From: Withheld [mailto:Withheld under section 9(2)(a)]
Sent: Monday, 29 August 2016 10:51 a.m.
To: Web Enquiry
Subject: RE: Continuous Glucose Monitor Funding

Hi,

I am emailing in regards to CGM's on the market now. As a diabetic type 1 of Wit years, I feel as though it is almost a necessity for me, due to complications with hypoglycemic unawareness from tight control over my blood glucose over the numerous years. It is frightening how quickly I can go from perfectly normal to being in a severe hypo in the past couple of weeks.

The implementation of wide scale funding for units of such could also help reduce the long term complications cause of ill diabetic control for a large majority of type 1 diabetics, thereby reducing unforeseen medical costs.

As the CGM's have improved significantly over the years, I feel as though It maybe worthwhile looking into providing funding for units such as the following;

https://www.dexcom.com/g5-mobile-cgm

It is an exciting prospect being able to have a constant update on blood glucose!

Feel free to contact me at anytime, and I look forward to hearing back from you

Thanks,

Withheld

From: Web Enquiry
Sent: Wednesday, 21 September 2016 11:25 am
To: 'Withheld' <Withheld under section 9(2)(a)>
Subject: RE: Continuous Glucose Monitor Funding

Hi Withh

Thank you for your email about Dexcom Continuous Glucose Monitoring Systems (CGMS). We appreciate you taking the time to provide us with your feedback on the benefits of such a system in the management of type 1 diabetes. I have passed your feedback on to the relevant Therapeutic Group Manager at PHARMAC who looks after diabetes products.

PHARMAC has not received a funding application for a CGMS before, and they haven't previously been considered for funding.

Anyone – a patient, a health professional or a pharmaceutical supplier – can make a funding application to PHARMAC. These are most often made by suppliers who are able to provide relevant research and clinical data, but as noted, this does not have to be the case You may however wish to contact a supplier of CGMS to find out if they have any intention to submit an application to PHARMAC. You can find more information about submitting a funding application, including application forms on the following link: http://www pharmac health nz/medicines/how medicines are funded/new-funding-applications/

You may be interested to know that PHARMAC does manage the process for considering funding for individual patients, called the NPPA process. NPPA is a mechanism for individual patients to receive funding for medicines not listed on the Pharmaceutical Schedule. Several criteria must be met before a NPPA application can be progressed. One of these is that the person has tried all suitable funded alternative treatments. You might find the question-and-answer leaflet on our website helpful. It provides general information about the NPPA process, and you can find it here: http://www.pharmac.health.nz/assets/nppa-consumer-info-sheet.pdf

Thank you for taking the time to write to us If you have any questions, please do not hesitate to contact us

Kind regards
Alexis Poppelbaum
PHARMAC

From: Withheld under section 9(2)(a) < Withheld under section 9(2)(a) >
Sent: Friday, 1 September 2017 4:18 pm
To: applications <applications@Pharmac govt.nz>
Subject: RE: Dexcom G5 CGM Funding Application
Attachments: form funding application docx, form funding-application pdf

Hi,

Please find the form attached. For what it's worth, I picked up a system Withheld under section 9(2)(a) and it has made life insurmountably better.

Withh

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**

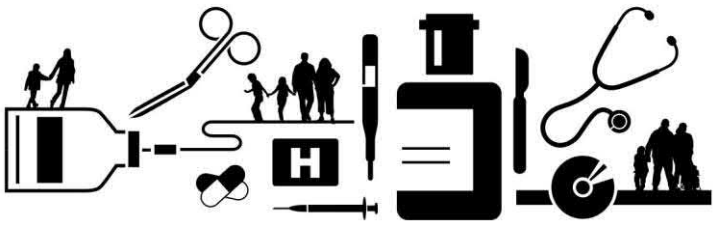
Post: **PO Box 10254**
The Terrace
Wellington 6143

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

Withheld

Department & DHB, practice or organisation

Click here to enter text

Email address

Withheld under section

Phone or pager

Withheld

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

Diabetics throughout New Zealand

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

Dexcom NZ

Proposed pharmaceutical

Chemical

Dexcom G5 Continuos Glucose Monitors

Presentations and strengths

Provides blood glucose results every 5 mins. Alerts for low levels and extreme fall rates

Brand name(s)

Dexcom

Suppliers (eg pharmaceutical companies, wholesalers)

Dexcom

Price

Receiver = $999 (lasts 2 years but isn't required as results can be shown on the dexcom app on a phone), transmitter =$750 (3 months), box of 4 sensors= $530 (1 month supply)

Is it registered by Medsafe?

