MSAC Application 1785

Dexcom ONE+ continuous glucose monitoring system for people with insulin dependent type 2 diabetes

Applicant: Australasian Medical & Scientific Limited

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1   PICO for Dexcom ONE+ continuous glucose monitoring system in people with type 2 diabetes and suboptimal glycaemic control who require insulin: PICO Set 1

Component	Description
Populations	People aged ≥2 years with type 2 diabetes (T2D) who have suboptimal glycaemic control confirmed by laboratory measured glycated haemoglobin (HbA1c) levels of >7.0% for adults and >6.5% for children and adolescents: Subpopulation 1: Require treatment with basal insulin and rapid acting insulin Subpopulation 2: Require treatment with basal insulin only

Prior tests	Diagnostic tests for T2D if
	    a) asymptomatic and at high risk (Australian type 2 diabetes risk assessment tool [AUSDRISK] score ≥12 or in specific high-risk categories):
	  • HbA1c ≥6.5% (48 mmol/mol) on two separate occasions, or
	  • fasting blood glucose (FBG) ≥7.0 mmol/L, or
	  • random blood glucose ≥11.1 mmol/L confirmed by a second abnormal FBG on a separate day, or
	  • oral glucose tolerance testing (OGTT) consisting of blood glucose measurement taken before (fasting) and two hours after an oral 75 g glucose load is taken. Diabetes is diagnosed if FBG ≥7.0 mmol/L or two-hour post-challenge blood glucose ≥11.1 mmol/L, or
	    b) if symptoms of hyperglycaemia present and
	  • a patient presenting with hyperglycaemic crisis, or
	  • a single elevated FBG ≥7.0 mmol/L, or
	  • single HbA1c ≥6.5% (48 mmol/mol), or
	  • a random blood glucose ≥11.1 mmol/L.

Intervention	Dexcom ONE+ Continuous Glucose Monitoring (CGM) System
Comparator/s	Self-monitoring of blood glucose (SMBG) using a finger prick blood sample.
Reference standard	Laboratory conducted plasma venous blood glucose test

Outcomes	**<u>Patient relevant outcomes</u>**
	Direct evidence for safety and effectiveness:
	Safety:
	  • Local adverse events (AEs) associated with glucose testing
	Effectiveness:
	  • T2D complications (e.g. cardiovascular and microvascular complications including kidney disease, neuropathy/nerve damage, retinopathy/eye disease, amputations/foot ulcers)
	  • Mortality
	  • Quality of life

Component	Description

	• Psychological health
	• Hypoglycaemic or hyperglycaemic events resulting in emergency room visit/hospitalisation
	Intermediate/surrogate outcomes:
	• Glycaemic control
	    ○ glycated haemoglobin (HbA1c)
	    ○ time in range (TIR), time below range (TBR) and time above range (TAR)
	    ○ number of hypoglycaemic/hyperglycaemic excursions
	    ○ glycaemic variability
	• Change in body weight/ body mass index (BMI)
	Additional outcomes using linked evidence approach:
	Analytical validity:
	• Accuracy, concordance
	• Monitoring (CGM or SMBG) failure rate
	Change in management:
	• Adherence to CGM or SMBG
	• Adherence to treatments
	• Uptake or alteration of lifestyle interventions (e.g. diet and exercise) and treatment (e.g. glucose-lowering therapy)
	<u>Other relevant considerations</u>
	• Acceptability, wearability and usability of CGM versus SMBG
	• Ability to share blood glucose data with physician, relative or carer
	• Patient/carer satisfaction
	• Self-efficacy (person's belief in their ability to effectively manage their T2D and achieve their clinical goals)
	• Work/school absenteeism and daily functioning
	<u>Healthcare system outcomes</u>
	• Cost, cost-effectiveness
	• Financial implications (financial impact, overall healthcare costs, etc.)

Assessment questions	What is the safety, effectiveness and cost-effectiveness of the Dexcom ONE+ CGM system versus SMBG in people aged ≥2 years with type 2 diabetes and suboptimal glycaemic control who require insulin therapy?

Purpose of application

An application requesting National Diabetes Services Scheme (NDSS) funding of the Dexcom ONE+ continuous glucose monitoring (CGM) system for monitoring of glucose levels in people aged ≥2 years with type 2 diabetes (T2D) and suboptimal glycaemic control requiring treatment with insulin was received from Australasian Medical & Scientific Limited by the Department of Health and Aged Care.

The clinical claim is that the use of the Dexcom ONE+ CGM system results in superior health outcomes and non-inferior safety compared to self-monitoring of blood glucose (SMBG). These health outcomes are as follows:

- Reduction in glycated haemoglobin (HbA1c) level
- Improved time in the normal glycaemic range[1]
- Reduced hyperglycaemic events
- Reduced hypoglycaemic events
- Improved quality of life (QoL)

PICO criteria

Population

The population is people aged ≥2 years with T2D and suboptimal glycaemic control (defined as confirmed laboratory measured HbA1c levels of >7.0% for adults and >6.5% for children and adolescents) who require insulin therapy. Two subpopulations are proposed in the MSAC application that are differentiated by the intensity of their insulin regimen, as follows:

Subpopulation 1: Require treatment with basal insulin and rapid acting insulin ("intensive insulin users"); this subpopulation also includes individuals receiving co-formulated or pre-mixed insulin.

Subpopulation 2: Require treatment with basal insulin only ("non-intensive insulin users")

Together, the two PICO subpopulations proposed in this MSAC application (intensive insulin users and non-intensive insulin users) account for all insulin-dependent people with T2D. The proposed population for NDSS funding of Dexcom ONE+ in the MSAC application is narrower than the proposed Therapeutic Goods Administration (TGA) indication. The Dexcom ONE+ CGM system is currently under evaluation by the TGA. The TGA-proposed indication is persons with diabetes mellitus age 2 years and older (i.e. without requirement for suboptimal glycaemic control). Dexcom ONE+ is designed to replace finger prick self-monitoring of blood glucose (SMBG) for diabetes mellitus treatment decisions.

