# MSAC Application 1786

## Freestyle Libre 2 for people with insulin-dependent type 2 diabetes, gestational diabetes and type 3c diabetes

# Application or referral for other medical service or health technology

**Application ID:**
HPP200211
**Application title:**
Freestyle Libre 2 for people with insulin-dependent type 2 diabetes, gestational diabetes and type 3c diabetes
**Submitting organisation:**
ABBOTT AUSTRALASIA PTY LTD
**Submitting organisation ABN:**
95000180389

# Application description

**Succinct description of the medical condition/s:**
Type 2 diabetes (T2D) is a chronic and progressive condition. Treatment of T2D follows a step-wise approach that can be intensified to meet individualised glycaemic (HbA1c) targets, including weight loss if possible, treatment with single or multiple oral therapies, injectable agents and insulin therapy (Australian Diabetes Society 2022).

This funding application is for people with T2D requiring insulin therapy, including all combinations with other medicines for T2D. All patients with T2D on insulin therapy are recommended to routinely monitor their blood glucose control via self-monitoring of blood glucose (SMBG). FreeStyle Libre 2 (FSL2) will provide a superior glucose monitoring alternative for this population.

Given the July 2024 recommendation from the Parliamentary Diabetes Inquiry we have also included gestational diabetes (diabetes with pregnancy) and others such as cystic-fibrosis related diabetes.

**Succinct description of the service or health technology:**
FreeStyle Libre 2 Continuous Glucose Monitoring System (FSL2) is a novel, sensor-based, factory-calibrated monitoring system with two key components: a disposable 14-day sensor (inserted into subcutaneous tissue at the back of the upper arm) and a reader (using either a smartphone App or a physical reader). This sensor includes an inbuilt transmitter that transits glucose data to the App or Reader. It is designed to continuously measure glucose levels in the interstitial fluid and provides glucose trends, variability, and patterns across a 24-hour period.

The FSL digital ecosystem includes two mobile medical Apps. The FreeStyle LibreLink to read glucose levels and FreeStyle LibreLinkUp to enable authorized caregivers to remotely receive alarms and glucose data. The app data can be automatically uploaded to LibreView, which enables patients and HCPs to see the full glycaemic picture including the Ambulatory Glucose Profile (AGP).

# Application contact details

**Are you applying on behalf of an organisation, or as an individual?**
Organisation
**Is the applicant organisation the organisation you are representing in the HPP today?**
Yes
**Applicant organisation name:**
ABBOTT AUSTRALASIA PTY LTD

# Application details

**Please select the program through which the health technology would be funded:**
National Diabetes Services Scheme

**Please provide justification for selecting the above program:**
The FreeStyle Libre 2 continuous glucose monitoring system is currently reimbursed through the NDSS for all Australians living with Type 1 diabetes.

As requested by the MSAC pre-assessment team, we are resubmitting the previously lodged application from June 2023, to consider reimbursement of FreeStyle Libre CGM products for patients living with Type 2 diabetes (T2DM) who require insulin.

The recent Parliamentary Diabetes Inquiry recommended equitable subsidised CGM access for individuals with insulin-dependent Type 3c diabetes, patients with gestational diabetes and for those with Type 2 diabetes requiring regular insulin. We have therefore updated this submission to include a summary of information to support CGM access for gestational diabetes and Type 3c diabetes. This Inquiry report was just recently released, so at this stage a summary of evidence for gestational diabetes and type 3 diabetes is attached and further details, background and financial impacts will be included in a full submission (ADAR), alongside any other information.

Further details have also been added to highlight the priority for a streamlined Health Technology Assessment (HTA) process for diabetes technology as recommended by key diabetes stakeholders..

**What is the type of service or health technology?**
Therapeutic

# PICO set

## Freestyle Libre 2 for people with insulin-dependent type 2 diabetes, gestational diabetes and type 3c diabetes

## Population

**Describe the population in which the proposed health technology is intended to be used:**
People with type 2 diabetes (T2D) requiring insulin therapy. This includes all combinations with other medicines for T2D. All patients with T2D on insulin therapy are recommended to routinely monitor their blood glucose control via self-monitoring of blood glucose (SMBG). FreeStyle Libre 2 (FSL2) will provide a superior glucose monitoring alternative for this population.

