application Manager.

I would like to make a consumer funding application for both devices listed above.

I understand there has been a pharmaceutical and clinician application made in respect of the Freestyle Libre CGM is this on the programme for discussion at the forthcoming (23/24 May) PTAC meeting?

I would like to lodge a funding application for both
Can you advise what information you require given there is already an application under consideration for the Freestyle Libre?

Sincerely,

Withheld under section
Withheld under

Sent from Yahoo Mail on Android

On Fri, Apr 12, 2019 at 12:00, Elena Saunders
<Withheld under section 9(2)(a)> wrote:
Dear Withheld,

Thanks for getting in touch with PHARMAC

As you are aware, we have received a funding application from the supplier of the Freestyle Libre Flash Glucose Monitoring System and this was considered by the Diabetes Subcommittee of PTAC at its March meeting. We have recorded your email as being in support to the supplier application.

With regards to the Dexcom G5 CGM system, we are in discussions with a number of suppliers to ensure we have the right information to support consideration of CGM systems more broadly CGM technology more generally was also reviewed by the Diabetes Subcommittee at its March meeting. Dexcom is one of the devices that was noted as part of this review. Again, we have recorded your email in support of the information we have received from the supplier of Dexcom.

The record of the Diabetes Subcommittee meeting will be made publicly available once it is finalised, this will likely be in early May. You will be able to find the record of the clinical advice we received

and keep track of the applications progress here. I am happy to notify you directly once it has been published if you would like?

In general, if you did wish to submit a formal funding application then the form outlining the information required is available on the PHARMAC website here. Please note that the information provided by the supplier includes a detailed summary of the product and available evidence, so I would encourage you to instead provide a letter or email regarding the product(s) you are interested in seeing funded by PHARMAC if you do wish to provide a submission in support of Freestyle and/or Dexcom. If you send it through to me then I would be more than happy to add it in further support to the information we have received from the relevant supplier.

Please let me know if I can provide you any further clarity.

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Withheld under section 9(2)(a)
Sent: Friday, 12 April 2019 12:09 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: Application for funding of Freestyle Libreville and Dexcom CGM

Dear Elena,

Thank you for your reply. I would appreciate if you could let me know when the information becomes publicly available. I'll endeavor to keep up with the link you posted also.

I look forward to a positive outcome.

Sincerely,
Withheld under section

Sent from Yahoo Mail on Android

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Wednesday, 3 April 2019 7:07 pm
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Chalikias, Peter <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: Requested information for FreeStyle Libre #2
Attachments: Withheld under section 9(2)(ba)(i)
Withheld under section 9(2)(ba)(i)
Importance: High

Dear Danae,

As previously discussed, we have provided relevant articles recently published and further real world data, including for New Zealand, for your and PTAC's interest

Please let me know if you require the Withheld under and this information in one consolidated package or have any questions

Also, could you please let us know whether there is any correspondence or outcomes from the Diabetes Sub Committee meeting held on the 19th of March and whether our application will be considered at the 23rd 24th of May PTAC meeting

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Wednesday, 10 April 2019 11:47 am
To: Danae Staples-Moon <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: Requested information for FreeStyle Libre #2

Dear Danae,

I wanted to touch base to confirm that you received my email on the 3rd of April with relevant articles recently published and further real-world data, including for New Zealand.

Also, could you please let us know whether there is any correspondence or outcomes from the Diabetes Sub Committee meeting held on the 19th of March and whether our application will be considered at the 23rd 24th of May PTAC meeting.

If you have already handed over diabetes responsibilities, it would be great to know Eleanor's contact details.

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

Original Message
From: April-Mae Marshall [mailto:Withheld under section 9(2)(a)]
Sent: Wednesday, 1 May 2019 8:36 AM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Subject: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Michael

Please see the attached in regards to the funding application for FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes advisory committee review

Regards
April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www pharmac govt nz

-----Original Message-----
From: Nobes, Michael S <[redacted]>
Sent: Wednesday, 1 May 2019 2:27 PM
To: Elena Saunders <[redacted]>
Cc: April-Mae Marshall <[redacted]>; Prakash, Deepak <[redacted]>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Elena,

Thank you for provision of the 19 March 2019 PTAC Diabetes Subcommittee Minutes

As outlined in my phone message, I'm hoping to clarify 2 aspects

First, in the PTAC Diabetes Subcommittee Minutes, Pharmac indicates in 'Application Status' that the Minutes will be reviewed by PTAC at its May 2019 meeting

Is this the current status, given that in your last email to me dated 18 April, you mentioned "we have not been successful in getting the item on the agenda for the May PTAC meeting"?

Second, do you have an indicative date for when the PTAC Diabetes Subcommittee Minutes will be posted on the Pharmac website?

Kind regards,
Michael

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O:
Withheld under
F:
+61 3 9855 8020
M:
Withheld under
Withheld under section 9(2)(a)

Original Message
From: Elena Saunders
Sent: Wednesday, 1 May 2019 3:12 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: April-Mae Marshall <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Further to our call just now, confirming the Diabetes Subcommittee minutes are now scheduled to be considered by PTAC at its May meeting. This supersedes the information I provided previously.

We hope to have the minutes posted on the PHARMAC website early next week

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 |
www.pharmac.govt.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Friday, 3 May 2019 5:29 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: April Mae Marshall <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)
Importance: High

Dear Elena,

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

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

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

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

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

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

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

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

If possible, could you please revert with the expected date for publication of the Minutes on the PHARMAC website.

Also, could you please update your filing nomenclature and contact details to reflect Abbott Diabetes Care as the business for ongoing reference to FreeStyle Libre rather than Abbott Diagnostics, since these are separate business units within the global Abbott Laboratories company

Regards,
Michael

Abbott
Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: April-Mae Marshall
Sent: Monday, 6 May 2019 2:23 pm
To: ' Withheld under section 9(2)(a) ' < Withheld under section 9(2)(a) >
Cc: Elena Saunders < Withheld under section 9(2)(a) >; ' Withheld under section 9(2)(a) ' < Withheld under section 9(2)(a) >; ' Withheld under section 9(2)(a) ' < Withheld under section 9(2)(a) >
Subject: RE: 2019-05-01 Abbott Diagnostics (Abbott Diabetes Care) Diabetes March 2019 Minutes (A1261282)

Dear Michael

Thank you for your response to our email regarding the Diabetes Subcommittee March 2019 Minutes.

As we noted in our letter of 1 May, we provided these minutes in order for you to advise us of any specific content that you felt should be withheld from publication. As also noted, in deciding whether to withhold any sections of this minute from public release, we follow the rules for withholding information specified in the Official Information Act 1982 (OIA).

Minutes are a reflection of what is discussed at a meeting by our members and are approved by the Chair as a record of the meeting, and as such it is not possible to amend them.

After considering Abbott's requests and discussing these with our legal advisors we have concluded that there are no grounds to withhold relevant sections under the OIA.

As we mentioned in our letter, your comments in relation to the public release of this minute do not prevent you from commenting on it or providing further information for consideration by PHARMAC at a later date.

We will notify you once the minute is published.

We have noted the change from Abbott Diagnostics to Abbott Diabetes Care for further communications.

Kind regards
April Mae Marshall

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Monday, 13 May 2019 12:14 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: April-Mae Marshall <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

Can I please confirm that the Diabetes Subcommittee minutes are still scheduled to be considered by PTAC at its May meeting?

I've noted the posted agenda below and assume this is only the list of applications rather than other agenda items such as consideration of subcommittee minutes

Applications

The **May 2019** PTAC meeting will review the applications below. Note this is draft and subject to change:

- **Buprenorphine transdermal patches** (persistent moderate/severe pain)
- **CDK4/6 inhibitors** (HR positive HER-2 negative advanced breast cancer 1st & 2nd endocrine agent)
- **Everolimus** (HR positive, HER-2 negative advanced breast cancer)
- **Nab-Paclitaxel** (metastatic breast cancer)
- **Capsaicin Cream** 0.075% (cannabinoid hyperemesis syndrome)
- **Baclofen oral solution** (muscle relaxant)
- **Prucalopride succinate** (chronic constipation)
- **Methylnaltrexone, subcutaneous injection** (Opioid-induced constipation in patients - outside of palliative care)
- **Glycomacropeptide** (PKU phenylketonuria)
- **Fluticasone foroate**/umeclidinium/vilanterol (COPD)
- **Fomepizole** (Methanol and ethylene glycol poisoning)

Regards,
Michael

Michael Nobes, Ph D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O:
Withheld under
F:
+61 3 9855-8020
M:
Withheld under
Withheld under section 9(2)(a)

From: Elena Saunders
Sent: Monday, 13 May 2019 12:18 pm
To: 'Nobes, Michael S' <Withheld under section 9(2)(a)>
Cc: April-Mae Marshall <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Yes, your understanding is correct. The Subcommittee minutes will be considered by PTAC at its May meeting.

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Monday, 27 May 2019 3:10 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: April-Mae Marshall <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

Can you advise when we'll be informed of last week's PTAC meeting outcome?

Is this provided to sponsors prior to circulation of meeting minutes?

Many thanks for your guidance on this matter

Kind regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: April Mae Marshall <Withheld under section 9(2)(a)>
Sent: Monday, 27 May 2019 2:26 PM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Cc: Elena Saunders <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael

We do not usually share the PTAC record in regards subcommittee meeting recommendation discussions prior to publication. This would only be done if the record of the PTAC meeting held commercially sensitive information that required an applicant consideration. Once the PTAC minute is written we will consider if this is necessary.

Letters to applicants will be sent out the end of July with publication of the minutes scheduled for 16 August 2019.

Kind regards
April-Mae Marshall

April Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Monday, 27 May 2019 4:31 pm
To: April-Mae Marshall <Withheld under section 9(2)(a)>
Cc: Elena Saunders <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Thank you, April Mae

We'll look forward to the letter end of July.

Cheers,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: April Mae Marshall <Withheld under section 9(2)(a)>
Sent: Thursday, 1 August 2019 1:55 PM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Cc: Elena Saunders <Withheld under section 9(2)(a)>; Prakash, Deepak <Withheld under section 9(2)(a)>; Chalikias, Peter <Withheld under section 9(2)(a)>
Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Michael

Please note the May 2019 PTAC record of the meeting (minutes) has been published. It can be seen @ https://www.pharmac.govt.nz/assets/ptac-minutes-2019-05.pdf.

Kind regards
April Mae

April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Thursday, 29 August 2019 4:09 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

I wanted to reach out to you to understand the next steps for review of FreeStyle Libre given the PTAC minutes regarding the Diabetes Subcommittee advice

"The Committee considered that PTAC and its Subcommittee's may not have the technical expertise to appropriately assess these devices and recommended that PHARMAC consider aligning its assessment of community devices such as continuous glucose monitoring technology and insulin pumps with the assessment framework currently being developed for hospital devices, particularly to ensure patient safety, usability, lifespan and technology upgrades were appropriately considered and managed."

Kind regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under
Withheld under section 9(2)

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Thursday, 29 August 2019 3:03 PM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Thanks for getting in touch.

We're evaluating options at the moment, so I can't give any guarantees. At this point the next stage in the process would be for the system to be ranked alongside the other options we have for investment within our fixed combined pharmaceutical budget (CPB). I am also looking at the possibility of seeking specialist advice in addition to that which we have received from PTAC and its Subcommittee to address some of the points noted below. If we do proceed with that approach I will let you know

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

PHARMAC Funding Application
10 October 2019

Chemical Name: Freestyle Libre Flash Monitoring System

Indication: For ALL Type 1 diabetics as an alternative option to funding test strips for finger prick testing.

Contents Page

Product Overview

Product Details

What type of request is the subject of this application?
New medical device for use in the community

If other, please specify

Have any sample(s) of the pharmaceutical been sent to Pharmac?

If a sample has been sent, please provide information that could help us to manage the sample.

Please attach suitable artwork and photographs of the packaging, product and product labelling in pdf or jpeg format

Pharmacological Information

What is the registered name of pharmaceutical?
Freestyle Libre Flash Monitoring System

What is the brand name(s) of the pharmaceutical?

Describe the principal pharmacological action of the pharmaceutical

What is the main goal of the treatment?

Please select the appropriate portfolio Therapeutic Group for this application
a162P000000FGx3QAG

Please select the appropriate portfolio Therapeutic Sub-Group for this application

Provide stability data for infusion treatments (if relevant)

Proposed Amendments to Schedule

Please provide details on the proposed indications for listing
For ALL Type 1 diabetics as an alternative option to funding test strips for finger prick testing

What setting will the product be used?

Where is the product likely to be used?

If other, please specify

Please provide a summary statement of the main therapeutic claims for the pharmaceutical and its proposed use

Dose

What recommended course of treatment including dose regimen is likely to be used in NZ clinical practice for each of the indications proposed for listing?

Were the dosage regimens used in the pivotal trials different from the dosage regimen likely to be used in NZ clinical practice? If so please provide details

Do you have any post marketing data on doseage in clincial practice? If so please provide details

Regulatory Status of The Product

Is the pharmaceutical registered by Medsafe for all indications for which funding is sought?

Please attach Medsafe-approved datasheets if the pharmaceutical is registered.

If registration of the pharmaceutical has been sought but is yet to be granted, please provide details

If the pharmaceutical is registered by Medsafe please provide details of the registered indications

Are other formulations of the product registered for use in NZ?

Pharmaceutical registered for indications overseas?

Provide names of OECD countries where registration has been approved or declined, including any box warnings that may apply

Provide details of other presentations or formulations of the pharmaceutical that have been submitted for approval, or are already approved, in other OECD countries

If the Medsafe registration document is unavailable, please attach copies of relevant Food and Drug Aministration (FDA) and/or European Mediciness Agency (EMA) assessment (note that these reports only need to be attached for unregistrered pharmaceuticals)

Patent Information

Patent information

If you are not the Patent Owner, do you have the right to sell or distribute the pharmaceutical in New Zealand?

If no, please provide further information

If you or the patent owner do not reside or have a place of business within New Zealand, please provide the name of your representative or the representative of the patent owner who resides or maintains a place of business in New Zealand and who is authorised to receive notices related to the patent

Pharmacological Information Table

Pharmaceutical form	If other, please specify	Pharmaceutical strength	Pack size
Other	Sensor		1 sensor

Product Overview Dose Measure of Treatment Table

What is the average duration of treatment (number)	What is the average duration of treatment (period)

Patent Information Table

Patent Number	Patent Expiry date	Type of Patent	If other please specify	Who is the Patent Owner?

Product Overview_Code Type Table

Identification code	Please specify the code value

Health Need

Patient Population

Who is the target population?
Type 1 Diabetics (approximately 25,000 NZers)

How many in NZ have the condition(s)? For each of the indications requested for consideration of funding, please provide estimates of the number of people in New Zealand who have the indication, the number of Māori people in New Zealand with the particular condition(s) and the number of Pacific people in New Zealand with the particular condition(s).

For each requested indication(s), please provide estimates of the morbidity associated with the condition (eg. annual number of hospitalisations).

Epidemiology Summary

Please attach the relevant tables

Disease and Its Impact

Please provide an overview of the disease or condition to be treated by the proposed pharmaceutical
Approximately 25,000 New Zealanders are diagnosed with Type 1 diabetes. Once diagnosed, they then have an ongoing burden to test their blood sugars before and after every meal, exercise and sleep for the rest of their lives. On top of this burden, they live with the fear of hypoglycemia which if not treated quickly can result in a coma, even death At the other end of the scale, if blood sugars

regularly run too high, they face the further burden of long term complications of the disease, which is also a burden on the public health system Finger prick tests are uncomfortable and very limited in the information that they provide, being just a snap shot of exactly what your blood sugar is at that given moment

Please provide details on the severity of symptoms experienced by the average patient

Does this disease or condition have an impact on patient health-related quality of life? If so, please provide details on areas of health-related quality of life that are likely to be impacted and severity

If possible, please provide information on the total undiscounted quality-adjusted life year (QALY) loss associated with the disease (i.e. QALY of patients with the disease compared with the QALY of the same age specific population in perfect health)

Please provide the source of information

Does the disease or condition impact on the health of family, whanau and/or wider society? Please explain
Type 1 diabetes requires constant attention. Finger prick testing before and after each meal, before and after exercise, before bed and during the night This relentless monitoring can and does frequently lead to emotional and physical overwhelm, giving a type 1 diabetic less time and energy to spend on caring for and spending quality time with family and others

Does the disease or condition impact on Maori health areas of focus and Maori health outcomes? Please explain

Does this indication disproportionately affect any populations that may already be experiencing a health disparities?

Is the disease or condition a Government health priority

If yes please indicate the disease or condition that is the priority

Current Treatment

What treatment(s) is currently used for this indication in New Zealand? Describe the current treatment algorithm of the target population

What sources of evidence were used to inform the current treatment algorithm?

How well do the current treatments work? Are there any associated risks or tolerability issues with the current treatments?

What is the recommended dose of current treatment(s) and dose equvalencies between current treatment and the proposed pharmaceutical?

What is the shelf life of the current treatment compared with the proposed pharmaceutical?

Are there any issues regarding the availability or suitability of existing treatments for this indication?

Would the pharmaceutical replace or complement existing treatments? Please explain.

Define and summarise how the proposed treatment may change the current treatment algorithm.

Health Need Patient Numbers Table

Year 1	Year 2	Year 3	Year 4	Year 5

Health Benefits

Identification and Selection of Studies

How was the literature searched? Provide details on the search strategy that was used to retrieve clinical studies and list the studies that meet the inclusion criteria

Provide a flow diagram of the number of studies included and excluded at each stage

Errata, editorials and journal correspondence relating to published trials

Register of all ongoing trials that should provide additional evidence in the next 12 months for the relevant indication(s)

What studies were identified in the literature search and which were excluded?

All identified randomised controlled trials that meet the inclusion criteria

All identified meta-analyses and systematic reviews that meet the inclusion criteria

High quality cohort studies and case-control studies that meet the inclusion criteria

Trial Design and Characteristics

Provide details on the methodology of the pivotal clinical trials that provide evidence on the clinical benefits of the pharmaceutical for the proposed indication

Please attach the relevant methodology information

What are the characteristics of the participants in each of the pivotal trials?

Please attach the relevant information

Trial Results

What were the outcomes and methods of analysis in the pivotal trials?

What did the pivotal trials show? Provide a summary of the study results for each relevant comparison and outcome

How relevant are the outcomes assessed in the clinical trials to clinical benefits and adverse effects expected in New Zealand clinical practice?

Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in new zealand

Discuss and justify any clinically important differences in the results between the different arms of a trial and between trials?

Does the pharmaceutical have similar, greater or fewer side effects and/or toxicity compared with current treatment options? Provide details

What adverse events were observed in the pivotal trial? What type and frequency of adverse events may be expected in NZ clinical practice? Are there any additional safety issues for the pharmaceutical compared to the relevant comparator if used in NZ clinical practice for this indication?

Please attach details of adverse events

Evidence on clinical adverse events (if differs from sources of evidence for clinical effectiveness)

What impact does the proposed pharmaceutical have on patient-reported outcome measures?

Interpretation of the Evidence

Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient of the pharmaceutical, relative to those of the comparator(s)

If available, the incremental health benefits of the proposal relative to the comparator can be provided in the form of quality-adjusted life year (QALY) gains

Please provide information on the consequences (or flow-on effects) to the health system if the pharmaceutical was funded.

Would funding the pharmaceutical have an effect on the Government's strategic intentions for the health system?

Health Benefits and Other Consequences Of Treatment

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?

Health Benefits Inclusion and exclusion criteria Table

Selection Criteria	Inclusion Criteria	Exclusion Criteria

Health Benefits Trial Outcomes Table

What were the study references for the pivotal trials?	What was the outcome definition for the pivotal trials?	What was the method of analysis for the pivotal trials?

Health Benefits Studies Included Table

Please identify the type of study	Please provide the full reference of the study

Health Benefits Results summary Table

Study reference	Outcome intervention n/N (%)	Outcome Comparator n/N (%)	Absolute difference (95% confidence interval) (p value)	Relative difference (95% confidence interval) (p value)

Costs and Savings

Price

What is the proposed pharmaceutical price?

Per pack of

What is the supplier's selling prices to wholesalers in other OECD countries where the pharmaceutical is marketed?

Are there any proposed special authority criteria or access restrictions that you would like pharmac to consider?

Please attach any proposed special authority criteria or access restrictions that you would like PHARMAC to consider?

Are there any proposed commercial terms of listing that you would like Pharmac to consider?

Please attach any proposed commercial terms of listing that you would like Pharmac to consider?

Uptake of Pharmaceutical Epidemiological Approach

Epidemiology over the first 5 years

Uptake of Pharmaceutical - Market Share Approach

Estimate the rate of growth of currently available pharmaceuticals over 5 years Where more than one likely to be substituted present the market share and rate growth for each item

Estimate the rate of substitution by proposed pharmaceutical for each year over 5 years

Estimate the units dispensed for proposed pharmaceutical for each year over 5 years that is above the growth projected in the market using historical data

Summary of market share

Budget Impact

Identify the currently available pharmaceuticals that are likely to be substituted by the proposed pharmaceutical and estimate the units dispensed of each of these currently available pharmaceuticals in the most recent 12 months

Are there any supplementary pharmaceuticals that may have an increased usage as a result of the proposed pharmaceutical being listed (e.g pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any supplementary pharmaceuticals that may have an decreased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any diagnostic tests that patients would require prior to receiving or during the treatment with the proposed pharmaceutical? Please specify

Would funding the pharmaceutical impact on the utilisation of other health sector services?

Average cost for a patient for treatment duration (if average treatment duration >12 months then enter cost for 12 months treatment)

Please attach the completed BIA template

Health Related Costs and Savings

Are there additional costs and/or savings to the person that are likely to be incurred if the pharmaceutical is funded?

Health-related costs and savings that may be experienced to the family, whānau and wider society of the person receiving the treatment

Cost Budget Impact Table

Budget to be impacted	Year 1	Year 2	Year 3	Year 4	Year 5

Cost_Uptake of Pharmaceutical Epidemiological Approach Table

Enter the year for years 1 to 5 from listing date	Please indicate the number of patients treated each year up to 5 years from listing date	Please indicate the number from incremental patients treated each year up to 5 years from listing date

Economic Analysis

Cost-utility analysis based on the methods outlined in the Prescription for Pharmacoeconomic Analysis (including all costs estimated in $NZ)

Please attach TreeAgeTM model or ExcelTM spreadsheet The models must be able to be amended

What is the base case estimate of cost-effectiveness, in QALYs per $million

What is the upper limit of the likely range of cost-effectiveness in QALYs per $million?

What is the lower limit of the likely range of cost-effectiveness in QALYs per $million?

Suitability

Features of the Pharmaceutical That Impact Its Use

Are there any features of the treatment that may impact on its use by the person receiving the treatment (eg method of delivery, accessibility, size, shape, taste)? If so, please explain

The system is so easy to start using, I literally received it, read the small directions pamphlet and had attached the sensor within a matter of minutes Application was also painless

Use of the Freestyle Libre Flash monitoring system means that the person receiving treatment would go from several invasive finger prick tests per day (up to 50 per week), to one application of the sensor every 14 days It allows for much more frequent testing, providing more knowledge and knowledge is power with Type 1 diabetes.

What features of the pharmaceutical may have an impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society?
Taking a blood glucose reading by others is so much more straight forward than a finger prick test as the user simply turns the reader on a and scans the sensor My children frequently scan my blood glucose, but have never performed a finger prick test on my behalf. If I was severely hypoglycemic and could not perform the test myself, others could easily do so on my behalf

What features of the pharmaceutical may have an impact on use by the health workforce?

Are there any other considerations that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or safety issues?

Declaration and Identification

Declaration

Please confirm if you have the right to supply the product for which funding is requested

I confirm that the company I represent has legal rights to the patents

I confirm that there are no non-patent intellectual property barriers

I have read and accept PHARMAC's standard terms of listing on the Pharmaceutical Schedule
False

Any variations on the standard terms of listing for PHARMAC to consider have been detailed in this application or provided within an attachment
False

I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application
False

I declare that all known published and unpublished clinical trials that I am aware of that are relevant to this application have been disclosed in the Application
False

I declare that I have obtained the appropriate permission or paid the appropriate copyright fee for any publication or other information provided in support of this application, and that the publications can be distributed internally by PHARMAC (including to PHARMAC committees) for the purpose of reviewing the application
False

Do you have any potential conflicts of interest relevant to this application
No

Provide a description of any conflicts you may have

I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker
Yes

I confirm the information provided in this Application is correct
Yes

Do you have any comments regarding any of the above declarations?

Identification

Name of person submitting application

Date of application
10 October 2019

Who is the primary contact first name for this application?
Withheld under

Who is the primary contact last name for this application?

What is the primary contact's job title for this application?

What is the primary contact email for this application?
Withheld under section 9(2)(a)

What is the primary contact phone number for this application?
Withheld under

Vaccines (Additional Information)

Pharmacological Information

For the proposed vaccine, please specify the number, identification and amounts of antigens (components)?

What is the formulation of the vaccine?

What is the nature of the immunising agent(s)?

What is vaccine presentation?

What are the external dimensions of the vaccine packed for storage?

Are there any requirements for cold chain management? Please specify

Proposed Amendments to the Pharmaceutical Schedule

Is this a new vaccine or an alternative vaccine? Please select

What is the proposed schedule of administration of the vaccine?

Are there any programme requirements for administration?

What health services will be affected?

Can a vaccination course that begins with the proposed vaccine be completed with a competing or alternative vaccine (or vice versa)?

Is there any expectation of a limited initial supply?

Is a catch-up programme required? If so, please provide details.

Patient Population

In addition to describing the patient population, justify the selection of the requested age range(s) of eligible individuals within the primary immunisation programme and catchup programme (if relevant).

Current Treatment

Is an alternative vaccine listed on the National Immunisation Schedule?

Compare the content and characteristics of the proposed and alternative vaccines

Health Benefits to the Family, Whanau and Wider Society

Provide evidence that indicates whether funding the vaccine is likely to provide indirect protection to non-immunised people through appropriate coverage (ie. herd immunity).

Special Foods (Additional Information)

Pharmacological Information

List all ingredients in the product

Attach a table on the micronutrient and macronutrient content of the product per 100 kcal, and per 100 g or 100 mL

Select type of product

If other, please specify

Confirm that the formula of the proposed product will supply the protein, energy, fatty acid, vitamin and mineral requirements for the patient if used as a sole source of nutrition Identify any additional nutritional needs.

Provide details on the products compatibility with currently available medical devices and consumables in New Zealand

Attach a table comparing the proposed product with the requirements of the Australia New Zealand Food Standards Code - Standard 2.9.1: Infant Formula Products, using the terminology of the code Confirm that the proposed product complies with this code or justify any deviations from particular parts of the code.

Regulatory Status of Product

Confirm that the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes requirements have been met

Proposed Amendments to the Pharmaceutical Schedule

Attach a table comparing the nutrient contents of the proposed and comparator products with the NZ RDI

Provide the instructions for preparation and use of the proposed product

Community Medical Devices (Additional Information)

Device Information

Describe the therapeutic purpose of the device

Provide details of pack contents and whether any accessories are included in the packs

Describe how the device is used

Please attach the instructions for use and/or the user guide

Does the device need to be used with a pharmaceutical or other technology? If so, is the pharmaceutical or technology is available and funded in New Zealand?

What is the lifespan of the device, and of any component parts, if applicable?

Are there any different models or versions of the device that are available? Does this have any consequences on the mode of action?

What properties or features of the device make it innovative or a significant modification when compared with other technologies of its type?

Regulatory Status of Device

WAND registration number

Date of registration to the WAND database

Proposed Amendments to the Pharmaceutical Schedule

What is the proposed use of the device, including any proposed restrictions to access?

How does the device (if it were digital for example) connect with/interoperability with NZ Health systems (eprescribing, ehealth records, is it bluetooth enabled etc)

Is the device used in standard care internationally? Please provide details

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)

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 !!!

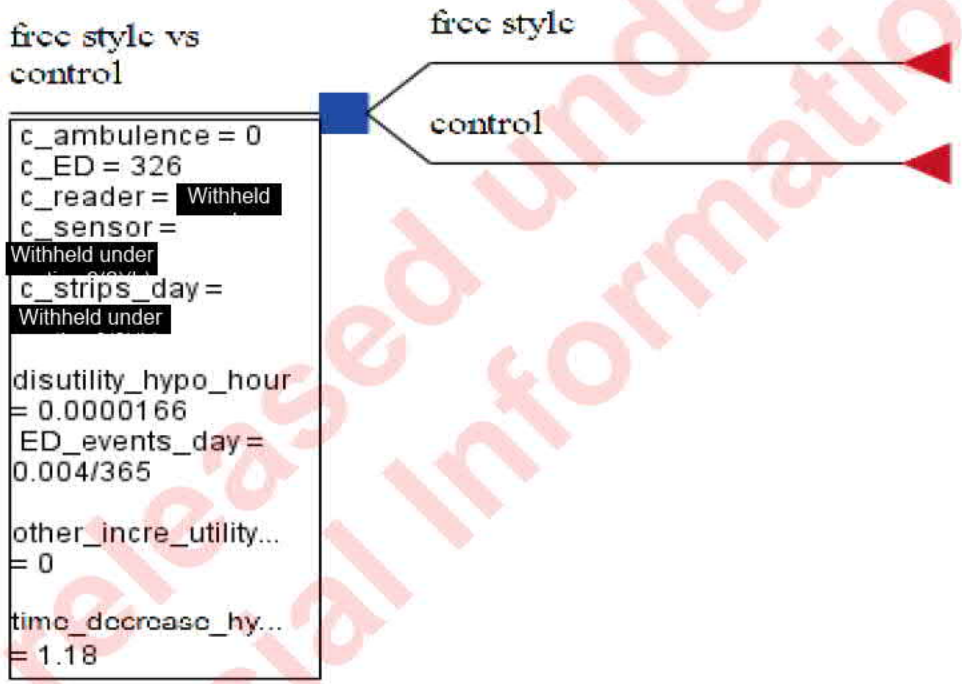
- Difference: 0.03 + or – 0.053 (might be 0 or even negative)

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



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	0.995-1
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)

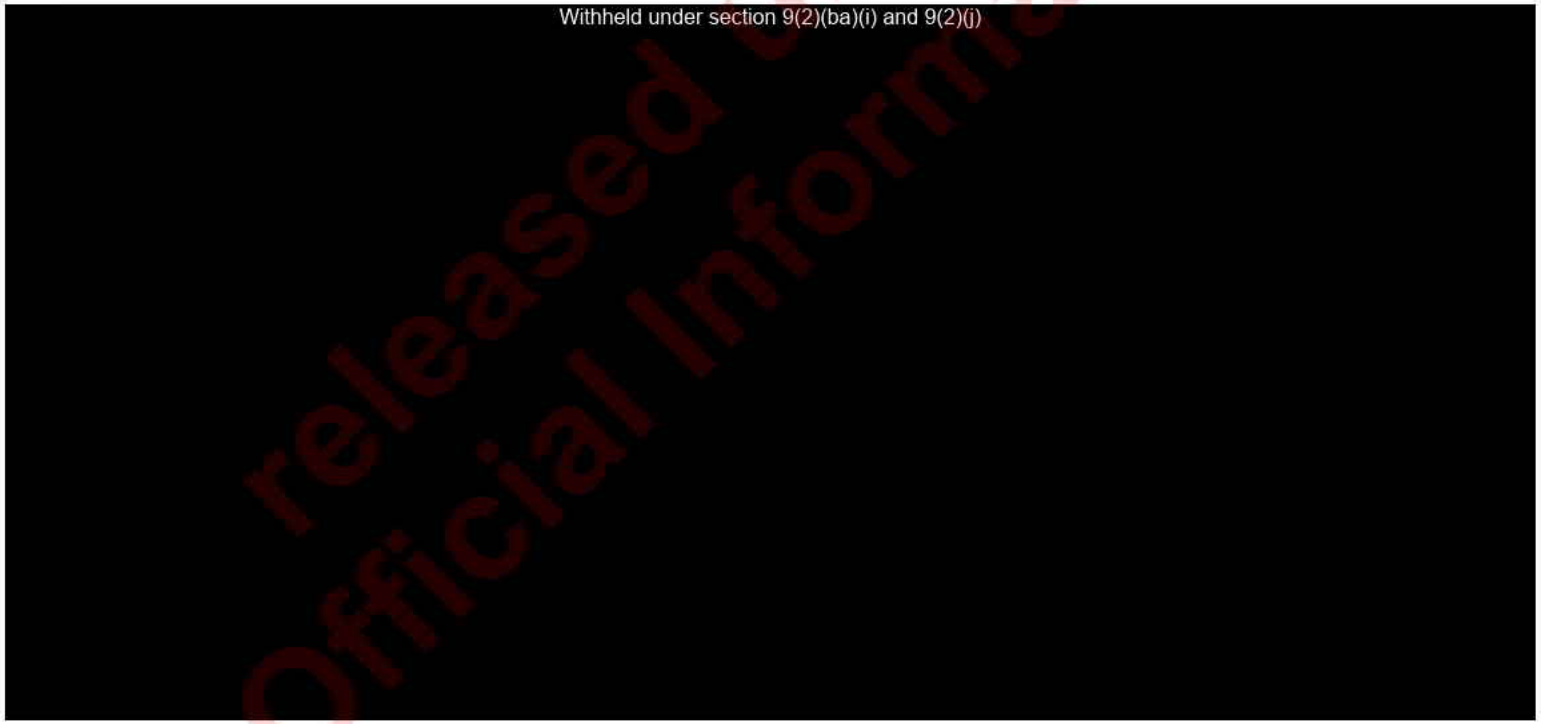
Sensitivity Analysis

- 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%.
- 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) 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).



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

BIA

Year	1	2	3	4	5	NPV
N of Type 1 Patients	25,300	26,565	27,893	29,288	30,752	
Uptake	0.4	0.6	0.7	0.8	0.9	
N of patients on Free style	10,120	15,939	19,525	23,430	27,677	
Total costs to DHB	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and	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)

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

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.

PHARMAC
TE PĀTAKA WHAIORANGA

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?)