PASC noted that the proposed population for use of Dexcom ONE+ CGM was people aged 2 years or older with T2D who have suboptimal glycaemic control who require insulin therapy where suboptimal glycaemic control was defined as HbA1c >7.0% for adults and >6.5% for children and adolescents. PASC also noted that the MSAC application included two subpopulations that are differentiated by the intensity of their insulin treatment regimen. Subpopulation 1 also referred to as "intensive insulin users" in the application

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1 Improved time in range refers to the time per day [% of CGM readings or minutes/hours] within the target glycaemic range of 70–180 mg/dL [3.9–10.0 mmol/L] for T2D as defined by the international consensus report for time in range for CGM (Battelino et al. 2019).

required treatment with basal insulin and rapid acting insulin; this subpopulation also included those individuals receiving co-formulated or pre-mixed insulin treatment. Subpopulation 2 or "non-intensive insulin users" required treatment with basal insulin only.

PASC noted that the definition of an "intensive insulin user" was different in the Dexcom ONE+ CGM (application 1785) and FreeStyle Libre 2 CGM applications (application 1786). In the FreeStyle Libre 2 CGM application, the subpopulation defined as "intensive insulin users" were those receiving three or more injections daily of basal insulin and prandial bolus insulin; this population did not include people receiving treatment with co-formulated or pre-mixed insulin. PASC also noted that the population included in the Dexcom ONE+ CGM application were required to have suboptimal glycaemic control. This was not a requirement included in the population definition in the FreeStyle Libre 2 CGM application. PASC noted the applicant's comments on the pre-PASC PICO document that research findings suggest the benefits of using CGM systems in the non-insulin dependent T2D population.

PASC recognised that there was likely to be a hierarchy of clinical need within the T2D population requiring insulin, with some patients having a greater need for CGM, such as those at increased risk of severe hypoglycaemia or people lacking hypoglycaemia awareness. PASC noted that other populations with T2D likely to have a high unmet need were indigenous Australian populations, children, pregnant women, people who are socially disadvantaged and people living in regional or remote areas.

The applicant's independent clinical expert noted that there was an argument to consider the inclusion of people with frequent hypoglycaemic episodes but with normal HbA1C levels in the proposed population (see discussion under Outcomes). PASC considered that it was open to the applicant to include this additional population.

Both CGMs (e.g. Dexcom ONE+) and Flash glucose monitors (GM) measure interstitial glucose levels. With a CGM, the glucose readings are automatically transmitted to the mobile app or receiver device via Bluetooth. With a Flash GM, the glucose readings are transmitted to the mobile app or the receiver device only when the sensor is scanned by passing (waving) the mobile app or receiver device over the sensor.

Currently, all people with type 1 diabetes (T1D) are eligible to apply for access to subsidised CGM products through the NDSS, as well as people under the age of 21 years who have other rare conditions that are similar to T1D if they have a listed eligible condition.[2] People with T1D who: hold valid concessional status; or are pregnant, planning pregnancy or immediately post-pregnancy; or are under the age of 21 years are eligible to access fully subsidised CGM products (i.e. no co-payment is required). People with T1D aged 21 years or older who do not hold valid concessional status can access these products with a co-payment.

Prevalence of T2D

Type 2 diabetes is the most common form of diabetes representing around 85–90% of all diabetes mellitus in Australia[3]. In 2021, almost 1 in 20 Australians (1.2 million or 4.6% of the population) were living with T2D based on NDSS registration and Australasian Paediatric Endocrine Group (APEG) state-based registers,

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2 NDSS. People with conditions very similar to type 1 diabetes are eligible to access the CGM Initiative through the NDSS. https://www.ndss.com.au/about-the-ndss/cgm-access/other-eligible-conditions-age-under-21-years/

3 Diabetes Australia, Type 2 diabetes https://www.diabetesaustralia.com.au/about-diabetes/type-2-diabetes/

although the true prevalence may be higher[4]. Around 45,700 people were newly diagnosed with T2D in Australia in 2021, i.e. around 125 people per day. Additionally, it was estimated in 2023 that around 15% of Australian adults aged ≥25 years (~2 million people) were either living with prediabetes or are at high risk of developing T2D and approximately 500,000 people had undiagnosed T2D (Diabetes Australia).

Males are 1.3 times more likely to be living with T2D than females and the prevalence of T2D increases with age, from 3.1% in people aged <40 years to 59% in people aged >65 years. The peak of prevalence is in people aged 80 – 84 years (22% and 17% for males and females, respectively) although the incidence and prevalence of T2D among children, adolescents and young adults (early-onset T2D) is increasing. A family history of T2D or having gestational diabetes during pregnancy increases the risk of developing T2D in addition to lifestyle factors such as poor diet, physical inactivity, smoking, and high alcohol consumption.

Aboriginal and Torres Strait Islander Australians have higher rates of T2D compared to the general population.[3] Other racial groups and ethnicities at increased risk of T2D include African American, Hispanic, Pacific Islander, Asian and Middle Eastern populations (Titmuss et al. 2024). The prevalence of T2D is higher in socially disadvantaged populations and those living in more remote areas of Australia. It was estimated in 2018-2019 that around 10.7% of all Aboriginal and Torres Strait Islander people (59,100 people) were living with T2D.[3] Onset in these communities often occurs at a younger age with more severe outcomes including premature mortality. T2D is a particular problem for indigenous children, with Western Australian data from 1990-2012 suggesting an incidence of 31.1 per 100,000 compared to 1.4 per 100,000 in non-indigenous children (Haynes et al. 2016).