The proposed T2D insulin-using population includes a subpopulation using intensive insulin therapy (IIT), i.e. patients requiring multiple daily insulin injections or (less commonly) continuous subcutaneous insulin infusion (CSII) who are recommended to undergo frequent monitoring of their blood glucose control (multiple times per day, e.g. with meals).

See the attached PICO information which provides further information on:
- Natural History of T2D and burden of disease
- Profile of an Australian T2D person
- Recommended treatments for T2D (including ADS treatment algorithm)
- Supportive figures and tables

Diabetes Australia recommends that subsidised access to flash glucose monitoring (sensors) should be made available to adults with type 1 diabetes or type 2 diabetes using insulin (Diabetes Australia 2017).

Abbott have focussed this application on a population of T2DM requiring insulin as this is where FreeStyle Libre has an established evidence base and HTA's have already been completed by comparable HTA bodies.

However, given the recent recommendation from the Parliamentary Diabetes Inquiry, Abbott has also included the population of insulin-dependent gestational diabetes and type 3c diabetes. This Inquiry report was just recently released, so at this stage a summary of evidence for gestational diabetes and type 3 diabetes is attached and further details, background, uptake estimates and financial impacts will be included in a full submission (ADAR), alongside any other information.

# Intervention

**Name of the proposed health technology:**
FreeStyle Libre 2 Continuous Glucose Monitoring System

# Comparator

**Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This include identifying health care resources that are needed to be delivered at the same time as the comparator service:**

SMBG with blood glucose test strips.

The Australian National Diabetes Audit (ANDA) data for 2021 indicates that 83.7% of people with T2D perform regular blood glucose monitoring, with 81.3% of these using finger pricking (Australian National Diabetes Audit 2022). Many patients with T2D report that they do not perform finger pricking as often as recommended by their HCP (31.8%) or are unsure of the recommended testing frequency (5.8%) (Australian National Diabetes Audit 2022). With current SMBG testing, 71.3% of Australians with T2D fail to meet a HbA1c target of 7% (Australian National Diabetes Audit 2022).

Once a patient with T2D requires insulin treatment, regular glucose monitoring is recommended (RACGP 2020b) and in the IIT subpopulation more frequent monitoring is recommended (RACGP 2020a), compared with the overall T2D insulin using population . Insulin, has a very narrow therapeutic index and hence requires careful, intensive, ongoing glucose monitoring to ensure appropriate dosage titration and maintenance (RACGP 2020a). A recent survey of Australia's leading diabetes health professionals suggests that Australian T2D IIT patients currently use SMBG testing within a range of 4 or less to 9 or more times per day.

# Outcomes

**Outcome description - please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:**

FSL2 is superior to SMBG for T2D patients on insulin in assisting patients to maintain glycaemic targets, with a significant impact in lowering HbA1c and longer-term outcomes such as reduction in cardiovascular events, diabetic neuropathy, retinopathy, nephropathy, and peripheral vascular diseases.

T2D insulin requiring population

This is similar to what was found in a modified Delphi survey of patients, endocrinologists, primary care physicians and healthcare funders with key priority outcomes identified as reducing the risk of heart attacks, lowering HbA1c levels and avoiding hypoglycaemic events (Neilson 2019).

The following outcomes have been accepted as being clinically meaningful in T2D to be measured in clinical trials and practice (FDA 2008, Neilson 2019):

- Shorter term outcomes:
    - Change in HbA1c from baseline (most important): HbA1c is the standard of care for testing and monitoring diabetes, specifically T2D (WHO 2011) and is measured every 3-6 months. HbA1c remains, according to FDA requirements, the primary outcome to be measured for the demonstration of glycemia-lowering efficacy for new diabetes drugs (FDA 2008). Target HbA1c levels in T2D patients should be tailored to the individual, balancing the improvement in microvascular complications with risk of hypoglycaemia (Cheung 2009).
    - Health-related quality of life (QoL)
    - Patient satisfaction
    - Avoiding hypoglycaemic events

- Intermediate to longer term outcomes (Neilson 2019):
    - Reduction in cardiovascular events (rated the most meaningful outcome)
    - Diabetes-related hospital admission rate
    - Weight loss
    - Reducing risk of diabetes-related kidney disease
    - Reducing risk of diabetes-related neuropathy/nerve damage
    - Reducing risk of emergency room visits from diabetes
    - Reducing risk of diabetes-related retinopathy/eye disease
    - Reducing risk of diabetes-related amputations and foot ulcers

