MSAC Application 1785

Dexcom ONE Continuous Glucose Monitoring System

PICO Set 1: Intensive Insulin Users with Type 2 Diabetes

Population

Describe the population in which the proposed health technology is intended to be used:
Type 2 diabetes (T2D) is a result of both impaired insulin production and the body's resistance to its action. Patients with T2D thus experience a relative deficiency of insulin, which leads to chronic hyperglycaemia. The long-term complications of T2D are potentially life-threatening, and include heart disease; stroke; eye disease, including retinopathy; kidney disease; peripheral vascular disease; nerve damage; foot problems; gum disease; and mental health impacts including treatment-related distress, anxiety, and depression (Diabetes Inquiry, paragraph, 4.40).

Generally, T2D is more prevalent among adults aged 45 and older, although there is an increasing number of diagnoses among younger individuals. In Australia, T2D constitutes approximately 80-90% of all diabetes cases and its prevalence is rising annually (Diabetes Australia). Aboriginal and Torres Strait Islander Australians experience significantly higher rates of diabetes, particularly T2D, compared to the general population (Diabetes Australia). Notably, diabetes onset in these communities occurs at younger ages and often results in more severe outcomes, including premature mortality. A family history of T2D substantially elevates the risk of developing T2D. Lifestyle factors such as poor diet, physical inactivity, smoking, and excessive alcohol consumption are major contributors to its prevalence.

Lifestyle changes, such as a healthier diet and increased physical activity, may slow the progression of T2D for some people; however, many will ultimately require regular insulin injections to manage their disease. This population of intensive insulin users is the subject of a separate set of PICO criteria. The population is defined by the need to have multiple daily injections (MDIs) of insulin. 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 ≥2 years
- Diagnosis of T2D
- Treated with basal insulin and rapid acting insulin
- Sub-optimal glycaemic control confirmed by laboratory measured HbA_{1c} levels of >7.0% for adults and >6.5% for children and adolescents.

Together, the two PICO populations proposed in this MSAC Application (intensive insulin users and non-intensive insulin users) account for the majority of insulin dependent patients with T2D.

Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the technology:
Early detection of T2D can reduce a person's risk of developing complications and improve long-term outcomes. The primary screening measure for T2D in the primary care setting is the Australian Diabetes Risk Assessment (AUSDRISK) tool. AUSDRISK assists people to assess their risk of developing T2D within the next five years. At risk populations should also undergo regular fasting blood glucose and HbA1c tests, followed by a glucose tolerance test when necessary (RACGP, 2020).

The diabetes referral pathway for individuals with T2D usually involves ongoing medical reviews/check-ups by a General Practitioner (GP) every 3 months with referrals made to a credentialled diabetes educator (CDE) who work closely with diabetes patients to educate and set goals (when needed) (ADEA, 2021).

Similar to the management of type 1 diabetes (T1D), it is expected that patients with T2D accessing the proposed health technology will be required to be registered on the National Diabetes Services Scheme (NDSS) and see an authorised health professional to determine whether they meet the eligibility criteria. Authorised health professionals may include endocrinologists, CDEs and other health professionals specialising in diabetes (physicians, paediatricians or nurse practitioners). While GPs are currently not considered authorised health professionals by the NDSS, widening access through the inclusion of GPs who currently prescribe and/or titrate insulin may reduce the treatment burden on secondary care. People with T2D already place a considerable burden on secondary care, with one in three people with T2D having a microvascular complication at diagnosis (Karter 2021).

Provide a rationale for the specifics of the eligible population:
Most people with T2D in Australia self-manage their blood glucose levels, with ~70% failing to meet their HbA1c goals (ANDA, 2022). This reflects current advice from clinical experts suggesting there is an urgent need for technologies to enable patients to more effectively meet their HbA1c targets via optimised self-management. Supporting people to effectively self-manage their diabetes leads to improved glucose control, reduction in chronic complications as well as improvements in health-related quality of life (HRQoL). This clinical need is particularly urgent in patients who require regular insulin injections to manage their diabetes.