People with T2D account for two-thirds of all Australians with diabetes requiring insulin. Estimates for insulin usage vary in Australia. The Australian National Diabetes Audit (ANDA) in 2022 reported that just over half (53.2%) of people with T2D included in the audit were being treated with insulin, either as a monotherapy or in combination with other glucose-lowering drugs (Australian National Diabetes Audit). According to data from the NDSS included in the application, 304,527 (25%) Australians living with T2D required insulin therapy as of 30 June 2023.[5] The ANDA in 2022 reported on the use of different insulin regimens among insulin users. These data suggested that 70.1% of people with T2D using insulin require intensive insulin therapy (basal and rapid acting insulin therapy regimens including pre-mixed or co-formulated insulin) and 27.2% require non-intensive insulin therapy (basal insulin therapy only). Additionally, the ANDA in 2022 estimated that 71% of all people with T2D (including both insulin requiring and non-insulin requiring populations) included in the audit had suboptimal glycaemic control despite treatment (lifestyle intervention or drug treatment), i.e. did not achieve the HbA1c target of ≤7% (Australian National Diabetes Audit). However, it should be noted that not all people with T2D included in the ANDA would have been set a target HbA1c as low as 7% by their diabetes healthcare professional as targets are individualised after consideration of other factors (e.g. age).

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4 Australian Government Australian Institute of Health and Welfare. Diabetes: Australian facts. https://www.aihw.gov.au/reports/diabetes/diabetes/contents/how-common-is-diabetes/type-2-diabetes

5 National Diabetes Services Scheme. Insulin Therapy. https://www.ndss.com.au/wp-content/uploads/Insulin-Therapy-1.pdf

Based on the above observations, the MSAC application estimated the following utilisation of insulin therapy for the proposed subpopulations:

- Subpopulation 1: 164,528 people with T2D requiring intensive insulin therapy in 2025 increasing to 176,834 people in 2028.
- Subpopulation 2: 63,461 people with T2D requiring non-intensive insulin therapy in 2025 increasing to 68,207 in 2028.

In Australia, blood glucose monitoring is recommended for all people with T2D using insulin (The Royal Australian College of General Practitioners 2020). It is unclear from data available in the application whether the anticipated uptake of CGM would be similar across all age groups.

Natural history and disease burden of T2D

T2D is a chronic and progressive condition that results from insulin resistance followed by pancreatic islet cell dysfunction causing a relative insulin deficiency. This is attributed to modifiable lifestyle-related risk factors interacting with non-modifiable and genetic risk factors. The relative insulin deficiency results in chronic hyperglycaemia and affects carbohydrate, protein and fat metabolism. This leads to potentially life-threatening long-term macrovascular and microvascular complications (e.g. cardiovascular disease, renal failure, eye problems), has a significant impact on mental health (e.g. diabetes distress, anxiety, depression) and significantly impacts on QoL.

A review of T2D in young adults in the United Kingdom reported that an increase in obesity and a less physically active lifestyle across the population over the last 20 years have contributed to onset of T2D at an earlier age (Htike et al. 2015). T2D in adolescents, children and young adults has been increasing with onset most commonly occurring with physiological insulin resistance during puberty; T2D is rarely observed in younger children. Glycaemic control in T2D during adolescence deteriorates more rapidly than in adults, due to higher insulin resistance and β-cell dysfunction, with a greater risk of complications and early mortality due to longer exposure to hyperglycaemia associated with earlier onset (Peña et al. 2020; The Royal Australian College of General Practitioners 2020; Titmuss et al. 2024; Wong et al. 2022). It is estimated that adolescents diagnosed with T2D lose ~15 years from their remaining life expectancy (Kao & Sabin 2016).

Prior testing

There are currently no national screening programs for T2D, pre-diabetes or obesity in Australia (Parliament of Australia).

Adults with T2D are usually diagnosed by their general practitioner (GP) either via a routine blood test that identifies abnormal glycaemia incidentally, without associated symptoms, or after presenting with characteristic symptoms of diabetes (e.g. increased thirst, urination, tiredness, blurred vision).

In Australia, regular screening for T2D is recommended for at-risk populations. 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 a primary care setting is the Australian Diabetes Risk Assessment (AUSDRISK) tool. AUSDRISK predicts a person's five-year risk of developing T2D. The Royal Australian College of General Practitioners (RACGP) handbook for T2D recommends using the AUSDRISK tool for screening of

asymptomatic adults aged ≥40 years (The Royal Australian College of General Practitioners 2020). The AUSDRISK tool is not validated for use in children, adolescents, younger adults or Aboriginal and Torres Strait Islanders. It is recommended that Aboriginal and Torres Strait Islander adults are screened annually using fasting blood glucose (FBG) and HbA1c testing due to their increased risk of developing T2D.

Adults who do not have symptoms of hyperglycaemia but are identified as being at increased risk of T2D during screening (AUSDRISK score >12 or with other designated risk factors) are assessed for the following diagnostic outcomes using venous blood tests (The Royal Australian College of General Practitioners 2020):

- HbA1c ≥6.5% (48 mmol/mol) tested on two separate occasions, or
- FBG ≥7.0 mmol/L, or
- random blood glucose ≥11.1 mmol/L confirmed by a second abnormal FBG on a separate day, or
- oral glucose tolerance test (OGTT) before (fasting) and two hours after an oral 75 g glucose load is taken. Diabetes is diagnosed as FBG ≥7.0 mmol/L or two-hour post-challenge blood glucose ≥11.1 mmol/L.

Prediabetes is a metabolic condition characterised by elevated blood glucose levels that do not meet the diagnostic criteria for T2D. People with prediabetes have an impaired fasting glucose (IFG), impaired glucose tolerance (IGT) and/or elevated HbA1c. If IFG or IGT are identified during testing, then subsequent diabetes screening is carried out annually. If initial tests are within the normal range, screening continues every 3 years or earlier if the individual's body mass index (BMI) increases. Prediabetes affects nearly 1 in 6 Australian adults over the age of 25 years. Unless lifestyle interventions such as change in diet, weight loss and increase in exercise are adopted, approximately 1 in 3 people with prediabetes will develop T2D within ten years. Additionally, people with prediabetes are already at increased risk of developing cardiovascular disease (Bell et al. 2020).