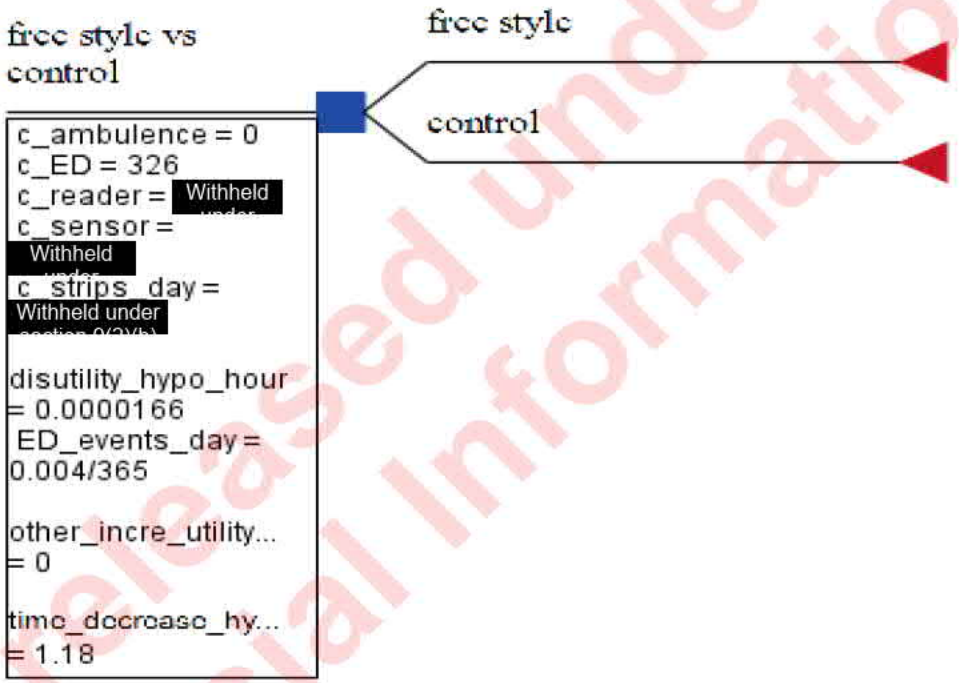
- Difference: 0.03 + or – 0.053 (might be 0 or even negative)

  → 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)

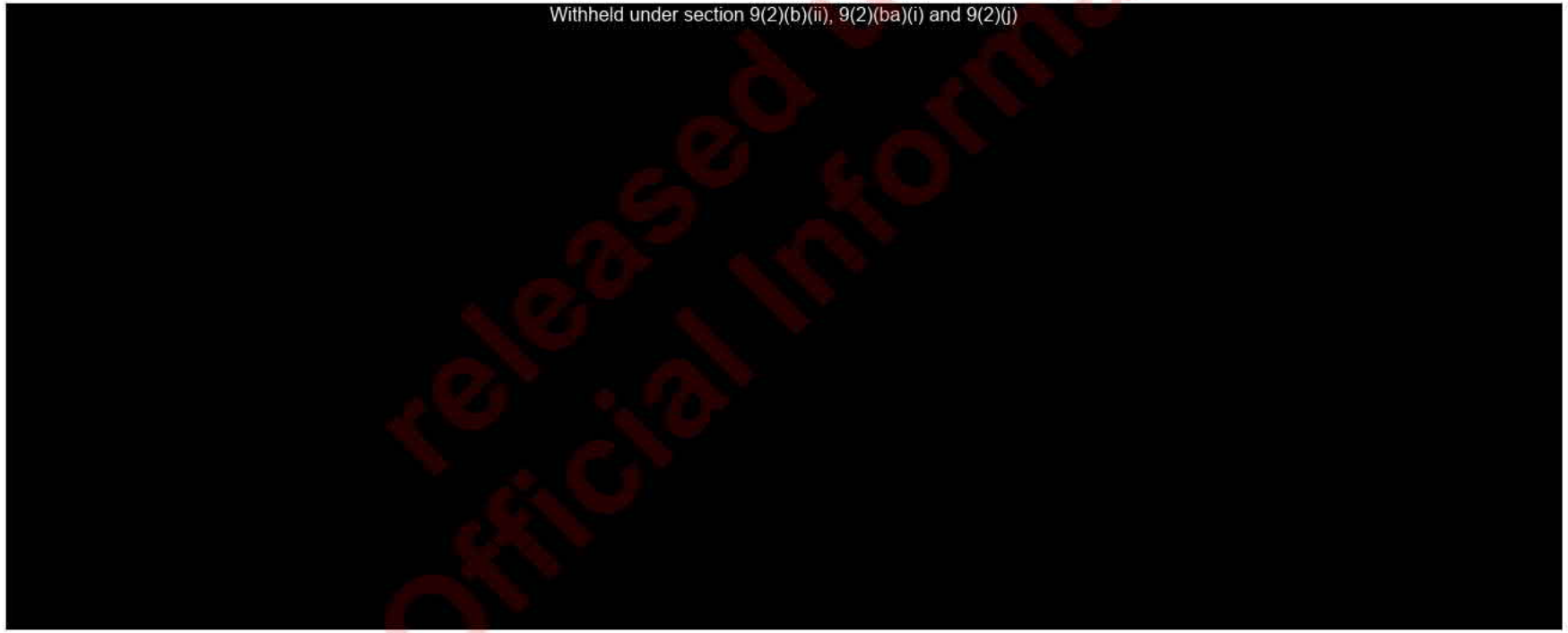
Sensitivity Analysis

- 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

2019 11 22
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

- Group noted application is for Type 1 diabetes The group discussed that there is significant health need and potential for health benefit in people with insulin dependent type 2 diabetes, but that these people were outside of the scope of the application. Attendees considered that a PHARMAC staff-initiated Schedule application may be the most appropriate avenue to consider this group in the absence of a supplier application.

PHARMAC
TE PĀTAKA WHAIORANGA

AGENDA

Prioritisation Meeting

To be held at the PHARMAC Office on

Tuesday 10 December 2019

Overall Agenda

1. Overview of meeting process
2 Acknowledgement of proposals funded since the last prioritisation meeting
3 Ranking of proposals on the 'only if cost neutral or cost saving' list
4 Ranking of proposals on the 'recommended for decline' list
5. Miscellaneous changes to proposal status to be acknowledged
6. Prioritisation of new proposals to the *Options for investment* list
7. Re-prioritisation of the proposals on the *Options for investment* list with updated information
8. Consideration and confirmation of al ranked prioritisations lists
9. Budget boundaries

Prioritisation Paper (Supplementary material)

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

- Section 1: Overview of meeting format
- Section 2: Factors for Consideration
- Section 3: Health need
- Section 4: Cost effectiveness
- Section 5: Government health priorities
- Section 6: Proposal summaries

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

New proposals to be prioritised to the *Options for investment* list

Each new item should take about 10 – 15 minutes.

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

Proposal	TGM	HE
Out of scope		
Freestyle Libre Flash Glucose Monitoring System Type 1 diabetes	ES	ND
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope Out of scope		

PHARMAC
TE PĀTAKA WHAIORANGA

Prioritisation Meeting

December 2019

Content

1. Proposals funded since the last meeting
2. Proposals recommend to the ‘cost-neutral/cost-saving’ list
3. Proposals ‘recommend for decline’
4. New items to be ranked on the OFI list
5. Re-rank items to the OFI list
6. Miscellaneous changes

New items to be ranked on the OFI list

Please refer to the following sections of this dossier for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

- Section 2: Factors for Consideration
- Section 3: Health Need
- Section 4: Cost-effectiveness
- Section 5: Government priorities
- Section 6: Proposal Summaries

Options for Investment – Speaking Order

Therapeutic Group Manager	• Introduces item. • Key therapeutic and commercial issues. • Why is it being prioritised today?
Health Economist	• Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? • Explain the key drivers of the cost-effectiveness result. • Explain the range of cost-effectiveness estimates.
Medical Directorate	Any other relevant clinical issues not yet raised.
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues.
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

New items to be ranked to the OFI list

Proposal	TGM	HE
Out of scope		
Freestyle Libre Flash Glucose Monitoring System – Type 1 diabetes	ES	ND
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope		
Out of scope Out of scope		

PHARMAC
Pharmaceutical Management Agency

Prioritisation Paper

Prioritisation Meeting to be held at the PHARMAC Office on

Tuesday 10 December 2019

Contents

In addition to the Prioritisation meeting agenda document, please refer to the following sections of this paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

Section 1: Prioritisation meeting format

The quarterly prioritisation meeting is a key step in PHARMAC's decision processes, where funding proposals are considered and ranked using the Factors for Consideration.

Formally, PHARMAC's assessment of funding proposals is a 'deliberative process', whereby all relevant different points of view are considered and traded off against one another. This contrasts with systems that use predetermined weights for each criterion

In a deliberative process, it is critical that all perspectives are considered by all people involved in the consensus decision This means that all meeting participants should have good opportunity to make sure that key points are heard and that they hear and understand the points raised from other perspectives.

This document includes only brief summaries of information about each proposal; for full details please refer to the relevant Technology Assessment Report and PTAC minutes.

Below is the protocol to structure the staff discussions during the prioritisation meeting. It builds on a successful process that PHARMAC has developed over many years, while giving it more structure as appropriate to the large group involved in each meeting.

Speaking order

Therapeutic Group Manager	Introduces item. Key therapeutic and commercial issues. Why is it being prioritised today?
Health Economist	Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? Explain the key drivers of the cost-effectiveness result. Explain the range of cost effectiveness estimates
Medical Directorate	Any other relevant clinical issues not yet raised
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

Section 2: Factors for consideration

Factors are presented here in the order they are listed in decision papers, 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
- Government Health Condition Priorities

Health Benefits

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

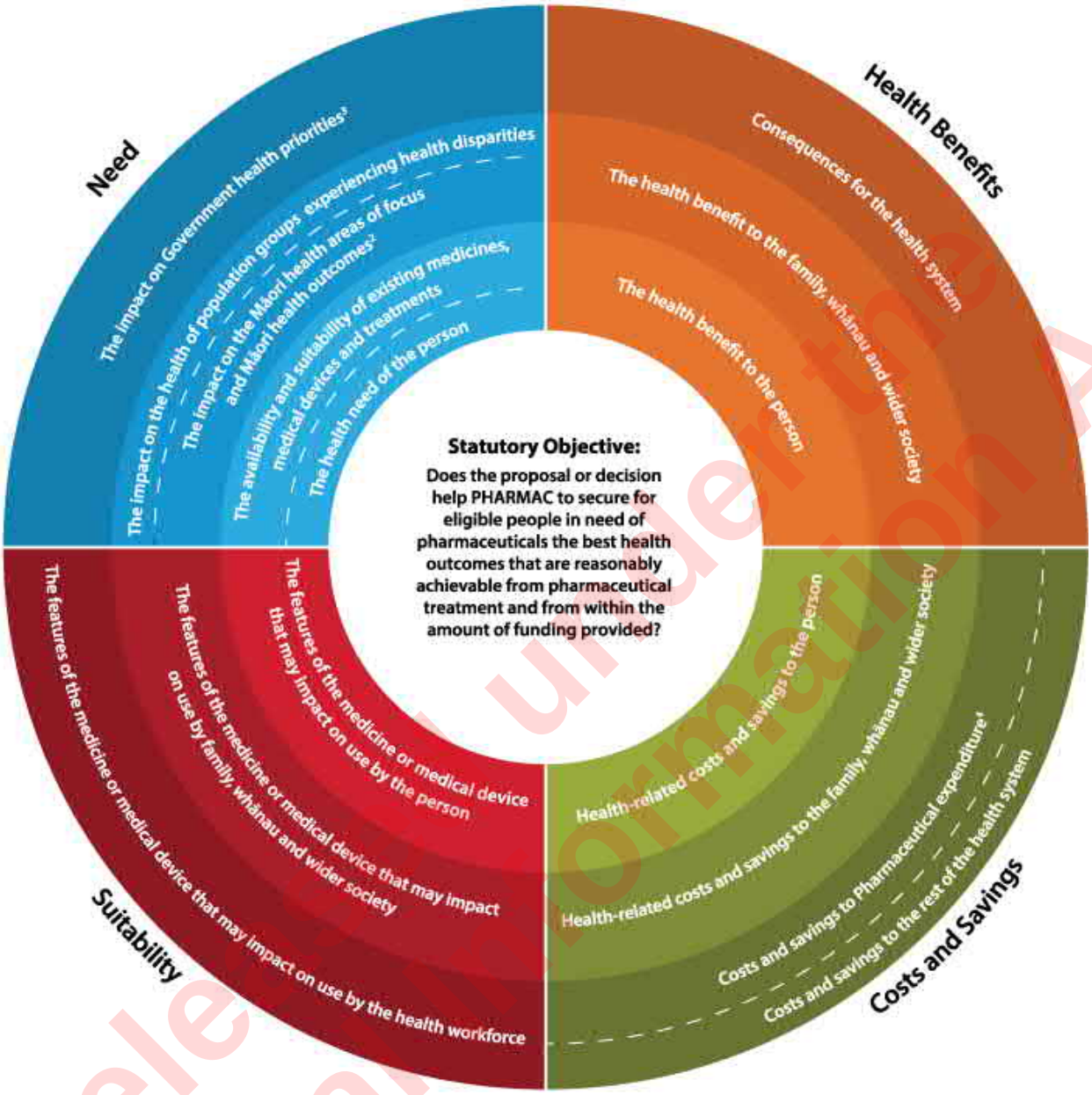
Suitability

- 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

Figure 1: PHARMAC Factors for Consideration



Section 3: Health Need.

For each item on the current Options for Investment list, these graphs show estimates of the health loss experienced by an average or typical patient in the relevant cohort with currently funded treatments They do not reflect the effect of the new products under consideration Each bar starts at the average age of onset of the specific disorder in question. Absolute values are shown in a separate table.

Out of scope

NEW Freestyle Libre Flash Glucose **Type 1 diabetes**

Out of scope

Table 1: Lifetime Health Need associated with conditions

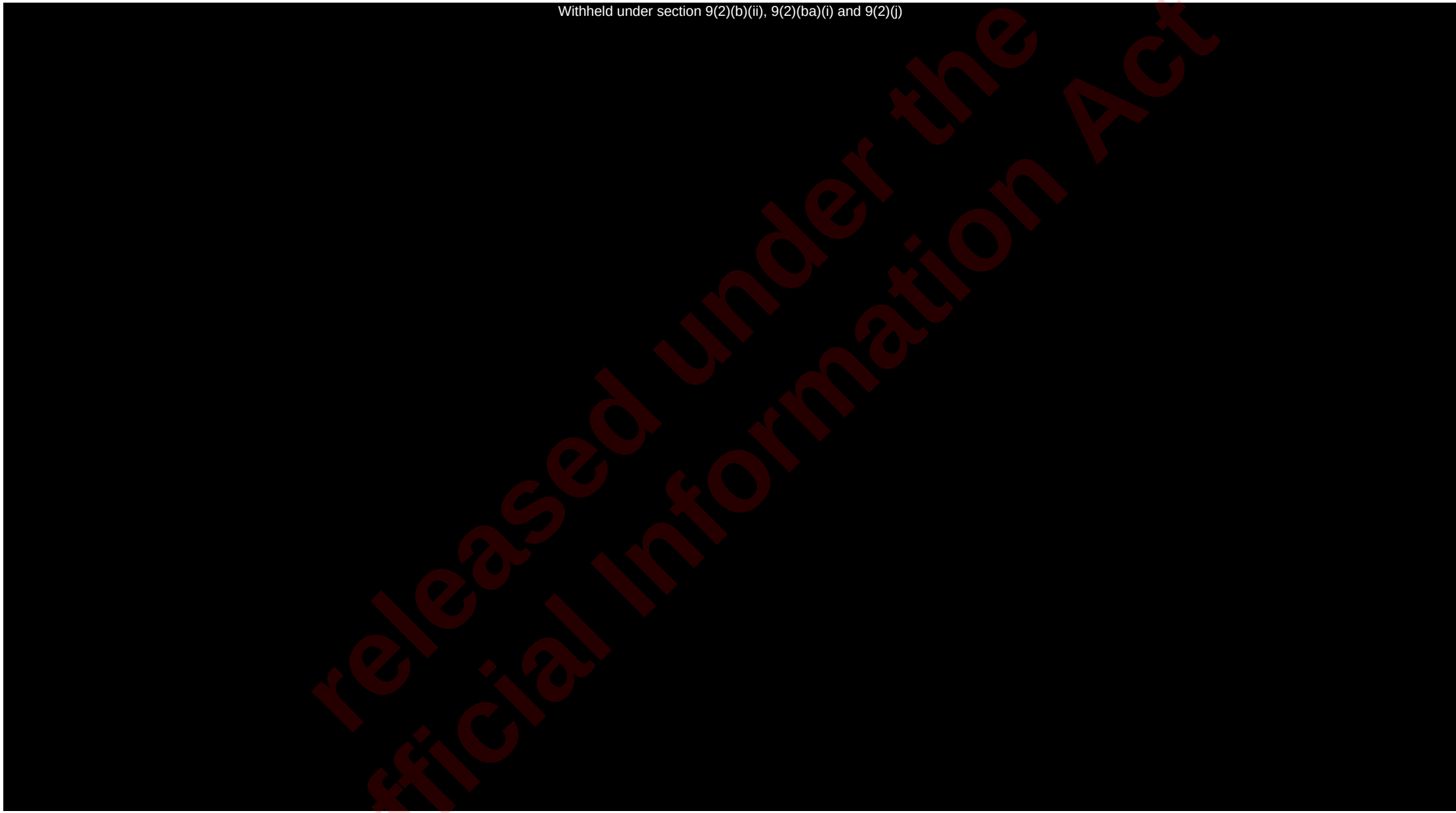
Pharmaceutical	Indication	Start Age	Lifetime QALYs lost
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of			
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of			
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope			

Freestyle Libre Flash Glucose Monitoring System	Type 1 diabetes	9.5	18
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope	Out of scope		Out of scope
Out	Out of scope		
	Out of scope		
Out of scope			
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		
Out of scope			
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		
Out of scope			
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			
Out of scope	Out of scope		Out of scope
Out of scope	Out of scope		
Out of scope			

Section 4: Cost effectiveness

Previously ranked proposals are shown in existing priority order New and updated proposals are placed roughly within the list as a starting point only Cost effectiveness ranges (0 to 70 QALYs per $1m) may extend off the chart; proposals that are completely off the chart or cost saving/cost neutral are detailed in the table on the next page; proposals with ranges within 0 to 70 QALYs per $1m and extending outside are providing in both the chart below and in the following table

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)

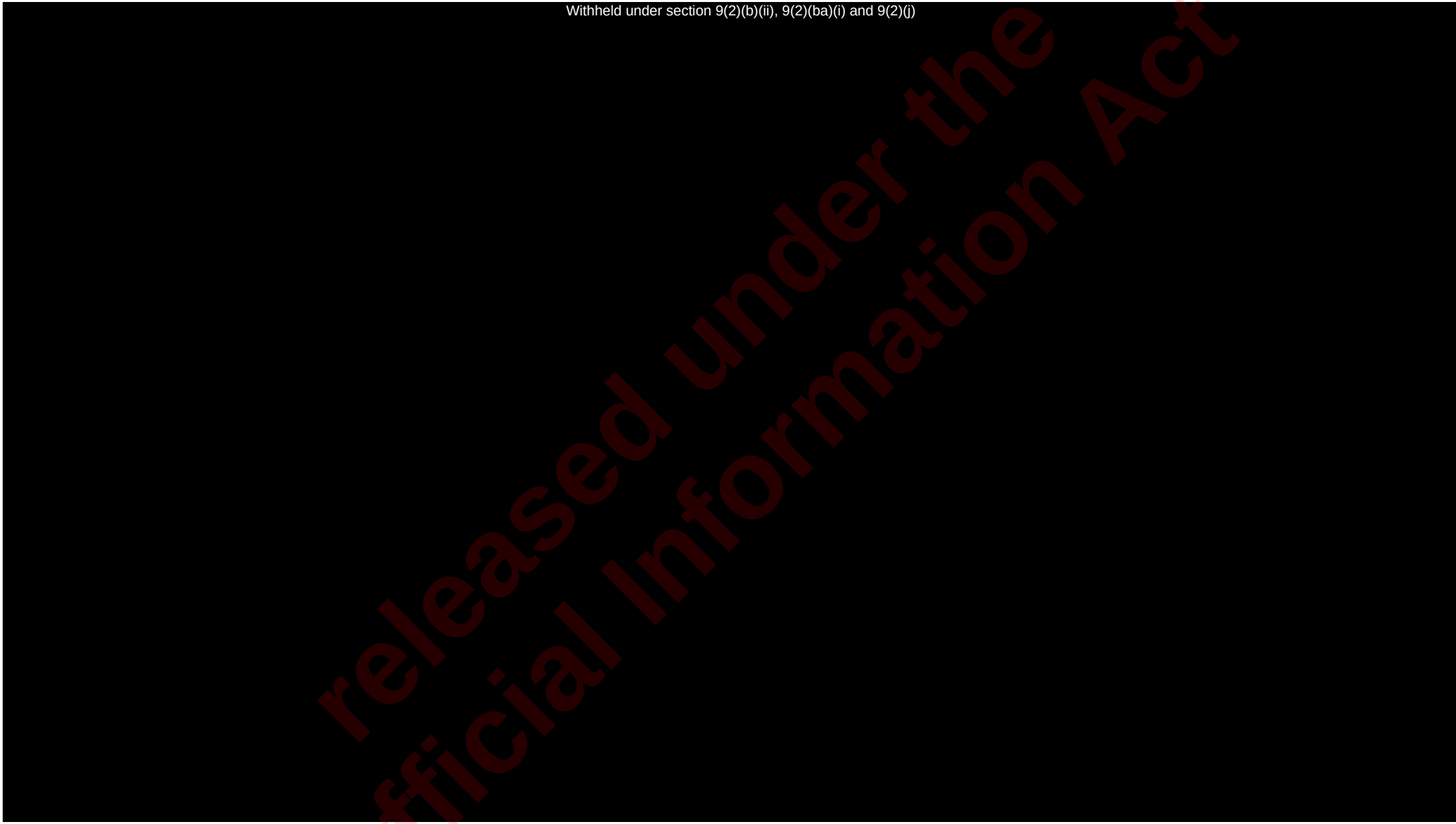


Table 2. Proposals where cost-effectiveness may be more than 70 QALYs per $1 million.

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

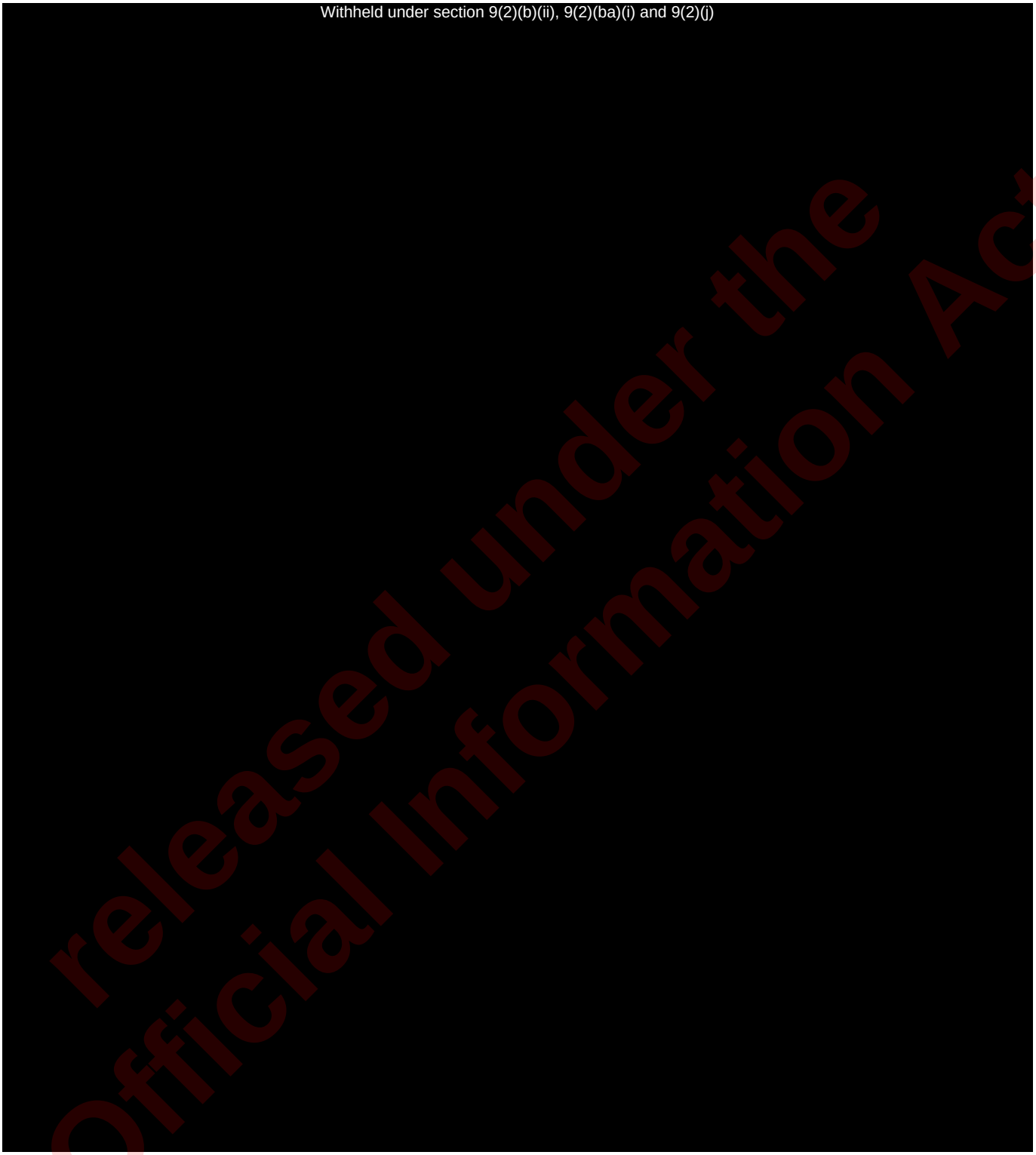
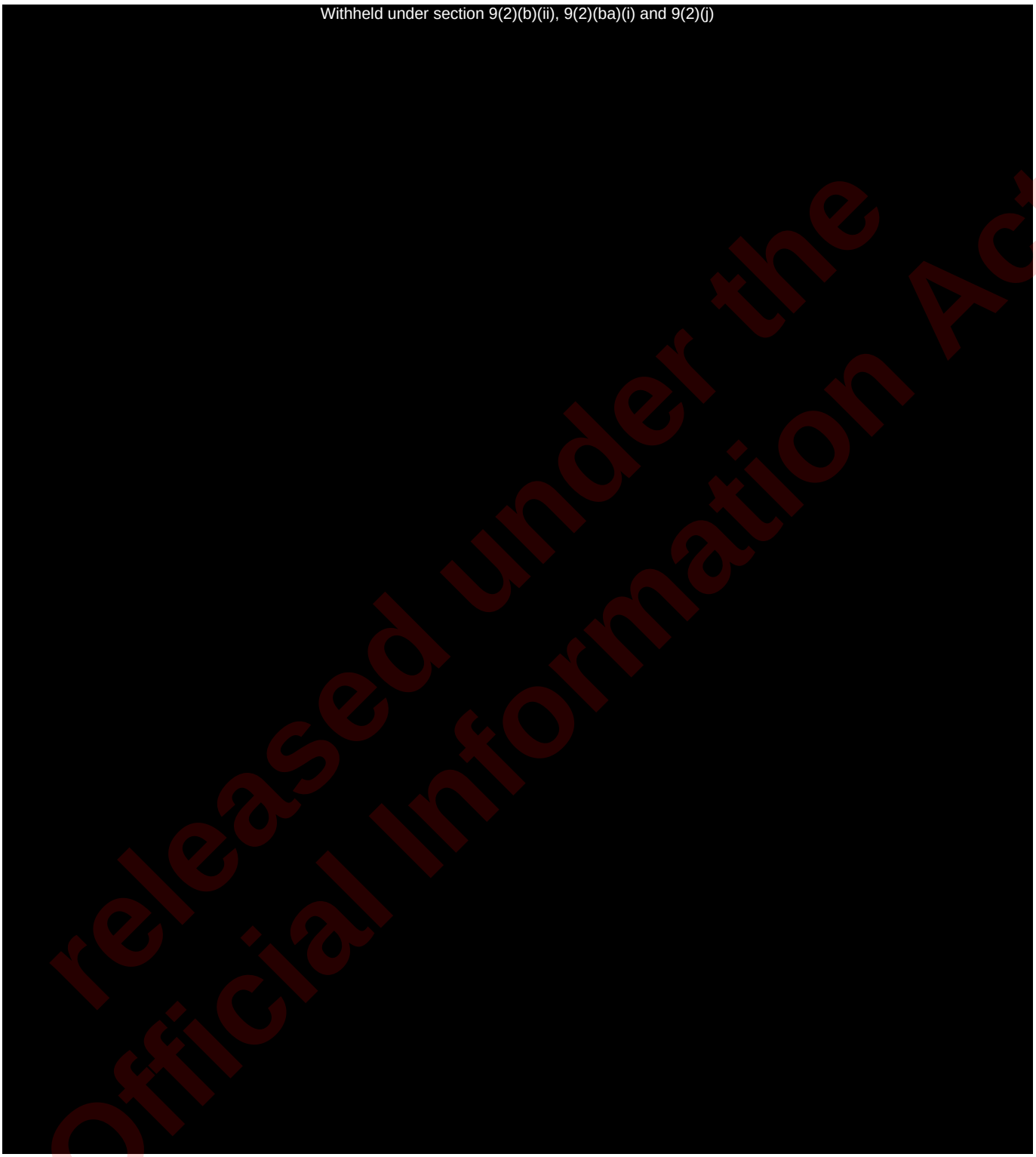


Table 3. Proposals with zero or negative cost-utility.

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



Section 5: Government health priorities

The impact on government health priorities

This factor asks whether the disease, condition, or illness is a Government health priority

Last updated: 20 September 2018

Disease, illness or condition	Interpretation for FFC
Alcohol and or drug addiction	Minimises harm from alcohol and drug dependence
Dementia and frailty	Reduces impact of dementia and frailty
End of life	Supports provision of high quality palliative care
Foetal Alcohol Spectrum Disorder	Reduces incidence of foetal alcohol spectrum disorders
Infectious diseases	Reduces transmission of infectious diseases, especially amongst those with newborn babies
Learning/ intellectual disabilities	Improves the health of people with learning or intellectual disabilities
Long-term conditions	Helps prevention, intervention, rehabilitation and wellbeing of people with LTCs
Mental health with a focus on youth, pregnant and postnatal women	Supports people to improve their mental health and / or address addiction, including: • pregnant or postnatal women experiencing mental health, alcohol and other drug conditions young people with, or at risk of developing, mild to moderate mental health issues
Obesity	Helps prevent or reduce obesity
Smoking cessation	Reduces smoking rates/Helps people to stop smoking.

Consequences for the health system

The Government sets various goals for the health system PHARMAC's decisions should consider whether and how its actions might support the Government's strategic intentions for the health system.

Last updated: 20 September 2018

Health system priority	Interpretation for FFC
Antimicrobial resistance	Supports optimal use of antimicrobials and minimises the emergence of antimicrobial resistance.
Closer to home / Making services more accessible, including shifting services	Supports integrated care. Treatment can be provided more conveniently to patients
Health equity	Enhances equitable health access and/or outcomes.
Increased immunisations	Increases immunisations/Improves prevention and ensures immunisation courses administered on time.
Supports the health of older people	Supports older people to stay healthy and independent and live well with long term conditions Reduces unnecessary acute admissions. Reduces inappropriate polypharmacy.
Supporting people to be 'health smart'	Supports best use of pharmaceuticals.

Section: 6: Proposal Summaries

This section has a dossier for each proposal on the Options for Investment list. Where multiple proposals are represented by one item, please refer to the name of the item

When data are not given for a Factor, the following terms are used:

No difference: Evidence found that shows no material difference or effect
None identified: Staff searched for relevant evidence and found none.
Not reviewed: Staff did not seek information on this Factor.

For more information on any proposal, refer to the Technology Assessment Report, to the relevant Objective file, or to the proposal's records in PharSight.

If you are reading this document on screen, select the Word menu option **View | Navigation Pane**. Click on the dossier's name to jump to the page.

Freestyle Libre Flash Glucose Monitoring System-Type 1 diabetes

Latest Clinical Recommendation: No Formal Recommendation from PTAC, 23/05/2019

Comparator: Finger-prick blood glucose (FPBG) monitoring via a blood glucose meter

NEED

Condition: Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta cells resulting in insulin deficiency Loss of endogenous insulin can lead to hyperglycemia and life threatening ketoacidosis

Health need of the person: Insulin is used to prevent severe hyperglycemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult. Over treatment results in hypoglycemia, which can range from mild and uncomfortable to life-threatening.

Health Need Of Family Whānau and Others: Evidence is emerging of significant caregiver stress among parents of children and adolescents with type-1 diabetes (Grover et al. Perspect Clin Res. 2016;7(1):32 39). The evidence is unclear regarding whether increased monitoring using the newer technology increases or reduces caregiver stress

Availability of existing alternatives: Self monitor using a blood glucose meter between 4 to 10 times per day (finger prick).

Māori Health Areas of Focus: No

Māori health need: None identified

Impact on population groups experiencing disparities: None identified

Government condition priorities: No

HEALTH BENEFITS

Health benefit to the person: Freestyle libre flash glucose monitoring system has been shown to decrease the amount of time a patient spends within the hypoglycaemic range per day, the number of severe hypoglycemia events per day Some evidence has been provided to suggest an improvement in quality of life compared to FPBG monitoring.

Health benefit to family, whanau: Probably reduction in caregiver stress resulting from remote monitoring of blood glucose levels via the Freestyle device This is likely to be even more so overnight when the current method requires waking a child and undertaking a finger prick. Furthermore, the device may allow carers more freedom to leave the patient in the care of others Conversely, some data indicates that the increased granularity of data available can increase the burden of stress to carers.

Health benefit to others: QALYs gained per person treated (lifetime NPV @3.5%) Probable reduction in stress for teachers / teacher aides who are involved in the daily care of children and adolescents whilst they are at school.

Consequences for health system: Freestyle libre flash glucose monitoring system could conceivably reduce the number of required emergency department admissions, and the number of diabetes related complications requiring treatment via the health system. The exact impact is unknown.

Government system priorities: No

COSTS AND SAVINGS (Lifetime NPV @3.5%).

Health costs to the person: A $5 prescription co pay will apply every three months.

Health costs to family, whanau, others: Not relevant

Pharmaceutical costs per person: Withheld per person per year compared to Withh for the current standard of care.

Costs to rest of health sector, per person: 4% net distribution costs will apply to this device. Note, no gross pricing has been provided by the supplier in their proposal.

SUITABILITY

Impact on use by the person: Freestyle libre flash glucose monitoring system involves application once every 14 days, involving one small prick. This compares to the current SMBG method, which can involve up to 10 pricks per day F'style provides near-continuous data readings.

Impact on use by others: Device enables remote monitoring of blood glucose via bluetooth uplink to multiple smart mobile devices

Impact on health workforce: Additional data availability may impact on clinical services, increasing the clinic time required to train individual on the use of the device as well as finger prick testing (which will still be required) and for the interpretation of a larger volu data.

COST EFFECTIVENESS

Point estimate = Wit QALYs per $1m

Likely range Withheld QALYs per $1m.

Possible range Withheld QALYs per $1m.

BUDGET IMPACT

Year	1	2	3	4	5
Patients	5300	7400	8800	9700	10200
Pharmaceutical costs	Withheld under With	Withheld under With	Withheld under With	Withheld under With	Withheld under Wit
Other health sector costs	$410,000.00	$580,000.00	$680,000.00	$720,000.00	$750,000.00
Total Health Sector Budget Impact	Withheld under With	Withheld under With	Withheld under With	Withheld under With	Withheld under Wit

Clinical advice indicates that an increase to clinic time per patient is likely due to the increase in data generated by FreeStyle libre This cost has been unaccounted for in this BIA.

