

# **MSAC Application 1785**

## **Dexcom ONE Continuous Glucose Monitoring System**

# Application for MBS eligible service or health technology

**Application ID:**

HPP200201

**Application title:**

Resubmission Dexcom ONE Continuous Glucose Monitoring System

**Submitting organisation:**

AUSTRALASIAN MEDICAL & SCIENTIFIC LIMITED

**Submitting organisation ABN:**

28051991372

## Application description

**Succinct description of the medical condition/s:**

Type 2 diabetes (T2D) is a condition characterised by insulin resistance and high blood sugar levels. In Australia it is estimated that ~70% of T2D patients fail to meet their HbA1c goals (ANDA 2022). Uncontrolled T2D is associated with complications that impact on quality of life and may increase the risk of death. Long term complications may be macrovascular (coronary artery disease, stroke) or microvascular (retinopathy, nephropathy, neuropathy). In the short term, poorly controlled T2D can lead to hypoglycaemic and hyperglycaemic events. In 2023, ~1.26 million Australians were living with T2D, of whom ~24% are estimated to use insulin (NDSS, 2023). In this application, patients with T2D who use insulin are classified as "intensive" and "non-intensive" insulin users, depending on the type of insulin regimen they use.

**Succinct description of the service or health technology:**

Dexcom ONE is a real time continuous glucose monitoring (RT-CGM) system consisting of a wearable sensor and transmitter which transmits data to a compatible smart device via a mobile app. Continuous monitoring allows people with T2D to accurately monitor their blood glucose levels in real time, helping them make informed decisions to manage their condition and reduce the risk of diabetes-related complications. In studies of intensive and non-intensive insulin users with T2D, the use of RT-CGM was associated with reductions in HbA1c, hypoglycaemia, hyperglycaemia and improved time in range (Beck 2017; Martens, 2021; Lind 2024). In recognition of these benefits, the recently completed Parliamentary Inquiry into diabetes noted "CGM technology should be made available to those with Type 2 diabetes requiring insulin and to others who have had glucose control difficulties".

## 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:**

AUSTRALASIAN MEDICAL & SCIENTIFIC LIMITED

## 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:**

Dexcom real time continuous glucose monitoring (RT-CGM) systems for type 1 diabetes (T1D) are currently funded through the National Diabetes Services Scheme (NDSS). In addition, the NDSS provides a range of diabetes products (such as glucose monitoring strips) for people living with type 2 diabetes (T2D). This is therefore the appropriate program to provide funding for RT-CGM in T2D, while MSAC is an appropriate pathway for assessing cost-effectiveness.

This resubmission has been lodged based on advice from the Department of Health and Aged Care (DOHAC) that it will now accept applications in relation to CGM for consideration by MSAC. Additionally, the recently completed Parliamentary Inquiry into "The State of Diabetes Mellitus in Australia in 2024" (the Inquiry) has produced a broad range of recommendations about the use of CGM technology, including the following:

"The Committee recommends that subsidised access to Continuous Glucose Monitors (CGMs) be further expanded. In the first instance, all access limitations in relation to patients with Type 1 diabetes should be removed. Furthermore, individuals with insulin-dependent Type 3c diabetes and patients with gestational diabetes should be made eligible for subsidised CGMs and for those with Type 2 diabetes requiring regular insulin. The Committee recommends prioritising the removal of age limitations on access to subsidised access for Type 1 diabetes patients" (Recommendation 15, Diabetes Inquiry).

Dexcom supports the move towards achieving equitable access to diabetes technologies for all types of insulin-dependent diabetes. We agree that the funding of insulin dependent 3c, gestational diabetes and insulin-dependent T2D is a priority, and we consider the appropriateness of co-payments based on age to be a policy matter for DOHAC. We note that while there may be a clinical need for CGM in patients with Type 3c diabetes and gestational diabetes, high quality evidence in these groups is still emerging. Therefore, this MSAC application focuses on patients with insulin-dependent T2D. With respect to this population, the Inquiry further noted "CGM technology should be made available to those with Type 2 diabetes requiring insulin and to others who have had glucose control difficulties", and also highlighted the fact that T2D disproportionately affects disadvantaged communities.