For adults presenting with symptoms suggestive of hyperglycaemia (e.g. tiredness, increased urination and thirst, frequent infections, blurred vision, loss of sensation, poor wound healing, weight loss), one of the following test outcomes is considered confirmatory of a diagnosis of T2D (The Royal Australian College of General Practitioners 2020):

- a patient presenting with hyperglycaemic crisis
- a single elevated FBG ≥7.0 mmol/L
- single HbA1c ≥6.5% (48 mmol/mol)
- a random blood glucose ≥11.1 mmol/L.

Adults with signs of insulin resistance (i.e. acanthosis nigricans, skin tags, central obesity, hirsutism) should also receive FBG or HbA1c tests for T2D.

Paediatric T2D is typically diagnosed in the second decade of life, coinciding with the physiological pubertal increase in insulin resistance (Peña et al. 2020). The Australasian consensus guidelines for screening, assessment and management of children and adolescents with T2D recommends targeted screening every 2 to 3 years in non-Indigenous children and adolescents aged >10 years or who have reached puberty (whichever occurs earlier) who are overweight or obese and have one or more additional risk factors (e.g.

family history of diabetes mellitus, race or ethnicity at increased risk) or signs of insulin resistance using the OGTT or HbA1c test (Peña et al. 2020). A diagnosis of T2D is confirmed using either the FGT, 2-hour OGTT or HbA1c test. Testing for diabetes autoantibodies is also carried out to rule out T1D, which occurs in children at a 10-fold higher rate than T2D. Further testing may also be carried out to exclude other rarer types of diabetes (Peña et al. 2020).

The Australasian consensus guideline recommends point-of-care HbA1c screening for all Aboriginal and Torres Strait Islander children aged ≥10 years with one or more risk factors (overweight/obese, family history of diabetes mellitus, signs of insulin resistance, other comorbid conditions and using psychotropic medications) as these children have an earlier age of T2D onset with T2D being reported in children aged ≤5 years (Peña et al. 2020). Screening is repeated at 6 monthly intervals if an individual is identified as being at-risk of diabetes or annually if no diabetes is confirmed during screening.

After a T2D diagnosis is established, a detailed assessment of the person with T2D is carried out including a full medical history, physical assessment, assessment of comorbidities that could impact on glycaemic control and assessment of cardiovascular risk status. Cardiovascular disease (CVD) is the leading cause of death in people with diabetes, making assessment, prevention and management of CVD risk a critical element of diabetes care. All people with T2D should be assessed for absolute CVD risk at diagnosis using a validated tool, unless they are already confirmed as being at high risk of CVD. The absolute CVD risk determines the frequency of CVD reassessment, ranging from every 2 years in those at low absolute risk (<10%) to as clinically indicated in those at high risk (>15%) (The Royal Australian College of General Practitioners 2020).

T2D management

The Australian Diabetes Society Type 2 Diabetes Glycaemic Management Algorithm updated in 2024 is based on the Australian Evidence-Based Clinical Guidelines for Diabetes from the Living Evidence for Diabetes Consortium (Figure 1) (Australian Diabetes Society, 2024). The Living Evidence for Diabetes Consortium is a collaboration between the Australian Diabetes Society, Diabetes Australia, the Australian Diabetes Educators Association and the Australasian Paediatric Endocrine Group, with representation from the Royal Australian College of General Practitioners, the Australian Government Department of Health and Aged Care, and Cochrane Australia (Australian Diabetes Society, 2024).

Because of its heterogeneity and complexity, T2D is managed using a multidisciplinary approach involving paediatric or adult endocrinologists, credentialled diabetes educators (CDE), dietitians, social workers and psychologists. The patient-centred management approach is individualised. Provision of adequate ongoing education and support for people living with T2D or their parents/carers is essential to achieve positive lifestyle changes and appropriate therapeutic management of T2D (Australian Diabetes Society ; Davies et al. 2022; The Royal Australian College of General Practitioners 2020).

Identification of prediabetes permits earlier introduction of diabetes self-management education and support to promote changes in health and lifestyle behaviours. Lifestyle changes (diet, weight management, smoking cessation, physical activity and management of mental health conditions) are the primary intervention for prediabetes and can slow or ideally prevent progression to T2D requiring treatment with glucose-lowering drugs and/or insulin. People with a confirmed diagnosis of T2D should also receive education and ongoing support for lifestyle changes including weight loss, healthy diet and

physical activity (The Royal Australian College of General Practitioners 2020). Any comorbidities that could impact on effective glycaemic control are also recorded for subsequent management. Intensive lifestyle changes, including weight loss, may achieve T2D remission, defined as HbA1c levels remaining <6.5% [48 mmol/mol] for at least three months in the absence of glucose-lowering drugs. If T2D remission criteria are met, HbA1c (or, if HbA1c unreliable, fasting plasma glucose or an oral glucose tolerance test) should be performed at least every 6 months to assess persistence of diabetes remission or relapse of diabetes (The Royal Australian College of General Practitioners 2024).

T2D is managed by using appropriate individualised glycaemic targets and subsequently maintaining glycaemic control in line with these targets to achieve an optimal balance between preventing complications associated with hyperglycaemia and reducing the risk of hypoglycaemia. In addition to managing glycaemia, management of cardio-renal risk associated with T2D is also important (The Royal Australian College of General Practitioners 2020).

Optimising glycaemic control can improve both immediate and longer-term health outcomes. Glycaemic control targets are individualised considering the benefits and risk of achieving the target HbA1c level, the individual's preferences and available support. The usual target HbA1c in adults with T2D is ≤7% (≤53 mmol/mol) and HbA1c levels should be assessed every 3 months (The Royal Australian College of General Practitioners 2020). For children and adolescents, the recommended target HbA1c level is lower at ≤6.5% (≤48 mmol/mol) due to the likely longer disease duration, the earlier development of T2D-associated complications and the higher mortality rate compared with T2D in adults (Peña et al. 2020). Pregnant women with T2D have an increased risk of poor pregnancy outcomes as observed for gestational diabetes (large or small for gestational age, maternal hypertensive complications, preterm birth, caesarean section, birth trauma, neonatal intensive care unit admission, and neonatal hypoglycaemia) (Rudland et al. 2020). The Australian Diabetes in Pregnancy Society (ADIPS) recommends that women with T2D planning a pregnancy require specialist care and should be advised about preparation for pregnancy, achieving and maintaining optimal glycaemic targets, and improving their outcomes; ideally, their HbA1c should be <6.5% prior to conception and during pregnancy (Callaway & Britten 2024; Rudland et al. 2020). The ADIPS guideline recommends glycaemic targets that are appropriate for both the preconception period and pregnancy for use with both SMBG and CGM (Rudland et al. 2020).