Unsure: https://www.pharmac.govt.nz/assets/seminar-diabetes-update-for-2016-dr-j-krebs.pdf (note its at the bottom of the presentation)

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

For entire system, or just the sensors and transmitter

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.

https://www pharmac govt nz/assets/seminar-diabetes-update-for-2016-dr-j-krebs pdf

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

People with type 2 diabetes, at the very least people with hypoglycemic unawareness

What is the expected dosing?

1 sensor/week (I've used it for 2-3 weeks, which appears to be pretty standard)

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

Lifetime

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?

Home setting

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

No, although they are constantly improving the technology

Treatment initiation

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

No

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.

No

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

Yes, fingerprick testing

Treatment continuation

How would treatment success be defined or measured?

Lower/more stable Hb1ac levels Less emergency hospital visits/deaths from diabetic comas

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

N/A

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

N/A, back to fingerpricks

Prescribing and dispensing

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

No

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?

GP's, any doctor

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

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.

For diabetics with hypoglycemi unawareness it allows for a much healthier life, with less anxiety. No longer need to test every 20-30mins, and can sleep easy knowing you have a backup alert for hypos and hypers (speaking from experience)

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

Just diabetic type 2's

Health need

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

Diabetic type 2's with diabetic unawareness

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

Fingerpricks for blood glucose levels

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

Not providing a good trend line of BGL unless testing every 10-20mins

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

It wouldn't replace the need for fingerprick testing but it would significantly reduce the need.

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

N/A

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?

N/A

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).

For diabetics with hypoglycemi unawareness it allows for a much healthier life, with less anxiety No longer need to test every 20-30mins, and can sleep easy knowing you have a backup alert for hypos and hypers. (speaking from experience)

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

Reallying too much on the CGM during dramatic fall rates as the CGM does really on interstitial fluid testing not blood testing, so there is a 10 15min lag time This can be prevented through education, saying that fingerpricks should be used in the circumstances, as stated by dexcom

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

N/A

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?

Less stress on family members/ parents of diabetics. The dexcom follow app allows for parents, or others to receive a persons CGM data if allowed.

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?

Less fingerpricks. Less diabetic complications within the populations, leading to less surgeries. Less hospital visits from diabetic comas. Less deaths.

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

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm533969 htm

Costs and savings

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

Costs and savings

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)?

I feel over the long term it could save a fair amount in long term diabetics

From: April Mae Marshall
Sent: Sunday, 24 September 2017 1:05 pm
To: '[redacted]' <[redacted]>
Subject: RE: Dexcom G5 CGM Funding Application

Dear [redacted]

Thank you for the funding application for Dexcom G5 CGM monitors for the diabetes, we are pleased to have the opportunity to consider this product for funding.

We will review this application and be in touch once it has been scheduled for consideration with the Pharmacology and Therapeutics Advisory Committee or its Diabetes Subcommittee.

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: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: [redacted] [mailto:[redacted]]
Sent: Tuesday, October 31, 2017 6:07 AM
To: April-Mae Marshall <[redacted]>
Subject: Re: Dexcom G5 CGM Funding Application

Hi April-Mae,

Has there been any further discussion about this matter?

[redacted]

From: April-Mae Marshall
Sent: Friday, 3 November 2017 3:32 pm
To: '[redacted]' <[redacted]>
Subject: RE: Dexcom G5 CGM Funding Application

Dear [redacted]

PHARMAC is currently reviewing applications for continuous glucose monitors and working with the suppliers of these products to ensure we have all the relevant information necessary for our assessment process

We will keep you updated with regards to our progress.