Dexcom agrees that all insulin dependent patients, regardless of diabetes type, should have access to RT-CGM. We also acknowledge that the Inquiry specifically noted that "The eligibility expansion should subsequently continue to gradually encompass all Australians with insulin-dependent diabetes" (paragraph 5.92, Diabetes Inquiry). Therefore, this application presents separate PICO criteria for "intensive" and "non-intensive" insulin users with T2D. Intensive insulin users are further progressed in their disease and require multiple daily injections (MDIs) consisting of basal insulin in combination with rapid acting insulin, while non-intensive insulin users are treated with a basal insulin regimen, with no regular use of rapid acting insulin. Although many patients on non-intensive insulin regimens will eventually progress to intensive insulin therapy, the two populations are distinct in terms of their clinical characteristics. For this

reason, the use of CGM is supported by different studies in these two populations. Both populations currently experience suboptimal long-term clinical outcomes due to poor glycaemic control. Whether funding for these populations should be staged is a matter for the Government and DOHAC; however, it is our view that both should be evaluated for effectiveness and cost-effectiveness in accordance with the recommendations of the Inquiry, and to inform government funding decisions.

Finally, the Inquiry noted that “there is a general consensus among medical professionals and patient groups that all insulin dependent patients, regardless of diabetes type, should have access to subsidised new technologies” (paragraph 5.65, Diabetes Inquiry). Accordingly, the use of RT-CGM in T2D is supported by a range of organisations including the Australian Diabetes Alliance, which includes Diabetes Australia, the Australian Diabetes Educators Association, the Australian Diabetes Society, JDRF Australia, the Australasian Diabetes in Pregnancy Society, and the Australian and New Zealand Society for Paediatric Endocrinology and Diabetes. As such, we believe an MSAC evaluation of CGM in T2D is strongly supported by the diabetes community.

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

Investigative

## **Application PICO Sets**

### **PICO set 1: T2D intensive insulin users**

#### **Population**

##### **Describe the population in which the proposed health technology is intended to be used:**

The population proposed in this PICO set consists of intensive insulin using patients with T2D with a suboptimal glycaemic profile defined by the following criteria:

- Aged  $\geq 2$  years
- Diagnosis of T2D
- Treated with basal insulin and rapid acting insulin
- Sub-optimal glycaemic control confirmed by laboratory measured HbA1c levels of  $>7.0\%$  for adults and  $>6.5\%$  for children and adolescents.

##### **Select the most applicable Medical condition terminology (SNOMED CT):**

Diabetes mellitus

#### **Intervention**

##### **Name of the proposed health technology:**

Dexcom ONE 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:**

No subsidised CGM systems to manage T2D through NDSS are available in Australia. Therefore, the main comparator for the proposed health technology would be SMBG.

The NDSS provides subsidised blood glucose monitoring strips for SMBG for a six-month period after an initial diagnosis of T2D. Ongoing access, in six-monthly increments, is available when assessed as clinically necessary and authorised by a general practitioner, credentialled diabetes educator, endocrinologist, nurse practitioner or other registered medical practitioner. In Australia, the frequency of SMBG testing is individualised; however, evidence suggests that an increased frequency of SMBG is correlated with improved HbA1c in both T1D and T2D (Karter, 2001) and international guidelines suggest SMBG is needed 6-10 times per day for those using intensive insulin regimens (ADA, 2023).

Repeated SMBG can be time consuming, inconvenient, and painful, consequently leading to poor compliance and impaired quality of life (Mostrom, 2017). Unlike continuous monitoring, SMBG can provide only a 'snapshot' of a patient's glycaemic status at the time of sampling. As such, it may not identify glucose excursions and does not provide patients with enough actionable information to support self-management (Ajjan, 2019).

## **Outcomes**

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

RT-CGM provides insulin users with T2D with actionable information, allowing them to optimise their self-management of blood glucose. This change in patient management leads to a reduction in HbA1c, improved time in range (TIR), and reductions in hypoglycaemic and hyperglycaemic events.

Reduced HbA1c leads to decreased incidence and progression of microvascular (i.e., retinopathy, nephropathy, and neuropathy) and macrovascular (i.e., cardiovascular disease, peripheral vascular, and ischemic heart disease) complications.

The use of RT-CGM substantially improves patients QoL through the avoidance of finger prick testing (Matza, 2017).

## **Specified restrictions for funding**

**Please add one or more items, with specified restriction for funding, for each Population / Intervention:**

**Proposed item:** AAAAA

**Is the proposed item restricted:**

Yes - restricted

**Provide a short description of the restriction:**

Real time continuous glucose monitoring (rt-CGM) for type 2 diabetes mellitus (T2DM) intensive insulin users

**Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:**

The proposed population consists of intensive insulin using patients with T2DM with a suboptimal glycaemic profile defined by the following criteria:

- Aged  $\geq 2$  years
- Diagnosis of T2DM
- Treated with basal insulin and rapid acting insulin
- Sub-optimal glycaemic control confirmed by laboratory measured HbA1c levels of  $>7.0\%$  for adults and  $6.5\%$  for children and adolescents

**Proposed price of supply:**

\$REDACTED

**Indicate the overall cost per patient of providing the proposed health technology:**

\$REDACTED

**Provide details and explain:**

Each Dexcom ONE transmitter lasts for 3 months and each sensor can be worn up to 10 days. It is expected that patients would use a maximum of 4 transmitters and 36 sensors per year, with a total annual cost of \$REDACTED.