End of document

Minutes of the PHARMAC Prioritisation Meeting

10 December 2019

Meeting attendees

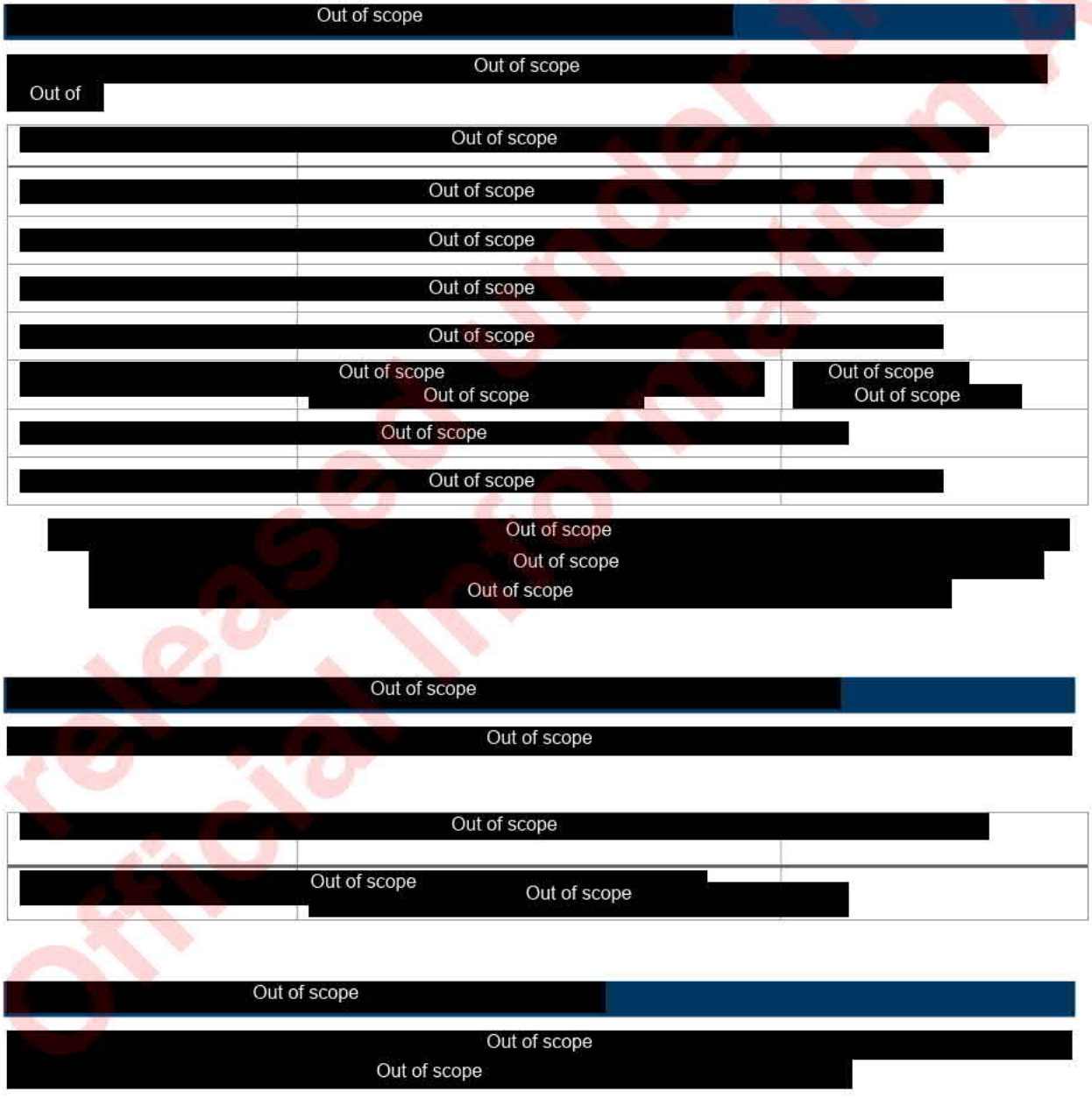
Adam McRae	Senior Implementation Lead
Adrienne Martin	Senior Therapeutic Group Manager/Team Leader
Andrew Oliver	Therapeutic Group Manager
Angie Enoka	Principal Adviser, Pacific
Ben Campbell-Macdonald	Manager, Health Economics
Beth Caudwell	Funding Application Advisor
Caroline De Luca	Senior Therapeutic Group Manager/Team Leader
Casim Alabere	Funding Coordinator
Catherine Kingsbury	Funding Coordinator
Catherine Proffitt	Strategic Planning & Performance Manager
Danae Staples Moon	Senior Therapeutic Group Manager
Denise Mundy	Senior Adviser, Devices Strategy & Development
Elena Saunders	Therapeutic Group Manager
Elliot English	Senior Analyst
Emma Clarke	Tender Analyst / Funding Application Advisor
Geraldine MacGibbon	Manager, Pharmaceutical Funding
Geoff Lawn	Business Architect
Georgia Cassidy	Funding Coordinator
Gregory Evans	Medical Advisory Registrar
Hannah Tibble-Gotz	Pharmaceutical Enquiries Management
Hayden Spencer	Senior Health Economist
Imani Ram	Panel Coordinator
Jason Arnold	Principal Analyst, Access Equity
Josh Wiles	Procurement Manager
Karen Jacobs-Grant	Senior Advisor Māori Responsiveness
Laura Baker	Therapeutic Group Manager
Logan Heyes	Therapeutic Group Manager
Mark Woodard	Director of Corporate Services
Melody Willis	Team Assistant/Project Administrator
Nathan Fox	Senior Health Economist
Peter Murray	Deputy Medical Director
Rachel Grocott	Senior Health Economist
Rachel Watt	Senior Policy Analyst
Rochelle West	Senior Funding Coordinator/Team Leader
Sandy Bhawan	Acting Manager, Access Equity
Sarita Von Afehlt	Therapeutic Group Manager

Scott Metcalfe	Chief Adviser Population Medicine/Deputy Medical Director
Tal Sharrock	Health Economist
Toni Broome	Panel Coordinator
Vivienne Rijnberg	Health Economist

Note: attendees may not have been present for the full duration of the meeting

Material considered

1. Meeting agenda
2. PHARMAC factors for consideration
3 Health need charts
4. Cost effectiveness chart
5. Government priorities
6 Full proposal summaries
7. Proposed additions to the Cost Neutral or Cost Saving list and the Recommended for Decline list
8 Projected budget boundaries



Freestyle Libre Flash Glucose Monitoring System – Type 1 diabetes (patients aged under 18 years requiring repeat inpatient care for hypoglycaemia and patients who are pregnant, breastfeeding or actively planning pregnancy).

Staff considered the information provided and noted the groups included in the defined T1DM patient sub-group. The meeting noted the potential fiscal risk given the current ambiguity of special authority access criteria, in particular the implications of ceasing treatment at 18 years of age and for women who access treatment whilst pregnant (or planning pregnancy) and are required to cease treatment after childbirth The meeting noted the lack of evidence indicating that this method results in better health outcomes, such as reduction of hospitalisations resulting from hypoglycaemic episodes or chronic hyperglycaemia related comorbidity. It was also noted that the system is considered more suitable for many patients than prick tests scripts, although there is uncertainty regarding the benefit to patients and parents in terms of glucose control and whether the additional information the meter provides further stress The meeting also noted the size of the Supplier claimed incremental quality of life gain associated with using flash glucose monitoring versus current finger prick based testing was uncertain Staff noted that type 1 diabetes is less prevalent in Māori, but there are greater complications in Māori for those who develop type 1 diabetes.

Freestyle Libre Flash Glucose Monitoring System Type 1 diabetes was ranked With on the *Options for Investment* list, above Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j), on basis of

cost effectiveness, Government priorities, and suitability, and below Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b), on basis of lower health need and cost-effectiveness.

Out of scope

Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope

Out of scope
Out of scope
Out of scope
Out of scope

Out of scope

Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope

Out of scope
Out of scope
Out of scope
Out of scope

Out of scope

Out of scope
Out of scope
Out of scope
Out of scope

Out of scope
Out of scope
Out of scope

Out of scope

Out of scope

Out of scope

Final review and confirmation of rankings

Staff confirmed the rankings of all the proposals on the Options for Investment list.

Explanation of the PHARMAC Options for Investment list

The Options for Investment list records the relative ranking of proposals for investment, to be progressed when it is affordable and practical to do so The list contains proposals that have health gains and have sufficient information to be prioritised using PHARMAC's Factors for Consideration. Proposals can then be compared with each other to derive a relative ranking for investment. An explanation of the columns in the list follows:

Priority The ranking of proposals within the Options for Investment list.

Proposal The name of the product, or a description of the group of products

Indication A general description of the restrictions that the product would be funded for or widened to. The actual restrictions placed on a funded proposal may be more detailed

PTAC priority Latest clinical recommendation, usually high, medium, low, or decline. Represents PTAC's overall opinion of the proposal with respect to all of the Factors for Consideration. Subcommittee recommendations are marked as such

Health Need – A proxy measure of the Health Need of the average patient, being estimated numbers of Quality Adjusted Life Years lost because of the condition, over a full lifetime under standard care.

QALYs per $1m Cost effectiveness results are presented as ranges to capture the uncertainty in input variables. The likely range represents PHARMAC's best estimate of cost-effectiveness. The possible range, shown in brackets, captures more of the uncertainty in the analysis and is obtained by varying more inputs and over a wider range

5-year NPV to the HML – the cost to the Hospital Medicines Budget over the first five years of listing (net present value, discounted at 8% p.a.). Note that this is reported as a separate column despite the HML and other Pharmaceutical Budgets being merged effective 1 May 2018.

5-year NPV to the CPB the cost to the Combined Pharmaceutical Budget over the first five years of listing (net present value, discounted at 8% p.a.), excluding costs in the HML column.

HML cost first 12 months the cost to the Hospital Medicines Budget in the 2019/20 fiscal year, assuming the earliest possible listing date.

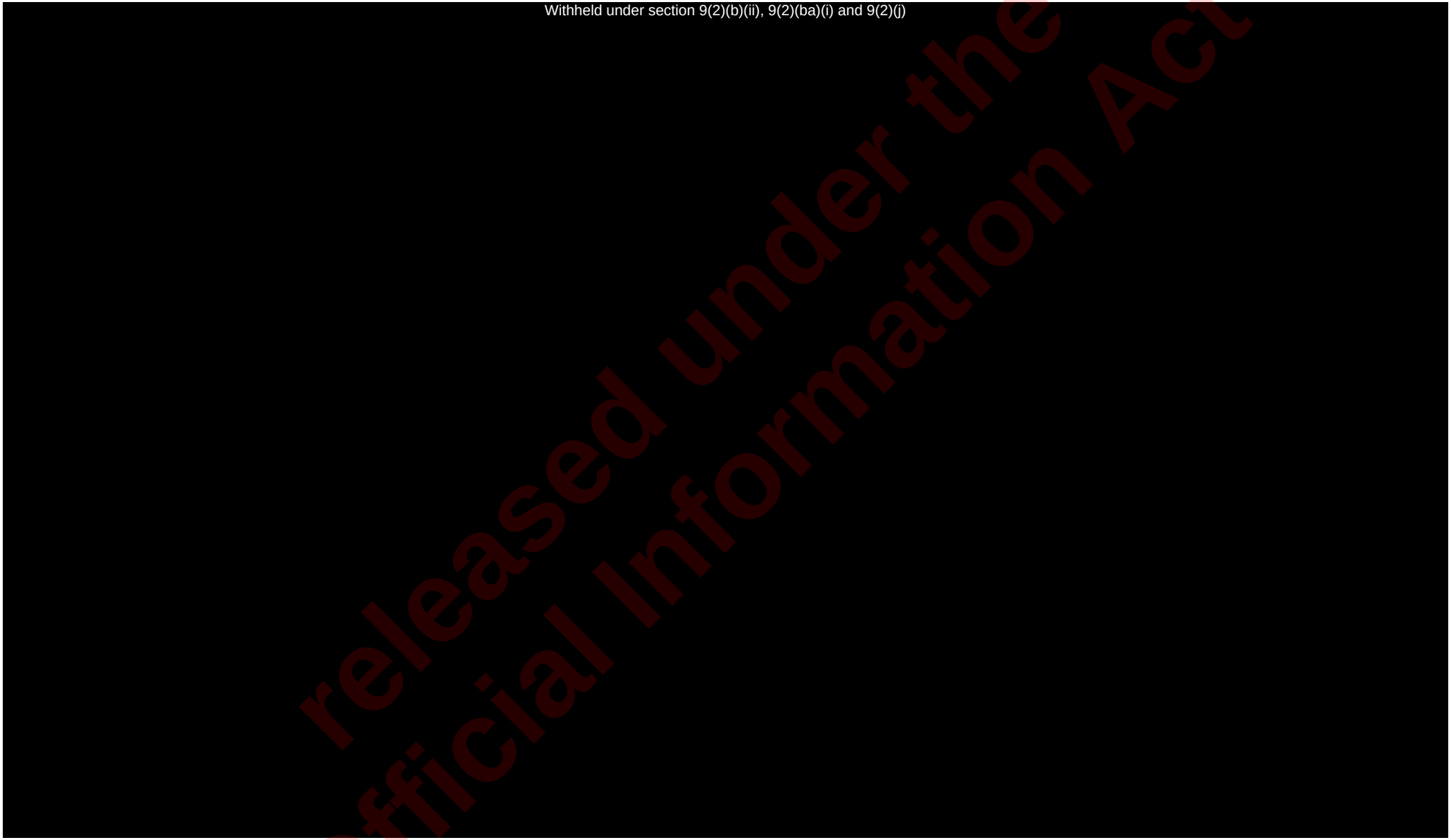
CPB cost first 12 months the cost to the rest of the Combined Pharmaceutical Budget in the 2019/20 fiscal year, assuming the earliest possible listing date.

Cumulative Pharmaceutical Cost (HML+CPB) impact on 2019/20 This column shows the estimated total budget impact (CBP+HML) in the 2019/20 financial year, it counts all proposals up to and including the current row. Each proposal's impact on the cumulative expenditure depends on how soon it could practically be funded, with proposals that begin later in the year having less impact At the time of the meeting, we estimated that if a proposal was not already being consulted on, then the earliest it could be funded would be December 2nd, 2019 Proposals that have known reasons for later listing dates have less impact on the 2019/20 fiscal year.

New proposals are in **bolded blue**. Updated proposals are in **bolded blue and begin with *RR*.**

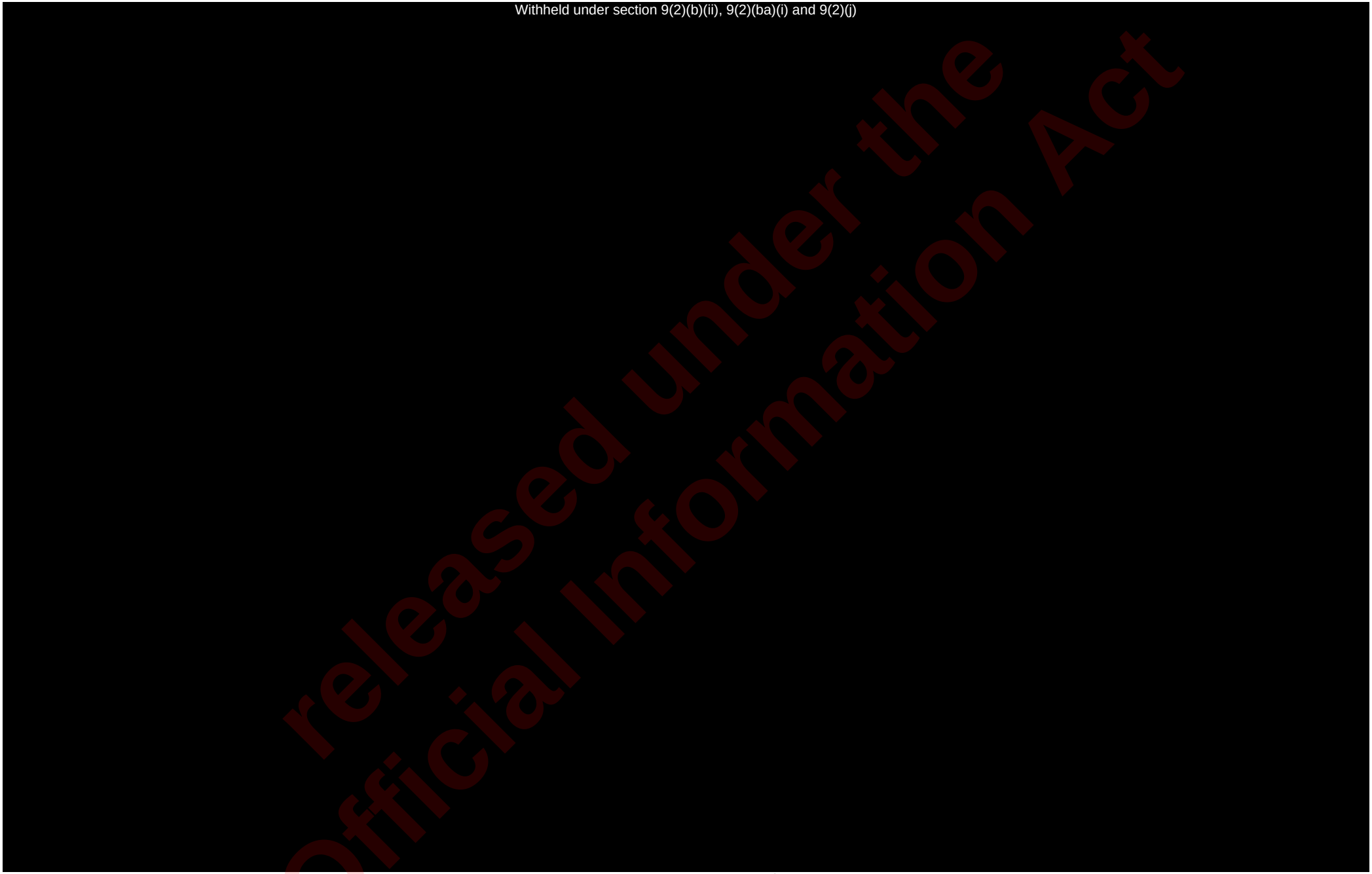
PHARMAC's Options for Investment list ranked by Factors for Consideration, as at 10th December 2019

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



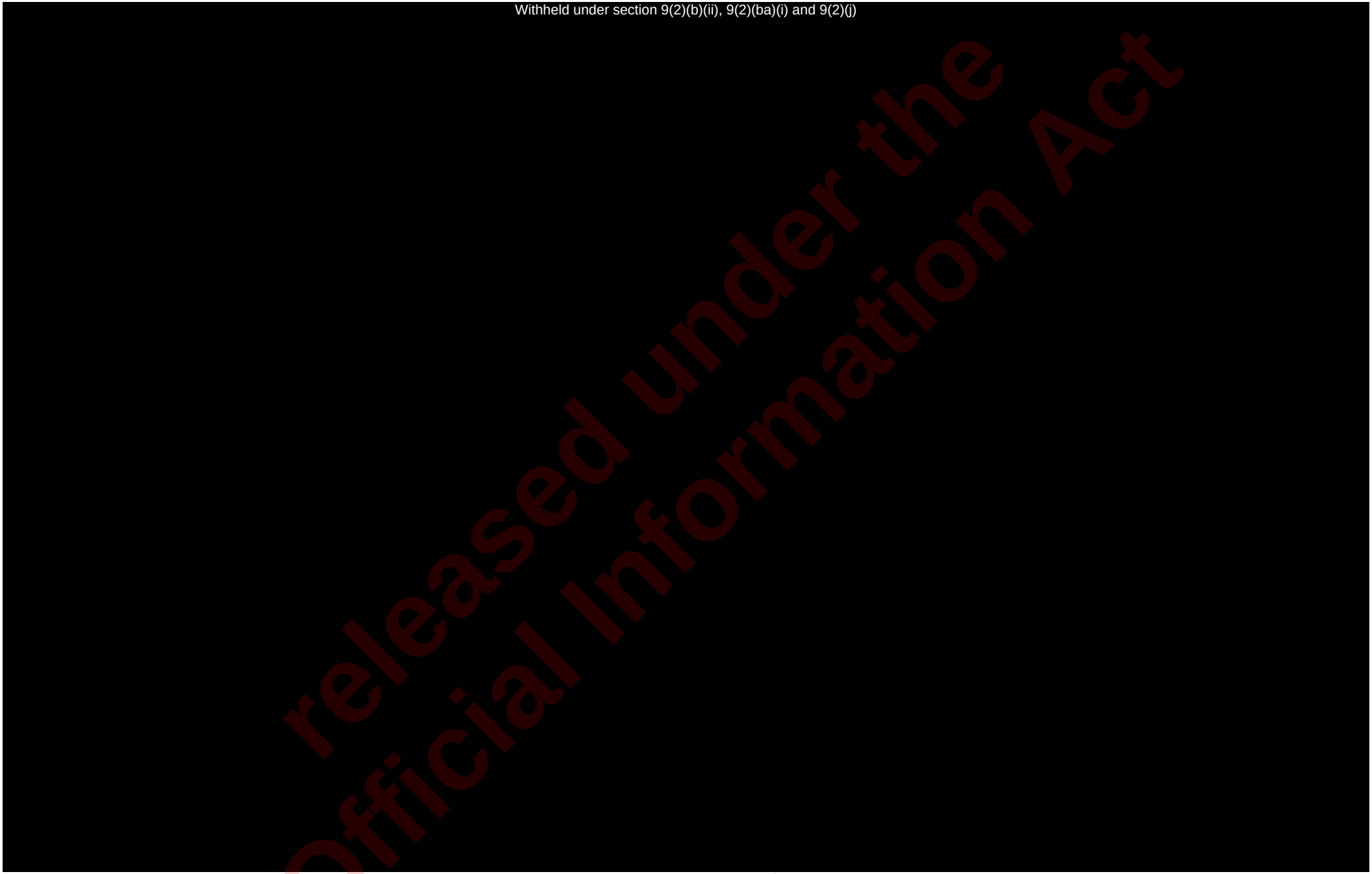
Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)

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

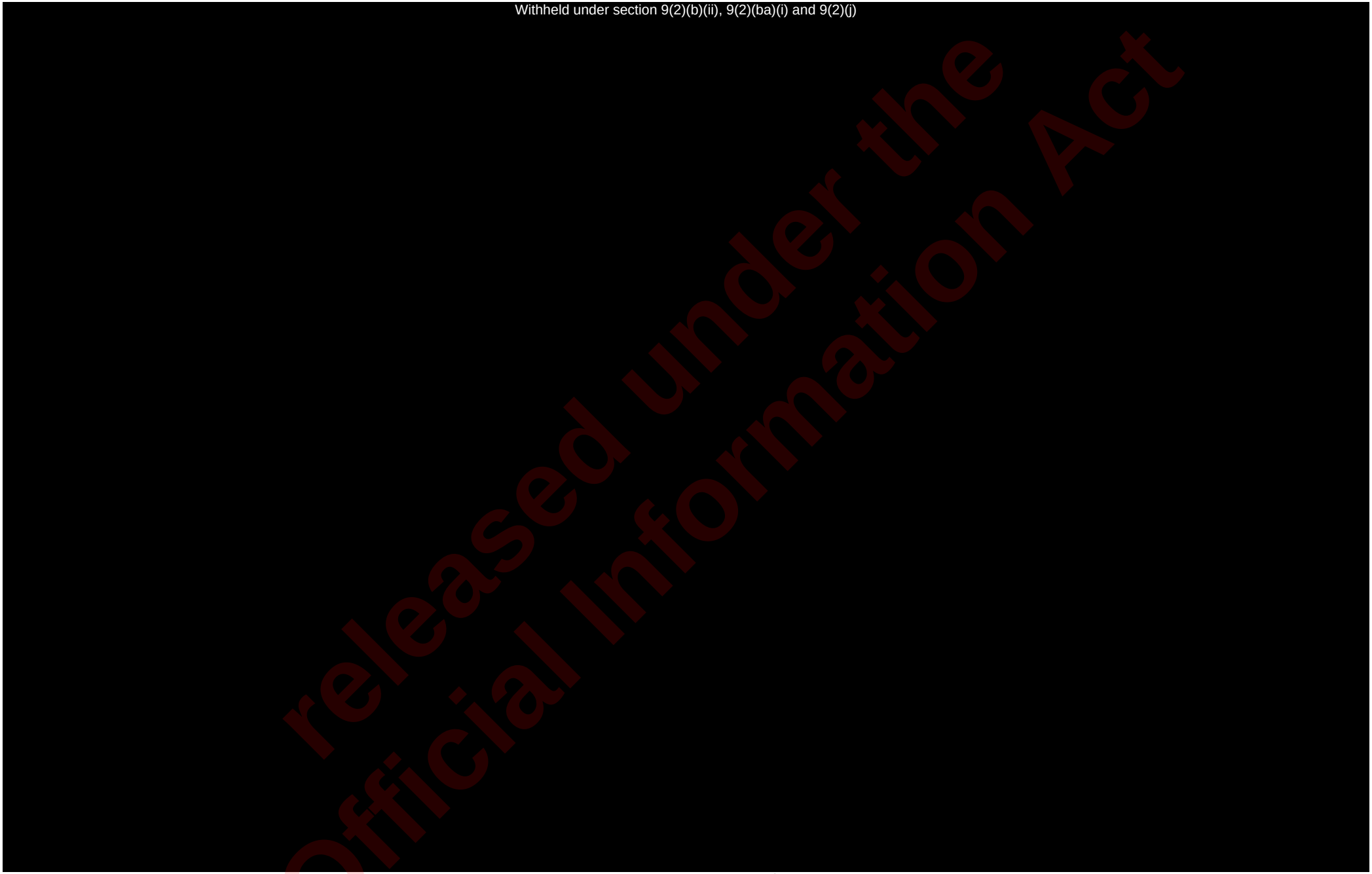


Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)

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

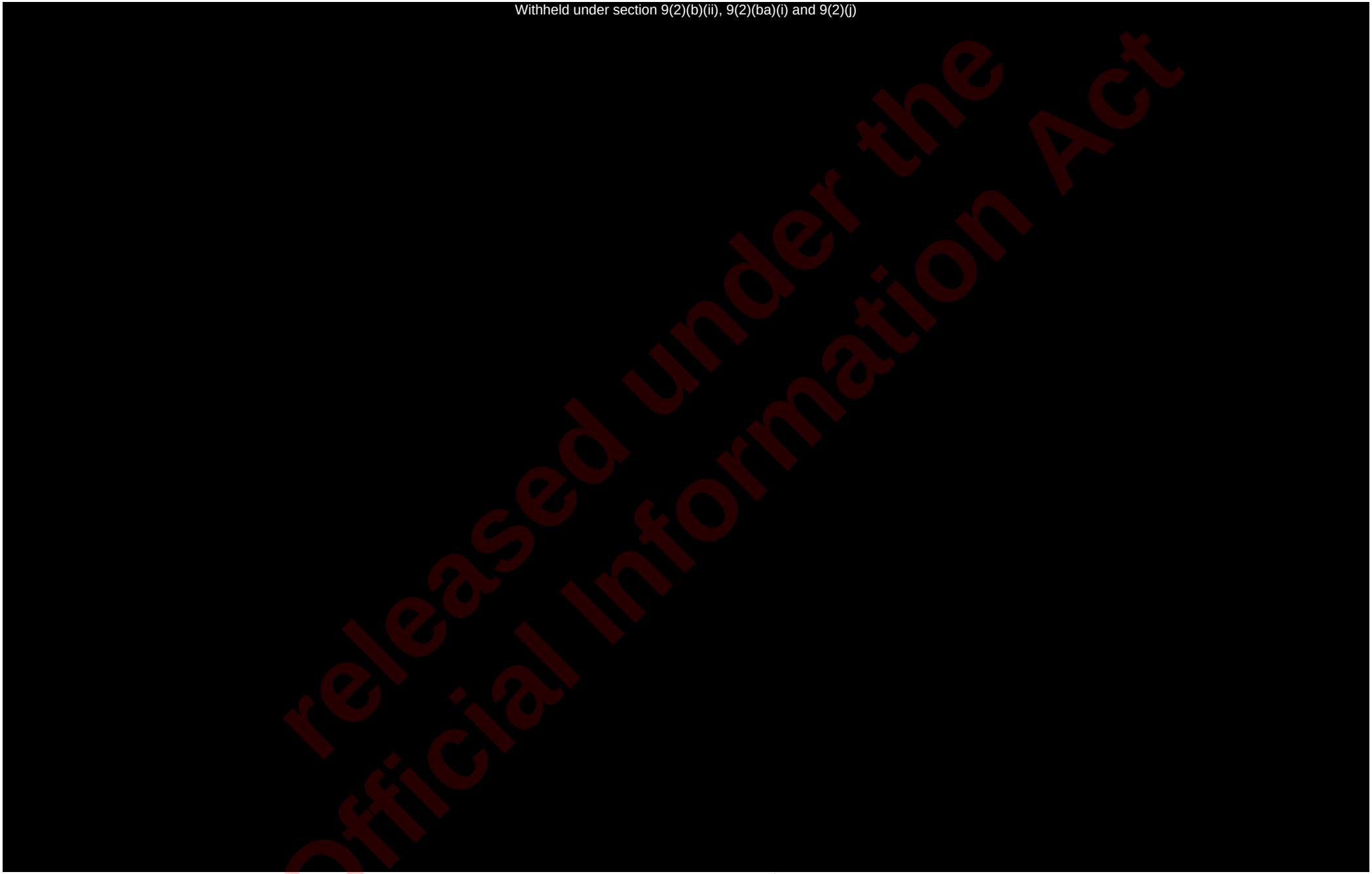


Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)



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

PHARMAC
Pharmaceutical Management Agency

Prioritisation Paper

Prioritisation Meeting to be held at the PHARMAC Office on

Tuesday 3 March 2020

Contents

In addition to the Prioritisation meeting agenda document, please refer to the following sections of this paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

Section 1: Prioritisation meeting format

The quarterly prioritisation meeting is a key step in PHARMAC's decision processes, where each current funding proposal is considered and ranked using the Factors for Consideration.

Formally, PHARMAC's assessment of funding proposals is a 'deliberative process', whereby all relevant different points of view are considered and traded off against one another. This contrasts with systems that use predetermined weights for each criterion

In a deliberative process, it is critical that all perspectives are considered by all people involved in the consensus decision This means that all meeting participants should have good opportunity to make sure that key points are heard and that they hear and understand the points raised from other perspectives.

This document includes only brief summaries of information about each proposal; for full details please refer to the relevant Technology Assessment Report and PTAC minutes.

Below is the protocol to structure the staff discussions during the prioritisation meeting. It builds on a successful process that PHARMAC has developed over many years, while giving it more structure as appropriate to the large group involved in each meeting.

Speaking order

Therapeutic Group Manager	Introduces item. Key therapeutic and commercial issues. Why is it being prioritised today?
Health Economist	Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? Explain the key drivers of the cost-effectiveness result. Explain the range of cost effectiveness estimates
Medical Directorate	Any other relevant clinical issues not yet raised
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

Section 2: Factors for consideration

Factors are presented here in the order they are listed in decision papers, 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
- Government Health Condition Priorities

Health Benefits

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

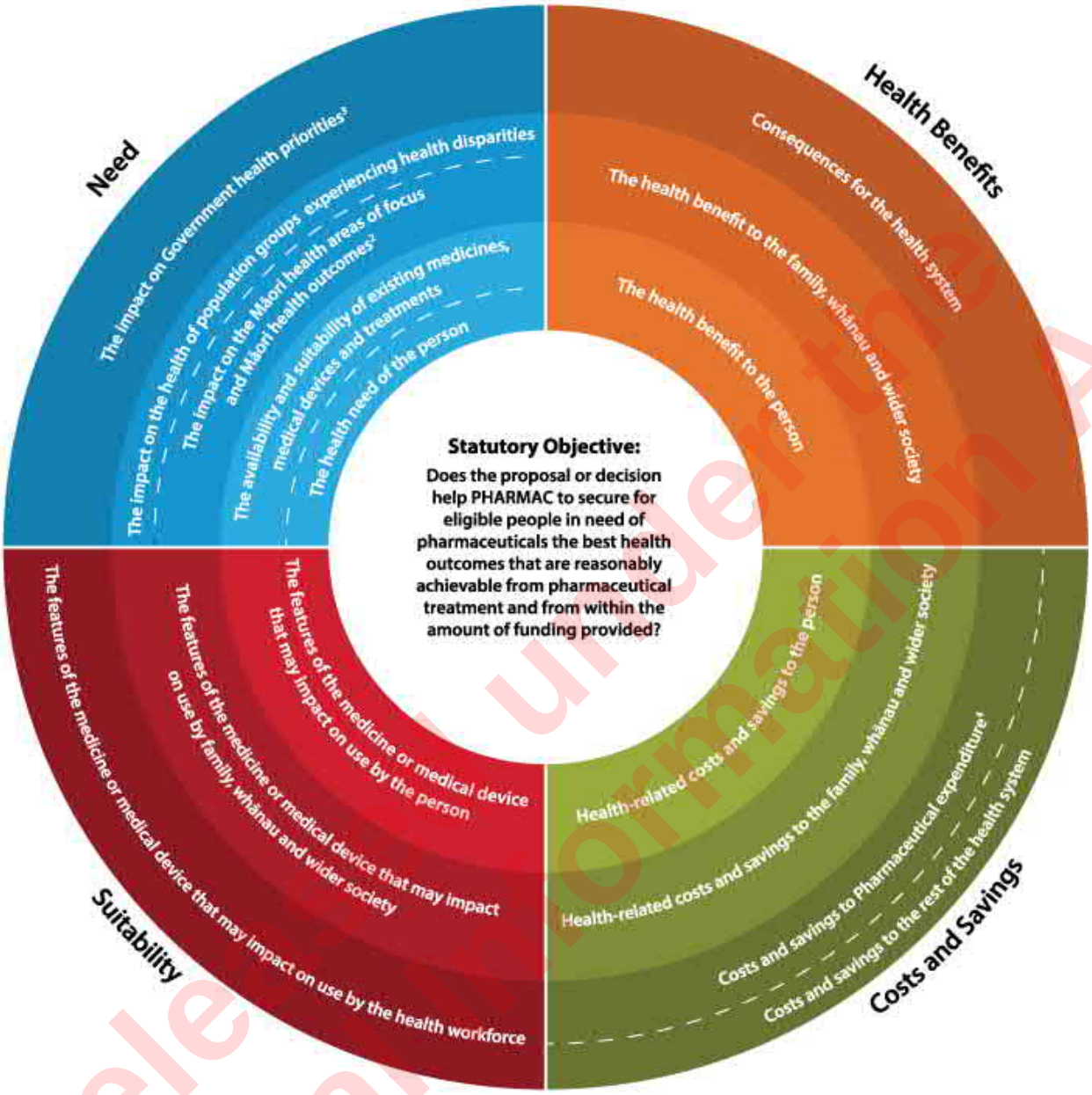
Suitability

- 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

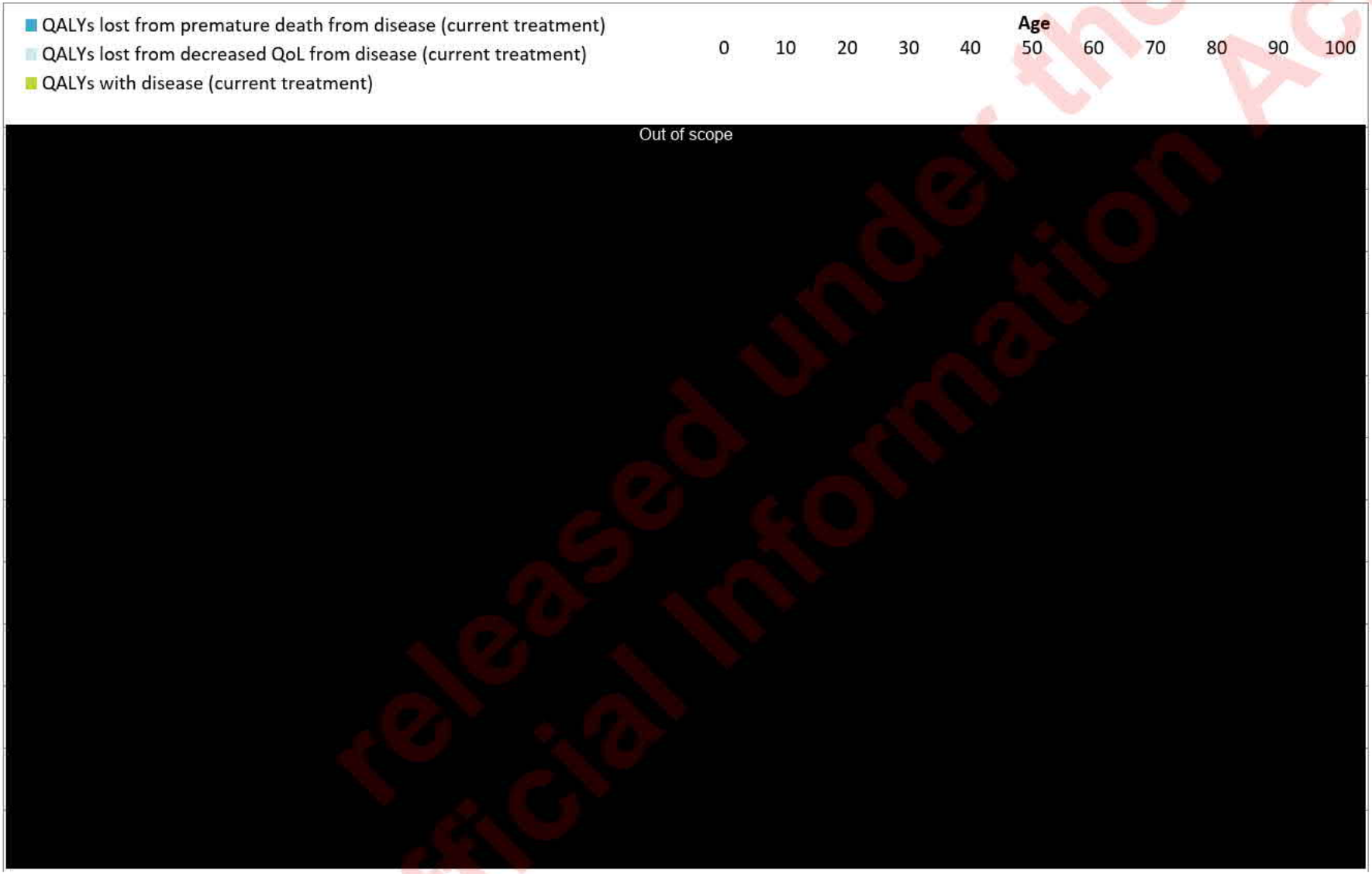
- Health related costs and savings to the person
- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system

Figure 1: PHARMAC Factors for Consideration



Section 3: Health Need.

These graphs show estimates of the health loss experienced by an average or typical patient in the relevant cohort with currently funded treatments for treatments on the current prioritisation list They do not reflect the effect of the new products under consideration Each bar starts at the average age of onset of the specific disorder in question. Absolute values are shown in a separate table.