The ADA clinical practice guideline on Diabetes Technology states that many individuals with diabetes on intensive insulin therapy require testing with SMBG 6 to 10 times a day, although individual needs may vary (ADA, 2023). These patients are at higher risk of glucose excursions leading to severe hypoglycaemic and hyperglycaemic events (Baretić 2020) as well as long term diabetic complications due to poor blood glucose control. In recognition of this clinical need, the recent Parliamentary Inquiry into "The State of Diabetes Mellitus in Australia in 2024" (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).

Although 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) of insulin, including rapid-acting (prandial) insulin, while non-intensive insulin users are treated with basal insulin and generally do not require use of rapid-acting insulin. Both populations currently experience suboptimal long-term clinical outcomes due to poor glycaemic control; however, they are distinct in terms of their clinical characteristics. Additionally, the effectiveness of CGM in the two populations is supported by studies in a range of insulin-dependent populations; however, the studies are broadly categorised based on the intensity of their insulin regimens. Therefore, it is appropriate for the cost-effectiveness of RT-CGM relative to SMBG to be modelled separately.

The eligible population (as defined above) is primarily based on key eligibility criteria from the DIAMOND trial (Beck, 2017) conducted in intensive T2D insulin users. In this study, intensive insulin use is defined as MDIs, defined as basal insulin in combination with rapid acting insulin. However, in line with the targets recommended in current Australian clinical practice guidelines, the definition of "suboptimal" HbA1c levels is ≥7.0% for adults (Colaguiri, 2009) and ≥6.5% for children and adolescents (Kao, 2016). These targets are supported by strong evidence. For example, the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that achieving an HbA1c of 7% with intensive therapy using insulin or sulfonylurea (in comparison to 7.9% in the conventional arm) led to a 25% risk reduction in microvascular outcomes (UKPDS, 1998).

Finally, although T2D in children and adolescents is rare, the rate of incidence is increasing in tandem with childhood obesity (Peña, 2020). Adolescents with T2D experience complications more frequently increased mortality rates compared with T1D (Dabelea, 2017; Al-Saeed, 2016). T2D is a particular problem in Indigenous children, with Western Australian data between 1990-2012 suggesting an incidence of 31.1 per 100,000 compared to 1.4 per 100,000 in non-indigenous children (Haynes, 2016). Given the urgent need for interventions to improve outcomes in these groups, the proposed population includes people with T2D aged ≥2 years.

Intervention

Name of the proposed health technology:
Dexcom ONE Continuous Glucose Monitoring System (Dexcom ONE)

Describe the key components and clinical steps involved in delivering the proposed health technology:
The Dexcom ONE consists of three major components:

- Dexcom ONE sensor (including wire)
- Dexcom ONE Bluetooth Low Energy (BLE) transmitter
- BLE enabled display device (mobile phone application and/or optional receiver)

Figure 1 Contents of the Dexcom One pack

The Dexcom ONE continuous glucose monitoring system is intended to continuously measure and report on glucose concentrations in the interstitial fluid. The sensor and transmitter are the

hardware components of the system. The Dexcom One mobile app can be downloaded to a compatible smart device to display glucose levels or alternatively, the receiver may be used.

The sensor is a single use device that includes the sensor wire, sensor housing and applicator. The sensor must be replaced after ten days of use (Figure 2). The sensor wire is the part of the sensor that is inserted under the skin (subcutaneously) to measure the glucose content of interstitial fluid. The transmitter is a reusable device that attaches to the top of the sensor housing and transmits glucose information from the sensor lead to the receiver or compatible smart device (Figure 3). The transmitter must be replaced after three months of use. The receiver is a reusable device that receives, stores, processes and displays the glucose information transmitted by the paired transmitter. The software components of the system can reside on a compatible iOS or Android device (which acts as the system display device). A list of compatible devices can be found here: dexcom.com/compatibility.