**How is the technology / service funded at present? (For example: research funding; State-based funding; self funded by patients; no funding or payment):**

No funding or payments

## 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 overall is claim is one of superior clinical efficacy versus SMBG based on any of the following outcomes:

- Reduction in HbA1c level
- Improved in time in range
- Reduced hyperglycaemic events
- Reduced hypoglycaemic events
- Improved quality of life

## Estimated utilisation

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

The NDSS reports 262,048 insulin users with T2D in June 2017, increasing to 304,527 in June 2023. Linear extrapolation of NDSS data between June 2017 and June 2023 (annual data) results in an estimated 331,044 insulin dependent patients in Year 1, increasing to 355,803 in Year 4. The Australian National Diabetes Audit (ANDA, 2022) reports the use of different insulin regimens among insulin users. These data suggest that 70.1% of patients qualify as intensive insulin users, and 27.2% are non-intensive insulin users. Premixed insulin regimens include a basal component co-formulated with a rapid acting component

and are therefore considered to be intensive insulin regimens. ANDA further estimates that 71% of T2D patients are uncontrolled. On this basis, it is estimated the eligible population will consist of 165,460 eligible T2D intensive insulin users in Year 1, increasing to 177,835 in Year 4.

**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):**

Lifetime

**What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):**

Sensors=36/year; transmitters=4/year

## **PICO set 2: T2D non-intensive insulin users**

### **Population**

**Describe the population in which the proposed health technology is intended to be used:** The population proposed in this PICO set consists of patients with T2D treated with a basal insulin regimen, and a suboptimal glycaemic profile defined by the following criteria:

- Aged  $\geq 2$  years
- Diagnosis of T2D
- Treated with a basal insulin regimen, with no regular use of rapid acting insulin
- Sub-optimal glycaemic control confirmed by laboratory measured HbA1c levels of  $>7.0\%$  for adults and  $>6.5\%$  for children and adolescents.

**Select the most applicable Medical condition terminology (SNOMED CT):**

Diabetes mellitus

### **Intervention**

**Name of the proposed health technology:**

Dexcom ONE 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:**

No subsidised CGM systems to manage T2D through NDSS are available in Australia. Therefore, the main comparator for the proposed health technology would be SMBG. The NDSS provides subsidised blood glucose monitoring strips for SMBG for a six-month period after an initial diagnosis of T2D. Ongoing access, in six-monthly increments, is available when assessed as clinically necessary and authorised by a general practitioner, credentialed diabetes educator, endocrinologist, nurse practitioner or other registered medical practitioner. In Australia, the frequency of SMBG testing is individualised; however, evidence suggests that an increased frequency of SMBG is correlated with improved HbA1c in both T1D and T2D (Karter, 2001). There is no clinical consensus around how often SMBG monitoring is needed for non-intensive insulin-treated people with T2D (ADA, 2023). However, Australian survey data suggest that on average, people with insulin-treated T2D test with SMBG three times a day (Holmes-Truscott, 2016).

Repeated SMBG can be time consuming, inconvenient, and painful, consequently leading to poor compliance and impaired quality of life (Mostrom, 2017). Unlike continuous monitoring, SMBG can provide only a 'snapshot' of a patient's glycaemic status at the time of sampling. As such, it may not identify glucose excursions and does not provide patients with enough actionable information to support self-management (Ajjan, 2019).

## Outcomes

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

RT-CGM provides insulin users with T2D with actionable information, allowing them to optimise their self-management of blood glucose. This change in patient management leads to a reduction in HbA1c, improved time in range (TIR), and reductions in hypoglycaemic and hyperglycaemic events.

Reduced HbA1c leads to decreased incidence and progression of microvascular (i.e., retinopathy, nephropathy, and neuropathy) and macrovascular (i.e., cardiovascular disease, peripheral vascular, and ischemic heart disease) complications.

The use of improved glucose monitoring substantially improves patients QoL through the avoidance of finger prick testing (Matza, 2017).