Survey respondents were also asked what were the most feasible outcomes that could be collected for T2D, with the top 5 being, reducing (Neilson 2019):

- HbA1c
- The risk of hospitalisations from diabetes
- Weight
- The risk of diabetes related kidney disease
- The risk of emergency room visits from diabetes

# Specified restrictions for funding

**Provide a short description of the restriction:**
People with type 2 diabetes requiring insulin therapy
**Proposed price of supply:**
$REDACTED
**Indicate the overall cost per patient of providing the proposed health technology:**
$REDACTED
**Provide details and explain:**
People with type 2 diabetes requiring insulin therapy currently purchase FSL2 through the webshop: https://www.freestylelibre.com.au/products.html
**How is the technology / service funded at present? (For example: research funding; State-based funding; self funded by patients; no funding or payment):**
Self-funded by patients with T2D on insulin.
FSL2 is subsidised via the National Diabetes Services Scheme for patients with T1D.

# Claims

**In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?**
Superior
**Please state what the overall claim is, and provide a rationale:**
The clinical claim is that FSL2 provides superior efficacy in terms of glycaemic control and non-inferior safety compared to SMBG.

The rationale for the claim is that use of FSL2 results in statistically and clinically significantly greater improved in glycaemic control (measured as HbA1c change in key trials and other markers of glycaemic control including time in glycaemic range and the occurrence of hypo/hyperglycaemia). Improvement in HbA1c outcomes observed in the clinical studies is

also associated with improved long term diabetes control and reduced development of diabetic complications. Use of FSL2 also results in reduced healthcare resource use(e.g. reduced hospital admissions), improved patient satisfaction and quality of life, reported in clinical trials and during real world use.

# Estimated utilisation

**Estimate the prevalence and/or incidence of the proposed population:**

Abbott have focussed this application on a population of T2DM requiring insulin as this is where FreeStyle Libre has an established evidence base and HTA's have already been completed by comparable HTA bodies.

However, given the recent recommendation from the Parliamentary Diabetes Inquiry, Abbott has also included the population of gestational diabetes and type 3c diabetes. This Inquiry report was just recently released, so at this stage a summary of evidence for gestational diabetes and type 3 diabetes is attached and further details, background, uptake estimates, and financial impacts will be included in a full submission (ADAR), alongside any other information.

Figures from the NDSS suggest that over 300,000 people with T2D were insulin users, during the 12 month period (June 2021 to May 2022). However, it is noted that the DUSC 2017 estimates of the number of T2D patients using insulin (and all combinations of insulin) in were somewhat lower than the NDSS reports of registered insulin users. At the end of July 2016, the DUSC reports ~248,000 people on insulin (with ~120,000 T1D and the remaining mostly T2D), whilst the NDSS snapshot reports 383,000 (with ~120,000 T1D and ~250,000 T2D). This highlights a 100,000+ difference in people using insulin combination treatment vs how many are registered to use insulin on the NDSS.

**Provide the percentage uptake of the proposed health technology by the proposed population:**

**Year 1 estimated uptake (%):**

REDACTED

**Year 2 estimated uptake (%):**

REDACTED

**Year 3 estimated uptake (%):**

REDACTED

**Year 4 estimated uptake (%):**

REDACTED

**Estimate the number of patients who will utilise the proposed technology for the first full year:**

REDACTED

**Will the technology be needed more than once per patient?**
Yes, multiple times
**Over what duration will the health technology or service be provided for a patient? (preferably a number of years):**
ongoing
**Optionally, provide details:**
As T2D is a chronic condition, the patient would be required to use this technology on a continuous basis. The reader and/or phone app are obtained at initiation, with the sensors recommended to be replaced every two weeks. The clinical studies highlighted in the summary of evidence include outcomes that are based on continuous use of the FSL2 sensors.
**What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):**
New sensor applied on skin every 14 days
**Optionally, provide details:**
Each FSL2 user will require to replace their FSL2 sensor every 14 days.

# Consultation

**List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:**

- Australian Diabetes Educators Association
- Australian Diabetes Society

**List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:**

- Diabetes Australia

**List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:**

- Individual companies providing blood glucose monitoring products.

# Regulatory information

**Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?**
Yes
**Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**
Yes
**Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**
Class III

**Please enter all relevant ARTG ID's:**

| ARTG ID | ARTG name |
|---|---|
| 358292 | FreeStyle Libre 2 Glucose Monitoring System |

**Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?**
Yes