Figure 2 Built in sensor applicator

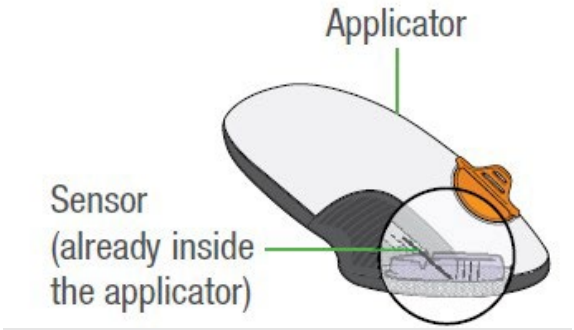
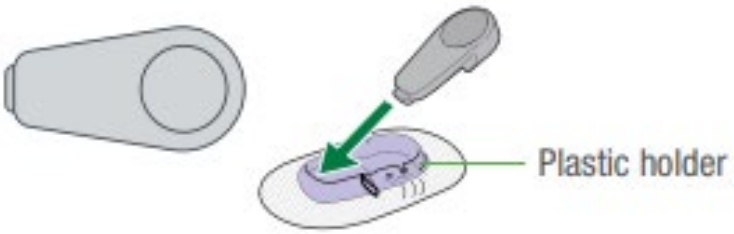


Figure 3 Reusable transmitter



Glucose readings are automatically transmitted from the transmitter to the receiver or compatible smart device every 5 minutes and can be checked by the person wearing the sensor and transmitter during the day without the need for SMBG (Figure 4). If readings do not match symptoms, the user is instructed to perform SMBG or seek medical advice.

Figure 4 Screenshot of the display device

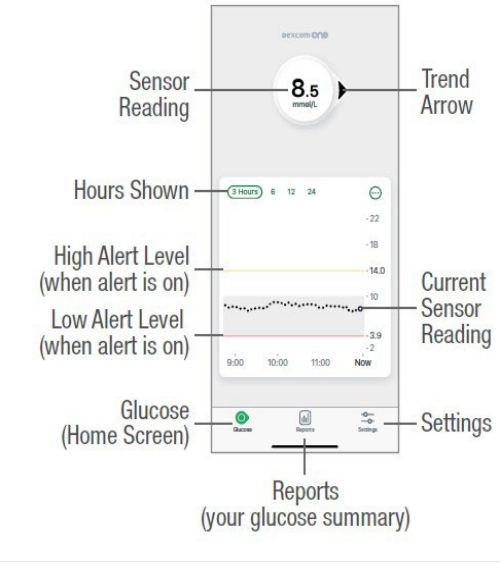


Table 1 Summary of Dexcom ONE product attributes and performance[a]

Feature	Dexcom One
Fingerprick SMBG test required	Not required for insulin dosing Required if glucose alerts and readings do not match symptoms or expectations, or if no trend arrow is displayed
Duration of sensor / transmitter life	10 days / 3 months
Data update cycle	Every 5 min automatically
Access to glucose values	Via smart device or optional receiver. No scanning required.
High/low glucose alerts	Yes
Predictive alert	No
Share and follow function	No
Connection with CSII pumps	No
Indications	≥2 years, T1D and T2D

a Note that TGA approval for Dexcom One is pending.

Note that other real-time continuous glucose monitoring (rtCGM) devices with advanced feature sets are currently available in Australia for the management of T1D providing additional functionality such as a predictive low glucose alert (urgent low soon alert) that lets the user know when their glucose is falling so fast it will drop to ≤ 3.1 mmol/L in less than 20 minutes, a 'share and follow function' and connectivity to pumps.

Identify how the proposed technology achieves the intended patient outcomes:

The goal of CGM therapy is to improve the management of diabetes by increasing the time in range (TIR) (70-180 mg/dL) whilst also reducing time below range to ultimately minimise the risk of developing T2D-related complications (Dovc, 2021). Continuous measurement of glucose levels allows patients to better manage their condition through diet, exercise, and insulin injections. It can also help avoid adverse events (AEs) such as severe hypoglycaemia and hyperosmolar hyperglycaemic state (HHS) occurring within the community setting, requiring emergency care (MacLeod, 1993). In the long term, maintaining optimal control of blood glucose can minimise the risk of microvascular diseases such as retinopathy and neuropathy, macrovascular complications

such as stroke and cardiovascular disease (CVD), as well as the risk of death. Furthermore, users will also experience quality of life (QoL) benefits from the avoidance of the burden of daily finger stick testing (Matza, 2017).

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?
Yes

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:
As is the case for products currently available for T1D through the NDSS, it is important for T2D patients and their clinicians to be able to differentiate and choose between different CGM systems to best suit the patient's needs and abilities. Different CGM systems report varying outcomes from clinical trials and have different functional features that may influence patient suitability and choice.