## Specified restrictions for funding

**Please add one or more items, with specified restriction for funding, for each Population / Intervention:**

**Proposed item:** AAAAA

**Is the proposed item restricted:**

Yes - restricted

**Provide a short description of the restriction:**

Real time continuous glucose monitoring (RT-CGM) for type 2 diabetes (T2D) non-intensive insulin users

**Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:**

The proposed population consists of patients with T2D treated with a basal insulin regimen, and a suboptimal glycaemic profile defined by the following criteria:

- Aged  $\geq 2$  years
- Diagnosis of T2D
- Treated with a basal insulin regimen, with no regular use of rapid acting insulin
- Sub-optimal glycaemic control confirmed by laboratory measured HbA1c levels of  $>7.0\%$  for adults and  $6.5\%$  for children and adolescents

**Proposed price of supply:**

\$REDACTED

**Indicate the overall cost per patient of providing the proposed health technology:**

\$REDACTED

**Provide details and explain:**

Each Dexcom ONE transmitter lasts for 3 months and each sensor can be worn up to 10 days. It is expected that patients would use a maximum of 4 transmitters and 36 sensors per year, with a total annual cost of \$REDACTED.

**How is the technology / service funded at present? (For example: research funding; State-based funding; self funded by patients; no funding or payment):**

No funding or payments

## 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 overall is claim is one of superior clinical efficacy versus SMBG based on any of the following outcomes:

- Reduction in HbA1c level
- Improved in time in range
- Reduced hyperglycaemic events
- Reduced hypoglycaemic events

- Improved quality of life

## Estimated utilisation

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

The NDSS reports 262,048 insulin users with T2D in June 2017, increasing to 304,527 in June 2023. Linear extrapolation of NDSS data between June 2017 and June 2023 (annual data) results in an estimated 331,044 insulin dependent patients in Year 1, increasing to 355,803 in Year 4. The Australian National Diabetes Audit (ANDA, 2022) reports the use of different insulin regimens among insulin users. These data suggest that 70.1% of patients qualify as intensive insulin users, and 27.2% are non-intensive insulin users. Premixed insulin regimens include a long or intermediate acting component co-formulated with a rapid acting component and are therefore considered to be intensive insulin regimens. ANDA further estimates that 71% of T2D patients are uncontrolled. On this basis, it is estimated the eligible population will consist of 64,201 eligible T2D non-intensive insulin users in Year 1, increasing to 69,003 in Year 4.

### 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):

Lifetime

### What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Sensors=36/year; transmitters=4/year

## Consultation

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

- AUSTRALASIAN DIABETES IN PREGNANCY SOCIETY LIMITED

- AUSTRALIA AND NEW ZEALAND SOCIETY FOR PAEDIATRIC ENDOCRINOLOGY AND DIABETES
- AUSTRALIAN DIABETES EDUCATORS' ASSOCIATION LIMITED
- AUSTRALIAN DIABETES SOCIETY LIMITED
- AUSTRALIAN PAEDIATRIC SOCIETY LTD
- AUSTRALIAN PRIMARY HEALTH CARE NURSES ASSOCIATION LTD
- PRIMARY CARE DIABETES SOCIETY OF AUSTRALIA LIMITED
- THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS LIMITED

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

- AUSTRALASIAN DIABETES IN PREGNANCY SOCIETY LIMITED
- AUSTRALIA AND NEW ZEALAND SOCIETY FOR PAEDIATRIC ENDOCRINOLOGY AND DIABETES
- AUSTRALIAN DIABETES EDUCATORS' ASSOCIATION LIMITED
- AUSTRALIAN DIABETES SOCIETY LIMITED
- AUSTRALIAN PAEDIATRIC SOCIETY LTD
- AUSTRALIAN PRIMARY HEALTH CARE NURSES ASSOCIATION LTD
- PRIMARY CARE DIABETES SOCIETY OF AUSTRALIA LIMITED
- THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS LIMITED

**List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:**

- AUSTRALASIAN DIABETES IN PREGNANCY SOCIETY LIMITED
- AUSTRALIA AND NEW ZEALAND SOCIETY FOR PAEDIATRIC ENDOCRINOLOGY AND DIABETES
- AUSTRALIAN DIABETES EDUCATORS' ASSOCIATION LIMITED
- AUSTRALIAN DIABETES SOCIETY LIMITED
- AUSTRALIAN PAEDIATRIC SOCIETY LTD
- AUSTRALIAN PRIMARY HEALTH CARE NURSES ASSOCIATION LTD
- THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS LIMITED

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

- DANII MEADS-BARLOW FOUNDATION LTD
- DIABETES AUSTRALIA
- JDRF AUSTRALIA
- NATIONAL DIABETES SERVICES SCHEME

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

- ABBOTT AUSTRALASIA PTY LTD
- MEDTRONIC AUSTRALASIA PTY LTD

## **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)?**

No

**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?**

No

**Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?**

No

**Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?**

No

**Is the therapeutic good in the process of being considered by the TGA?**

Yes

**Please provide the TGA Application ID:**

DV-2023-CA-02238-1

**Please provide the TGA submission date (DD/MM/YYYY):**

17/02/2023