Out of scope

Freestyle Libre Flash Glucose	Type 1 diabetes	

Out of scope

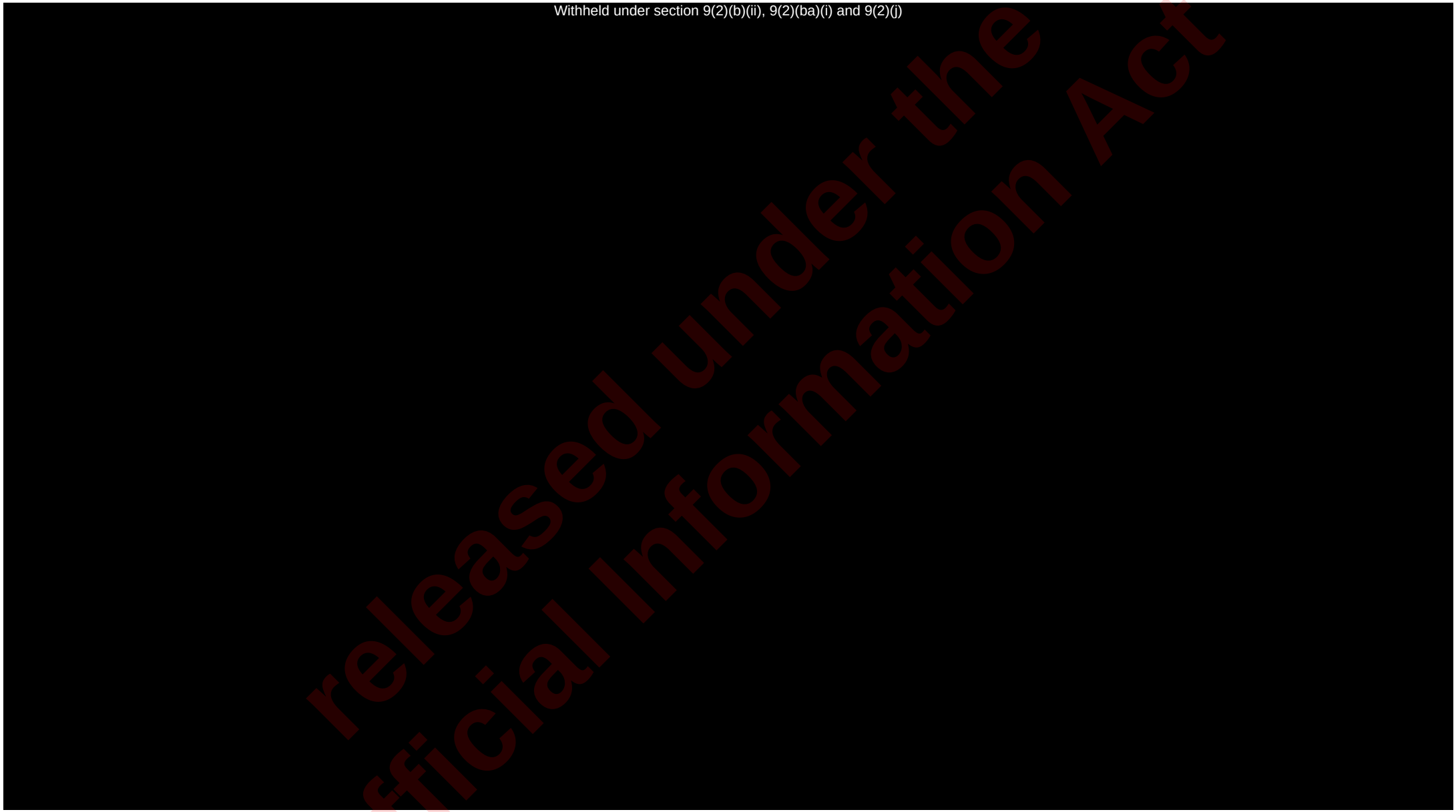
Table 1: Lifetime Health Need associated with conditions

Drug	Indication	Lifetime QALYs lost
Out of scope		
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		
Out of scope		Out
	Out of scope	
	Out of	
Out of scope		
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		O
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		Out
	Out of scope	
Out of scope		
Out of scope		
Out of scope		
Out of scope	Out of scope	Out
Out of scope	Out of scope	
Out of scope		
Out of scope		Out
	Out of scope	
	Out	
Out of scope		
Out of scope		O
	Out of scope	
Out of scope		
Freestyle Libre Flash Glucose Monitoring System	Type 1 diabetes	18

Section 4: Cost effectiveness

Previously ranked proposals are shown in existing priority order New proposals are placed roughly within the list as a starting point only. Cost effectiveness ranges (0 to 70 QALYs per $1m) may extend off the chart; proposals that are completely off the chart or cost-saving/cost neutral are detailed in the table on the next page; proposals with ranges within 0 to 70 QALYs per $1m and extending outside are providing in both the chart and the table

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)

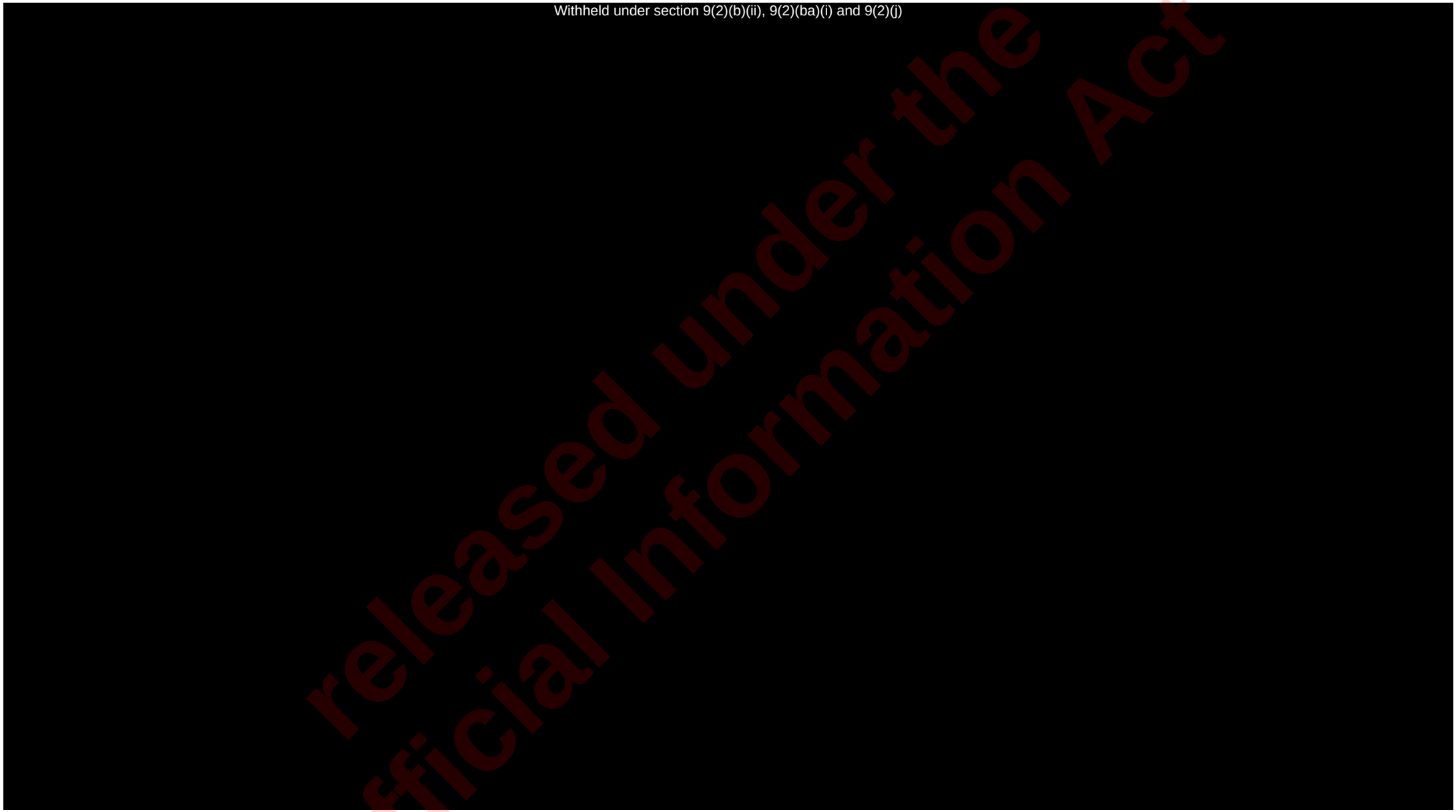
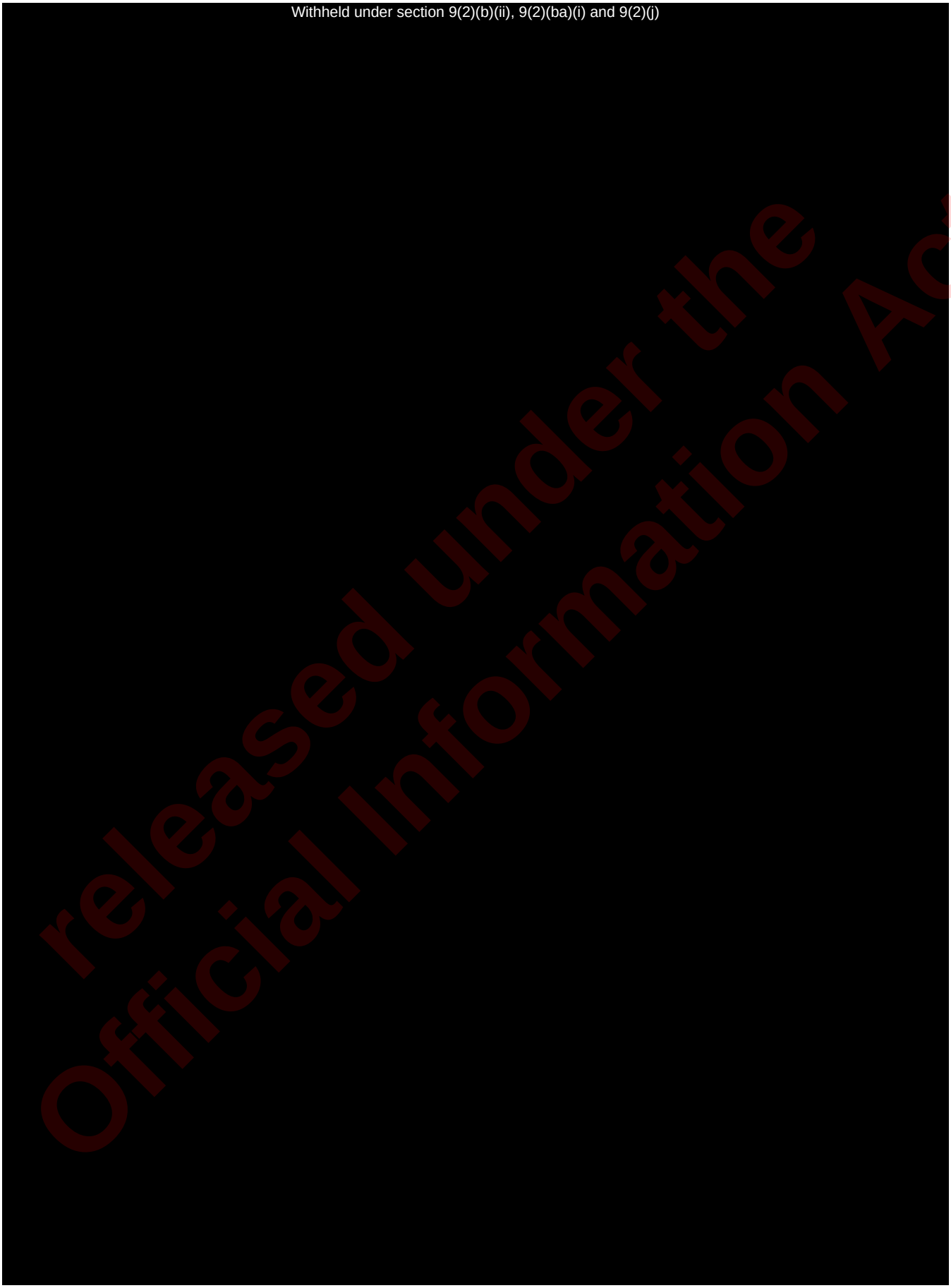
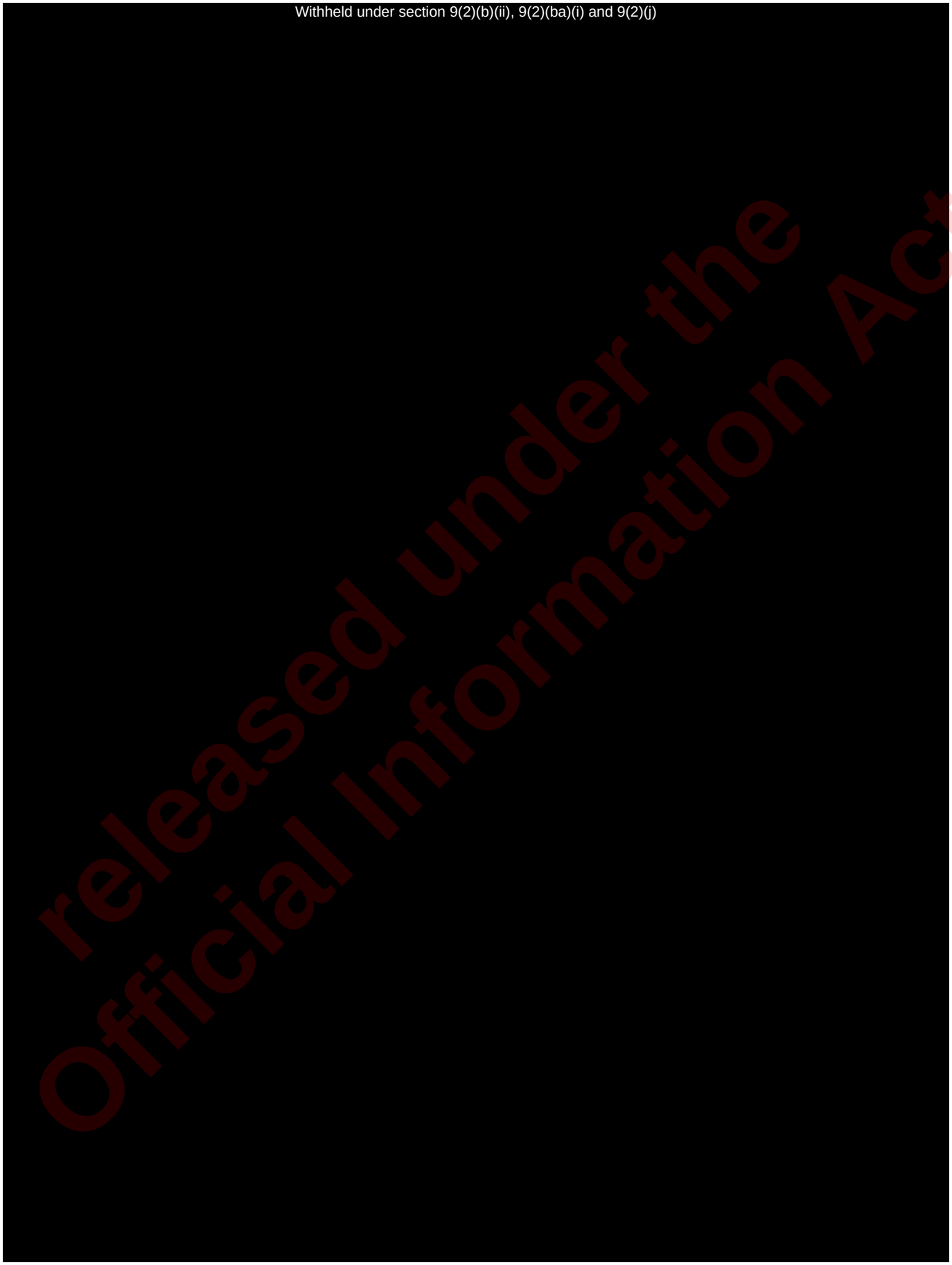


Table 2 Proposals where cost effectiveness may be more than 70 QALYs per $1 million

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)



Section 5: Government health priorities

The impact on government health priorities

This factor asks whether the disease, condition, or illness is a Government health priority.

Last updated: September 2018

Disease, illness or condition	Interpretation for FFC
Alcohol and or drug addiction	Minimises harm from alcohol and drug dependence
Dementia and frailty	Reduces impact of dementia and frailty
End of life	Supports provision of high quality palliative care
Foetal Alcohol Spectrum Disorder	Reduces incidence of foetal alcohol spectrum disorders
Infectious diseases	Reduces transmission of infectious diseases, especially amongst those with newborn babies
Learning/ intellectual disabilities	Improves the health of people with learning or intellectual disabilities
Long term conditions	Helps prevention, intervention, rehabilitation and wellbeing of people with LTCs
Mental health with a focus on youth, pregnant and postnatal women	Supports people to improve their mental health and / or address addiction, including: • pregnant or postnatal women experiencing mental health, alcohol and other drug conditions young people with, or at risk of developing, mild to moderate mental health issues
Obesity	Helps prevent or reduce obesity
Smoking cessation	Reduces smoking rates/Helps people to stop smoking

Consequences for the health system

The Government sets various goals for the health system. PHARMAC's decisions should consider whether and how its actions might support the Government's strategic intentions for the health system.

Last updated: September 2018

Health system priority	Interpretation for FFC
Antimicrobial resistance	Supports optimal use of antimicrobials and minimises the emergence of antimicrobial resistance
Closer to home / Making services more accessible, including shifting services	Supports integrated care Treatment can be provided more conveniently to patients.
Health equity	Enhances equitable health access and/or outcomes.
Increased immunisations	Increases immunisations/Improves prevention and ensures immunisation courses administered on time.
Supports the health of older people	Supports older people to stay healthy and independent and live well with long term conditions Reduces unnecessary acute admissions. Reduces inappropriate polypharmacy.
Supporting people to be 'health smart'	Supports best use of pharmaceuticals

Section: 6: Proposal Summaries

This section has a dossier for each proposal on the Options for Investment list Where multiple proposals are represented by one item, please refer to the name of the item.

When data are not given for a Factor, the following terms are used:

No difference: Evidence found that shows no material difference or effect.
None identified: Staff searched for relevant evidence and found none
Not reviewed: Staff did not seek information on this Factor

For more information on any proposal, refer to the Technology Assessment Report, to the relevant Objective file, or to the proposal's records in PharSight.

If you are reading this document on screen, select the Word menu option **View | Navigation Pane** Click on the dossier's name to jump to the page

Freestyle Libre Flash Glucose Monitoring System-Type 1 diabetes

Latest Clinical Recommendation: No Formal Recommendation from PTAC, 23/05/2019

Comparator: Finger prick blood glucose (FPBG) monitoring via a blood glucose meter.

NEED

Condition: Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta cells resulting in insulin deficiency. Loss of endogenous insulin can lead to hyperglycemia and life threatening ketoacidosis

Health need of the person: 18

Insulin is used to prevent severe hyperglycemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult Over treatment results in hypoglycemia, which can range from mild and uncomfortable to life threatening

Health Need Of Family Whānau and Others: Evidence is emerging of significant caregiver stress among parents of children and adolescents with type-1 diabetes (Grover et al. Perspect Clin Res. 2016;7(1):32-39). The evidence is unclear regarding whether increased monitoring using the newer technology increases or reduces caregiver stress.

Availability of existing alternatives:

Self-monitor using a blood glucose meter between 4 to 10 times per day (finger-prick).

Māori Health Areas of Focus:

Māori health need:

Impact on population groups experiencing disparities:none identified

Government condition priorities:

HEALTH BENEFITS

Health benefit to the person: QALYs gained per person (lifetime NPV @3 5%)

Health benefit to family, whanau: QALYs gained per person treated (lifetime NPV @3.5%). Probable reduction in caregiver stress resulting from remote monitoring of blood glucose levels via the Freestyle device. This is likely to be even more so overnight when the current method requires waking a child and undertaking a finger prick. Furthermore, the device may allow carers more freedom to leave the patient in the care of others Conversely, some data indicates that the increased granularity of data available can increase the burden of stress to carers.

Health benefit to others: QALYs gained per person treated (lifetime NPV @3 5%) Probable reduction in stress for teachers / teacher aides who are involved in the daily care of children and adolescents whilst they are at school.

Consequences for health system:

Freestyle libre flash glucose monitoring system could conceivably reduce the number of required emergency department admissions, and the number of diabetes related complications requiring treatment via the health system The exact impact is unknown

Government system priorities:

COSTS AND SAVINGS (Lifetime NPV @3.5%).

Health costs to the person: Incremental costs
A $5 prescription co pay will apply every three months.

Health costs to family, whanau, others: Incremental costs
Not relevant.

Pharmaceutical costs per person: Incremental costs
Withheld per person per year compared to Withh for the current standard of care.

Costs to rest of health sector, per person: Incremental costs
4% net distribution costs will apply to this device Note, no gross pricing has been provided by the supplier in their proposal

Total incremental costs per person (NPV): =

SUITABILITY

Impact on use by the person: Freestyle libre flash glucose monitoring system involves application once every 14 days, involving one small prick. This compares to the current SMBG method, which can involve up to 10 pricks per day. F'style provides near continuous data readings

Impact on use by others: Device enables remote monitoring of blood glucose via bluetooth uplink to multiple smart mobile devices.

Impact on health workforce: Additional data availability may impact on clinical services, increasing the clinic time required to train individual on the use of the device as well as finger prick testing (which will still be required) and for the interpretation of a larger volu data

COST EFFECTIVENESS

Point estimate = Wit QALYs per $1m
Likely range Withheld QALYs per $1m.
Possible range Withheld QALYs per $1m.

BUDGET IMPACT

Year	1	2	3	4	5
Patients	0	0	0	0	0
Cost to patients, family, whānau	$0.00	$0.00	$0.00	$0.00	$0.00
Pharmaceutical costs	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit
Other health sector costs	$410,000 00	$580,000 00	$680,000 00	$720,000 00	$750,000 00
Total Health Sector Budget Impact	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit

Clinical advice indicates that an increase to clinic time per patient is likely due to the increase in data generated by FreeStyle libre. This cost has been unaccounted for in this BIA.

Minutes of the PHARMAC Prioritisation Meeting

04/03/2020

Meeting attendees

Adam McRae	Senior Therapeutic Group Manager, Team Leader
Andrew Oliver	Senior Therapeutic Group Manager
Ben Campbell Macdonald	Manager, Health Economics
Beth Caudwell	Funding Application Advisor
Danae Staples-Moon	Senior Therapeutic Group Manager, Team Leader
Elena Saunders	Therapeutic Group Manager
Emma Clarke	Funding Application Advisor
Eric Matthews	Health Economist
Evan Hinds	Health Economist
Geraldine MacGibbon	Manager, Pharmaceutical Funding
Gina Armstrong	Funding Application Advisor
Greg Evans	Medical Advisor Registrar
Hayden Spencer	Senior Health Economist
Imani Ram	Panel Coordinator
Jason Arnold	Principal Analyst
Jayne Watkins	Senior Adviser/Team leader
Karen Jacobs-Grant	Senior Advisor Māori Responsiveness
Laura Baker	Therapeutic Group Manager
Logan Heyes	Therapeutic Group Manager
Mark Woodard	Director of Corporate Services
Melody Willis	Team Assistant/Project Administrator
Peter Murray	Deputy Medical Director
Peter Yoo	Therapeutic Group Manager
Rebekah Heap	Strategic Planning & Performance Principal Advisor
Rachel Grocott	Senior Health Economist
Rachel Watt	Senior Policy Analyst
Sandy Bhawan	Acting Manager, Access Equity
Sarah Beri	Manager, Analysis
Sarah Fit	Chief Executive
Scott Metcalfe	Chief Adviser Population Medicine/Deputy Medical Director
Tal Sharrock	Senior Health Economist
Vivienne Rijnberg	Health Economist

Note: attendees may not have been present for the full duration of the meeting

Material considered

1. Meeting agenda
2. PHARMAC factors for consideration
3 Health need charts
4. Cost effectiveness chart
5. Government priorities
6 Full proposal summaries
7. Proposed additions to the Cost Neutral or Cost Saving list and the Recommended for Decline list
8 Projected budget boundaries

[redacted]

[redacted]

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	

[redacted]

[redacted]

[redacted]		
[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Proposals re prioritised with updated information

Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes
(PHARMConnect)

Staff considered the information provided, and noted that this proposal was previously ranked for a subpopulation of patients with type one diabetes that the Diabetes Subcommittee had advised had a greater health need compared to the wider T1DM population, namely, those under the age of 18 years of age and women who were pregnant or were planning pregnancy.

PHARMAC staff noted that funding of the previously ranked subpopulation was not possible in practice and considered it was more appropriate to consider funding of all T1DM patients. As a result, this updated proposal was noted to supersede the previously ranked proposal

The group noted that T1DM patients who use flash glucose monitoring experience a health benefit from not having to test their blood sugars with a finger prick test regularly through the day, less risks and impacts from hypoglycaemia and having less fear of going into a hypoglycaemic state when compared to the current status quo of finger prick testing. This health benefit is balanced with the cost of the device and its consumables, as well as a reduction in the number of test strips used daily. Staff noted that although the prevalence of type 1 diabetes in Māori is lower than non Māori diabetes, the severity of disease is greater for Māori. In addition, it was noted that diabetes in general is a Māori health area of focus and a Government health priority.

FreeStyle Libre flash glucose monitoring system was ranked With on *Options for Investment* list The relative rank of the proposal was unchanged from when it was previously considered in December 2019. The rationale minuted at the December 2019 meeting is outlined below:

> *'Freestyle Libre Flash Glucose Monitoring System Type 1 diabetes was ranked above* Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j) *, on basis of cost effectiveness, Government priorities, and suitability, and below* Withheld under Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) *, on basis of lower health need and cost-effectiveness'*

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Review of the *Options for Investment List*

Staff confirmed the rankings of all the proposals on the Options for Investment list.

Explanation of the PHARMAC Options for Investment list

The Options for Investment list records the relative ranking of proposals for investment, to be progressed when it is affordable and practical to do so. The list contains proposals that have health gains and have sufficient information to be prioritised using PHARMAC's Factors for Consideration Proposals can then be compared with each other to derive a relative ranking for investment An explanation of the columns in the list follows:

Priority The ranking of proposals within the Options for Investment list

Proposal The name of the product, or a description of the group of products

Indication A general description of the restrictions that the product would be funded for or widened to. The actual restrictions placed on a funded proposal may be more detailed

Health Need A proxy measure of the individual Health Need (disease severity) of the average patient, being estimated numbers of Quality Adjusted Life Years lost for a person because of the condition, over a full remaining lifetime under standard care, compared with full health expectancy

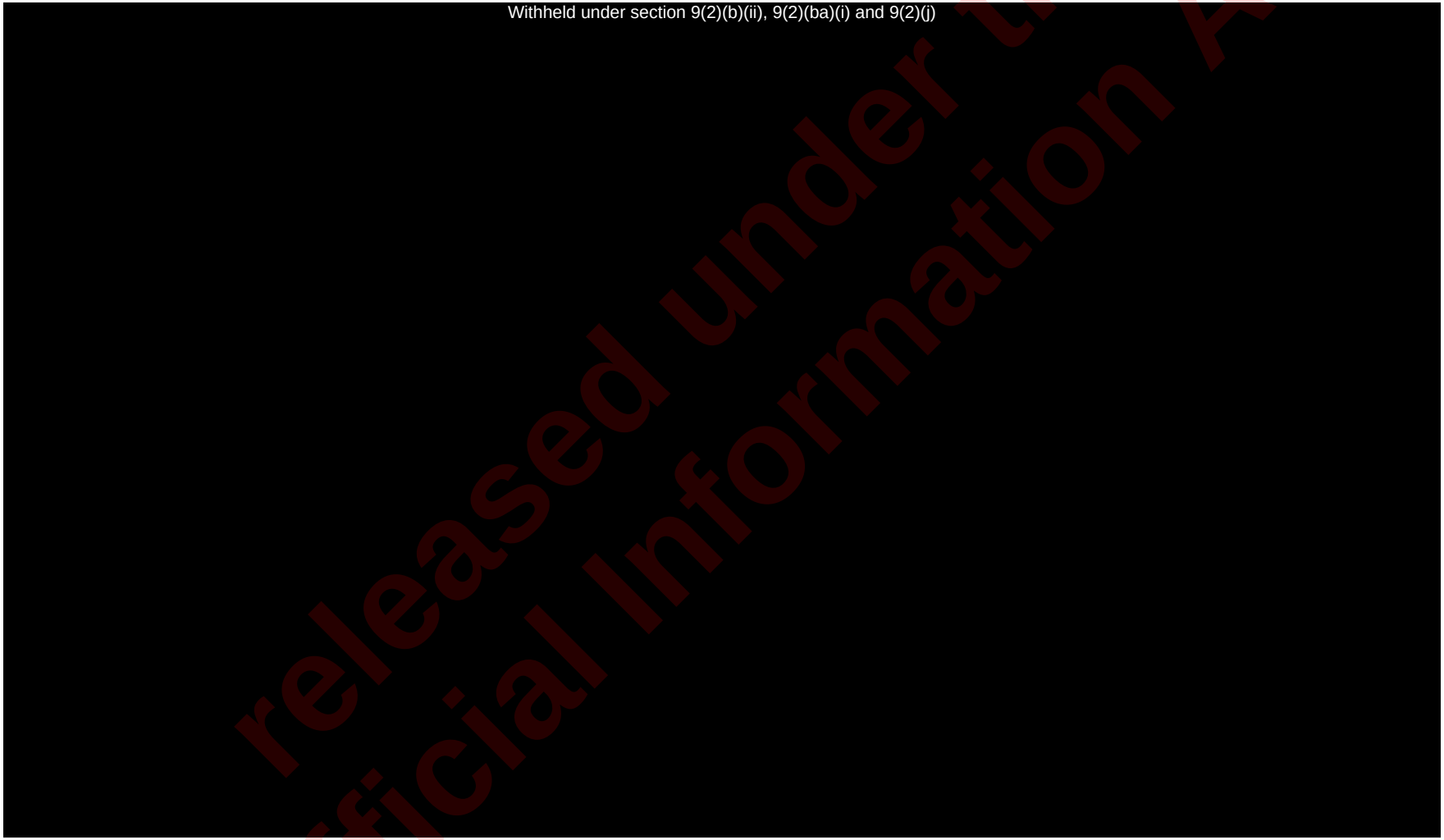
QALYs per $1m Cost effectiveness results are presented as ranges to capture the uncertainty in input variables. The likely range represents PHARMAC's best estimate of cost-effectiveness. The possible range, shown in brackets, captures more of the uncertainty in the analysis and is obtained by varying more inputs and over a wider range.

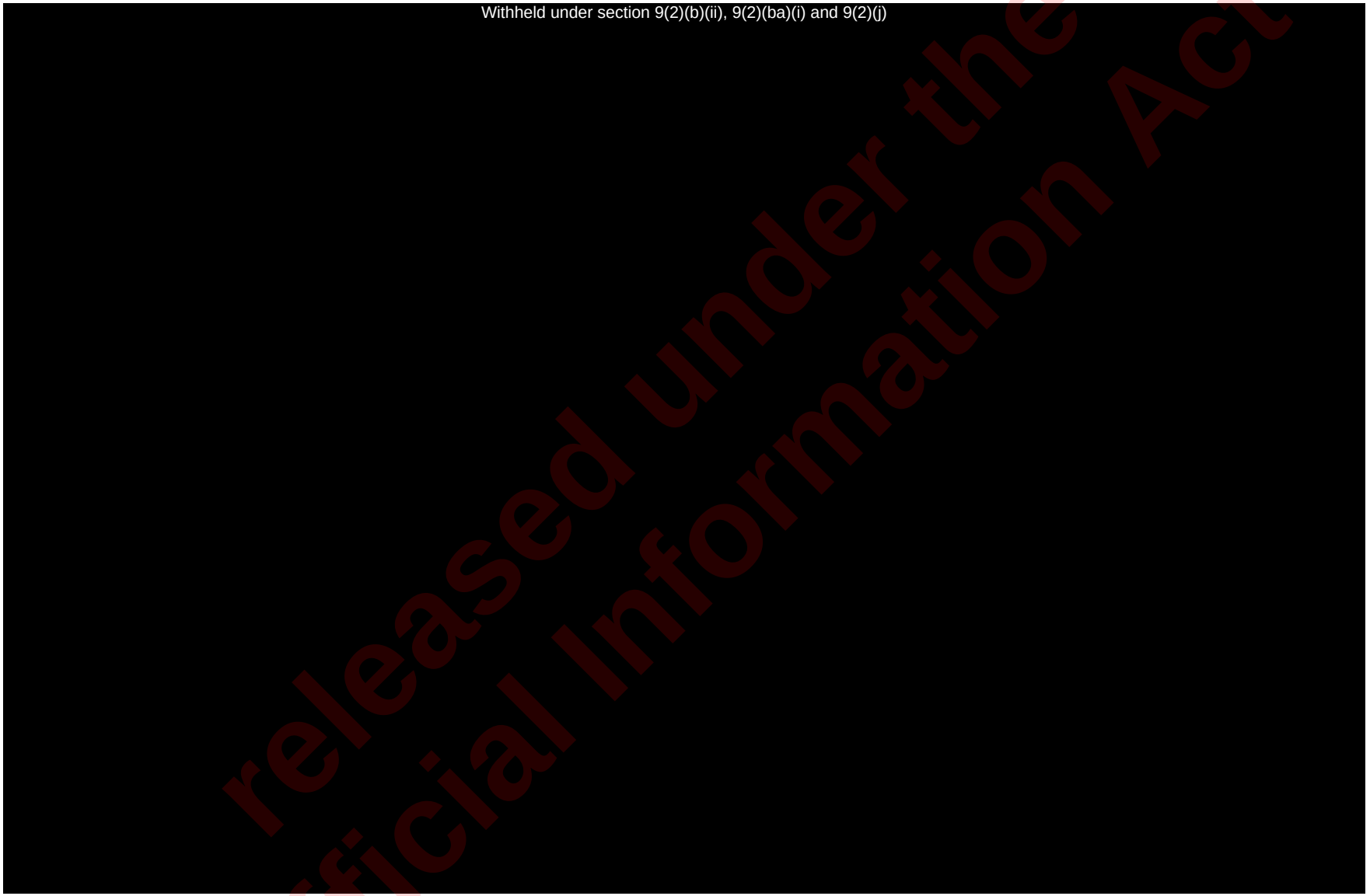
5-year NPV to the CPB the cost to the Combined (hospital and community) Medicines Budget over the first five years of listing (net present value, discounted at 8% p.a.).