This Type 2 Diabetes Glycaemic Management Algorithm should be read in conjunction with the Living Evidence Guidelines in Diabetes (please click here).

All patients should receive education regarding lifestyle measures: healthy diet, physical activity and weight management. +

Determine the individual's HbA1c target – commonly ≤53 mmol/mol (7.0%) but should be appropriately individualised (refer to ADS position statement).

+ Weight loss of ≥10% will likely allow a reduction or cessation of glucose lowering medication. Consider intensive weight management options including:
• Low energy or very low energy diets with meal replacements
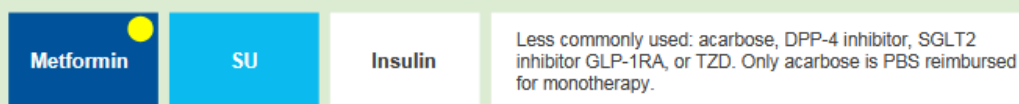• Pharmacotherapy
• Bariatric surgery.

Click here for the Australian Obesity Management Algorithm

Review treatment: if not at target HbA1c or if presence of cardiovascular/chronic kidney disease –
• Check patient understanding of self-management including drug treatment
• Ensure current therapies are clinically appropriate including comorbidities/ therapies impacting glycaemic control
• Review medication adherence
• Assess tolerability, adverse effects and risk of interactions

(left vertical bar) Review treatment in 3 months. If HbA1c not at target Reinforce lifestyle measures and review weight management strategies.

MONOTHERAPY: Metformin is the usual monotherapy unless contraindicated or not tolerated

| Metformin 🟡 | SU | Insulin | Less commonly used: acarbose, DPP-4 inhibitor, SGLT2 inhibitor GLP-1RA, or TZD. Only acarbose is PBS reimbursed for monotherapy. |

DUAL THERAPY: Choice of treatment – add on an oral agent or injectable therapy
Choice of dual therapy should be guided by clinical considerations (presence of, or high risk of, cardiovascular disease, heart failure, chronic kidney disease, hypoglycaemia risk, obesity), side effect profile, contraindications and cost.

| SGLT2 inhibitor 🟢 | GLP-1RA* 🟢 | DPP-4 inhibitor 🟡 | SU 🟠 | Insulin | Less commonly used are: acarbose or TZD. |

MULTIPLE THERAPIES: Choice of treatment : include additional oral agent or GLP-1 RA or insulin
Choice of agents should be guided by clinical considerations as above. Note: combinations not approved by PBS include GLP-1RA with SGLT2i. Consider reviewing any previous medication that has not reduced HbA1c by ≥0.5% after 3 months and take into consideration glycaemic AND non-glycaemic benefits.

| SGLT2 inhibitor 🟢 | GLP-1RA 🟢 | DPP-4 inhibitor 🟡 | SU | Insulin | Less commonly used are: acarbose or TZD. |

THEN...

To intensify treatment to meet glycaemic targets
• If on metformin+SU+DPP-4i, consider adding SGLT2i, or switching DPP-4i to a GLP-1RA, or an SGLT2i.
• When adding incretin therapy, use either a DPP4i or GLP-1RA (not both together).

• If on basal insulin, consider adding SGLT2i or GLP-1RA or bolus insulin with meals, or change to premixed/coformulated insulin.
• If on metformin+DPP4i+SGLT2i consider adding SU or insulin.

With increasing clinical complexity consider specialist endocrinology consultation

*Combinations not approved by PBS include GLP-1RA with SGLT2i. Use of PBS-subsidised GLP-1 RAs in combination with an SGLT2i is permitted when the SGLT2i is prescribed for an indication other than T2D (e.g. chronic kidney disease or heart failure). PBS-subsidised GLP-1 RA can only be commenced if SGLT2i has not achieved a clinically meaningful glycaemic response or if there is a contraindication/intolerance to an SGLT2i. PBS-subsidised GLP-1RA can only be combined with PBS-subsidised SGLT2i if the SGLT2i is being prescribed through the heart failure or CKD PBS code. Consider reviewing any previous medication that has not reduced HbA1c by ≥0.5% after 3 months, and consider glycaemic AND non-glycaemic benefits.

🟢 *Recommendation for* addition of a SGLT2i (or GLP-1RA where SGLT2i is not tolerated or contraindicated) to other glucose lowering medication(s) in adults with type 2 diabetes who also have cardiovascular disease, multiple cardiovascular risk factors and/or kidney disease.

🟡 *Conditional recommendation for* metformin as first-line monotherapy in adults with type 2 diabetes.

🟡 *Conditional recommendation for* DPP-4i addition to other glucose lowering medication(s) in adults with type 2 diabetes who have cardiovascular disease, multiple cardiovascular risk factors and/or kidney disease, and are unable to be prescribed an SGLT2i or a GLP-1RA due to either intolerance or contraindication.

For more details click here to access the Living Evidence Guidelines in Diabetes.

🟠 *Conditional recommendation against* sulphonylurea being first choice medication to add to metformin as dual therapy as it may increase risk of hypoglycaemia.

🟦 Dark blue boxes indicate usual therapeutic strategy (order is not meant to denote any specific preference); usual refers to commonly available, evidence based, cost effective therapy.

🟦 Light blue boxes denote alternate approaches (order is not meant to denote any specific preference).

⬜ White boxes indicate less commonly used approaches.