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):
Yes/No

Provide details and explain:
Based on the duration of sensor and transmitter life, it is expected that a patient would require a maximum of 4 transmitters and 36 sensors per year (refer to Product Manual attached).

If applicable, advise which health professionals will be needed to provide the proposed health technology:

- Endocrinologists
- CDEs
- Other health professionals specialising in diabetes (physicians, paediatricians or nurse practitioners)
- Optimally inclusive of GPs with a special interest in diabetes who currently prescribe and/or titrate insulin

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:
N/A

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:
N/A

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?
Yes

Provide details and explain:
As noted previously, eligibility for RT-CGM through the NDSS should be determined by an authorised health professional. To deliver the proposed service, specific requirements determined by the NDSS must be met by authorised health professionals.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:

- ☒ Consulting rooms
- ☐ Day surgery centre
- ☐ Emergency Department
- ☐ Inpatient private hospital
- ☐ Inpatient public hospital
- ☐ Laboratory
- ☒ Outpatient clinic
- ☒ Patient's home
- ☐ Point of care testing
- ☒ Residential aged care facility
- ☐ Other (please specify)

Is the proposed health technology intended to be entirely rendered inside Australia?
Yes

Provide additional details on the proposed health technology to be rendered outside of Australia:
N/A

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 includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Provide a name for your comparator:
Standard blood glucose monitoring (SMBG).

Provide an identifying number for your comparator (if applicable):
N/A

Provide a rationale for why this is a comparator:
In Australia, individuals with T2D can currently purchase subsidised blood glucose monitoring strips (i.e., SMBG) through the NDSS. 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 the following categories: intercurrent illness, medications affecting blood glucose, critical need for self-monitoring, diabetes management change, diabetes management not stable (see https://www.ndss.com.au/products/blood-glucose-testing-strips/).

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). In comparison, RT-CGM especially in patients requiring MDIs of insulin, helps patients understand the link between blood glucose, food, exercise, and insulin. It also, informs them of when to take action, to potentially prevent dangerous glycaemic excursions as such averting a costly hospital admission (Oglesby, 2006; Menzin, 2001; Zelada, 2023). Over time these readings provide actionable information enabling an optimised diabetes glucose management strategy whilst also maintaining time in target range and leading to a reduction in HbA_1c.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

☐ None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☐ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☒ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:

It is expected that most patients using the proposed health technology (RT-CGM) would do so for most of the time as they no longer have a need for routine SMBG, which is associated with inferior clinical outcomes and poorer QoL (Matza, 2017; Beck, 2017). This is supported by findings from the DIAMOND trial, where adherence to the proposed technology was high with a mean use of 6.7 days per week over 24 weeks, indicating most people who receive RT-CGM would use it >95% of the time.

Outcomes

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

As noted previously, RT-CGM provides people with T2D with actionable information enabling an optimised diabetes glucose management strategy leading to a reduction in HbA1c, improved time in range (TIR), a reduction in hypoglycaemic and hyperglycaemic events and an increase in quality of life.

HbA1c

☒ Health benefits
☐ Health harms
☐ Resources

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

HbA1c is the most widely accepted measure of overall, long-term blood glucose control in patients with diabetes. It reflects the mean glucose concentration over the past 2-3 months. Reduced HbA_{1c} leads to decreased incidence and progression of microvascular (i.e., retinopathy, nephropathy, and neuropathy) and macrovascular (i.e., cardiovascular disease [CVD], peripheral vascular, and ischemic heart disease) complications. This also results in a reduction in long-term diseases associated with these complications, such as diabetic neuropathy which is responsible for a large proportion of non-traumatic lower-extremity amputations as well renal disease, heart disease, stroke, erectile dysfunction, and hyperosmolar hyperglycaemic states (HSS).

Time in range of 3.89 to 9.99 mmol/L

☒ Health benefits
☐ Health harms
☐ Resources
☐ Value of knowing

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

The therapeutic advantages of improvement in the target range (3.89 to 9.99 mmol/L) in the short term translate to reduced rates of both hypoglycaemia and hyperglycaemia and as such are health benefits (as described below). In the DIAMOND (2017) trial, time in range was defined as 70-180mg/dL (3.89-9.99 mmol/L).