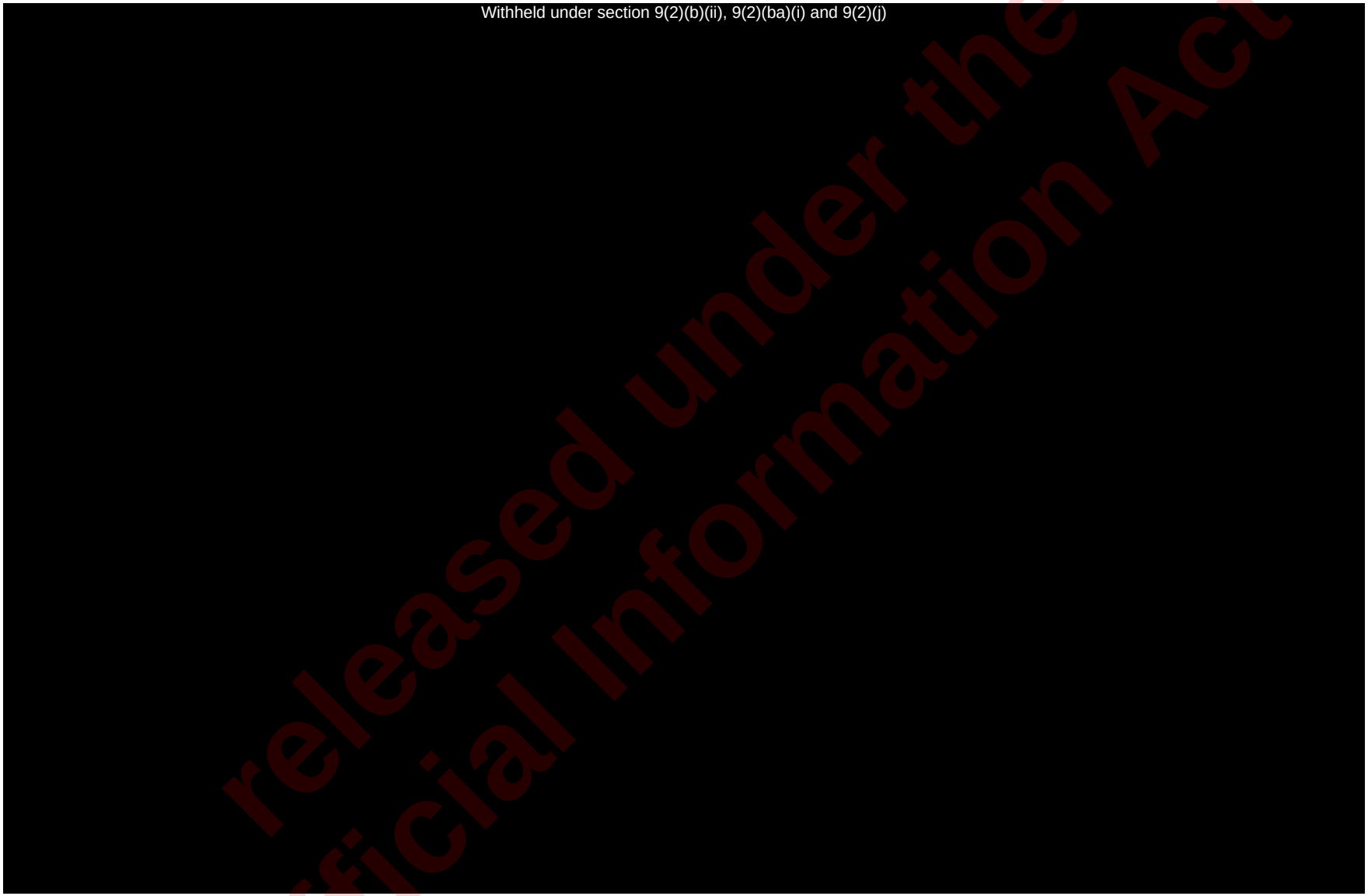
5-year NPV to the DHB – the cost to the DHB Budget over the first five years of listing (net present value, discounted at 8% p a)

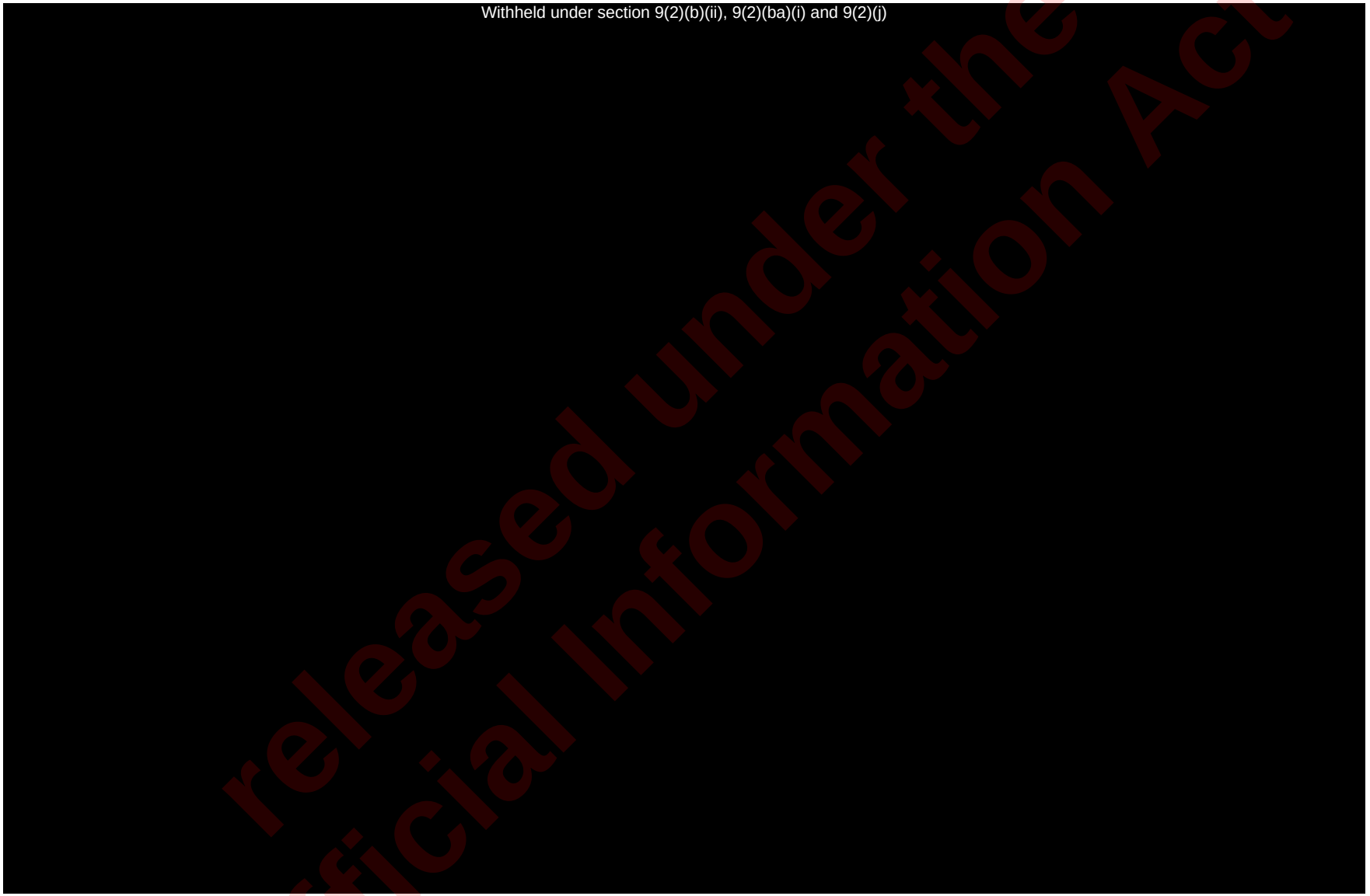
New proposals are in **blue**. Updated proposals are in **green.**

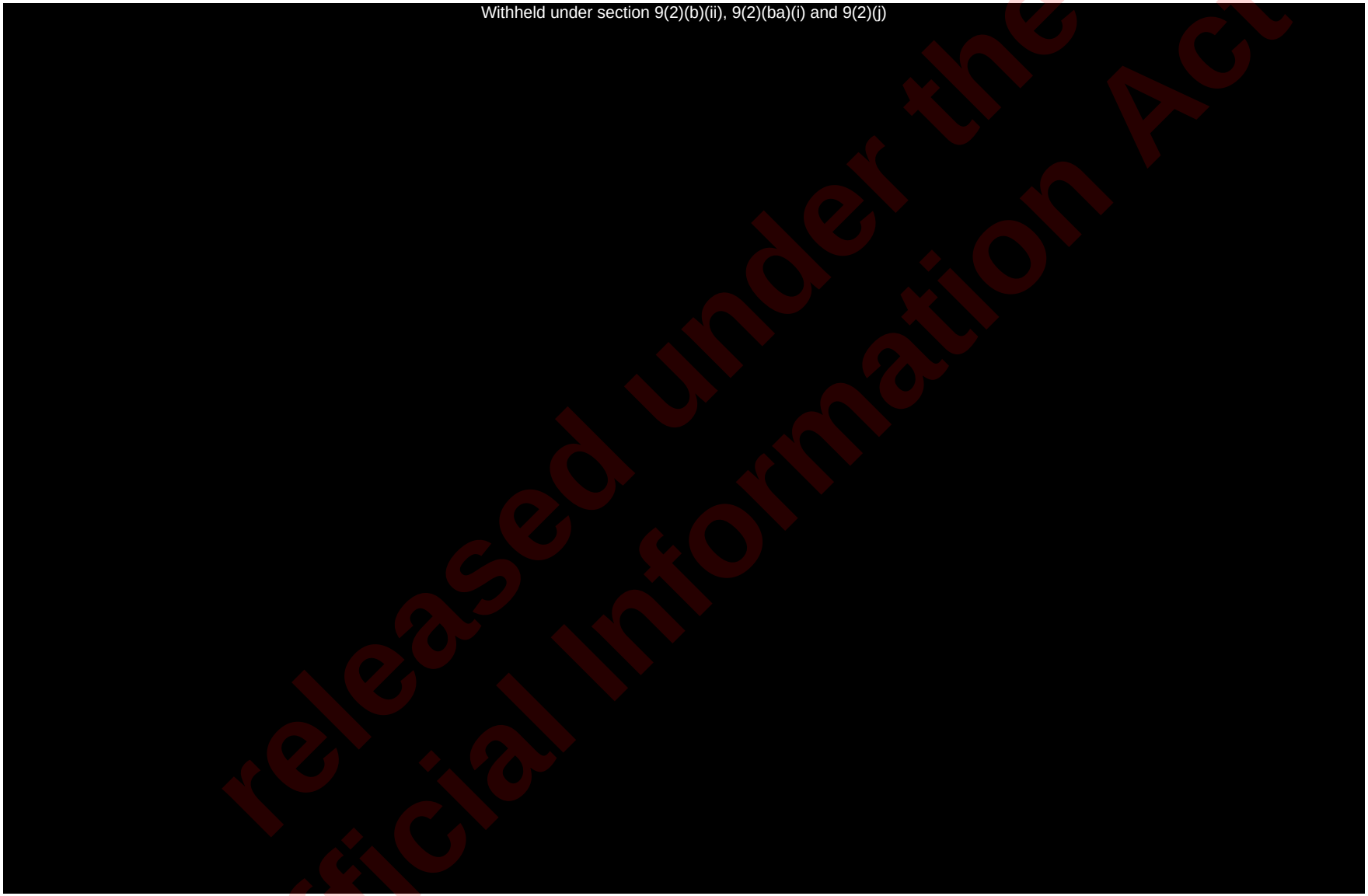
PHARMAC's Options for Investment list ranked by Factors for Consideration, as at 3rd June 2020

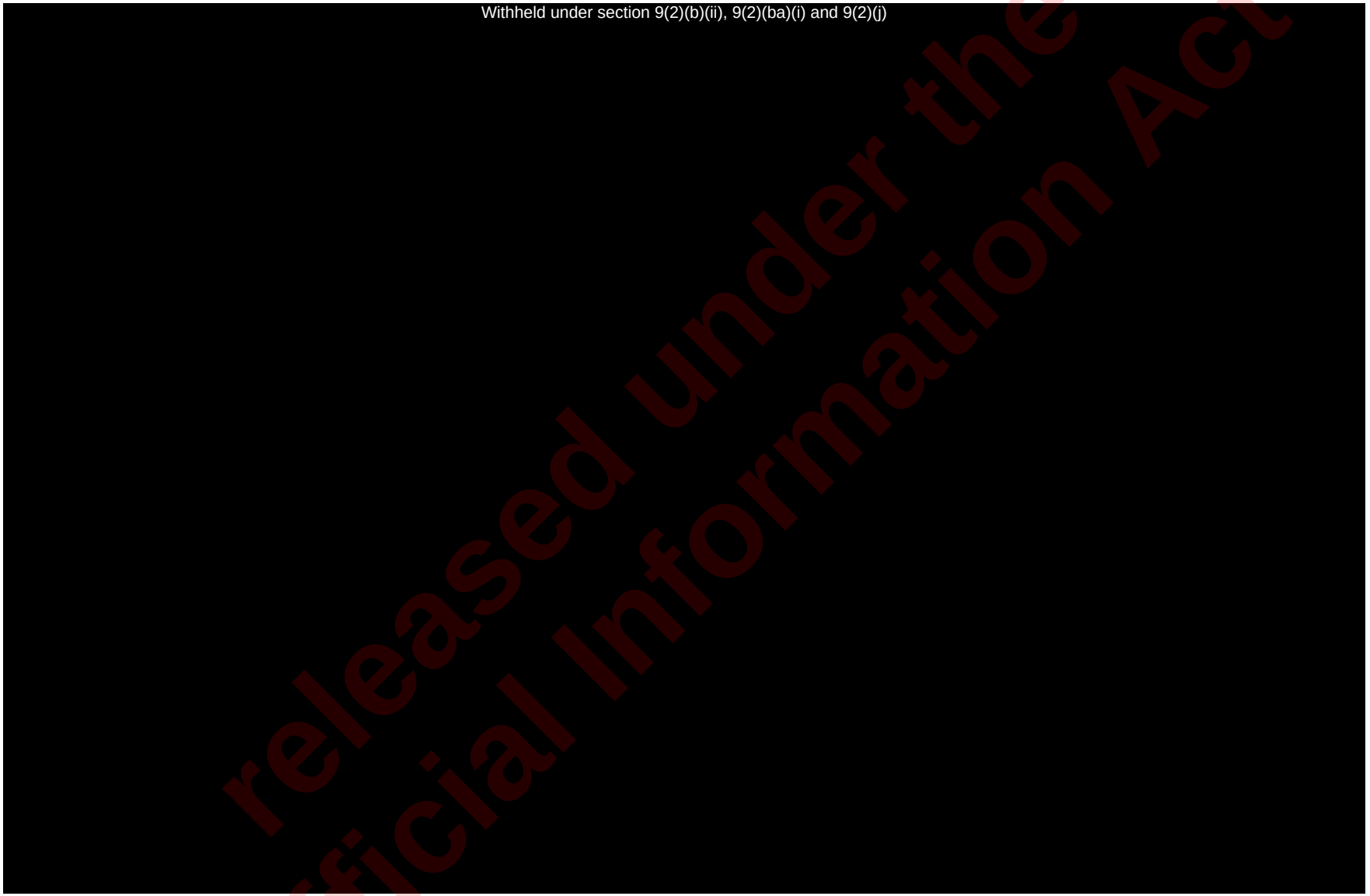












From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Thursday, 19 March 2020 6:57 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

As recently discussed, we'll work on 2 deliverables:

1. Withheld under section 9(2)(ba)(i)
   Withheld under section
2. Withheld under section 9(2)(ba)(i)
   Withheld under section 9(2)(ba)(i)

Please note as a caveat on delivery dates that Abbott is now instigating COVID-19-related workplace/home arrangements that will impact on our capacity and could potentially become more difficult with time.

Regards,
Michael

Abbott
Michael Nobes, Ph.D.
Market Access Director
ANZ
Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia
O: Withheld under
F: +61 3 9855-8020
M: Withheld under
Withheld under section 9(2)

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Monday, 23 March 2020 9:36 AM
To: Nobes, Michael S <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Gina Armstrong <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Thanks so much for this Please note that we will likely need to postpone the clinical advice meeting for this. While this has not yet been confirmed, please don't worry too much about the deadlines we discussed. We appreciate the challenges in this rapidly evolving circumstance As early as you can will be sufficient at this point.

Take care, and be kind

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

Keep in touch! If you would like to receive consults and communications from PHARMAC please sign up here.

From: Nobes, Michael S <Withheld under section 9(2)(a)>
Sent: Monday, 23 March 2020 11:50 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Prakash, Deepak <Withheld under section 9(2)(a)>; Gina Armstrong <Withheld under section 9(2)(a)>
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Thanks for your understanding, Elena.

We'll continue working towards these timelines and keep you posted of progress

Good luck with containment in NZ

Regards,
Michael

Abbott

Michael Nobes, Ph.D.
Market Access Director
ANZ

Abbott Diabetes Care
666 Doncaster Rd
Doncaster VIC 3108
Australia

O: Withheld under
F: +61 3 9855 8020
M: Withheld under Withheld under section 9(2)

PHARMAC Funding Application
18 April 2020

Chemical Name: Cgm

Indication: Diabetes

Contents Page

Product Overview

Product Details

What type of request is the subject of this application?
New medical device for use in the community

If other, please specify

Have any sample(s) of the pharmaceutical been sent to Pharmac?

If a sample has been sent, please provide information that could help us to manage the sample.

Please attach suitable artwork and photographs of the packaging, product and product labelling in pdf or jpeg format

Pharmacological Information

What is the registered name of pharmaceutical?
Cgm

What is the brand name(s) of the pharmaceutical?
Libre freestyle

Describe the principal pharmacological action of the pharmaceutical

What is the main goal of the treatment?

Please select the appropriate portfolio Therapeutic Group for this application
Diabetes

Please select the appropriate portfolio Therapeutic Sub-Group for this application

Provide stability data for infusion treatments (if relevant)

Proposed Amendments to Schedule

Please provide details on the proposed indications for listing
Diabetes

What setting will the product be used?

Where is the product likely to be used?

If other, please specify

Please provide a summary statement of the main therapeutic claims for the pharmaceutical and its proposed use

Dose

What recommended course of treatment including dose regimen is likely to be used in NZ clinical practice for each of the indications proposed for listing?

Were the dosage regimens used in the pivotal trials different from the dosage regimen likely to be used in NZ clinical practice? If so please provide details

Do you have any post marketing data on doseage in clincial practice? If so please provide details

Regulatory Status of The Product

Is the pharmaceutical registered by Medsafe for all indications for which funding is sought?

Please attach Medsafe-approved datasheets if the pharmaceutical is registered.

If registration of the pharmaceutical has been sought but is yet to be granted, please provide details

If the pharmaceutical is registered by Medsafe please provide details of the registered indications

Are other formulations of the product registered for use in NZ?

Pharmaceutical registered for indications overseas?

Provide names of OECD countries where registration has been approved or declined, including any box warnings that may apply

Provide details of other presentations or formulations of the pharmaceutical that have been submitted for approval, or are already approved, in other OECD countries

If the Medsafe registration document is unavailable, please attach copies of relevant Food and Drug Aministration (FDA) and/or European Mediciness Agency (EMA) assessment (note that these reports only need to be attached for unregistrered pharmaceuticals)

Patent Information

Patent information

If you are not the Patent Owner, do you have the right to sell or distribute the pharmaceutical in New Zealand?

If no, please provide further information

If you or the patent owner do not reside or have a place of business within New Zealand, please provide the name of your representative or the representative of the patent owner who resides or maintains a place of business in New Zealand and who is authorised to receive notices related to the patent

Pharmacological Information Table

Pharmaceutical form	If other, please specify	Pharmaceutical strength	Pack size
Other	Sensor	N/a	1 per pack

Product Overview Dose Measure of Treatment Table

What is the average duration of treatment (number)	What is the average duration of treatment (period)

Patent Information Table

Patent Number	Patent Expiry date	Type of Patent	If other please specify	Who is the Patent Owner?

Product Overview_Code Type Table

Identification code	Please specify the code value

Health Need

Patient Population

Who is the target population?

How many in NZ have the condition(s)? For each of the indications requested for consideration of funding, please provide estimates of the number of people in New Zealand who have the indication, the number of Māori people in New Zealand with the particular condition(s) and the number of Pacific people in New Zealand with the particular condition(s).

For each requested indication(s), please provide estimates of the morbidity associated with the condition (eg. annual number of hospitalisations).

Epidemiology Summary

Please attach the relevant tables

Disease and Its Impact

Please provide an overview of the disease or condition to be treated by the proposed pharmaceutical
Type 1 diabetes

Please provide details on the severity of symptoms experienced by the average patient

Does this disease or condition have an impact on patient health-related quality of life? If so, please provide details on areas of health-related quality of life that are likely to be impacted and severity

If possible, please provide information on the total undiscounted quality-adjusted life year (QALY) loss associated with the disease (i.e. QALY of patients with the disease compared with the QALY of the same age specific population in perfect health)

Please provide the source of information

Does the disease or condition impact on the health of family, whanau and/or wider society? Please explain

Does the disease or condition impact on Maori health areas of focus and Maori health outcomes? Please explain

Does this indication disproportionately affect any populations that may already be experiencing a health disparities?

Is the disease or condition a Government health priority

If yes please indicate the disease or condition that is the priority

Current Treatment

What treatment(s) is currently used for this indication in New Zealand? Describe the current treatment algorithm of the target population

What sources of evidence were used to inform the current treatment algorithm?

How well do the current treatments work? Are there any associated risks or tolerability issues with the current treatments?

What is the recommended dose of current treatment(s) and dose equvalencies between current treatment and the proposed pharmaceutical?

What is the shelf life of the current treatment compared with the proposed pharmaceutical?

Are there any issues regarding the availability or suitability of existing treatments for this indication?

Would the pharmaceutical replace or complement existing treatments? Please explain.

Define and summarise how the proposed treatment may change the current treatment algorithm.

Health Need Patient Numbers Table

Year 1	Year 2	Year 3	Year 4	Year 5

Health Benefits

Identification and Selection of Studies

How was the literature searched? Provide details on the search strategy that was used to retrieve clinical studies and list the studies that meet the inclusion criteria

Provide a flow diagram of the number of studies included and excluded at each stage

Errata, editorials and journal correspondence relating to published trials

Register of all ongoing trials that should provide additional evidence in the next 12 months for the relevant indication(s)

What studies were identified in the literature search and which were excluded?

All identified randomised controlled trials that meet the inclusion criteria

All identified metaanalyses and systematic reviews that meet the inclusion criteria

High quality cohort studies and case-control studies that meet the inclusion criteria

Trial Design and Characteristics

Provide details on the methodology of the pivotal clinical trials that provide evidence on the clinical benefits of the pharmaceutical for the proposed indication

Please attach the relevant methodology information

What are the characteristics of the participants in each of the pivotal trials?

Please attach the relevant information

Trial Results

What were the outcomes and methods of analysis in the pivotal trials?

What did the pivotal trials show? Provide a summary of the study results for each relevant comparison and outcome.

How relevant are the outcomes assessed in the clinical trials to clinical benefits and adverse effects expected in New Zealand clinical practice?

Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in new zealand

Discuss and justify any clinically important differences in the results between the different arms of a trial and between trials?

Does the pharmaceutical have similar, greater or fewer side effects and/or toxicity compared with current treatment options? Provide details

What adverse events were observed in the pivotal trial? What type and frequency of adverse events may be expected in NZ clinical practice? Are there any additional safety issues for the pharmaceutical compared to the relevant comparator if used in NZ clinical practice for this indication?

Please attach details of adverse events

Evidence on clinical adverse events (if differs from sources of evidence for clinical effectiveness)

What impact does the proposed pharmaceutical have on patient-reported outcome measures?

Interpretation of the Evidence

Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient of the pharmaceutical, relative to those of the comparator(s)

If available, the incremental health benefits of the proposal relative to the comparator can be provided in the form of quality-adjusted life year (QALY) gains

Please provide information on the consequences (or flowon effects) to the health system if the pharmaceutical was funded.

Would funding the pharmaceutical have an effect on the Government's strategic intentions for the health system?

Health Benefits and Other Consequences Of Treatment

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?

Health Benefits Inclusion and exclusion criteria Table

Selection Criteria	Inclusion Criteria	Exclusion Criteria

Health Benefits Trial Outcomes Table

What were the study references for the pivotal trials?	What was the outcome definition for the pivotal trials?	What was the method of analysis for the pivotal trials?

Health Benefits Studies Included Table

Please identify the type of study	Please provide the full reference of the study

Health Benefits Results summary Table

Study reference	Outcome intervention n/N (%)	Outcome Comparator n/N (%)	Absolute difference (95% confidence interval) (p value)	Relative difference (95% confidence interval) (p value)

Costs and Savings

Price

What is the proposed pharmaceutical price?

Per pack of

What is the supplier's selling prices to wholesalers in other OECD countries where the pharmaceutical is marketed?

Are there any proposed special authority criteria or access restrictions that you would like pharmac to consider?

Please attach any proposed special authority criteria or access restrictions that you would like PHARMAC to consider?

Are there any proposed commercial terms of listing that you would like Pharmac to consider?

Please attach any proposed commercial terms of listing that you would like Pharmac to consider?

Uptake of Pharmaceutical - Epidemiological Approach

Epidemiology over the first 5 years

Uptake of Pharmaceutical Market Share Approach

Estimate the rate of growth of currently available pharmaceuticals over 5 years. Where more than one likely to be substituted present the market share and rate growth for each

item

Estimate the rate of substitution by proposed pharmaceutical for each year over 5 years

Estimate the units dispensed for proposed pharmaceutical for each year over 5 years that is above the growth projected in the market using historical data

Summary of market share

Budget Impact

Identify the currently available pharmaceuticals that are likely to be substituted by the proposed pharmaceutical and estimate the units dispensed of each of these currently available pharmaceuticals in the most recent 12 months

Are there any supplementary pharmaceuticals that may have an increased usage as a result of the proposed pharmaceutical being listed (eg. pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any supplementary pharmaceuticals that may have an decreased usage as a result of the proposed pharmaceutical being listed (e.g. pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any diagnostic tests that patients would require prior to receiving or during the treatment with the proposed pharmaceutical? Please specify

Would funding the pharmaceutical impact on the utilisation of other health sector services?

Average cost for a patient for treatment duration (if average treatment duration >12 months then enter cost for 12 months treatment)

Please attach the completed BIA template

Health Related Costs and Savings

Are there additional costs and/or savings to the person that are likely to be incurred if the pharmaceutical is funded?

Health-related costs and savings that may be experienced to the family, whānau and wider society of the person receiving the treatment

Cost Budget Impact Table

Budget to be impacted	Year 1	Year 2	Year 3	Year 4	Year 5

Cost_Uptake of Pharmaceutical Epidemiological Approach Table

Enter the year for years 1 to 5 from listing date	Please indicate the number of patients treated each year up to 5 years from listing date	Please indicate the number from incremental patients treated each year up to 5 years from listing date

Economic Analysis

Cost-utility analysis based on the methods outlined in the Prescription for Pharmacoeconomic Analysis (including all costs estimated in $NZ)

Please attach TreeAgeTM model or ExcelTM spreadsheet The models must be able to be amended

What is the base case estimate of cost-effectiveness, in QALYs per $million

What is the upper limit of the likely range of cost-effectiveness in QALYs per $million?

What is the lower limit of the likely range of cost-effectiveness in QALYs per $million?

Suitability

Features of the Pharmaceutical That Impact Its Use

Are there any features of the treatment that may impact on its use by the person receiving the treatment (eg method of delivery, accessibility, size, shape, taste)? If so, please explain
A Cgm is known to help diabetics to improve their blood glucose levels thus preventing complications of diabetes.

What features of the pharmaceutical may have an impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society?

What features of the pharmaceutical may have an impact on use by the health workforce?

Are there any other considerations that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or

safety issues?

Declaration and Identification

Declaration

Please confirm if you have the right to supply the product for which funding is requested

I confirm that the company I represent has legal rights to the patents

I confirm that there are no non-patent intellectual property barriers

I have read and accept PHARMAC's standard terms of listing on the Pharmaceutical Schedule.
False

Any variations on the standard terms of listing for PHARMAC to consider have been detailed in this application or provided within an attachment
False

I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application
False

I declare that all known published and unpublished clinical trials that I am aware of that are relevant to this application have been disclosed in the Application
False

I declare that I have obtained the appropriate permission or paid the appropriate copyright fee for any publication or other information provided in support of this application, and that the publications can be distributed internally by PHARMAC (including to PHARMAC committees) for the purpose of reviewing the application.
False

Do you have any potential conflicts of interest relevant to this application
No

Provide a description of any conflicts you may have

I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker
Yes

I confirm the information provided in this Application is correct
Yes

Do you have any comments regarding any of the above declarations?

Identification

Name of person submitting application

Date of application
18 April 2020

Who is the primary contact first name for this application?
Withheld under

Who is the primary contact last name for this application?

What is the primary contact's job title for this application?

What is the primary contact email for this application?
Withheld under section 9(2)

What is the primary contact phone number for this application?
Withheld under

Vaccines (Additional Information)

Pharmacological Information

For the proposed vaccine, please specify the number, identification and amounts of antigens (components)?

What is the formulation of the vaccine?

What is the nature of the immunising agent(s)?

What is vaccine presentation?

What are the external dimensions of the vaccine packed for storage?

Are there any requirements for cold chain management? Please specify

Proposed Amendments to the Pharmaceutical Schedule

Is this a new vaccine or an alternative vaccine? Please select

What is the proposed schedule of administration of the vaccine?

Are there any programme requirements for administration?

What health services will be affected?

Can a vaccination course that begins with the proposed vaccine be completed with a competing or alternative vaccine (or vice versa)?

Is there any expectation of a limited initial supply?

Is a catch-up programme required? If so, please provide details.

Patient Population

In addition to describing the patient population, justify the selection of the requested age range(s) of eligible individuals within the primary immunisation programme and catch-up programme (if relevant)

Current Treatment

Is an alternative vaccine listed on the National Immunisation Schedule?

Compare the content and characteristics of the proposed and alternative vaccines

Health Benefits to the Family, Whanau and Wider Society

Provide evidence that indicates whether funding the vaccine is likely to provide indirect protection to non-immunised people through appropriate coverage (ie herd immunity)

Special Foods (Additional Information)

Pharmacological Information

List all ingredients in the product

Attach a table on the micronutrient and macronutrient content of the product per 100 kcal, and per 100 g or 100 mL

Select type of product

If other, please specify

Confirm that the formula of the proposed product will supply the protein, energy, fatty acid, vitamin and mineral requirements for the patient if used as a sole source of nutrition Identify any additional nutritional needs.

Provide details on the products compatibility with currently available medical devices and consumables in New Zealand

Attach a table comparing the proposed product with the requirements of the Australia New Zealand Food Standards Code - Standard 2.9.1: Infant Formula Products, using the terminology of the code Confirm that the proposed product complies with this code or justify any deviations from particular parts of the code.

Regulatory Status of Product

Confirm that the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for

Special Medical Purposes requirements have been met

Proposed Amendments to the Pharmaceutical Schedule

Attach a table comparing the nutrient contents of the proposed and comparator products with the NZ RDI

Provide the instructions for preparation and use of the proposed product

Community Medical Devices (Additional Information)

Device Information

Describe the therapeutic purpose of the device

Provide details of pack contents and whether any accessories are included in the packs

Describe how the device is used

Please attach the instructions for use and/or the user guide

Does the device need to be used with a pharmaceutical or other technology? If so, is the pharmaceutical or technology is available and funded in New Zealand?

What is the lifespan of the device, and of any component parts, if applicable?

Are there any different models or versions of the device that are available? Does this have any consequences on the mode of action?

What properties or features of the device make it innovative or a significant modification when compared with other technologies of its type?

Regulatory Status of Device

WAND registration number

Date of registration to the WAND database

Proposed Amendments to the Pharmaceutical Schedule

What is the proposed use of the device, including any proposed restrictions to access?

How does the device (if it were digital for example) connect with/interoperability with NZ Health systems (e-prescribing, e-health records, is it bluetooth enabled etc)

Is the device used in standard care internationally? Please provide details

PHARMAC Funding Application
18 April 2020

Chemical Name: Continuous glucose monitor

Indication: improved blood sugar control to minimise diabetes related complications and improve quality of life in all diabetic patients

Contents Page

Product Overview

Product Details

What type of request is the subject of this application?
New medical device for use in the community

If other, please specify

Have any sample(s) of the pharmaceutical been sent to Pharmac?

If a sample has been sent, please provide information that could help us to manage the sample.

Please attach suitable artwork and photographs of the packaging, product and product labelling in pdf or jpeg format

Pharmacological Information

What is the registered name of pharmaceutical?
Continuous glucose monitor

What is the brand name(s) of the pharmaceutical?
Freestyle libre

Describe the principal pharmacological action of the pharmaceutical

What is the main goal of the treatment?

Please select the appropriate portfolio Therapeutic Group for this application
Diabetes

Please select the appropriate portfolio Therapeutic Sub-Group for this application

Provide stability data for infusion treatments (if relevant)

Proposed Amendments to Schedule

Please provide details on the proposed indications for listing
improved blood sugar control to minimise diabetes related complications and improve quality of life in all diabetic patients

What setting will the product be used?

Where is the product likely to be used?

If other, please specify

Please provide a summary statement of the main therapeutic claims for the pharmaceutical and its proposed use

Dose

What recommended course of treatment including dose regimen is likely to be used in NZ clinical practice for each of the indications proposed for listing?

Were the dosage regimens used in the pivotal trials different from the dosage regimen likely to be used in NZ clinical practice? If so please provide details

Do you have any post marketing data on doseage in clincial practice? If so please provide details

Regulatory Status of The Product

Is the pharmaceutical registered by Medsafe for all indications for which funding is sought?

Please attach Medsafe-approved datasheets if the pharmaceutical is registered.

If registration of the pharmaceutical has been sought but is yet to be granted, please provide details

If the pharmaceutical is registered by Medsafe please provide details of the registered indications

Are other formulations of the product registered for use in NZ?

Pharmaceutical registered for indications overseas?

Provide names of OECD countries where registration has been approved or declined, including any box warnings that may apply

Provide details of other presentations or formulations of the pharmaceutical that have been submitted for approval, or are already approved, in other OECD countries

If the Medsafe registration document is unavailable, please attach copies of relevant Food and Drug Aministration (FDA) and/or European Mediciness Agency (EMA) assessment (note that these reports only need to be attached for unregistrered pharmaceuticals)

Patent Information

Patent information

If you are not the Patent Owner, do you have the right to sell or distribute the pharmaceutical in New Zealand?

If no, please provide further information

If you or the patent owner do not reside or have a place of business within New Zealand, please provide the name of your representative or the representative of the patent owner who resides or maintains a place of business in New Zealand and who is authorised to receive notices related to the patent

Pharmacological Information Table

Pharmaceutical form	If other, please specify	Pharmaceutical strength	Pack size

Product Overview Dose Measure of Treatment Table

What is the average duration of treatment (number)	What is the average duration of treatment (period)

Patent Information Table

Patent Number	Patent Expiry date	Type of Patent	If other please specify	Who is the Patent Owner?

Product Overview_Code Type Table

Identification code	Please specify the code value

Health Need

Patient Population

Who is the target population?

How many in NZ have the condition(s)? For each of the indications requested for consideration of funding, please provide estimates of the number of people in New Zealand who have the indication, the number of Māori people in New Zealand with the particular condition(s) and the number of Pacific people in New Zealand with the particular condition(s).

For each requested indication(s), please provide estimates of the morbidity associated with the condition (eg. annual number of hospitalisations).

Epidemiology Summary

Please attach the relevant tables

Disease and Its Impact

Please provide an overview of the disease or condition to be treated by the proposed pharmaceutical
Type 1 diabetes

Please provide details on the severity of symptoms experienced by the average patient

Does this disease or condition have an impact on patient health-related quality of life? If so, please provide details on areas of health-related quality of life that are likely to be impacted

and severity.

If possible, please provide information on the total undiscounted quality-adjusted life year (QALY) loss associated with the disease (ie QALY of patients with the disease compared with the QALY of the same age specific population in perfect health)

Please provide the source of information

Does the disease or condition impact on the health of family, whanau and/or wider society? Please explain
Yes

Does the disease or condition impact on Maori health areas of focus and Maori health outcomes? Please explain

Does this indication disproportionately affect any populations that may already be experiencing a health disparities?
Yes

Is the disease or condition a Government health priority

If yes please indicate the disease or condition that is the priority

Current Treatment

What treatment(s) is currently used for this indication in New Zealand? Describe the current treatment algorithm of the target population

What sources of evidence were used to inform the current treatment algorithm?

How well do the current treatments work? Are there any associated risks or tolerability issues with the current treatments?

What is the recommended dose of current treatment(s) and dose equvalencies between current treatment and the proposed pharmaceutical?

What is the shelf life of the current treatment compared with the proposed pharmaceutical?

Are there any issues regarding the availability or suitability of existing treatments for this indication?

Would the pharmaceutical replace or complement existing treatments? Please explain.

Define and summarise how the proposed treatment may change the current treatment algorithm.

Health Need Patient Numbers Table

Year 1	Year 2	Year 3	Year 4	Year 5

Health Benefits

Identification and Selection of Studies

How was the literature searched? Provide details on the search strategy that was used to retrieve clinical studies and list the studies that meet the inclusion criteria

Provide a flow diagram of the number of studies included and excluded at each stage

Errata, editorials and journal correspondence relating to published trials

Register of all ongoing trials that should provide additional evidence in the next 12 months for the relevant indication(s)

What studies were identified in the literature search and which were excluded?

All identified randomised controlled trials that meet the inclusion criteria

All identified meta-analyses and systematic reviews that meet the inclusion criteria

High quality cohort studies and case-control studies that meet the inclusion criteria

Trial Design and Characteristics

Provide details on the methodology of the pivotal clinical trials that provide evidence on the clinical benefits of the pharmaceutical for the proposed indication

Please attach the relevant methodology information

What are the characteristics of the participants in each of the pivotal trials?

Please attach the relevant information

Trial Results

What were the outcomes and methods of analysis in the pivotal trials?

What did the pivotal trials show? Provide a summary of the study results for each relevant comparison and outcome

How relevant are the outcomes assessed in the clinical trials to clinical benefits and adverse effects expected in New Zealand clinical practice?

Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in new zealand

Discuss and justify any clinically important differences in the results between the different arms of a trial and between trials?

Does the pharmaceutical have similar, greater or fewer side effects and/or toxicity compared with current treatment options? Provide details

What adverse events were observed in the pivotal trial? What type and frequency of adverse events may be expected in NZ clinical practice? Are there any additional safety issues for the pharmaceutical compared to the relevant comparator if used in NZ clinical practice for this indication?

Please attach details of adverse events

Evidence on clinical adverse events (if differs from sources of evidence for clinical effectiveness)

What impact does the proposed pharmaceutical have on patient-reported outcome measures?

Interpretation of the Evidence

Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient of the pharmaceutical, relative to those of the comparator(s)

If available, the incremental health benefits of the proposal relative to the comparator can be provided in the form of quality-adjusted life year (QALY) gains

Please provide information on the consequences (or flowon effects) to the health system if the pharmaceutical was funded.

Would funding the pharmaceutical have an effect on the Government's strategic intentions for the health system?

Health Benefits and Other Consequences Of Treatment

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?

Health Benefits Inclusion and exclusion criteria Table

Selection Criteria	Inclusion Criteria	Exclusion Criteria

Health Benefits Trial Outcomes Table

What were the study references for the pivotal trials?	What was the outcome definition for the pivotal trials?	What was the method of analysis for the pivotal trials?

Health Benefits Studies Included Table

Please identify the type of study	Please provide the full reference of the study

Health Benefits Results summary Table

Study reference	Outcome intervention n/N (%)	Outcome Comparator n/N (%)	Absolute difference (95% confidence interval) (p value)	Relative difference (95% confidence interval) (p value)

Costs and Savings

Price

What is the proposed pharmaceutical price?

Per pack of

What is the supplier's selling prices to wholesalers in other OECD countries where the pharmaceutical is marketed?

Are there any proposed special authority criteria or access restrictions that you would like pharmac to consider?

Please attach any proposed special authority criteria or access restrictions that you would like PHARMAC to consider?

Are there any proposed commercial terms of listing that you would like Pharmac to consider?

Please attach any proposed commercial terms of listing that you would like Pharmac to consider?

Uptake of Pharmaceutical Epidemiological Approach

Epidemiology over the first 5 years

Uptake of Pharmaceutical Market Share Approach

Estimate the rate of growth of currently available pharmaceuticals over 5 years Where more than one likely to be substituted present the market share and rate growth for each item

Estimate the rate of substitution by proposed pharmaceutical for each year over 5 years

Estimate the units dispensed for proposed pharmaceutical for each year over 5 years that is above the growth projected in the market using historical data

Summary of market share

Budget Impact

Identify the currently available pharmaceuticals that are likely to be substituted by the proposed pharmaceutical and estimate the units dispensed of each of these currently available pharmaceuticals in the most recent 12 months

Are there any supplementary pharmaceuticals that may have an increased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any supplementary pharmaceuticals that may have an decreased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any diagnostic tests that patients would require prior to receiving or during the treatment with the proposed pharmaceutical? Please specify

Would funding the pharmaceutical impact on the utilisation of other health sector services?

Average cost for a patient for treatment duration (if average treatment duration >12 months then enter cost for 12 months treatment)

Please attach the completed BIA template

Health Related Costs and Savings

Are there additional costs and/or savings to the person that are likely to be incurred if the pharmaceutical is funded?

Health-related costs and savings that may be experienced to the family, whānau and wider society of the person receiving the treatment

Cost Budget Impact Table

Budget to be impacted	Year 1	Year 2	Year 3	Year 4	Year 5

Cost_Uptake of Pharmaceutical Epidemiological Approach Table

Enter the year for years 1 to 5 from listing date	Please indicate the number of patients treated each year up to 5 years from listing date	Please indicate the number from incremental patients treated each year up to 5 years from listing date

Economic Analysis

Cost-utility analysis based on the methods outlined in the Prescription for Pharmacoeconomic Analysis (including all costs estimated in $NZ)

Please attach TreeAgeTM model or ExcelTM spreadsheet The models must be able to be amended

What is the base case estimate of cost-effectiveness, in QALYs per $million

What is the upper limit of the likely range of cost-effectiveness in QALYs per $million?

What is the lower limit of the likely range of cost-effectiveness in QALYs per $million?

Suitability

Features of the Pharmaceutical That Impact Its Use

Are there any features of the treatment that may impact on its use by the person receiving the treatment (eg method of delivery, accessibility, size, shape, taste)? If so, please explain
Better blood sugar control

What features of the pharmaceutical may have an impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society?
Better blood sugar control = longer life

What features of the pharmaceutical may have an impact on use by the health workforce?

Are there any other considerations that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or safety issues?

Declaration and Identification

Declaration

Please confirm if you have the right to supply the product for which funding is requested

I confirm that the company I represent has legal rights to the patents

I confirm that there are no non-patent intellectual property barriers

I have read and accept PHARMAC's standard terms of listing on the Pharmaceutical Schedule.
False

Any variations on the standard terms of listing for PHARMAC to consider have been detailed in this application or provided within an attachment
False

I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application
False

I declare that all known published and unpublished clinical trials that I am aware of that are relevant to this application have been disclosed in the Application
False

I declare that I have obtained the appropriate permission or paid the appropriate copyright fee for any publication or other information provided in support of this application, and that the publications can be distributed internally by PHARMAC (including to PHARMAC committees) for the purpose of reviewing the application.
False

Do you have any potential conflicts of interest relevant to this application
No

Provide a description of any conflicts you may have

I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker
Yes

I confirm the information provided in this Application is correct
Yes

Do you have any comments regarding any of the above declarations?

Identification

Name of person submitting application

Date of application
18 April 2020

Who is the primary contact first name for this application?
Myself

Who is the primary contact last name for this application?

What is the primary contact's job title for this application?

What is the primary contact email for this application?
Withheld under section 9(2)(a)

What is the primary contact phone number for this application?
Withheld under

Vaccines (Additional Information)

Pharmacological Information

For the proposed vaccine, please specify the number, identification and amounts of antigens (components)?

What is the formulation of the vaccine?

What is the nature of the immunising agent(s)?

What is vaccine presentation?

What are the external dimensions of the vaccine packed for storage?

Are there any requirements for cold chain management? Please specify

Proposed Amendments to the Pharmaceutical Schedule

Is this a new vaccine or an alternative vaccine? Please select

What is the proposed schedule of administration of the vaccine?

Are there any programme requirements for administration?

What health services will be affected?

Can a vaccination course that begins with the proposed vaccine be completed with a competing or alternative vaccine (or vice versa)?

Is there any expectation of a limited initial supply?

Is a catch-up programme required? If so, please provide details.

Patient Population

In addition to describing the patient population, justify the selection of the requested age

range(s) of eligible individuals within the primary immunisation programme and catch-up programme (if relevant)

Current Treatment

Is an alternative vaccine listed on the National Immunisation Schedule?

Compare the content and characteristics of the proposed and alternative vaccines

Health Benefits to the Family, Whanau and Wider Society

Provide evidence that indicates whether funding the vaccine is likely to provide indirect protection to non-immunised people through appropriate coverage (ie. herd immunity)

Special Foods (Additional Information)

Pharmacological Information

List all ingredients in the product

Attach a table on the micronutrient and macronutrient content of the product per 100 kcal, and per 100 g or 100 mL

Select type of product

If other, please specify

Confirm that the formula of the proposed product will supply the protein, energy, fatty acid, vitamin and mineral requirements for the patient if used as a sole source of nutrition Identify any additional nutritional needs.

Provide details on the products compatibility with currently available medical devices and consumables in New Zealand

Attach a table comparing the proposed product with the requirements of the Australia New Zealand Food Standards Code - Standard 2.9.1: Infant Formula Products, using the terminology of the code Confirm that the proposed product complies with this code or justify any deviations from particular parts of the code.

Regulatory Status of Product

Confirm that the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes requirements have been met

Proposed Amendments to the Pharmaceutical Schedule

Attach a table comparing the nutrient contents of the proposed and comparator products with the NZ RDI

Provide the instructions for preparation and use of the proposed product

Community Medical Devices (Additional Information)

Device Information

Describe the therapeutic purpose of the device

Provide details of pack contents and whether any accessories are included in the packs

Describe how the device is used

Please attach the instructions for use and/or the user guide

Does the device need to be used with a pharmaceutical or other technology? If so, is the pharmaceutical or technology is available and funded in New Zealand?

What is the lifespan of the device, and of any component parts, if applicable?

Are there any different models or versions of the device that are available? Does this have any consequences on the mode of action?

What properties or features of the device make it innovative or a significant modification when compared with other technologies of its type?

Regulatory Status of Device

WAND registration number

Date of registration to the WAND database

Proposed Amendments to the Pharmaceutical Schedule

What is the proposed use of the device, including any proposed restrictions to access?

How does the device (if it were digital for example) connect with/interoperability with NZ Health systems (e-prescribing, e-health records, is it bluetooth enabled etc)

Is the device used in standard care internationally? Please provide details

PHARMAC Funding Application
18 April 2020

Chemical Name: Freestyle libre flash glucose monitor

Indication: Type 1 diabetic, insulin dependent.
have suffered severe diabetic retinopathy

Contents Page

Product Overview

Product Details

What type of request is the subject of this application?
New medical device for use in the community

If other, please specify

Have any sample(s) of the pharmaceutical been sent to Pharmac?

If a sample has been sent, please provide information that could help us to manage the sample.

Please attach suitable artwork and photographs of the packaging, product and product labelling in pdf or jpeg format

Pharmacological Information

What is the registered name of pharmaceutical?
Freestyle libre flash glucose monitor

What is the brand name(s) of the pharmaceutical?
Freestyle libre

Describe the principal pharmacological action of the pharmaceutical

What is the main goal of the treatment?

Please select the appropriate portfolio Therapeutic Group for this application
Diabetes

Please select the appropriate portfolio Therapeutic Sub-Group for this application

Provide stability data for infusion treatments (if relevant)

Proposed Amendments to Schedule

Please provide details on the proposed indications for listing
Type 1 diabetic, insulin dependent.
have suffered severe diabetic retinopathy

What setting will the product be used?

Where is the product likely to be used?

If other, please specify

Please provide a summary statement of the main therapeutic claims for the pharmaceutical and its proposed use

Dose

What recommended course of treatment including dose regimen is likely to be used in NZ clinical practice for each of the indications proposed for listing?

Were the dosage regimens used in the pivotal trials different from the dosage regimen likely to be used in NZ clinical practice? If so please provide details

Do you have any post marketing data on doseage in clincial practice? If so please provide details

Regulatory Status of The Product

Is the pharmaceutical registered by Medsafe for all indications for which funding is sought?

Please attach Medsafe-approved datasheets if the pharmaceutical is registered.

If registration of the pharmaceutical has been sought but is yet to be granted, please provide details

If the pharmaceutical is registered by Medsafe please provide details of the registered indications

Are other formulations of the product registered for use in NZ?

Pharmaceutical registered for indications overseas?

Provide names of OECD countries where registration has been approved or declined, including any box warnings that may apply

Provide details of other presentations or formulations of the pharmaceutical that have been submitted for approval, or are already approved, in other OECD countries

If the Medsafe registration document is unavailable, please attach copies of relevant Food and Drug Aministration (FDA) and/or European Mediciness Agency (EMA) assessment (note that these reports only need to be attached for unregistrered pharmaceuticals)

Patent Information

Patent information

If you are not the Patent Owner, do you have the right to sell or distribute the pharmaceutical in New Zealand?

If no, please provide further information

If you or the patent owner do not reside or have a place of business within New Zealand, please provide the name of your representative or the representative of the patent owner who resides or maintains a place of business in New Zealand and who is authorised to receive notices related to the patent

Pharmacological Information Table

Pharmaceutical form	If other, please specify	Pharmaceutical strength	Pack size

Product Overview Dose Measure of Treatment Table

What is the average duration of treatment (number)	What is the average duration of treatment (period)

Patent Information Table

Patent Number	Patent Expiry date	Type of Patent	If other please specify	Who is the Patent Owner?

Product Overview_Code Type Table

Identification code	Please specify the code value

Health Need

Patient Population

Who is the target population?

How many in NZ have the condition(s)? For each of the indications requested for consideration of funding, please provide estimates of the number of people in New Zealand who have the indication, the number of Māori people in New Zealand with the particular condition(s) and the number of Pacific people in New Zealand with the particular condition(s).

For each requested indication(s), please provide estimates of the morbidity associated with the condition (eg. annual number of hospitalisations).

Epidemiology Summary

Please attach the relevant tables

Disease and Its Impact

Please provide an overview of the disease or condition to be treated by the proposed pharmaceutical
Type 1 diabetes

Please provide details on the severity of symptoms experienced by the average patient

Does this disease or condition have an impact on patient health-related quality of life? If so, please provide details on areas of health-related quality of life that are likely to be impacted

and severity.

If possible, please provide information on the total undiscounted quality-adjusted life year (QALY) loss associated with the disease (ie QALY of patients with the disease compared with the QALY of the same age specific population in perfect health)

Please provide the source of information

Does the disease or condition impact on the health of family, whanau and/or wider society? Please explain
Yes due to the blood sugar changing it impacts behaviour, activity and mental capacity

Does the disease or condition impact on Maori health areas of focus and Maori health outcomes? Please explain

Does this indication disproportionately affect any populations that may already be experiencing a health disparities?

Is the disease or condition a Government health priority

If yes please indicate the disease or condition that is the priority

Current Treatment

What treatment(s) is currently used for this indication in New Zealand? Describe the current treatment algorithm of the target population

What sources of evidence were used to inform the current treatment algorithm?

How well do the current treatments work? Are there any associated risks or tolerability issues with the current treatments?

What is the recommended dose of current treatment(s) and dose equvalencies between current treatment and the proposed pharmaceutical?

What is the shelf life of the current treatment compared with the proposed pharmaceutical?

Are there any issues regarding the availability or suitability of existing treatments for this indication?

Would the pharmaceutical replace or complement existing treatments? Please explain.

Define and summarise how the proposed treatment may change the current treatment algorithm.

Health Need Patient Numbers Table

Year 1	Year 2	Year 3	Year 4	Year 5

Health Benefits

Identification and Selection of Studies

How was the literature searched? Provide details on the search strategy that was used to retrieve clinical studies and list the studies that meet the inclusion criteria

Provide a flow diagram of the number of studies included and excluded at each stage

Errata, editorials and journal correspondence relating to published trials

Register of all ongoing trials that should provide additional evidence in the next 12 months for the relevant indication(s)

What studies were identified in the literature search and which were excluded?

All identified randomised controlled trials that meet the inclusion criteria

All identified meta-analyses and systematic reviews that meet the inclusion criteria

High quality cohort studies and case-control studies that meet the inclusion criteria

Trial Design and Characteristics

Provide details on the methodology of the pivotal clinical trials that provide evidence on the clinical benefits of the pharmaceutical for the proposed indication

Please attach the relevant methodology information

What are the characteristics of the participants in each of the pivotal trials?

Please attach the relevant information

Trial Results

What were the outcomes and methods of analysis in the pivotal trials?

What did the pivotal trials show? Provide a summary of the study results for each relevant comparison and outcome

How relevant are the outcomes assessed in the clinical trials to clinical benefits and adverse effects expected in New Zealand clinical practice?

Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in new zealand

Discuss and justify any clinically important differences in the results between the different arms of a trial and between trials?

Does the pharmaceutical have similar, greater or fewer side effects and/or toxicity compared with current treatment options? Provide details

What adverse events were observed in the pivotal trial? What type and frequency of adverse events may be expected in NZ clinical practice? Are there any additional safety issues for the pharmaceutical compared to the relevant comparator if used in NZ clinical practice for this indication?

Please attach details of adverse events

Evidence on clinical adverse events (if differs from sources of evidence for clinical effectiveness)

What impact does the proposed pharmaceutical have on patient-reported outcome measures?

Interpretation of the Evidence

Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient of the pharmaceutical, relative to those of the comparator(s)

If available, the incremental health benefits of the proposal relative to the comparator can be provided in the form of quality-adjusted life year (QALY) gains

Please provide information on the consequences (or flowon effects) to the health system if the pharmaceutical was funded.

Would funding the pharmaceutical have an effect on the Government's strategic intentions for the health system?

Health Benefits and Other Consequences Of Treatment

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?

Health Benefits Inclusion and exclusion criteria Table

Selection Criteria	Inclusion Criteria	Exclusion Criteria

Health Benefits Trial Outcomes Table

What were the study references for the pivotal trials?	What was the outcome definition for the pivotal trials?	What was the method of analysis for the pivotal trials?

Health Benefits Studies Included Table

Please identify the type of study	Please provide the full reference of the study

Health Benefits Results summary Table

Study reference	Outcome intervention n/N (%)	Outcome Comparator n/N (%)	Absolute difference (95% confidence interval) (p value)	Relative difference (95% confidence interval) (p value)

Costs and Savings

Price

What is the proposed pharmaceutical price?

Per pack of

What is the supplier's selling prices to wholesalers in other OECD countries where the pharmaceutical is marketed?

Are there any proposed special authority criteria or access restrictions that you would like pharmac to consider?

Please attach any proposed special authority criteria or access restrictions that you would like PHARMAC to consider?

Are there any proposed commercial terms of listing that you would like Pharmac to consider?

Please attach any proposed commercial terms of listing that you would like Pharmac to consider?

Uptake of Pharmaceutical Epidemiological Approach

Epidemiology over the first 5 years

Uptake of Pharmaceutical Market Share Approach

Estimate the rate of growth of currently available pharmaceuticals over 5 years Where more than one likely to be substituted present the market share and rate growth for each item

Estimate the rate of substitution by proposed pharmaceutical for each year over 5 years

Estimate the units dispensed for proposed pharmaceutical for each year over 5 years that is above the growth projected in the market using historical data

Summary of market share

Budget Impact

Identify the currently available pharmaceuticals that are likely to be substituted by the proposed pharmaceutical and estimate the units dispensed of each of these currently available pharmaceuticals in the most recent 12 months

Are there any supplementary pharmaceuticals that may have an increased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any supplementary pharmaceuticals that may have an decreased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any diagnostic tests that patients would require prior to receiving or during the treatment with the proposed pharmaceutical? Please specify

Would funding the pharmaceutical impact on the utilisation of other health sector services?

Average cost for a patient for treatment duration (if average treatment duration >12 months then enter cost for 12 months treatment)

Please attach the completed BIA template

Health Related Costs and Savings

Are there additional costs and/or savings to the person that are likely to be incurred if the pharmaceutical is funded?

Health-related costs and savings that may be experienced to the family, whānau and wider society of the person receiving the treatment

Cost Budget Impact Table

Budget to be impacted	Year 1	Year 2	Year 3	Year 4	Year 5

Cost_Uptake of Pharmaceutical Epidemiological Approach Table

Enter the year for years 1 to 5 from listing date	Please indicate the number of patients treated each year up to 5 years from listing date	Please indicate the number from incremental patients treated each year up to 5 years from listing date

Economic Analysis

Cost-utility analysis based on the methods outlined in the Prescription for Pharmacoeconomic Analysis (including all costs estimated in $NZ)

Please attach TreeAgeTM model or ExcelTM spreadsheet The models must be able to be amended

What is the base case estimate of cost-effectiveness, in QALYs per $million

What is the upper limit of the likely range of cost-effectiveness in QALYs per $million?

What is the lower limit of the likely range of cost-effectiveness in QALYs per $million?

Suitability

Features of the Pharmaceutical That Impact Its Use

Are there any features of the treatment that may impact on its use by the person receiving the treatment (eg method of delivery, accessibility, size, shape, taste)? If so, please explain

What features of the pharmaceutical may have an impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society?

What features of the pharmaceutical may have an impact on use by the health workforce?

Are there any other considerations that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or safety issues?

Declaration and Identification

Declaration

Please confirm if you have the right to supply the product for which funding is requested

I confirm that the company I represent has legal rights to the patents

I confirm that there are no non-patent intellectual property barriers

I have read and accept PHARMAC's standard terms of listing on the Pharmaceutical Schedule
False

Any variations on the standard terms of listing for PHARMAC to consider have been detailed in this application or provided within an attachment
False

I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application
False

I declare that all known published and unpublished clinical trials that I am aware of that are relevant to this application have been disclosed in the Application
False

I declare that I have obtained the appropriate permission or paid the appropriate copyright fee for any publication or other information provided in support of this application, and that the publications can be distributed internally by PHARMAC (including to PHARMAC committees) for the purpose of reviewing the application
False

Do you have any potential conflicts of interest relevant to this application
No

Provide a description of any conflicts you may have

I agree that the product details information provided in the online form can be made publicly available on the Application Tracker
No

I confirm the information provided in this Application is correct
Yes

Do you have any comments regarding any of the above declarations?

Identification

Name of person submitting application

Date of application
18 April 2020

Who is the primary contact first name for this application?
Withheld under

Who is the primary contact last name for this application?

What is the primary contact's job title for this application?

What is the primary contact email for this application?
Withheld under section 9(2)(a)

What is the primary contact phone number for this application?
Withheld under

Vaccines (Additional Information)

Pharmacological Information

For the proposed vaccine, please specify the number, identification and amounts of antigens (components)?

What is the formulation of the vaccine?

What is the nature of the immunising agent(s)?

What is vaccine presentation?

What are the external dimensions of the vaccine packed for storage?

Are there any requirements for cold chain management? Please specify

Proposed Amendments to the Pharmaceutical Schedule

Is this a new vaccine or an alternative vaccine? Please select

What is the proposed schedule of administration of the vaccine?

Are there any programme requirements for administration?

What health services will be affected?

Can a vaccination course that begins with the proposed vaccine be completed with a competing or alternative vaccine (or vice versa)?

Is there any expectation of a limited initial supply?

Is a catch-up programme required? If so, please provide details

Patient Population

In addition to describing the patient population, justify the selection of the requested age range(s) of eligible individuals within the primary immunisation programme and catch-up

programme (if relevant).

Current Treatment

Is an alternative vaccine listed on the National Immunisation Schedule?

Compare the content and characteristics of the proposed and alternative vaccines

Health Benefits to the Family, Whanau and Wider Society

Provide evidence that indicates whether funding the vaccine is likely to provide indirect protection to non-immunised people through appropriate coverage (ie. herd immunity).

Special Foods (Additional Information)

Pharmacological Information

List all ingredients in the product

Attach a table on the micronutrient and macronutrient content of the product per 100 kcal, and per 100 g or 100 mL

Select type of product

If other, please specify

Confirm that the formula of the proposed product will supply the protein, energy, fatty acid, vitamin and mineral requirements for the patient if used as a sole source of nutrition. Identify any additional nutritional needs

Provide details on the products compatibility with currently available medical devices and consumables in New Zealand

Attach a table comparing the proposed product with the requirements of the Australia New Zealand Food Standards Code Standard 291: Infant Formula Products, using the terminology of the code. Confirm that the proposed product complies with this code or justify any deviations from particular parts of the code

Regulatory Status of Product

Confirm that the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes requirements have been met

Proposed Amendments to the Pharmaceutical Schedule

Attach a table comparing the nutrient contents of the proposed and comparator products with the NZ RDI

Provide the instructions for preparation and use of the proposed product

Community Medical Devices (Additional Information)

Device Information

Describe the therapeutic purpose of the device

Provide details of pack contents and whether any accessories are included in the packs

Describe how the device is used

Please attach the instructions for use and/or the user guide

Does the device need to be used with a pharmaceutical or other technology? If so, is the pharmaceutical or technology is available and funded in New Zealand?

What is the lifespan of the device, and of any component parts, if applicable?

Are there any different models or versions of the device that are available? Does this have any consequences on the mode of action?

What properties or features of the device make it innovative or a significant modification when compared with other technologies of its type?

Regulatory Status of Device

WAND registration number

Date of registration to the WAND database

Proposed Amendments to the Pharmaceutical Schedule

What is the proposed use of the device, including any proposed restrictions to access?

How does the device (if it were digital for example) connect with/interoperability with NZ Health systems (eprescribing, ehealth records, is it bluetooth enabled etc)

Is the device used in standard care internationally? Please provide details

AGENDA

Diabetes Subcommittee Meeting

Wednesday 29 April 2020
9.00 am 3.30 pm

PHARMAC Offices
Tait Room
Level 9, 40 Mercer Street, Wellington

Time	Agenda item	Discussion leader
9:00 am	**Arrival (coffee/tea provided)**	
9 05 am	Welcome and introductions	Chair
9 10 am	Declarations of conflicts of interest	Chair /All
9:15 am	PHARMAC Update • PHARMAC's strategic direction (TBC) • PHARMAC and medicines access equity	Catherine Proffitt? Sandy Bhawan
10:00 am	Action points	Chair /All
10:15 am	Minutes review • Record of the previous Diabetes Subcommittee meeting, 19 March 2019 • Review of relevant diabetes minutes from PTAC since previous Diabetes Subcommittee meeting	Chair /All
10.30 am	**Morning tea (provided)**	
11 00 am	Therapeutic Group Review [To delete below content prior to agenda distribution] • NPPA review • Insulin pump access criteria • Insulin pumps transition feedback • Review of usage of insulin pump consumables • NZMS – Basal IQ • Insulin pump recalls/safety alerts	TBC chair/SMEs
12.45 pm	**Lunch (provided)**	
1.15 pm	SGLT 2/GLP 1/DPP-4 RFP bid evaluation (TBC)	TBC
1:45 pm	Insulin glargine supply risk/biosimilar planning	TBC
2:15 pm	Diabetes technology discussion • Insulin pumps – commercial proposals • CGMSs commercial proposals • Potential procurement approaches	TBC

3 30 pm	**Afternoon tea (provided)**	
3.45 pm	Freestyle Libre for Type 2 diabetes	TBC
4.30 pm	Any other business	Chair/all
5 00 pm	**Meeting close**	

Correspondence/matters arising

PHARMAC
TE PĀTAKA WHAIORANGA

PHARMACEUTICAL SCHEDULE APPLICATION

To: Diabetes Subcommittee

From: Funding Application Advisor

Date: April 2020

FreeStyle Libre Flash Glucose Monitoring (FGM) System for the measurement of interstitial fluid glucose levels in individuals with type 2 diabetes (>4 years of age?)

SUMMARY OF PHARMACEUTICAL			
Brand Name	FreeStyle Libre	**Chemical Name**	N/A
Indications	Type 2 diabetes (>4 years of age)?	**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**	March 2020?
MOH Restrictions	N/A	**Proposal type**	[New listing/Widen listing]
Current Subsidy	NA	**Proposed Restriction**	Special Authority
Proposed Subsidy	$XX* per XX tablets	**Manufacturer's Surcharge**	Nil
Market Data	Year 1	Year 2	Year 3
Number of Patients†	X	X	X
Net Cost to Schedule†	$XX	$XX	$XX
Net Cost to DHBs (5-year NPV, 8%)	$XX		

DHBs, District health board; MOH, Ministry of Health; NPV, Net Present Value.
* Proposed net price.
†Supplier estimate.

QUESTIONS TO SUBCOMMITTEE

Note to PTAC 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

Need

1. Does **[the pharmaceutical]** have the same or similar therapeutic effect to any pharmaceuticals currently listed on the Pharmaceutical Schedule, in the requested indication? If so, which pharmaceutical (or therapeutic subgroup) and at what dose does it have the same or similar effect? Are there currently any problems with access to them, or their availability?

2 How severe is the health need of patients with **[indication]**? Please describe the health need of a person with a condition over their lifetime on current treatment (even if **[the pharmaceutical]** would only be used during childhood).

3. What is the Committee's view of the patient number estimates by the applicant and PHARMAC staff?

4. What are the health needs of families and whānau of people with **[indication]** (including long term effects) or of wider society? How severe are these needs?

5. Does **[indication]** disproportionally affect:

    - Māori?
    - Pacific people?
    - Other groups already experiencing health disparities relative to the wider New Zealand population (eg. NZ Dep 9 10 deprivation, refugees/asylum seekers)?

6. What is the strength and quality of evidence in relation to health needs due to this indication?

Health benefit

7. Does **[the pharmaceutical]** provide any additional health benefit or create any additional risks compared with other funded treatment options? If so, what benefits or risks are different from alternative treatments?

8. Which patient population would benefit most from **[the pharmaceutical]**?

    [NB to TGMs, to delete once read: Think about Special Authority restrictions]

9. What is the strength and quality of evidence, including its relevance to NZ, for health benefits that may be gained from **[the pharmaceutical]**?

10. Would **[the pharmaceutical]** produce a health benefit for family, whānau or wider society, additional to the health benefits for people with **[indication]**? If so how, and what is the strength and quality of evidence for this benefit?

11 Should **[the pharmaceutical]** be funded, are there any consequences to the health system that have not been noted in the application?

    [NB: Think about whether suggestions may be useful for the Committee]

Suitability

12. Are there any non-clinical features of the **[the pharmaceutical]** tablet formulation (e.g. size, shape) that may impact on use, either by the patient, by family, or by healthcare workers, that have not been considered in the application?

    [NB: Think about if there any suitability issues that may affect the application e g is a paediatric formulation required?]

Costs and savings

13 Does the information in the PICO table (Table X) accurately reflect the intended population, intervention, comparator and outcome, should **[the pharmaceutical]** be funded for **[the indication]**? If not, how should this be adjusted?

14. With which pharmaceuticals would **[the pharmaceutical]** be used in combination, and which pharmaceuticals would it replace, in treating the requested indication?

15. Would the use of **[the pharmaceutical]** create any significant changes in health-sector expenditure other than for direct treatment costs (e.g. diagnostic testing, nursing costs or treatment of side effects)?

    [NB: Do we need further advice around timing and uptake of the treatment? Do we need specific advice or review of clinical assumptions/inputs in CUA?]

General

16. Is there any data or information missing from the application, in particular clinical trial data and commentary?

    [NB: publication bias, missing trials, opposing editorials]

Recommendations

17 [Should **[the pharmaceutical]** be listed in the Pharmaceutical Schedule?] OR [Should the listing of **[the pharmaceutical]** in the Pharmaceutical Schedule be extended to the treatment of **[the indication]**]?

- Name the Factors for Consideration particularly relevant to a positive or negative recommendation and explain why each is relevant.

[NB: Think about any restrictions patient subgroups? Start/stopping criteria? Dispensing frequency?]

18. If **[listing / widened access]** is recommended, what priority rating would you give to this proposal? **[low / medium / high / only if cost neutral]**?

19. Does the Committee have any recommendations additional to the application?

    [NB: Is there anything else we need to consider under Factors for Consideration?]

PURPOSE OF THIS PAPER

The purpose of this paper is to seek advice from the Subcommittee regarding an application from [supplier] for the use of FreeStyle Libre FGM System for the measurement of interstitial fluid glucose levels in individuals with type 2 diabetes (T2DM)

DISCUSSION

BACKGROUND

Previous consideration of continuous or flash glucose monitoring systems

Currently, there are no continuous glucose monitoring (CGM) or FGM systems on the Pharmaceutical Schedule, however PHARMAC has received applications from various suppliers for there products. These include an application for FreeStyle Libre in 2018 for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes, and an application for Guardian 3 and Guardian Connect CGM system received in 2019 which will be presented at this meeting (April 2020) also.

Previous consideration of FreeStyle Libre

PHARMAC has previously considered a funding application for FreeStyle Libre (2018) for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes This application was given a high priority by the Subcommittee and has been ranked. FreeStyle libre has not been considered for any T2DM indications.

Need

Description of the disease

T2DM is the most common form of diabetes and is characterised by high blood glucose in the context of insulin resistance and relative insulin deficiency. High blood glucose for an extended period is associated with serious adverse health outcomes, such as heart disease, nerve damage, chronic kidney disease, eye problems, and ‘diabetic foot’

T2DM is a life ling disease which is most often diagnosed after the age of 40, however an increasing number of teenagers and children are developing T2DM

Epidemiology

Diabetes is a major health burden for New Zealand as prevalence continues to grow, with the total estimated prevalence in New Zealand exceeding 200,000 people (includes both type 1 and 2 diabetes, but mainly type 2) Higher prevalence rates have been reported in the Māori, Pacific Peoples and Asian populations than the European/other populations, with 4.6% in the European/other population, 7 1% in the Māori population, 11 2% in the Pacific peoples population and 7.5% in the Asian population in 2018/19 (NZ Health Survey published 2020).

The health need of the person

Individuals with T2DM usually present with regular infections, poor eyesight or blurred vision, frequent urination, often feeling thirsty and hungry, and lack of energy.

Long term damage from high blood pressure, high cholesterol, and damage to blood vessels and circulation can be avoided through lifestyle changes that prevent high blood glucose such as weight loss, healthy eating and increased physical activity. If this is not enough, T2DM patients can take medications such as metformin, and occasionally insulin

As with type 1, patients with T2DM monitor their blood glucose levels using a finger prick test, sometimes multiple times per day In general, those suffering from T2DM have a decreased quality of life (QoL) when complications or comorbidities start to develop. Conversely, some factors that has been shown to improve QoL was more frequent glucose testing, and more physical exercise.

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

The current standard of care for assessing blood glucose levels in patients with T2DM is to self monitor using a blood glucose meter multiple times per day. This involves pricking a finger with a lancet, plying a drop or two of blood to a test strip, and inserting the test strip into a reader. 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 funded flash or continuous glucose monitoring systems for use within New Zealand

The health need of family, whānau, and wider society

Caring for an individual with T2DM can place a substantial burden on family and whānau as management of T2DM requires daily responsibilities and a co ordinated level of care between family members and health specialists. Family and whānau may also suffer emotional and psychological distress when caring for their loved one with T2DM.

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

T2DM is more prevalent in the Māori population than the non-Māori population. According to the MoH, in 2013/14 the total prevalence of type 2 diabetes (those diagnosed after age 25) was 4.7% in the Māori population vs 2.4% in the non-Māori population. Māori are also more likely than non Māori to have renal failure associated with diabetes. Similarly, rates of lower limb amputation with concurrent diabetes for Māori were over 3 times that of non Māori in 2012–14.

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

Diabetes is more prevalent in the Pacific population (11.0%) compared to the European/Other population (4 6%) in New Zealand, according to the most recent New Zealand Health Survey. It is unclear what proportion of this represents T2DM, but it is known that type 1 diabetes is more prevalent in the European population so T2DM in the Pacific population will be the majority.

PHARMAC staff could not identify any other New Zealand specific data regarding population groups experiencing health disparities associated with type 2 diabetes; however,

international studies indicate that low socioeconomic status is associated with higher levels of morbidity and mortality for individuals with diabetes

The impact on Government health priorities

The prevention, intervention, rehabilitation, and wellbeing of people with long-term conditions such as type 2 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 2 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

XX

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 Scotland)

Australia: As of 1 March 2020, 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
- children and young people ages under 21 years with type 1 diabetes
- 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

There is no indication of consideration to fund FreeStyle Libre for type 2 diabetes patients in Australia.

England: As of April 2019, FreeStyle Libre was funded for people with type 1 diabetes in England via the NHS if they 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.

Canada: As of September 2019, Free Style Libre sensors and readers were funded in Ontario through the Ontario Drug Benefit (ODB) programme. All ODB recipients managing with insulin therapy with a valid prescription from a physician or nurse practitioner are eligible to receive FreeStyle Libre.

Québec is also funding FreeStyle Libre (as of July 2019) as a part of basic prescription drug insurance plan on the list of exceptional medications. People with diabetes who meet the following criteria will be eligible:

- adults aged 18 years and older who have at least 2 years of experience in self managing their diabetes and;
- intensive insulin therapy and;
- frequent or severe hypoglycemia problems and;
- the necessity of glycemia self-monitoring a minimum of eight times per day

Scotland: Many Health Boards in Scotland now offer FreeStyle Libre for type 1 diabetes patients. Patients must meet the following criteria, as well as Health Board specific criteria:

- Inject insulin regularly: You must use intensive insulin therapy this is multiple (typically four or five) daily injections or insulin pump therapy
- Attend training: You need to attend a locally provided flash glucose monitoring education session
- Scan regularly: You must agree to scan glucose levels no less than six times per day
- Share glucose data: You must agree to share glucose data with their diabetes clinic
- Have the knowledge and skills to self manage: You must have attended a recognised diabetes structured education programme and/or the clinical team are satisfied that the person (or carer) has required knowledge/skills to self manage diabetes.

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

Evidence Summary

The supplier has identified XX trials that provide the primary evidence for the health benefits of XX for the treatment of XX. A summary of these trials is provided in the table below (Table XX).