PBS = Pharmaceutical Benefits Scheme, HF = heart failure, CKD = chronic kidney disease, SU = sulfonylurea, TZD = thiazolidinedione, DPP-4i = dipeptidyl peptidase-4 inhibitor, GLP-1RA = glucagon like peptide-1 receptor agonist, SGLT2i = sodium glucose co-transporter inhibitor.

Figure 1 The Australian Diabetes Society T2D glycaemic management algorithm

Source: (Australian Diabetes Society, 2024)

Treatment of T2D to establish glycaemic control follows a stepwise approach (Figure 1) (Australian Diabetes Society, 2024). If glycaemic targets are not achievable using lifestyle interventions alone within three months, glucose-lowering therapy should be started to reduce the risk of microvascular complications due to uncontrolled hyperglycaemia. There are several oral or injectable glucose-lowering therapies that can be considered for use, either as monotherapy, dual therapy or multiple therapies. Available drug classes include biguanide (metformin), sulfonylureas (SU), sodium-glucose cotransporter-2 (SGLT2) inhibitors, glucagon-like peptide-1 receptor agonists (GLP-1RA), dipeptidylpeptidase-4 (DPP-4) inhibitors and insulin. Alpha-1-glucosidase inhibitors or thiazolidinediones (TZD) are less frequently used therapies (Figure 1). Most patients receive oral glucose-lowering therapies initially, before being considered for an injectable therapy or insulin if blood glucose cannot be maintained within the target range. Metformin is the preferred first line treatment for T2D in adults. Metformin reduces hepatic gluconeogenesis, increases insulin-stimulated glucose uptake in fat and muscle, and does not usually cause hypoglycaemia. If glycaemic targets are not achieved, the Australian guidelines recommend that dual therapy can be considered to improve glycaemic control by addition of a DPP-4 inhibitor or SGLT2 inhibitor or GLP-1RA to the monotherapy (Figure 1). Dose adjustments to and/or addition of glucose-lowering therapies should be carried out so that target HbA1c levels are achieved within 3 to 6 months of treatment initiation. Each class of glucose-lowering therapy has different side effects (e.g. weight gain or increased risk of hypoglycaemia) that can impact on the individual's quality of life. Changes and adjustments to T2D treatment require careful clinical assessment and ongoing consultation with the individual receiving therapy (or their parent/carer) in line with a person-centred approach to diabetes management (The Royal Australian College of General Practitioners 2020).

In contrast to the general T2D population, risk of hypoglycaemia, impaired hypoglycaemia awareness, and complications from insulin are higher in older people with T2D and people who are more vulnerable (e.g. after a recent hospitalisation, poor social support, comorbidity) (Battelino et al. 2019; Bremer et al. 2009). More conservative glycaemic targets and treatments with a lower risk of hypoglycaemia should be selected for these populations. For example, guidance for these populations is to reduce time below 3.9 mmol/L glucose in the hypoglycaemic range to less than 1% of daily time (15 minutes) rather than for less than 4% of daily time (1 hour) as recommended for other people with T2D (unless pregnant) (Battelino et al. 2019; The Royal Australian College of General Practitioners 2024).

Insulin for T2D management

Insulin is an effective glucose-lowering agent for T2D and can be titrated to suit an individual's requirements. As insulin has a narrow therapeutic index, its use for glycaemic control must be carefully monitored. If glycaemic control by a patient's existing glucose-lowering treatment is suboptimal, initiating insulin treatment should not be delayed. Reluctance on the part of the individual or their clinician to initiate insulin when glycaemic targets are not achieved is referred to as "therapeutic inertia" and is often multifactorial. Targeted interventions addressing the reasons for therapeutic inertia have been shown to improve glycaemic management and increase appropriate insulin use (Davies et al. 2022).

Patients usually start insulin treatment using either basal insulin or co-formulated insulin/premixed insulin (basal, intermediate-acting and rapid-acting insulin in varying combinations), individualised according to clinical need.

Starting doses of basal insulin are estimated based on body weight (0.1–0.2 units/kg/day) and the degree of hyperglycaemia, with individualised insulin dose titration over a period of days to weeks, as needed. The main action of basal insulin treatment is to control hepatic glucose production and limit hyperglycaemia overnight and between meals. Basal insulin has a slightly lower risk of hypoglycaemia, particularly if the fasting glucose level is consistently above the target range.

Non-insulin glucose-lowering medicines are generally continued when insulin is started as their presence has many observed benefits (e.g. clinically relevant reductions in mean HbA1c, all-cause mortality, heart failure and kidney failure amongst people with T2D and an HbA1c ≥7% (≥53 mmol/mol)).

Many people with T2D require more intensive insulin therapy, i.e. insulin with meals (prandial insulin) and basal insulin, to achieve their glycaemic target. People with T2D are generally more insulin resistant than those with T1D, require higher daily insulin doses, and have lower rates of hypoglycaemia. Intensification of insulin treatment can be achieved by using multiple daily injections of bolus prandial rapid acting insulin which is similar to the normal physiologic release of insulin, along with basal insulin. Alternatively, a co-formulated or premixed insulin may be used. Premixed insulins have various combinations of different concentrations of intermediate-acting basal insulins and rapid-acting insulins and may be more appropriate and simpler for a patient where fasting and postprandial glucose are both consistently elevated. However, dosage adjustment can be more complex with premixed and co-formulated insulins as both insulin components are adjusted simultaneously with an increased risk of hypoglycaemia. Initiation or changes to the type and/or regimen of insulin should ideally be made following consultation with diabetes specialists, CDE and dietitians.

A range of devices are available to deliver insulin, including insulin pens, syringes and pumps for continuous subcutaneous insulin infusion or hybrid closed loops depending on patient preference, clinical need and ability to self-manage injections. A CDE or a diabetes nurse practitioner can provide patient support during insulin initiation, and a GP or CDE can provide authorisation to allow patients to access syringes or pen needles for insulin through the NDSS. Insulin pumps are not currently subsidised for people with T2D and NDSS subsidy is currently only available for insulin pump consumables for people with T1D. Reimbursement of CGM for T2D for use as part of a hybrid closed loop system would require expansion of the reimbursement criteria for insulin pumps and consumables to include people with T2D; this falls outside of the scope of the current application and the applicant has confirmed that evidence for the use of insulin pumps in the T2D setting will not be included in the assessment report.