Hypoglycaemic events

☒ Health benefits
☐ Health harms
☐ Resources
☐ Value of knowing

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

Hypoglycaemic events are generally defined as follows: level 1, glucose ≤2.5%; level 2, glucose <2.4%; and level 3, severe events requiring third-party intervention independent of a defined glucose value (Seaquist, 2013). In the DIAMOND trial, RT-CGM outcomes included time spent in hypoglycaemia (<70 mg/dL, <60, and <50 mg/dL). Severe hypoglycaemia was also defined as an event that required assistance from another person to administer carbohydrate, glucagon, or other resuscitative actions). It can be inferred from the definitions above that these concentrations were used to define hypoglycaemia and severe hypoglycaemia, respectively, with the latter outcomes included as reported adverse events (AEs) within the trial.

The burden of hypoglycaemia among patients with T2D is significant and is associated with mortality and morbidity. Profound and prolonged hypoglycaemia may cause transient or persistent neurological deficits (Jeon 2016). It also contributes to absenteeism from work or schools and loss of productivity (Lambert-Obry 2022).

Hyperglycaemic events

☒ Health benefits

☐ Health harms
☐ Resources
☐ Value of knowing

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

Severe hyperglycaemia results from high blood sugar levels over a long period of time and can lead to serious complications including HHS. HHS usually affects older people. Coma may develop in some patients and neurological impairment is common.

In the DIAMOND trial, RT-CGM outcomes included the length of time per day the glucose concentration was hyperglycaemic (>180, >250 and >300 mg/dL). It can be inferred from the definitions above that these concentrations were used to define hyperglycaemia, severe hyperglycaemia and diabetic ketoacidosis included as reported adverse events (AEs) within the trial.

Quality of life

☒ Health benefits
☐ Health harms
☐ Resources
☐ Value of knowing

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

Patients using RT-CGM may experience QoL benefits from the avoidance of daily finger stick testing (Matza, 2017). In addition, the availability of RT-CGM will have indirect benefits in the form of improved QoL for carers and parents of children with T2D. Those living with the condition continue to report not only suboptimal health metrics, but also high burden related to care practices (Niccolucci, 2013; DAWN 2 study).

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
☐ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:
The overall claim is one of superior clinical efficacy versus SMBG based on any of the following outcomes:

- Reduction in HbA_{1c} level
- Improved time in range
- Reduced hyperglycaemic events
- Reduced hypoglycaemic events
- Improved QoL

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?
The evidence base used to support the proposed technology demonstrates that the use of RT-CGM results in a reduction in HbA_{1c} and improved time in range leading to improved glycaemic control which translates to reductions in the incidence of short-term and long-term complications of T2D, reduced healthcare resources and improvements in QoL.

Identify how the proposed technology achieves the intended patient outcomes:
As above.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management? Yes

A change in health outcome? Yes

Other benefits? Yes

Provide a rationale, and information on other benefits if relevant:
SMBG finger pricks impose a substantial burden on patients in terms of QoL. The use of improved glucose monitoring substantially improves patients QoL through the avoidance of finger prick testing (Matza, 2017).

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?
☒ More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:
Although the acquisition costs of the Dexcom ONE RT-CGM system are higher than SMBG, it is expected to result in some cost savings by removing the need for routine SMBG and reducing healthcare resource utilisation associated with short- and long-term diabetic complications. Microvascular and macrovascular outcomes projections indicate that RT-CGM use for diabetes management in people with T2D on intensive insulin therapy results in significant cost savings due to the reductions in diabetic complications (Alshannaq, 2024).

The RT-CGM system's ability to prevent severe hypoglycaemic events and DKAs has been shown to decrease emergency room visits and inpatient hospitalizations, as noted in Karter et al. 2021 study. The use of RT-CGM by patients with T2D resulted in a significant reduction in diabetes-related medical costs that amounted to USD 424 per member per month mainly due to a reduction in in-patient hospitalizations (Norman, 2022). Additionally, a reduction in HbA1c which is expected with CGM use has been linked to lower healthcare and diabetes-related costs (Bansal, 2018; Lage & Boye, 2020; Fitch, 2013).