Either Table XX: Summary of evidence for XX for the treatment of XX

Trial	Study Design	Patients Group(s)	No. Patients	Intervention	Duration	Efficacy *[specify endpoint if useful]*	Safety	Citation
EXAMPLE	Phase 3 Randomised (1:1) Double-blind Placebo-controlled	Mild-to-moderate UC refractory to baseline mesalamine	N = 458	Budesonide CR 9 mg Placebo	8 weeks	13.0% budesonide CR vs 7.5% placebo (*P*=0.049)	AEs: 31.8% budesonide CR vs 27.1% placebo	Rubin et al. J Crohns Colitis. 2017;11:785-791

OR Table XX: Summary of evidence for XX for the treatment of XX

Citation	Study Design	Patient No.	Objective	Key Messages
				•
American Diabetes Association. Diabetes Care. 2016;39:S39-S46.	ADA standard of care recommendations	N/A	To provide information on the components of diabetes care, general treatment goals, and tools to evaluate the quality of care	• "Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. Fifteen minutes after treatment, if SMBG shows continued hypoglycaemia, the treatment should be repeated. Once SMBG returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia."

Literature Search

PHARMAC staff conducted a PubMed search (search terms: XX AND XX) and identified no additional publications regarding XX for XX that were not identified by the supplier.

Consequences for the health system

[See Government health priorities 2018/2019 (orange table) A1067875]

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

PICO (Population, Intervention, Comparator, Outcome)

Table X below summarises PHARMAC staff's interpretation of the PICO for [**the pharmaceutica**l] if it were to be funded in New Zealand for [**the indication**]

This PICO captures key clinical contexts, helping review the proposal and frame any future economic assessment by PHARMAC We seek the [**Committee's/Subcommittee's**] advice on the content in the table below.

Note that the PICO may change as clinical and other features evolve.

Table X: PICO for [**the pharmaceutical**] if it were to be funded in New Zealand for [**the indication**]

Population	[write here ….] *[Outline the target population for the pharmaceutical. Consider the line of therapy, sequence of therapies, disease, disease subgroup, age, severity, disease stage, failed treatments, toxicity/intolerance) Refer to Special Authority criteria if applicable.]*
Intervention	[write here ….] *[Outline the intervention pharmaceutical Detail the dose, dosing frequency (includes no. of cycles, stat courses), treatment duration, conditions for treatment cessation]*
Comparator(s) (NZ context)	[write here] *[Outline the therapy or therapies that the defined patient population would receive currently (status quo – including best supportive care). Detail the dose, dosing frequency (Includes no. of cycles, stat courses), treatment duration, conditions for treatment cessation.]*
Outcome(s)	[write here ….] *[Outline the key therapeutic outcome(s).* 1 *Define therapeutic intent(s) (eg. cure, palliation, life-extending (increased OS), symptom or disability improvement, reduced adverse effects, bridging to transplant, conditioning prior to other treatments, better suitability, benefits to others (now or future, eg. foetal survival/wellbeing, cocooning, herd immunity, antimicrobial stewardship).* 2. *Define the outcome and the outcome measure (eg. overall or intermediate survival, quality of life, improved disease severity by what measure)* 3. *Define the timeframe to achieve the outcome(s) (eg. stat, lifetime)* 4 *Detail the source of the outcome the above outcome data (trial name/reference)* *Eg The key therapeutic intent of drug A is to improve quality of life by lessening severity of QRS disease symptoms by 10 points in the ABC scale over a 6 months period, as demonstrated in trial XYZ.]*
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg. line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation). **C**omparator: Details the therapy(s) that the patient population would receive currently (status quo including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation). **O**utcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data	

Costs and savings to pharmaceutical expenditure

Cost per patient

XX

Estimated Incremental Total Cost of Listing

[Include supplier estimates of the likely patient uptake and total cost of listing Remember to note if supplier estimates are net or gross to the pharmaceutical budget; if gross then estimate the net impact.]

International Prices

Country	Source	Strength	Pack Size	Local Price	Exchange Rate ([Source/date])	Price ($NZ)
Proposal				-	-	
[United Kingdom]	[BNF]			[£]		
Etc						

Costs and savings to the rest of the health system

[Net costs/offsets per patient to the health system, excluding the treatment]

Cost Effectiveness (combining the Health Benefits and Costs quadrants)

[Key assumptions, counterfactual, size of benefit for which clinical outcomes, quantity and quality of life gains and health sector costs, discounted $QALYS/$1million]

[Summaries of relevant assessments internationally, including NICE, SMC, CADTH, PBAC.]

APPENDICES

Appendix 1: XX

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

Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes

19/05/2020

Tal Sharrock, Senior Health Economist

In preparation for Full Prioritisation meeting scheduled June 2020

Background 1

- Proposal received in November 2017
- Diabetes Subcommittee March 2019 – High priority
- PTAC May 2019
  - Unable to endorse the Subcom priority based on quality of evidence, absence of HR-QOL benefit and uncertain health need
  - Proposal did not fit well in medicine assessment framework and may be more appropriately considered as a medical device.
  - PTAC and Subcommittee's may not have the skills to assess this type of technology

Background 2

- HE assessed taken to December 2019 Prioritisation
  - Significant changes between pre-prioritisation and prioritisation
  - Different HE taking on work
    - Peer review and complete previous work
    - Update BIA for a wider group of type 1 diabetes patients.

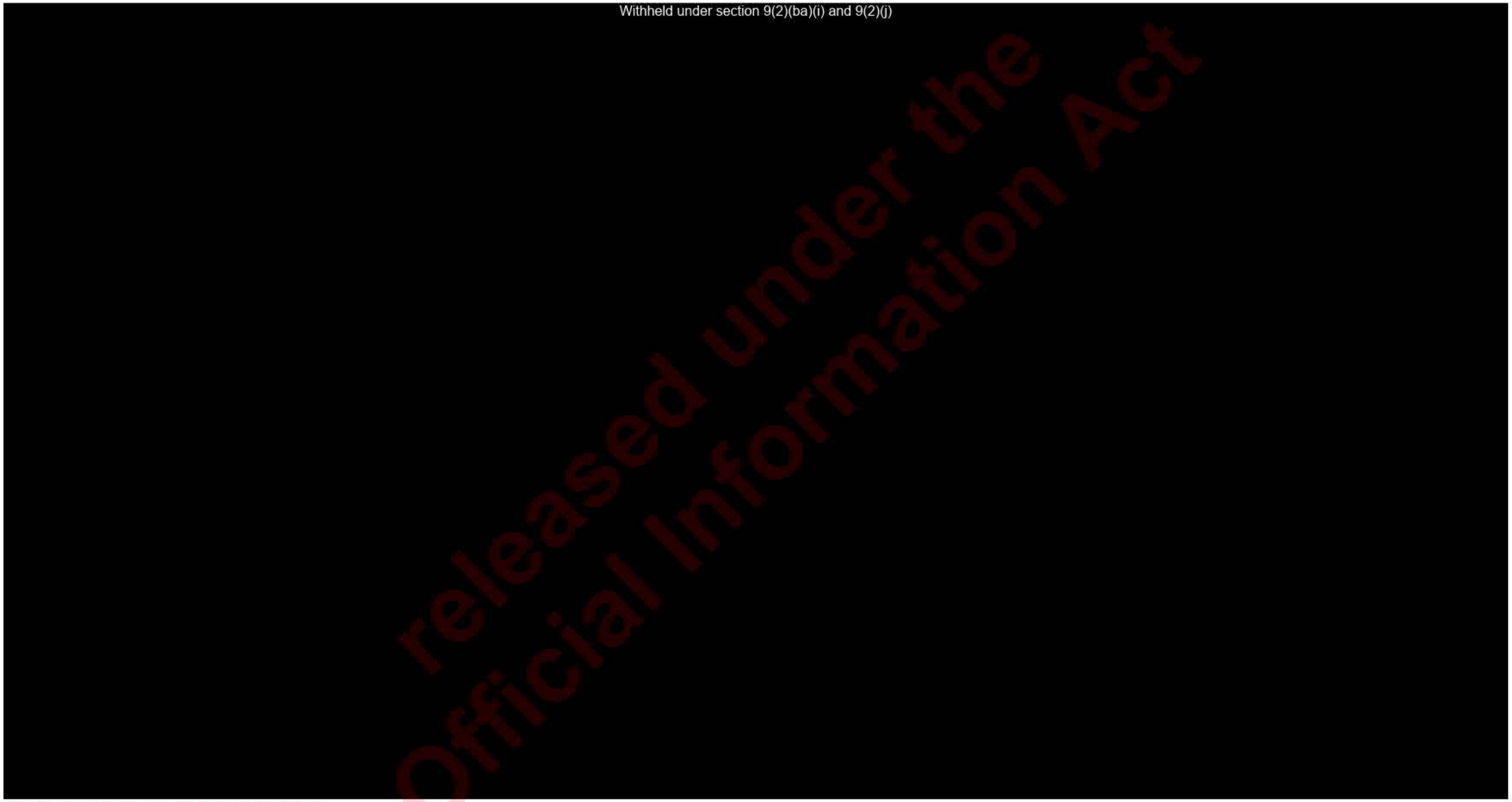
PICO

Objective	• Blood glucose levels need to be maintained within a range • Diabetics need to be able to test their blood sugar to know their blood sugar level and dose insulin appropriately to keep it within range
Population	1. Type 1 diabetics select group incl. under 18 y/o, severe uncontrolled diabetes leading to hospitalisation or pregnant/actively trying to get pregnant/breastfeeding (See special authority) 2. All type 1 diabetics (new)
Intervention	Freestyle libre flash glucose monitoring (determining blood glucose by scanning a device over an arm patch
Comparator	Self-monitoring using finger prick testing and a blood glucose meter
Outcome	QOL gain from reduce type in hypo and decrease finger prick testing
Need	Prevalence of type 1 diabetes is higher in European than Māori and Pacific peoples, Māori and Pacific peoples have worse long-term outcomes

CUA – daily model

	Costs	Utility
Costs	• Reader Withheld under every 2 years • Sensor Withheld under section every 14 day • **Average daily cost of intervention =** Withheld under	0.882
Comparator	• Current people use 10-14 test strips a day • IMPACT 5.5 to 0.5 strips per day – change of 4 • **Decrease of 7 test strips per day =** Withheld under **(**Withheld under **per strip)** **Note:** price per strip incorrect in previous model	0.851
Incremental	**$5.04**	0.03
	QALYs per million	With held

CUA result will not differ between eligible population



BIA

	2020	2021	2022	2023	2024	NPV
Number of type 1 diabetics	27,325	28,371	29,457	30,584	31,755	
Number of type 1 diabetics underage of 18 and 50% of women of childbearing ages (31%)	8,339	8,658	8,989	9,334	9,691	
Uptake	0.6	0.8	0.9	0.9	0.9	
SA population						
SA population taking freestyle post uptake	5,003	6,926	8,091	8,400	8,722	
CPB (Sensor + reader - test strips)	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under
DHB (4% pharmacy margin)	$0.36	$0.50	$0.58	$0.60	$0.62	$2.25
All type 1 diabetics						
Wider population taking freestyle post uptake	16,395	22,697	26,511	27,526	28,579	
CPB (Sensor + reader - test strips) $million	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under section
DHB (4% pharmacy margin) $million	$1.17	$1.62	$1.90	$1.97	$2.05	$7.37

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

Costs Lower sensitivity

Parameter	Value
Fear of hypoglycemic epidose	0.995 to 1
Severe hypoglycemics episodes	0.85
QALYs gain from avoid hypo per hour	Withheld under section 9(2)(ba)(i) and 9(2)(j)

PHARMAC
Pharmaceutical Management Agency

Pre-Prioritisation Meeting Minutes 19 May 2020

Attendees

Presenter: Tal Sharrock

HEs: Eric Matthews, Hayden Spencer, Vivienne R, Evan Hinds, Ben Campbell-Macdonald (manager)

TGMs/FAAs: Laura Baker, Danae Staples Moon, Logan Heyes, Peter Yoo, Andrew Oliver, Emily Clarke, Gina Armstrong, Beth Caudwell

MDs: Scott Metcalfe, Peter Murray

Policy: [*policy analyst name, title*]

Analysis: [*analyst name, title*]

Maori Responsiveness: [*team member name, title*]

Access Equity: [*team member name, title*]

Other:

Discussion

Vismodegib

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Freestyle libre (re-rank)

- The proposal background was noted.
- Application for type 2 insulin dependants? Yes handling separately currently receiving clinical advice.
- The proposal PICO was noted
- Model structure, costs and utilities noted
- Happy with decrease of 7 test strips per day? Maybe check offline? Tested in sensitivity analysis.
- Happy with HU increment Hayden noted the evidence was uncertain regarding this? Scott- plausible that there would be a decrement in HU
- Happy with utility decrement of 0 03? Scott to check study offline related to HU decrement
- Scott wondering if 10 per day pricks was at the high end, which would influence the HU and the cost offset. Didn't realize it was quite sensitive and so might require further input
- Reality is that patients with this they will use it entirely and use the sensor entirely and only prick once a fortnight Due to nature of peoples laziness Believe they are only meant to use the sensor alongside normal pricking
-

Action items

  - Take offline to look further at the evidence

PHARMAC
TE PĀTAKA WHAIORANGA

Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes

27/05/2020

Tal Sharrock, Senior Health Economist

In preparation for Full Prioritisation meeting scheduled June 2020

Where we are at:

- Proposal for Special Authority group was taken to Prioritisation in December 2019
- Proposal for all type 1 diabetes to go to Prioritisation in June 2020
  - Update BIA for wider group
  - Decision that definition of patients in the SA group was not ‘do-able’ in reality – wider group to supersede the SA group as a proposal on the OFI
  - Different HE, wanted to check CUA assumptions has there appeared to change made between pre-prioritisation and prioritisation in Q4 2019 which had a large impact on results.
  - Discussion at pre-prioritisaiton 2020 re-assumptions – decision to continue discussion at a hot topic (i.e now)

PICO

Objective	• Blood glucose levels need to be maintained within a range • Diabetics need to be able to test their blood sugar to know their blood sugar level and dose insulin appropriately to keep it within range
Population	~~1. Type 1 diabetics select group incl. under 18 y/o, severe uncontrolled diabetes leading to hospitalisation or pregnant/actively trying to get pregnant/breastfeeding (See special authority)~~ 2. All type 1 diabetics (new)
Intervention	Freestyle libre flash glucose monitoring (determining blood glucose by scanning a device over an arm patch
Comparator	Self-monitoring using finger prick testing and a blood glucose meter
Outcome	QOL gain from reduce type in hypo and decrease finger prick testing
Need	Prevalence of type 1 diabetes is higher in European than Māori and Pacific peoples, Māori and Pacific peoples have worse long-term outcomes

Foundational assumptions

- Costs
  - Reader Withheld under section 9(2)(b)(ii), every 2 years (supplier app)
  - Sensor Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and every 14 day (supplier app)
  - **Average daily cost of intervention =** Withheld under section 9(2)(b)(ii), 9(2)(ba)(i)

Key assumptions to consider today

- Incremental utility gain
- Offsets
  - Reduction in insulin strips
  - Decrease in hospital admissions as a result of reduction in hypos

What should be the base-case values?

What should be a sensitivity analysis values?

Utility 1:

- Matza et al 2017
  - TTO study in UK general population given disease descriptions
  - Results:
    - 37% ranked flash higher,
    - 62% ranked standard and finger print the same
  - 0.031 utility gain per year – 0.0000849 per day
  - This is currently the base-case

Table 2 – Health state utility scores* (N = 209).

Two diabetes health states differing only in glucose monitoring strategy, mean ± SD		Difference between health states, mean ± SD	t Test comparing the two health state means	
Sensor-based (flash) glucose monitoring	Conventional glucose monitoring		t Statistic (paired)	P value
0.882 ± 0.121	0.851 ± 0.140	0.030 ± 0.053	8.3	<0.0001

TTO, time trade-off.

* These scores were obtained via TTO interviews, and they are on a scale anchored with 0 representing dead and 1 representing full health.

Utility 2:

- Assumes no gain from finger pricking – could be zero
- Some utility gain for decreased time in hypo/resulting in hospitalisation
- 0.995 (fear of hypo episode -source unknown)
- 0.85 (hypo episode – source unknown)
- Incremental of 0.145 per year or 0.0000166 per hour
- IMPACT – decrease in 1.18 hrs (x above value)
- Current utility lower limit

Utility 3:

- Utility gain: upper limit of Matza et al + hypo benefit
- 0.030+0.053 = 0.083 per year
  - 0.00023 per day (prick only)
  - 0.00025 per day (prick + hypo benefit)
- Current upper utility limit

Table 2 – Health state utility scores* (N = 209).

Two diabetes health states differing only in glucose monitoring strategy, mean ± SD		Difference between health states, mean ± SD	t Test comparing the two health state means	
Sensor-based (flash) glucose monitoring	Conventional glucose monitoring		t Statistic (paired)	P value
0.882 ± 0.121	0.851 ± 0.140	0.030 ± 0.053	8.3	<0.0001

TTO, time trade-off.

* These scores were obtained via TTO interviews, and they are on a scale anchored with 0 representing dead and 1 representing full health.

Summary of incremental gain and the resulting cost-effectiveness

Incremental Utility (per day)	QALYs $million (based on current model)
0.2 x 10^4	W ith
0.8 x 10^4	With held
2.3 x 10^4	With held

Cost-off set 1: test strips

- Insulin test strips
  - After rebate Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) per strip (**Note:** price per strip incorrect in previous model)
- Some clinical advice that people use 4-10 test strips a day
- IMPACT trial
  - 5.5 to 0.5 strips per day – change of 4 strips per day
- Base case currently a reduction of 7 test strips per day = 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) per strip)

Change in test strips	QALYs per $ million
3.5	Withheld
7	Withheld
14	Withheld

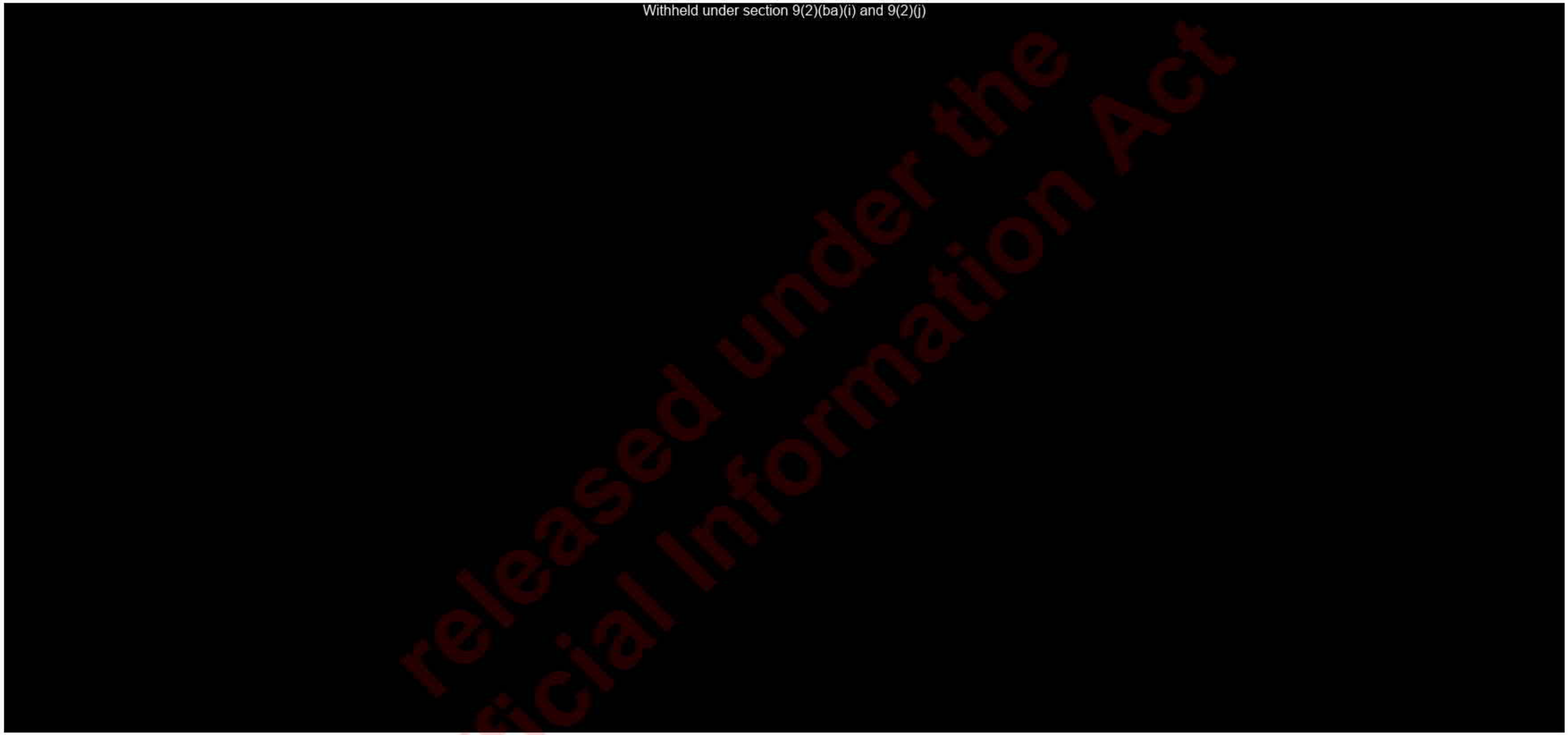
Cost-offset 2: hospitalisation

- Propose that unless we thing these previous assumptions are incorrect we leave as is – not material to base-case or ranges

Input	Low Value	Base Value	High Value	QALYs Gained per $ Million
Risk of emergency departments per day	0	0.00001	$0.0003	Withheld under section
Costs of ambulances	$0	$0	$695	Withheld under section
Costs of emergency admissions	$163	$326	$489	Withheld under section

Appendix slides for reference if required

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



Base-case	Lower utility gain	Higher utility gian	Cost of sensor x1.5	Half incremental decrease in test strips	Double incremental decrease in test strips	Reader was free
	Utility gain of a gain in 1.18hr avoided in hypo 0.00002 per day	Utility gain of 0.00023 per day – 95% CI of Mataz et al				

BIA – for noting

	2020	2021	2022	2023	2024	NPV
Number of type 1 diabetics	27,325	28,371	29,457	30,584	31,755	
Number of type 1 diabetics underage of 18 and 50% of women of childbearing ages (31%)	8,339	8,658	8,989	9,334	9,691	
Uptake	0.6	0.8	0.9	0.9	0.9	
All type 1 diabetics						
Wider population taking freestyle post uptake	16,395	22,697	26,511	27,526	28,579	
CPB (Sensor + reader - test strips) $million	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under	Withheld under section
DHB (4% pharmacy margin) $million	$1.17	$1.62	$1.90	$1.97	$2.05	$7.37

CUA – daily model

	Costs	Utility
Costs	• **Average daily cost =** Withheld under	0.882
Comparator	**Decrease of 7 test strips per day = Withheld under (Withheld under per strip)**	0.851
Incremental	Withheld under	0.03
QALYs per million		With held

CUA result will not differ between eligible population

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

PHARMAC
Pharmaceutical Management Agency

Hot topic Meeting Minutes 27/05/2020

Application: FreeStyle Libre® flash glucose monitoring system for Type 1 diabetes

Key documents relating to this hot topic

Hot topic slides	 2020-05-27 Pre-prioritisation.Hot
Diabetes SC minutes	FreeStyle Libre section (March 2019)
PTAC minutes	Review of Diabetes SC minutes (May 2019)
IMPACT study	Bolinder et al. Lancet. 2016; 388(10057):2254 63
FPGM in NZ	Metcalfe et al. NZMJ. 2014;127(1406): ISSN 1175-8716
SELFY study	Campbell et al. Pediatr Diabetes. 2018;19(7):1294 1301.

Attendees:

Presenter: Tal Sharrock, **HEs**: Eric Matthews, Hayden Spencer, Ben Campbell-Macdonald, **TGMs/FAAs:** Elena Saunders, Danae Staples-Moon, **MDs:** Scott Metcalfe, Greg Evans

Discussion

Context to meeting

Group noted that FreeStyle Libre® flash glucose monitoring was first ranked on the OFI at the December 2019 prioritisation meeting for a defined subgroup of type-1 diabetes mellitus (T1DM) patients who were considered by the Diabetic Subcommittee at the meeting held in March 2019.

PHARMAC staff have subsequently considered that the proposed subpopulation of T1DM patients would be practically challenging to restrict access to as a distinct subpopulation, as opposed to funding FreeStyle Libre® flash glucose monitoring for the entire T1DM community.

As such, this meeting sought to replace the existing ranked FreeStyle Libre® proposal for the subpopulation of T1DM patients with a new updated proposal for the entire T1DM population.

It was also noted that the health economist who assisted with the original PHARMAC analysis was no longer working for the organisation and as such it was considered appropriate to review the assumptions underpinning our economic evaluation of this proposal.

PICO

Group noted the proposed PICO as presented in the slides. Consensus was reached that the PICO as presented was appropriate except for the outcomes, which needed to account for the benefit that flash glucose monitoring would provide for patients in alleviating to some degree the fear of having a hypoglycaemic event.

The PICO agreed upon at this meeting is outlined in the table below:

Population	Any of: 1. Patient has type-1 diabetes mellitus 2. Patient has undergone pancreatectomy 3 Patient has cystic fibrosis-related diabetes
Intervention	FreeStyle Libre® flash glucose monitoring
Comparator	Finger prick blood glucose monitoring (FPGM)
Outcomes	Health related quality of life (HRQOL) gain from: 1. Reduction in time spent in hypoglycaemia resulting from improved glycaemic monitoring 2 Reduction in finger pricking required for glycaemic monitoring 3. Reduction in fear of hypoglycaemic events

Clinical recommendation for funding

Group discussed the clinical advice recommendation given by the Diabetes Subcommittee at the March 2019 meeting, which has been recorded internally as a low priority recommendation for funding

Action points:

1. TGMs to review documentation around clinical recommendation.
2. Proposal to be ranked with low subcommittee recommendation.

Utility gain-discussion

The utility values and how they were derived in the original PHARMAC economic analysis was presented for both the base-case, lower sensitivity limit and upper sensitivity limit (see slides for detail)

- Consensus was reached that the baseline health state utilities associated with glucose monitoring devices as reported in the Matza et al 2017 paper were plausible and appropriate to base our economic modelling on. These estimates were:
    - 0.851 for conventional monitoring (FPGM)
    - 0.882 for flash glucose monitoring
- These baseline health state utilities resulted in an incremental HRQOL of 0.031 gained per year for patients using flash glucose monitoring compared to patients using FPGM.
- Group considered that the Matza el al 2017 paper represented the best currently available evidence to inform the HRQOL increment that could realistically be obtained from using flash glucose monitoring vs finger-prick glucose monitoring. The group also acknowledged that there were known limitations with the Matza et al 2017 study design, and that other HTA agencies had considered the evidence constituted low grade evidence.
- The group further noted that there is a considerable body of HRQOL data likely to emerge in the short to medium term, including an EQ-5D study currently being conducted in New Zealand in adolescents with T1DM.
- It was noted that the Matza et al 2017 findings informed the economic modelling for FreeStyle Libre® as undertaken by Healthcare Improvement Scotland and that considerable effort had been undertaken to validate the economic analysis via external peer review conducted at the University of Edinburgh
- It was noted that the original PHARMAC analysis (as informed the original December 2019 ranking) incorporated an improbably high HRQOL value to inform the high possible CUA estimate as currently ranked on the OFI.
    - The group noted that the earlier high possible CUA estimate was based on the upper limit (i e top of the 95% confidence interval) of estimated HRQOL as reported in the Matza et al 2017 paper (0 083)
- The group felt that the gain of less time in hypos and accompanying improvement in HRQOL (as originally estimated in the PHARMAC analysis informing the December 2019 ranking) was reasonable to include in the base case of this updated analysis.
    - The reduction in time spent in hypoglyacaemia due to flash glucose monitoring was informed by the results of the Bolinder et al 2016 paper (reduction of 1 18 hours per day)
- The group felt that it was also appropriate to add the utility gain that would occur as a result of a lower fear of hypo events in general with free style.
    - The group noted the values already presented from TAR68 that living with fear of hypo events has a QOL of 0 995 or a loss of 0 005 from full health
    - The group considered that flash glucose monitoring would not alleviate all of this health loss but assuming a proportion of it would be alleviated was reasonable.

Action point: HE to add HRQOL gain from reduced fear of hypo events to the base case of the model and consider to what degree this would be reduced by to be reasonable.

- The group discussed that it could be beneficial to check a 3% incremental health gain against previous economic assessments to see if the order of magnitude was reasonable **(ACTION:** HE)
- The group noted that the HRQOL gain is likely greater in children/younger people that adults
- Group agreed that sensitivity analysis around the base-case utility should be conducted using +/ 25% in the likely CUA range and 50% in the possible CUA range.
- Group noted that it was important to note that the decrement of having a hypo was one off and assumed full recover. Considered a reasonable approach to the assessment give the available data and evidence.

Test strip use per day

Consensus was reached at the meeting that the estimated test strip use in each arm of the model should be considered as:

Arm of model	**Base case consumption of test strips**	**Source**
FreeStyle Libre®	0.5 test strips per day	IMPACT study
FPBG	4 test strips per day	Metcalfe et al, 2014.

- Group noted that although the supplier for FreeStyle Libre® has their own branded test strips it was reasonable to assume the test strips in this analysis are the ones we currently fund.
- Group noted an error on the slides that clinical advice should read 4 10 test strips a day not 10-14 as was presented (HE updated this on the slide post meeting)
- Group noted that the model includes an incremental cost of test strips rather than attributing test strips to each arm

Action point: CUA model to be adjusted to reflect test strip consumption in each arm as outlined in the table above.

- Group noted that lancets are not funded by PHARMAC and are purchased by the patient and therefore are not included in the CUA modelling.

Action point: HE to acknowledge lancet self-funding in TAR as a saving that would be incurred by patients if FreeStyle Libre® was to be funded in New Zealand

- Group felt the original estimated incremental reduction in test strip consumption per day of 7 was likely to high
- MD noted and circulated research done in NZ which suggested people used 112 per user per month, which equated to 4 test strips per day (Metcalfe et al, 2014)

- It was noted that the supplier had considered a median of 6 test strips per day was appropriate to inform the supplier provided CUA modelling. It was noted that this estimate of 6 had been informed by a study conducted in Australia (Miller et al. Diabetes Care. 2013;36(7):2009-14)
- Group considered that that NZ paper was more relevant and up to date.
- Group considered it would be appropriate to use a daily average of 0.5 test strips in the intervention arm as per the IMPACT trial and 4 per day in the comparator arm Group agreed that sensitivity analysis with 6 and 10 daily test strips in the comparator arm only should be modelled.

Other offsets

- Group noted that as is the case currently, cost-offsets from a small reduction in hospitalisations was appropriate to include in the base-case
- Group noted that results published in the SELFY study suggested that patients using FreeStyle Libre® were likely to consume a 4% higher insulin daily dose (IDD) compared to patients using FPGM.
    - The group considered that it was difficult to establish whether a 4% higher IDD constituted a clinically significant difference that could be extrapolated to the wider T1DM population.
    - Consensus was reached that it was appropriate to acknowledge the possibility of a marginally higher IDD qualitatively in the TAR, though not to include this uncertain incremental cost in the updated modelling.

PHARMAC
TE PĀTAKA WHAIORANGA

AGENDA

Prioritisation Meeting

To be held at the PHARMAC Office on

Tuesday 2 June 2020

Overall Agenda

1. Overview of meeting process
2 Acknowledgement of proposals funded since the last prioritisation meeting
3 Ranking of proposals on the 'only if cost neutral or cost saving' list
4 Ranking of proposals on the 'recommended for decline' list
5. Miscellaneous changes to proposal status to be acknowledged
6. Prioritisation of new proposals to the *Options for investment* list
7. Re-prioritisation of the proposals on the *Options for investment* list with updated information
8. Consideration and confirmation of al ranked prioritisations lists
9. Budget boundaries

Prioritisation Paper (Supplementary material)

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

- Section 1: Overview of meeting format
- Section 2: Factors for Consideration
- Section 3: Health need
- Section 4: Cost effectiveness
- Section 5: Government health priorities
- Section 6: Proposal summaries

Out of scope
Out of scope
Out of scope
Out of scope

Out of scope

Out of scope

Out of scope

Out of scope
Out of scope
Out of scope
Out of scope
Out of scope

Out of scope

Out of scope

Out of scope
Out of scope

Out of scope
Out
Out of
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of scope
Out of
Out of scope
Out of scope
Out of
Out of scope

Proposals to be re prioritised with updated information

Re-ranked items should take 3 - 5 minutes each.

Please refer to the Prioritisation Paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation

Proposal	Reason	TGM	HE
Freestyle Libre - all Type 1 diabetes	Re-visit old model/BIA	ES	TS
Out of scope			
Out of scope		Out of	
	Out of scope		
Out of scope		Out of	
	Out		

PHARMAC
TE PĀTAKA WHAIORANGA

Prioritisation Meeting

June 2020

Content

1. Zoom polling
2. Proposals funded since the last meeting
3. Proposals recommend to the ‘cost-neutral/cost-saving’ list
4. Proposals ‘recommend for decline’
5. New items to be ranked on the OFI list
6. Re-rank items to the OFI list
7. Miscellaneous changes

Zoom polling

- Zoom polling to assist ranking
- Question, should this proposal be moved?
  - Move up
  - Move down
  - Remain in place
- Please ensure you have joined the zoom meeting on your laptop/tablet, to participate in polling.

Options for Investment – Speaking Order

Therapeutic Group Manager	• Introduces item. • Key therapeutic and commercial issues. • Why is it being prioritised today?
Health Economist	• Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? • Explain the key drivers of the cost-effectiveness result. • Explain the range of cost-effectiveness estimates.
Medical Directorate	Any other relevant clinical issues not yet raised.
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues.
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

Re-rank items to the OFI list (1)

Proposal	Reason	TGM	HE
Freestyle Libre - all Type 1 diabetes	Re-visit old model/BIA	ES	TS
Out of scope			
Out of scope			
Out of scope	Out of scope	Out of scope	
Out of scope			
Out of scope			
Out of scope			
Out of scope			
Out of scope			

PHARMAC
Pharmaceutical Management Agency

Prioritisation Paper

Prioritisation Meeting to be held at the PHARMAC Office on

Tuesday 2 June 2020

Contents

In addition to the Prioritisation meeting agenda document, please refer to the following sections of this paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

Section 1: Prioritisation meeting format

The quarterly prioritisation meeting is a key step in PHARMAC's decision processes, where each current funding proposal is considered and ranked using the Factors for Consideration.

Formally, PHARMAC's assessment of funding proposals is a 'deliberative process', whereby all relevant different points of view are considered and traded off against one another. This contrasts with systems that use predetermined weights for each criterion

In a deliberative process, it is critical that all perspectives are considered by all people involved in the consensus decision This means that all meeting participants should have good opportunity to make sure that key points are heard and that they hear and understand the points raised from other perspectives.

This document includes only brief summaries of information about each proposal; for full details please refer to the relevant Technology Assessment Report and PTAC minutes.

Below is the protocol to structure the staff discussions during the prioritisation meeting. It builds on a successful process that PHARMAC has developed over many years, while giving it more structure as appropriate to the large group involved in each meeting.