Routine SMBG is not recommended for people with T2D who are only using oral glucose-lowering therapies (except for sulfonylureas, which are associated with an increased risk of hypoglycaemia). SMBG is recommended for patients with T2D who are using insulin and can self-manage their insulin dose. Targets for SMBG for people with T2D are 4.0–7.0 mmol/L for fasting blood glucose and pre-prandial blood glucose, and 5.0–10.0 mmol/L for postprandial blood glucose (The Royal Australian College of General Practitioners 2020).

An alternative option to SMBG is use of CGM although this is not currently funded in Australia for people with T2D requiring insulin.

PASC queried whether people with T2D who require insulin and have suboptimal glycaemic control, would remain eligible for CGM if they no longer require insulin to achieve glycaemic control and therefore

potentially blood glucose monitoring would no longer be required for their T2D. PASC noted that withdrawing an effective intervention is an ethical dilemma. It was considered likely that such a change would occur in only a small number of people. In theory, people achieving "remission" would no longer be eligible for subsidised CGM as they would no longer require insulin. However, PASC acknowledged that any decision to discontinue insulin and hence the requirement for blood glucose monitoring is complex and multifactorial. Therefore, PASC considered that the appropriate time to discontinue NDSS subsidised access to CGM would likely need to be based on the clinical judgement of the treating diabetes healthcare professional.

Rationale

Although 4 in 5 (80%) of all patients with T2D included in the ANDA performed regular SMBG using the finger prick method, ~71% of all patients with T2D included in the ANDA were unable to achieve their HbA1c target, which was lower than reported for people with T1D (80.4%) using either SMBG or CGM (Australian National Diabetes Audit). The MSAC application emphasised that supporting people with T2D to self-manage their diabetes more effectively leads to improved glycaemic control, reduction in chronic complications as well as improvements in health-related quality of life (HRQoL).

People with T2D using insulin are at increased risk of severe hypoglycaemic as well as long term diabetic complications due to poor blood glucose control. They require effective monitoring of blood glucose to guide self-management of their insulin therapy. Although the frequency of SMBG is individualised, a more intensive insulin regimen usually requires more frequent SMBG reflecting the increased risk of hypoglycaemia. The American Diabetes Association (ADA) clinical practice guideline on diabetes technology states that individuals with diabetes (T1D and T2D) on intensive insulin therapy have to carry out SMBG using a finger prick blood sample between 6 to 10 times a day, although individual needs may vary (American Diabetes Association 2024c). There is no clinical consensus around how often SMBG is needed for people with T2D using basal insulin (Subpopulation 2) (American Diabetes Association 2024c). However, Australian survey data suggested that people with T2D using basal insulin carry out SMBG on average 3 times per day (Holmes-Truscott et al. 2016). Women with T2D may be required to increase the frequency of their SMBG to help them achieve the recommended glycaemic target in the preconception period and during pregnancy (Rudland et al. 2020).

An alternative option to SMBG is CGM. The recently updated 2024 RACGP guidelines for T2D management states that CGM should be considered for continual or intermittent use in all individuals with T2D on IIT (multiple daily injections or insulin pumps), subject to individual factors and the availability of resources (The Royal Australian College of General Practitioners 2024). Individuals who might benefit most from CGM include those at increased risk of hypoglycaemia, those with hypoglycaemic unawareness and/or those with high glycaemic variability. The guidelines considered that intermittent use of CGM can be a useful adjunct to use of SMBG. The minimum duration of CGM to obtain enough data to effectively characterise and interpret glycaemia patterns has been reported as at least 7 days (The Royal Australian College of General Practitioners 2024).

In recognition of this clinical need, the recent Parliamentary Inquiry into "The State of Diabetes Mellitus in Australia in 2024" 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) (Parliament of Australia).

Intervention

The intervention proposed for both Subpopulation 1 (intensive insulin users) and Subpopulation 2 (non-intensive insulin users) is real-time CGM using the Dexcom ONE+ CGM system. The applicant indicated in their pre-PASC response that they wished to update the intervention included in the application from Dexcom ONE to Dexcom ONE+ system, the latest iteration of the device. Dexcom ONE+ is currently in the process of final TGA approval. A comparison table summarising the differences between Dexcom ONE+ and Dexcom ONE is provided below (Table 2).

PASC noted that the applicant had updated the proposed intervention included in the application from Dexcom ONE to the latest iteration of the device, Dexcom ONE+. PASC considered that the change was acceptable and noted that Dexcom ONE+ offered additional features compared to Dexcom ONE including a smaller sensor with in-built transmitter, improved accuracy, shorter warm-up time after application to the skin, supported blood glucose data sharing with up to 10 followers (friends, family, and carers) and blood glucose data sharing with a diabetes healthcare professional to aid remote diabetes support and telehealth consultations.

PASC noted that Dexcom ONE+ was currently undergoing TGA evaluation.

PASC confirmed that use of CGM is already fully subsidised via the NDSS for people with T1D and people aged under 21 years with eligible rare conditions similar to T1D.

PASC noted that in principle it supported a device-agnostic consideration of CGM.

Dexcom ONE+ continuously measures and reports on glucose concentrations in interstitial fluid. Dexcom ONE+ is designed to replace finger prick SMBG for treatment decisions. Unlike earlier versions of CGM devices, the Dexcom ONE+ system is factory calibrated so adjunctive use of SMBG using finger prick testing of blood glucose is not required for ongoing calibration of the device during use.