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:
Management/monitoring

The National Evidence Based Guideline for Blood Glucose Control in T2D (Colagiuri, 2009) is the only published evidence-based guideline for the management of T2D in Australia and is now relatively out of date. With respect to the question *"how should blood glucose control be assessed?"* the National Evidence Based Guideline recommends:

"Self-monitoring of blood glucose (SMBG) should be considered in all people with type 2 diabetes but the decision to perform SMBG, and the frequency and timing of testing, should be individualised. (Grade C)"

More recently published and relevant evidence-based recommendations from the American Diabetes Association (ADA) on diabetes technology recommend use of RT-CGM in people with diabetes on multiple daily injections of insulin (ADA, 2023).

The Living Evidence for Diabetes Consortium has developed evidence-based guidelines containing selected recommendations regarding medications for blood glucose management in adults with diabetes; however, the guideline did not address the question of whether CGM should be used to manage T2D.

The RACGP Guidelines on the management of T2D state *"There is an emerging role for continuous glucose monitoring and flash glucose monitoring in patients with T2D on complex insulin regimens who have not achieved their glycaemic targets; however, this technology is not available through the NDSS for people with type 2 diabetes"* (RACGP, 2020). Advice from local clinical experts suggests there is an urgent need for interventions to improve the management of T2D in Australia. Although T1D has an earlier onset, patients with T2D often have worse HbA1c levels as they are often less well-informed and/or med. Therefore, there is a strong clinical rationale for the use of RT-CGM in T2D patients. Although the clinical need is likely to be higher for intensive users of insulin than for non-intensive insulin users, non-intensive insulin users would be expected to benefit substantially from improved glucose monitoring and the avoidance of finger prick testing. In recognition of this clinical need, the recent Parliamentary Inquiry into "The State of Diabetes Mellitus in Australia in 2024" (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).*

Treatment

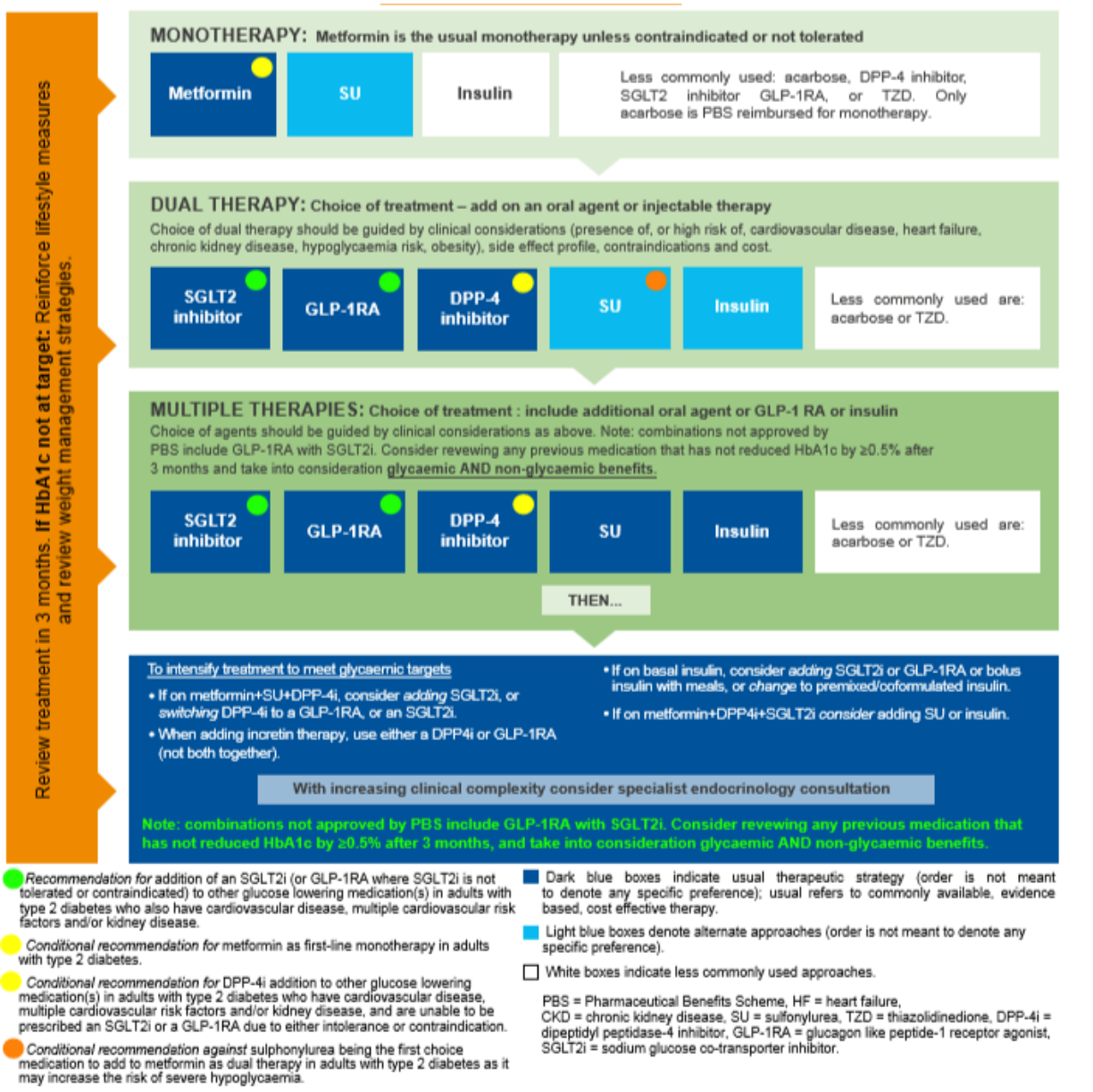
Recommendations for treatment in the management of T2D intensive insulin users is derived from the Australian Diabetes Society (ADS) published in 2020 (ADS, 2020).

