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