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**

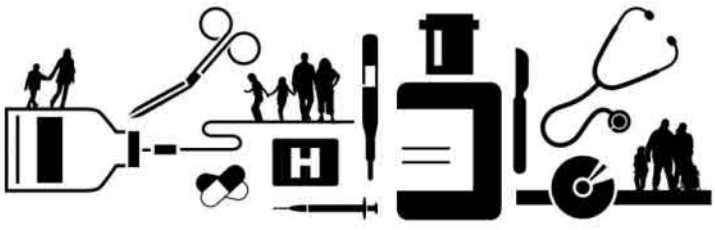
Post: **PO Box 10254**
The Terrace
Wellington 6143

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."