The management algorithm for T2D is presented in Figure 5. There are currently several classes of medications that are prescribed for the management of T2D including metformin, sulfonylurea

(SU), basal insulin, sodium-glucose co-transporter 2 (SGLT2) inhibitors, Glucagon-like peptide-1 receptor agonists (GLP-1RA), and dipeptidyl peptidase-4 (DPP-4) inhibitors. These classes work via different mechanisms to lower blood glucose levels and improve overall glycaemic management. People with T2D may receive these medications in combination with basal insulin if required.

The recommended treatments as specified above are then intensified following no response after 3 months to meet glycaemic targets. If on basal insulin, patients may progress to rapid acting insulin with meals. These patients, termed intensive insulin users are thus considered eligible for the intended intervention per the criteria noted above.

Figure 5 Algorithm for the treatment of T2D



Is there any expectation that the clinical management algorithm *before* the health technology is used will change due to the introduction of the proposed health technology?
No

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:
N/A

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:
The proposed health technology will be used in conjunction with oral and injectable medications and/or basal with rapid acting insulin to treat diabetes.

Explain what other healthcare resources are used in conjunction with the comparator health technology:
The comparator health technology is used in conjunction with oral and injectable medications and/or basal with rapid acting insulin to treat diabetes.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:
The introduction of the new health technology will displace the current use/need for routine SMBG/finger prick testing. For some patients, there may be changes in the use of oral medications and/or insulin associated with improved blood sugar control. As noted above, international guidelines suggest SMBG is needed 6-10 times per day for those using intensive insulin regimens (ADA, 2023).

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:
After using RT-CGM patients would continue to be assessed by a GP or diabetes educator every 3 months to monitor HbA1c levels and optimise therapies.

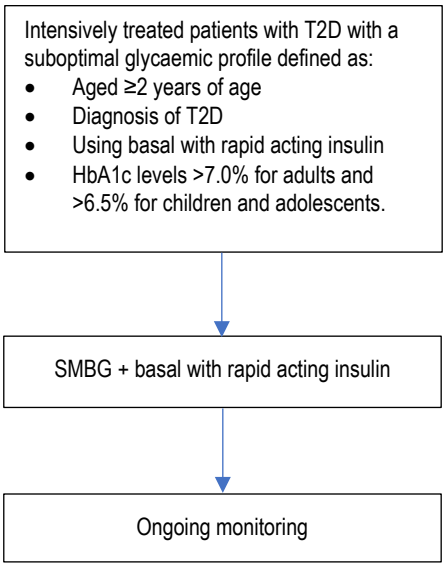
Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the comparator health technology:

Currently, patients receiving SMBG should be assessed by a GP or diabetes educator every 3 months to monitor HbA1c levels and optimise therapies.