Regards

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

On Mon, Jan 15, 2018 at 11:02 AM Withheld under section < Withheld under section 9(2)(a) > wrote:
Hey April-Mae,

Just wondering if there was any further action in this matter?

Withh old
Sent from my iPhone

From: Withheld under section < Withheld under section 9(2)(a) >
Sent: Thursday, 10 December 2020 11:32 am
To: April Mae Marshall < Withheld under section 9(2)(a) >
Cc: Web Enquiry <enquiry@Pharmac.govt.nz>
Subject: Re: Dexcom G5 CGM Funding Application

Hi April,

Any news on this?

Thanks,

Withh old

From: April-Mae Marshall < Withheld under section 9(2)(a) >
Sent: Thursday, 10 December 2020 2:36 pm
To: Elena Saunders < Withheld under section 9(2)(a) >; Web Enquiry <enquiry@Pharmac govt.nz>
Subject: FW: Dexcom G5 CGM Funding Application

Hi Elena and Enquiries Team

I am passing this on as I am unsure what the plans are for the item noted above
Can you please discuss and respond.

BTW I would like to let Withh old know I have forwarded this but will wait to hear if it does sit with the TGM or Enquiries.

Kind Regards
April Mae Marshall

April Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under section 9(2)(a) | M: Withheld under section 9(2)(a) | P: +64 4 460 4990 | www pharmac govt nz

From: Ross Hunt <Withheld under section>
Sent: Tuesday, 31 July 2018 6:00 pm
To: James Harris <Withheld under section 9(2)(a)>
Cc: 'Trish Snegirev' <Withheld under section 9(2)>
Subject: Economic modelling to support funding application for Real-Time Glucose Monitoring System
Attachments: AMCP ECONOMIC MODEL G6 MEDICAID v2.xlsx, AMCP ECONOMIC MODEL G6 COMMERCIAL v3.xlsx

Hi James – hope all is well with you.

I am preparing an application on behalf of NZ Medical & Scientific for a new Continuous Glucose Monitoring System manufactured by the US company Dexcom Inc. The system is unique in that it connects via Bluetooth to multiple iOS and android devices to provide real-time blood glucose data to high risk diabetics and their care givers, without the need for regular fingerstick calibration. Both Trish Snegirev of NZMS and I have been liaising with Danae Staples-Moon on the content and timing of the submission.

Dexcom have developed an Excel "cost prevention" model for Medicaid-like populations and a similar "cost benefit" model for health plan populations, which I am attaching. Both models offset the avoided costs associated with managing hypoglycaemic events against the CGM system costs. The inputs are validated US costings. In considering the local appropriateness of the models I'm mindful of a couple of things:

1. PHARMAC's preference for Cost Utility analyses
2. A paucity of reliable local cost input data

Given this, I'm wondering if I can ask you to provide feedback on the value of the models to your assessment process? If you see merit, could I also ask for any meaningful input data sources you can suggest?

Many thanks, and best regards

Ross

Ross Hunt
Principal

Axess Consultancy Limited
Market Access Partners

Mobile Withheld under | Land Withheld under | Email Withheld under section

From: James Harris
Sent: Tuesday, 7 August 2018 5:17 pm
To: 'Ross Hunt' <Withheld under section>
Cc: Danae Staples-Moon <Withheld under section 9(2)(a)>
Subject: RE: Economic modelling to support funding application for Real-Time Glucose Monitoring System

Hello Ross,

Thank you for seeking early advice on the modelling approach for Continuous Glucose Monitoring System

In response to your specific question:

- Yes, a transaction that is cost-saving to the health sector can be supported by a cost-minimisation model as you suggest. We only need to analyse health (utility) gain if there is a net cost to the sector.
- For costs, the best starting point is our Cost Resource Manual (at https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/) It has unit costs for many of the items in that model; the Ministry of Health should be able to supply the others; please don't hesitate to let me know if any are hard to track down.

With best wishes,

James

James Harris | Manager, Health Economics

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