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

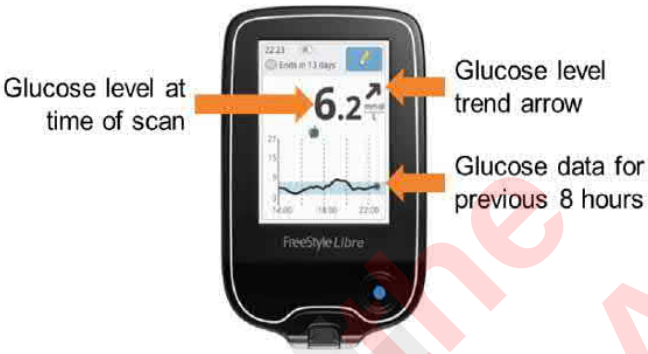
The FreeStyle Libre system has three components: a disposable sensor, a reader, and optional software

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