Speaking order

Therapeutic Group Manager	Introduces item. Key therapeutic and commercial issues. Why is it being prioritised today?
Health Economist	Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? Explain the key drivers of the cost-effectiveness result. Explain the range of cost effectiveness estimates
Medical Directorate	Any other relevant clinical issues not yet raised
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

Section 2: Factors for consideration

Factors are presented here in the order they are listed in decision papers, 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
- Government Health Condition Priorities

Health Benefits

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

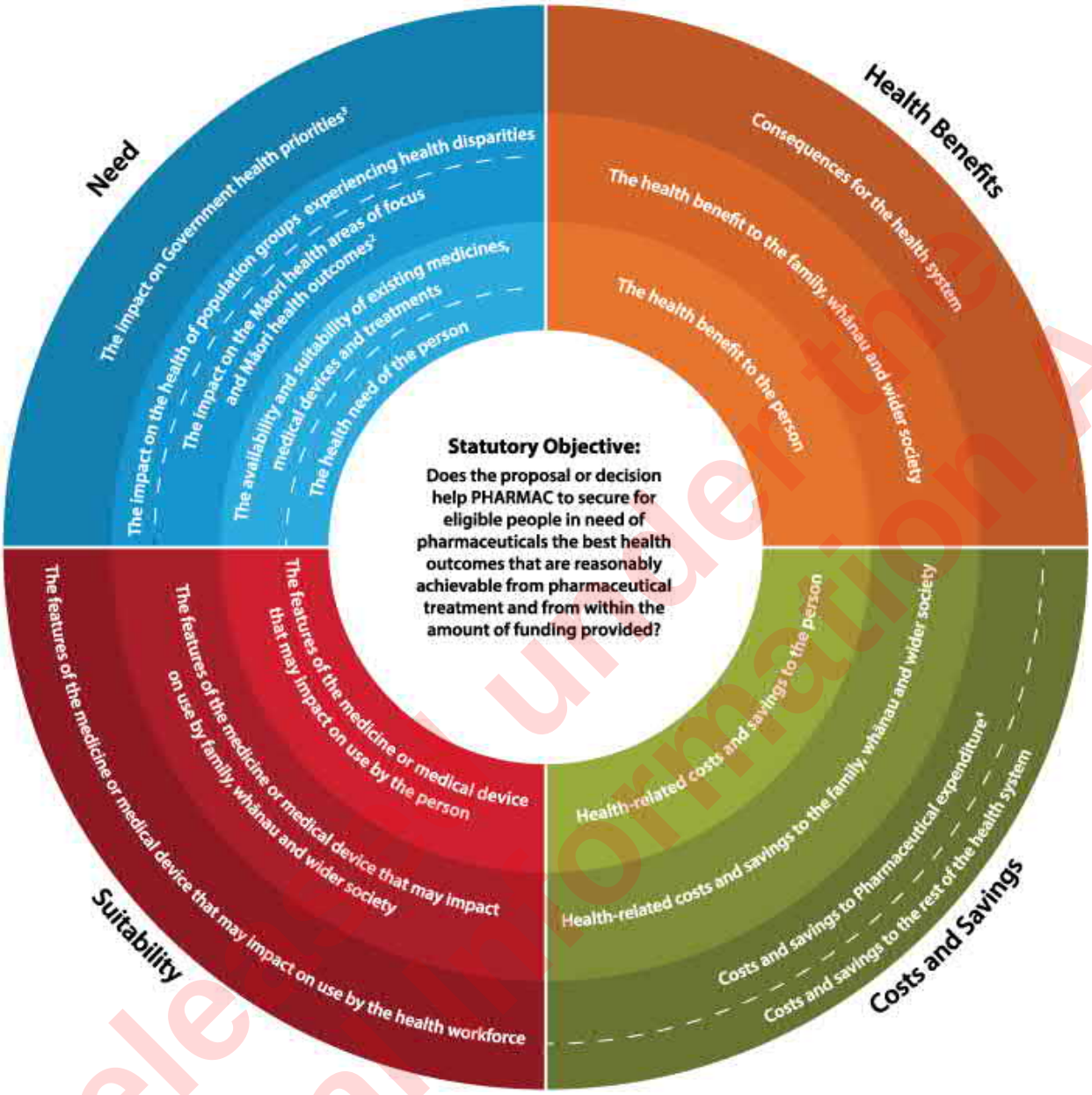
Suitability

- 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

Figure 1: PHARMAC Factors for Consideration



Section 3: Health Need.

These graphs show estimates of the health loss experienced by an average or typical patient in the relevant cohort with currently funded treatments for treatments on the current prioritisation list They do not reflect the effect of the new products under consideration Each bar starts at the average age of onset of the specific disorder in question. Absolute values are shown in a separate table.

Out of scope

Freestyle Libre Flash Glucose	Type 1 diabetes	

Out of scope

Table 1: Lifetime Health Need associated with conditions

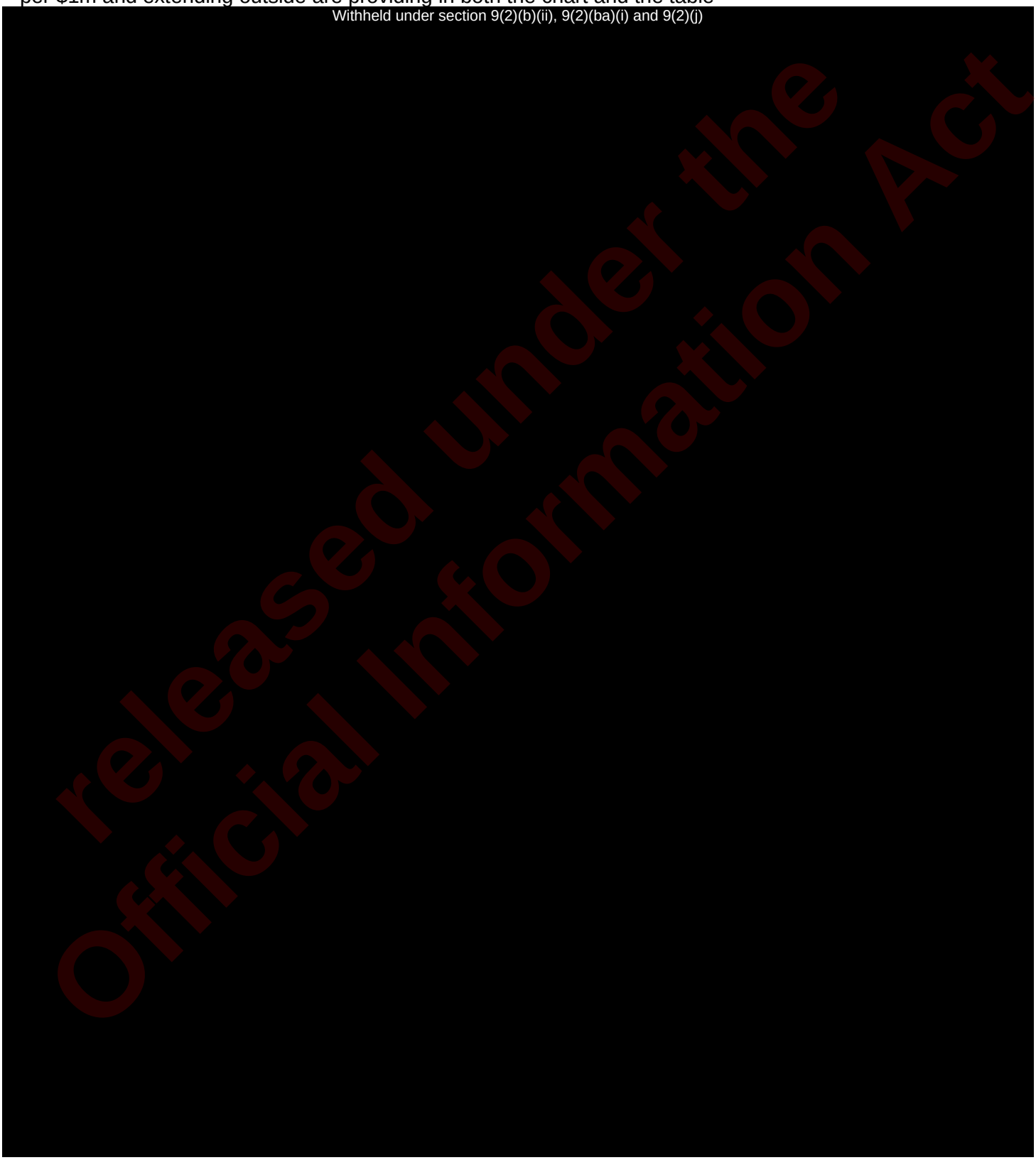
Drug	Indication	Lifetime QALYs lost
Out of scope	Out of scope	Out
Out of scope		
Out of scope		
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope		
Out of scope	Out of scope	Out
	Out of	
Out of scope		
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	O
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope	Out of scope	Out
Out of scope		
Out of scope		
Out of scope		
Out of scope	Out of scope	Out
Out of scope	Out of scope	
Out of scope		
Out of scope		
Out of scope	Out of scope	Out
	Out	
Out of scope		
Out of scope	Out of scope	O
	Out of scope	
Out of scope		

Freestyle Libre Flash Glucose Monitoring System	Type 1 diabetes	18
Out of scope	Out of scope	Out
	Out of scope	
	Out of scope	
Out of scope	Out of scope	Out
	Out of scope	
Out of scope	Out of scope	
Out of scope		
Out of scope		
Out of scope	Out of scope	Out
	Out of scope	
	Out of scope	
Out of scope		
Out of scope	Out of scope	
Out of scope		
Out of scope		
Out of scope	Out of scope	
Out of scope		
Out of scope		
Out of scope	Out of scope	O
Out of scope	Out of scope	
Out of		
Out of scope	Out of scope	O
Out of scope	Out of scope	
Out of		
Out of scope	Out of scope	O
Out of scope	Out of scope	
Out of		
Out of scope	Out of scope	
Out of scope		
Out of		
Out of scope	Out of scope	
Out of scope		
Out of		
Out of scope	Out of scope	Out
Out of scope	Out of scope	
Out of		
Out of scope	Out of scope	
Out of scope		
Out of scope	Out of scope	O
Out of scope	Out of scope	
Out of scope	Out of scope	O
Out of scope	Out of scope	
Out of scope	Out of scope	
Out of scope		
Out of scope	Out of scope	
Out of scope		
Out of scope		
Out of scope		

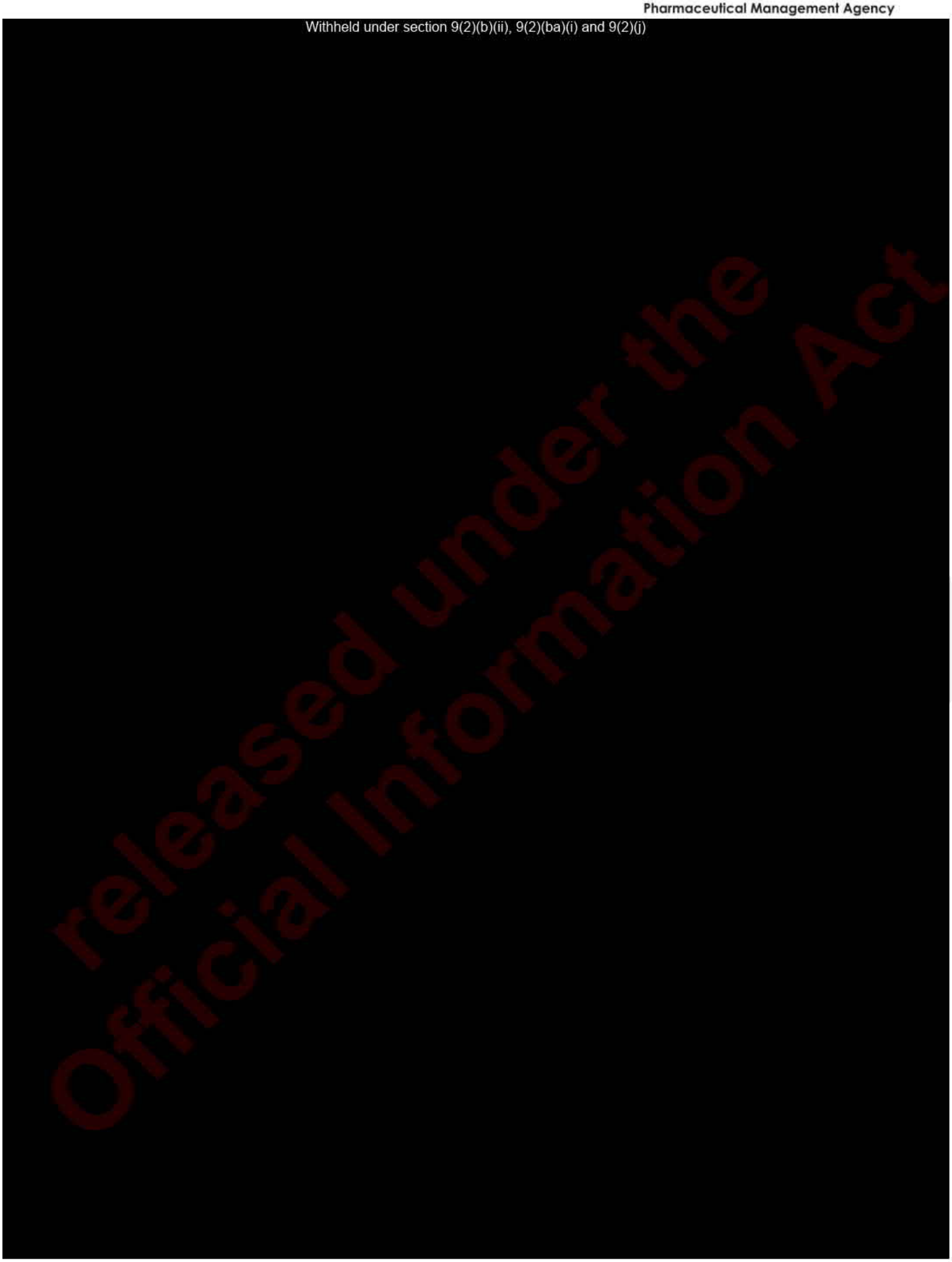
Section 4: Cost effectiveness

Previously ranked proposals are shown in existing priority order New proposals are placed roughly within the list as a starting point only. Cost-effectiveness ranges (0 to 70 QALYs per $1m) may extend off the chart; proposals that are completely off the chart or cost saving/cost neutral are detailed in the table on the next page; proposals with ranges within 0 to 70 QALYs per $1m and extending outside are providing in both the chart and the table

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)



Section 5: Government health priorities

The impact on government health priorities

This factor asks whether the disease, condition, or illness is a Government health priority.

Last updated: 15 May 2020

Priority or specific health condition	Interpretation for FFC
Priority 1	
Child wellbeing	PHARMAC's decisions will help improve child wellbeing and support children to have a healthy start in life.
Priority 2	
Mental wellbeing	PHARMAC's decisions will help improve mental wellbeing. For PHARMAC, this includes treatment for alcohol and drug addiction.
Priority 3	
Prevention	PHARMAC's decisions will improve wellbeing by preventing health conditions This includes issues such as: • smoking cessation • immunising against infectious diseases • antimicrobial stewardship • sexual health.
Priority 4	
Health equity	PHARMAC's decisions will support better population outcomes, supported by a strong and equitable public health and disability system We are focused on achieving equity in health outcomes and enhancing equitable access to medicines This includes a specific focus on achieving pae ora (healthy futures) for Māori as Te Tiriti partners. Read more about Te Whaioranga ***PHARMAC's equity priorities*** • Priority populations: Māori, Pacific people, low socio-economic status, refugees, rural populations. • Priority health conditions: cardiovascular disease, diabetes, asthma, COPD, gout
Priority 5	
Primary health care	PHARMAC's decisions will support better population health and outcomes supported by primary care We are focused on strengthening primary care through making medicines available and accessible in primary care settings
Specific health conditions	
Rare diseases	This covers conditions that meet PHARMAC's definition of a rare disease (1:50,000 population).
Cancer	We consider that this includes all cancer conditions. However, note that some specific cancers (lung and breast) have a particular focus for PHARMAC under the Hauora Arotahi Māori health areas of focus

Long-term conditions	We consider that long term conditions includes (but is not limited to): • diabetes • cardiovascular disease • chronic respiratory disease • neurological diseases (such as dementia)
Infectious diseases	We consider that this covers both treatments for and immunisation to prevent infectious diseases We will also continue to promote the responsible use of antimicrobials (including antibiotics) – antimicrobial stewardship

Hauora Arotahi

PHARMAC's Hauora Arotahi (Māori health areas of focus) are:

- mental health
- diabetes
- heart health
- respiratory health
- cancer (lung and breast).

Section: 6: Proposal Summaries

This section has a dossier for each proposal on the Options for Investment list Where multiple proposals are represented by one item, please refer to the name of the item.

When data are not given for a Factor, the following terms are used:

No difference: Evidence found that shows no material difference or effect.
None identified: Staff searched for relevant evidence and found none
Not reviewed: Staff did not seek information on this Factor

For more information on any proposal, refer to the Technology Assessment Report, to the relevant Objective file, or to the proposal's records in PharSight

If you are reading this document on screen, select the Word menu option **View | Navigation Pane** Click on the dossier's name to jump to the page

Freestyle Libre Flash Glucose Monitoring System-Type 1 diabetes

Latest Clinical Recommendation: No Formal Recommendation from PTAC, 23/05/2019

Comparator: Finger prick blood glucose (FPBG) monitoring via a blood glucose meter.

NEED

Condition: Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta cells resulting in insulin deficiency. Loss of endogenous insulin can lead to hyperglycemia and life threatening ketoacidosis

Health need of the person: 18

Insulin is used to prevent severe hyperglycemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult Over treatment results in hypoglycemia, which can range from mild and uncomfortable to life threatening

Health Need Of Family Whānau and Others: Evidence is emerging of significant caregiver stress among parents of children and adolescents with type-1 diabetes (Grover et al. Perspect Clin Res. 2016;7(1):32-39). The evidence is unclear regarding whether increased monitoring using the newer technology increases or reduces caregiver stress.

Availability of existing alternatives: Self monitor using a blood glucose meter between 4 to 10 times per day (finger-prick).

Māori Health Areas of Focus: Yes

Māori health need: Disease burden among Māori more severe

Impact on population groups experiencing disparities: None identified

Government condition priorities: Yes. Long term condition

HEALTH BENEFITS

Health benefit to the person: Freestyle libre flash glucose monitoring system has been shown to decrease the amount of time a patient spends within the hypoglycaemic range per day, the number of severe hypoglycemia events per day. Some evidence has been provided to suggest an improvement in quality of life compared to FPBG monitoring

Health benefit to family, whanau: Probable reduction in caregiver stress resulting from remote monitoring of blood glucose levels via the Freestyle device. This is likely to be even more so overnight when the current method requires waking a child and undertaking a finger prick. Furthermore, the device may allow carers more freedom to leave the patient in the care of others. Conversely, some data indicates that the increased granularity of data available can increase the burden of stress to carers

Health benefit to others: Probable reduction in stress for teachers / teacher aides who are involved in the daily care of children and adolescents whilst they are at school.

Consequences for health system: Freestyle libre flash glucose monitoring system could conceivably reduce the number of required emergency department admissions, and the number of diabetes related complications requiring treatment via the health system The exact impact is unknown

Government system priorities: Health equity

COSTS AND SAVINGS (Lifetime NPV @3.5%).

Health costs to the person: A $5 prescription co-pay will apply every three months.

Health costs to family, whanau, others: Not relevant.

Pharmaceutical costs per person: Net cost per person of Withheld per person per year

Costs to rest of health sector, per person: 4% net distribution costs will apply to this device. Note, no gross pricing has been provided by the supplier in their proposal.

SUITABILITY

Impact on use by the person: Freestyle libre flash glucose monitoring system involves application once every 14 days, involving one small prick. This compares to the current SMBG method, which can involve up to 10 pricks per day F'style provides near continuous data readings.

Impact on use by others: Device enables remote monitoring of blood glucose via bluetooth uplink to multiple smart mobile devices

Impact on health workforce: Additional data availability may impact on clinical services, increasing the clinic time required to train individual on the use of the device as well as finger prick testing (which will still be required) and for the interpretation of a larger volu data.

COST EFFECTIVENESS

Point estimate = Wit QALYs per $1m.

Likely range Withheld QALYs per $1m

Possible range Withheld QALYs per $1m.

BUDGET IMPACT

Year	1	2	3	4	5
Patients	16,400	22,700	26,500	27,500	28,600
Pharmaceutical costs	Withheld	Withheld	Withheld	Withheld	Withheld
Other health sector costs	$0 99m	$1 38m	$1 62m	$1 68m	$1 74m
Total Health Sector Budget Impact	Withheld	Withheld	Withheld	Withheld	Withheld

PHARMAC Funding Application
2 August 2020

Chemical Name: Freestyle Libre Flash monitoring system

Indication: Funding for type 1 diabetic for monitoring blood glucose.

Contents Page

Product Overview

Product Details

What type of request is the subject of this application?
New medical device for use in the community

If other, please specify
Freestyle Libre Flash monitoring system

Have any sample(s) of the pharmaceutical been sent to Pharmac?

If a sample has been sent, please provide information that could help us to manage the sample

Please attach suitable artwork and photographs of the packaging, product and product labelling in pdf or jpeg format

Pharmacological Information

What is the registered name of pharmaceutical?
Freestyle Libre Flash monitoring system

What is the brand name(s) of the pharmaceutical?
Freestyle Libre Flash monitoring system

Describe the principal pharmacological action of the pharmaceutical

What is the main goal of the treatment?

Please select the appropriate portfolio Therapeutic Group for this application
Diabetes

Please select the appropriate portfolio Therapeutic Sub-Group for this application

Provide stability data for infusion treatments (if relevant)

Proposed Amendments to Schedule

Please provide details on the proposed indications for listing
Funding for type 1 diabetic for monitoring blood glucose

What setting will the product be used?
Only community

Where is the product likely to be used?

If other, please specify

Please provide a summary statement of the main therapeutic claims for the pharmaceutical and its proposed use

Dose

What recommended course of treatment including dose regimen is likely to be used in NZ clinical practice for each of the indications proposed for listing?
prn

Were the dosage regimens used in the pivotal trials different from the dosage regimen likely to be used in NZ clinical practice? If so please provide details

Do you have any post marketing data on doseage in clincial practice? If so please provide details

Regulatory Status of The Product

Is the pharmaceutical registered by Medsafe for all indications for which funding is sought?
Unknown

Please attach Medsafeapproved datasheets if the pharmaceutical is registered

If registration of the pharmaceutical has been sought but is yet to be granted, please provide details

If the pharmaceutical is registered by Medsafe please provide details of the registered indications

Are other formulations of the product registered for use in NZ?

Pharmaceutical registered for indications overseas?

Provide names of OECD countries where registration has been approved or declined, including any box warnings that may apply

Provide details of other presentations or formulations of the pharmaceutical that have been submitted for approval, or are already approved, in other OECD countries

If the Medsafe registration document is unavailable, please attach copies of relevant Food and Drug Aministration (FDA) and/or European Mediciness Agency (EMA) assessment (note that these reports only need to be attached for unregistrered pharmaceuticals)

Patent Information

Patent information

If you are not the Patent Owner, do you have the right to sell or distribute the pharmaceutical in New Zealand?

If no, please provide further information

If you or the patent owner do not reside or have a place of business within New Zealand, please provide the name of your representative or the representative of the patent owner who resides or maintains a place of business in New Zealand and who is authorised to receive notices related to the patent

Pharmacological Information Table

Pharmaceutical form	If other, please specify	Pharmaceutical strength	Pack size
Other	Blood glucose monitoring system	N/A	N/A

Product Overview Dose Measure of Treatment Table

What is the average duration of treatment (number)	What is the average duration of treatment (period)

Patent Information Table

Patent Number	Patent Expiry date	Type of Patent	If other please specify	Who is the Patent Owner?

Product Overview_Code Type Table

Identification code	Please specify the code value

Health Need

Patient Population

Who is the target population?
Type one diabetics

How many in NZ have the condition(s)? For each of the indications requested for consideration of funding, please provide estimates of the number of people in New Zealand who have the indication, the number of Māori people in New Zealand with the particular condition(s) and the number of Pacific people in New Zealand with the particular condition(s).

For each requested indication(s), please provide estimates of the morbidity associated with the condition (eg. annual number of hospitalisations).

Epidemiology Summary

Please attach the relevant tables

Disease and Its Impact

Please provide an overview of the disease or condition to be treated by the proposed

pharmaceutical
Type one diabetes Insulin dependent and Requires multiple blood glucose readings throughout the day. With current funded Caresens meters multiple finger pricks (limits the number of readings during the day) and no way of knowing if blood glucose is falling or rising Blood glucose levels are essential to determine bolus mealtime dosing.

Please provide details on the severity of symptoms experienced by the average patient

Does this disease or condition have an impact on patient health-related quality of life? If so, please provide details on areas of health-related quality of life that are likely to be impacted and severity.

If possible, please provide information on the total undiscounted quality-adjusted life year (QALY) loss associated with the disease (ie QALY of patients with the disease compared with the QALY of the same age specific population in perfect health)

Please provide the source of information

Does the disease or condition impact on the health of family, whanau and/or wider society? Please explain
Poorly controlled diabetes has numerous well known health consequencesincluding increased risks of ischaemic heart disease, diabetic nephropathy, diabetic retinopathy and maculopathy and peripheral vascular disease Overly tight control leads to hypoglycaemic episodes potentially having an impact on motor vehicle accidents, work place accidents and general morbidity and mortality

Does the disease or condition impact on Maori health areas of focus and Maori health outcomes? Please explain
The current system has a negative impact on maori health outcomes as cost is a significant factor in current use At $50 per week this cost is usually beyonds the means of middle and lower income New Zealanders thus disproportionately affecting maori

Does this indication disproportionately affect any populations that may already be experiencing a health disparities?
Yes - as above. Freestyle Libre Flash monitoring system curently being self funded by those that can afford it and they describe it as "life changing"

Is the disease or condition a Government health priority

If yes please indicate the disease or condition that is the priority

Current Treatment

What treatment(s) is currently used for this indication in New Zealand? Describe the current treatment algorithm of the target population
Caresens blood glucose meters

What sources of evidence were used to inform the current treatment algorithm?

How well do the current treatments work? Are there any associated risks or tolerability issues with the current treatments?
As above - they provide useful data but a significant barrier is the frequent finger pricking and difficulties in interpreting results.

What is the recommended dose of current treatment(s) and dose equvalencies between current treatment and the proposed pharmaceutical?

What is the shelf life of the current treatment compared with the proposed pharmaceutical?

Are there any issues regarding the availability or suitability of existing treatments for this indication?
as above

Would the pharmaceutical replace or complement existing treatments? Please explain

Define and summarise how the proposed treatment may change the current treatment algorithm
Would not change the current clinical management. Instead it would make clinical management more effective

Health Need Patient Numbers Table

Year 1	Year 2	Year 3	Year 4	Year 5

Health Benefits

Identification and Selection of Studies

How was the literature searched? Provide details on the search strategy that was used to retrieve clinical studies and list the studies that meet the inclusion criteria

Provide a flow diagram of the number of studies included and excluded at each stage

Errata, editorials and journal correspondence relating to published trials

Register of all ongoing trials that should provide additional evidence in the next 12 months for the relevant indication(s)

What studies were identified in the literature search and which were excluded?

All identified randomised controlled trials that meet the inclusion criteria

All identified meta-analyses and systematic reviews that meet the inclusion criteria

High quality cohort studies and case-control studies that meet the inclusion criteria

Trial Design and Characteristics

Provide details on the methodology of the pivotal clinical trials that provide evidence on the clinical benefits of the pharmaceutical for the proposed indication

Please attach the relevant methodology information

What are the characteristics of the participants in each of the pivotal trials?

Please attach the relevant information

Trial Results

What were the outcomes and methods of analysis in the pivotal trials?

What did the pivotal trials show? Provide a summary of the study results for each relevant comparison and outcome

How relevant are the outcomes assessed in the clinical trials to clinical benefits and adverse effects expected in New Zealand clinical practice?

Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in new zealand
yes

Discuss and justify any clinically important differences in the results between the different arms of a trial and between trials?

Does the pharmaceutical have similar, greater or fewer side effects and/or toxicity compared with current treatment options? Provide details
Fewer- finger pricking not required

What adverse events were observed in the pivotal trial? What type and frequency of adverse events may be expected in NZ clinical practice? Are there any additional safety issues for the pharmaceutical compared to the relevant comparator if used in NZ clinical practice for this indication?

Please attach details of adverse events

Evidence on clinical adverse events (if differs from sources of evidence for clinical effectiveness)

What impact does the proposed pharmaceutical have on patient-reported outcome measures?

Interpretation of the Evidence

Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient of the pharmaceutical, relative to those of the comparator(s)
as per attached

If available, the incremental health benefits of the proposal relative to the comparator can be provided in the form of quality-adjusted life year (QALY) gains

Please provide information on the consequences (or flow-on effects) to the health system if the pharmaceutical was funded
Positive outcome- less morbidity from hypoglycaemic episodes. Better control of HbA1C would reduce diabetic complications which are a significant cost to the Health System

Would funding the pharmaceutical have an effect on the Government's strategic intentions

for the health system?

Health Benefits and Other Consequences Of Treatment

Would this treatment provide any health benefits or risks to any people beyond the individual who was receiving treatment? If so, what benefits or risks would result?
Improves diabetes control

Health Benefits Inclusion and exclusion criteria Table

Selection Criteria	Inclusion Criteria	Exclusion Criteria

Health Benefits Trial Outcomes Table

What were the study references for the pivotal trials?	What was the outcome definition for the pivotal trials?	What was the method of analysis for the pivotal trials?

Health Benefits Studies Included Table

Please identify the type of study	Please provide the full reference of the study

Health Benefits Results summary Table

Study reference	Outcome intervention n/N (%)	Outcome Comparator n/N (%)	Absolute difference (95% confidence interval) (p value)	Relative difference (95% confidence interval) (p value)

Costs and Savings

Price

What is the proposed pharmaceutical price?

Per pack of

What is the supplier's selling prices to wholesalers in other OECD countries where the pharmaceutical is marketed?

Are there any proposed special authority criteria or access restrictions that you would like pharmac to consider?

Please attach any proposed special authority criteria or access restrictions that you would like PHARMAC to consider?

Are there any proposed commercial terms of listing that you would like Pharmac to consider?

Please attach any proposed commercial terms of listing that you would like Pharmac to consider?

Uptake of Pharmaceutical Epidemiological Approach

Epidemiology over the first 5 years

Uptake of Pharmaceutical - Market Share Approach

Estimate the rate of growth of currently available pharmaceuticals over 5 years Where more than one likely to be substituted present the market share and rate growth for each item

Estimate the rate of substitution by proposed pharmaceutical for each year over 5 years

Estimate the units dispensed for proposed pharmaceutical for each year over 5 years that is above the growth projected in the market using historical data

Summary of market share

Budget Impact

Identify the currently available pharmaceuticals that are likely to be substituted by the proposed pharmaceutical and estimate the units dispensed of each of these currently available pharmaceuticals in the most recent 12 months

Are there any supplementary pharmaceuticals that may have an increased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any supplementary pharmaceuticals that may have an decreased usage as a result of the proposed pharmaceutical being listed (eg pharmaceuticals co-administered with the proposed pharmaceutical or used to treat clinically-significant adverse reactions to the

proposed pharmaceutical) ? Based on estimated utilisation changes, estimate the financial impact in each year over five years for each of the forms and strengths of each of the identified medicines

Are there any diagnostic tests that patients would require prior to receiving or during the treatment with the proposed pharmaceutical? Please specify

Would funding the pharmaceutical impact on the utilisation of other health sector services?

Average cost for a patient for treatment duration (if average treatment duration >12 months then enter cost for 12 months treatment)

Please attach the completed BIA template

Health Related Costs and Savings

Are there additional costs and/or savings to the person that are likely to be incurred if the pharmaceutical is funded?

Health-related costs and savings that may be experienced to the family, whānau and wider society of the person receiving the treatment

Cost Budget Impact Table

Budget to be impacted	Year 1	Year 2	Year 3	Year 4	Year 5

Cost_Uptake of Pharmaceutical - Epidemiological Approach Table

Enter the year for years 1 to 5 from listing date	Please indicate the number of patients treated each year up to 5 years from listing date	Please indicate the number from incremental patients treated each year up to 5 years from listing date

Economic Analysis

Costutility analysis based on the methods outlined in the Prescription for Pharmacoeconomic Analysis (including all costs estimated in $NZ)

Please attach TreeAgeTM model or ExcelTM spreadsheet. The models must be able to be amended

What is the base case estimate of cost-effectiveness, in QALYs per $million

What is the upper limit of the likely range of cost-effectiveness in QALYs per $million?

What is the lower limit of the likely range of cost-effectiveness in QALYs per $million?

Suitability

Features of the Pharmaceutical That Impact Its Use

Are there any features of the treatment that may impact on its use by the person receiving the treatment (eg method of delivery, accessibility, size, shape, taste)? If so, please explain
No need for finger pricking. More conveient use

What features of the pharmaceutical may have an impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society?
Easier for families to help monitor BSLs

What features of the pharmaceutical may have an impact on use by the health workforce?
?

Are there any other considerations that PHARMAC should be aware of in relation to the administration of this pharmaceutical, such as infusion time, compounding requirements or safety issues?
No

Declaration and Identification

Declaration

Please confirm if you have the right to supply the product for which funding is requested

I confirm that the company I represent has legal rights to the patents

I confirm that there are no non-patent intellectual property barriers

I have read and accept PHARMAC's standard terms of listing on the Pharmaceutical Schedule.
False

Any variations on the standard terms of listing for PHARMAC to consider have been detailed in this application or provided within an attachment
False

I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application
False

I declare that all known published and unpublished clinical trials that I am aware of that are relevant to this application have been disclosed in the Application
True

I declare that I have obtained the appropriate permission or paid the appropriate copyright fee for any publication or other information provided in support of this application, and that the publications can be distributed internally by PHARMAC (including to PHARMAC committees) for the purpose of reviewing the application
False

Do you have any potential conflicts of interest relevant to this application
No

Provide a description of any conflicts you may have

I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker
Yes

I confirm the information provided in this Application is correct
Yes

Do you have any comments regarding any of the above declarations?

Identification

Name of person submitting application

Date of application
2 August 2020

Who is the primary contact first name for this application?
Withheld under

Who is the primary contact last name for this application?

What is the primary contact's job title for this application?

What is the primary contact email for this application?
Withheld under section 9(2)

What is the primary contact phone number for this application?
Withheld

Vaccines (Additional Information)

Pharmacological Information

For the proposed vaccine, please specify the number, identification and amounts of antigens (components)?

What is the formulation of the vaccine?

What is the nature of the immunising agent(s)?

What is vaccine presentation?

What are the external dimensions of the vaccine packed for storage?

Are there any requirements for cold chain management? Please specify

Proposed Amendments to the Pharmaceutical Schedule

Is this a new vaccine or an alternative vaccine? Please select

What is the proposed schedule of administration of the vaccine?

Are there any programme requirements for administration?

What health services will be affected?

Can a vaccination course that begins with the proposed vaccine be completed with a competing or alternative vaccine (or vice versa)?

Is there any expectation of a limited initial supply?

Is a catch-up programme required? If so, please provide details

Patient Population

In addition to describing the patient population, justify the selection of the requested age range(s) of eligible individuals within the primary immunisation programme and catch-up programme (if relevant)

Current Treatment

Is an alternative vaccine listed on the National Immunisation Schedule?

Compare the content and characteristics of the proposed and alternative vaccines

Health Benefits to the Family, Whanau and Wider Society

Provide evidence that indicates whether funding the vaccine is likely to provide indirect protection to non-immunised people through appropriate coverage (ie. herd immunity).

Special Foods (Additional Information)

Pharmacological Information

List all ingredients in the product

Attach a table on the micronutrient and macronutrient content of the product per 100 kcal, and per 100 g or 100 mL

Select type of product

If other, please specify

Confirm that the formula of the proposed product will supply the protein, energy, fatty acid, vitamin and mineral requirements for the patient if used as a sole source of nutrition Identify any additional nutritional needs.

Provide details on the products compatibility with currently available medical devices and consumables in New Zealand

Attach a table comparing the proposed product with the requirements of the Australia New Zealand Food Standards Code - Standard 2.9.1: Infant Formula Products, using the terminology of the code Confirm that the proposed product complies with this code or justify any deviations from particular parts of the code.

Regulatory Status of Product

Confirm that the Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes requirements have been met

Proposed Amendments to the Pharmaceutical Schedule

Attach a table comparing the nutrient contents of the proposed and comparator products with the NZ RDI

Provide the instructions for preparation and use of the proposed product

Community Medical Devices (Additional Information)

Device Information

Describe the therapeutic purpose of the device

Provide details of pack contents and whether any accessories are included in the packs

Describe how the device is used

Please attach the instructions for use and/or the user guide

Does the device need to be used with a pharmaceutical or other technology? If so, is the

pharmaceutical or technology is available and funded in New Zealand?

What is the lifespan of the device, and of any component parts, if applicable?

Are there any different models or versions of the device that are available? Does this have any consequences on the mode of action?

What properties or features of the device make it innovative or a significant modification when compared with other technologies of its type?

Regulatory Status of Device

WAND registration number

Date of registration to the WAND database

Proposed Amendments to the Pharmaceutical Schedule

What is the proposed use of the device, including any proposed restrictions to access?

How does the device (if it were digital for example) connect with/interoperability with NZ Health systems (eprescribing, ehealth records, is it bluetooth enabled etc)

Is the device used in standard care internationally? Please provide details