Describe and explain any differences in the healthcare resources used *after* the proposed health technology vs. the comparator health technology:
After the use of RT-CGM, patients will be managed in essentially the same way; however, it is expected that there would be decreased consumption of resources due to the avoidance of short-term (i.e., hypo and hyperglycaemia) and long-term (e.g., CVD) complications of T2D.

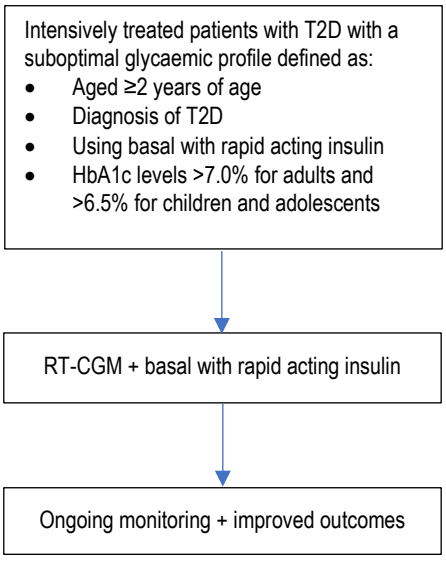
Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:

Figure 6 Clinical management algorithm for uncontrolled T2D intensive insulin users without proposed health technology



Abbreviations: SMBG=standard monitoring of blood glucose; T2D=type 2 diabetes.

Figure 7 Clinical management algorithm for uncontrolled T2D intensive insulin users with proposed health technology



Abbreviations: T2D=type 2 diabetes; RT-CGM=real-time continuous glucose monitoring.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

Trial ID	Type of study design	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
Randomised trials					
DIAMOND Beck (2017)	Multicentre, parallel group, open-label, randomised trial conducted at 15 endocrinology practices in the US.	Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections.	The study objective was to determine the effectiveness of CGM in adults with T2D receiving MDIs of insulin. A total of 158 eligible patients were randomised to either CGM (N=79) or usual care (N=79). The primary outcome was HbA1c reduction at week 24 (6 months).	Link	2017
DIAMOND Billings (2018)			Subgroup analysis of DIAMOND which investigated whether study participants at progressively higher baseline HbA1c levels benefit from using rtCGM.	Link	2018

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2GO-CGM Lever (2024) (Note: 56% of study population were on rapid acting insulin)	Multicentre, 12-week randomised trial conducted at specialist Diabetes services in Waikato, Canterbury and the southern regions of New Zealand.	Real time continuous glucose monitoring in high-risk people with insulin-requiring type 2 diabetes: A Randomised controlled trial.	The study objective was to investigate the impact of real-time continuous glucose monitoring (rtCGM) on glycaemia in a predominantly Indigenous (Māori) population of adults with insulin-requiring type 2 diabetes (T2D) in New Zealand. A total of 67 eligible patients were randomised to either CGM (N=33) or SMBG (N=34). The primary outcome was TIR (3.9–10.0 mmol/L) between the intervention and control group during weeks 10 to 12.	Link	2024
Single-arm trials					
Chao (2023) ANSHIN	Prospective, interventional study with a single-arm primary phase and a randomised secondary phase.	Assessing non-adjunctive CGM safety at home and in new markets (ANSHIN).	The study enrolled 77 adults with T1D or T2D. Participants wore blinded CGMs during a run-in phase with SMBG followed by a 16-week intervention phase and then a randomized 12-week extension phase with treatment based on CGM values. The primary outcome was change in HbA1c.	Link	2023

Trial ID	Type of study design	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
Observational trials					
Karter (2021)	Retrospective, observational cohort study using the data from the Northern California integrated health care delivery System.	Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes.	The study objective was to estimate clinical outcomes of real-time CGM initiation. A total of 41,753 eligible patients were included as either real-time initiators (N=3,806) or real-time CGM non-initiators (N=37,947). The outcomes included HbA1c and ED visits at 12 months before and 12 months after baseline.	Link	2021