The Dexcom ONE+ system consists of two main components:

- Dexcom ONE+ sensor which includes an in-built transmitter and the sensor wire
- Bluetooth-enabled display device, either a smart phone with the Dexcom ONE+ app or an optional receiver

Components of the Dexcom ONE+ system should not be worn during magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. Also, the system should not be exposed to an Advanced Imaging Technology (AIT) body scanner (also called a millimetre wave scanner) or scanned through a baggage X-ray machine.

The main consumable associated with Dexcom ONE+ is the sensor (all-in-one transmitter and sensor including sensor wire). The sensor wire is the part of the sensor that is inserted subcutaneously to measure glucose levels in the interstitial fluid. The sensor can be applied to the skin on either the abdomen or back of arms (also on the buttocks in children aged 2 to 6 years) using the inbuilt sensor applicator (Figure 2). The sensor is waterproof up to 2.4 metres and 24 hours. The sensor automatically sends glucose information every 5-minutes from the sensor wire to the receiver or Dexcom ONE+ app on a compatible smart device (Figure 3). With the Dexcom ONE+ CGM System, the sensor is replaced every 10 days (plus a

12-hour grace period if required). Therefore, it is anticipated that people with T2D using the Dexcom ONE+ system will require 36 sensors per year.
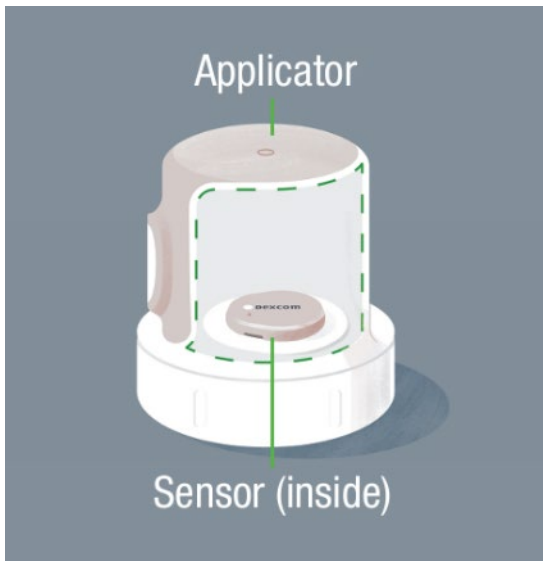

Figure 2 Dexcom ONE+ in-built applicator containing the sensor

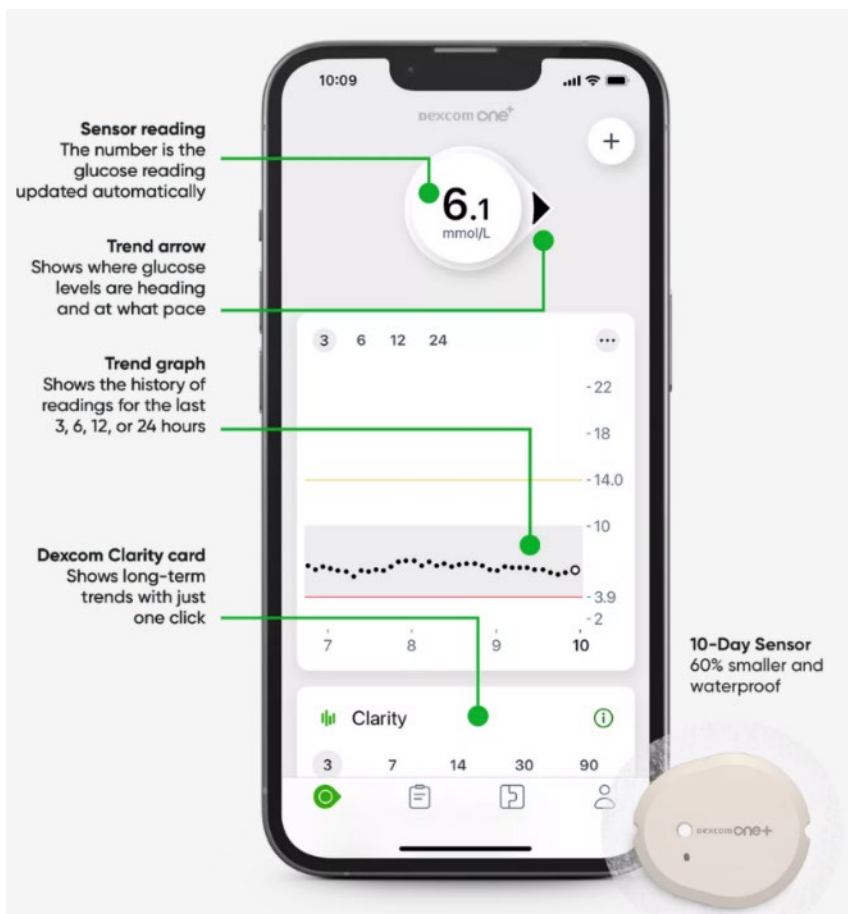Source: Image provided by the applicant.

Figure 3 Dexcom ONE+ app on a smart phone and the Dexcom ONE+ sensor

Source: Image provided by the applicant.

The Dexcom ONE+ mobile app can be downloaded onto a compatible iOS or Android device and acts as the system display device (Figure 4). Alternatively, the Dexcom ONE+ receiver is a reusable device that receives, stores, processes and displays the glucose information from the sensor; it displays the same information as the mobile app. Glucose readings are automatically sent from the transmitter built into the sensor to the receiver or Dexcom ONE+ app on the compatible smart device every 5 minutes providing the display device is within range (10 metres) of the sensor. Glucose readings can be checked by the person wearing the sensor throughout the day without the need for SMBG using a finger prick blood sample.

The system has optional high or low glucose alerts which must be turned on during system set-up with the user alerted by sound or vibration; this will not override normal smart device settings (e.g. if the sound is turned off). The system display includes the glucose reading in mmol/L, a glucose trend arrow and a trend graph/ambulatory glucose profile (AGP) showing the recorded glucose levels over time. Trend arrows help the user predict the rate and direction of their glucose change in the next 30 minutes. If no trend arrow is displayed due to a device fault, SMBG testing with a glucose test strip is temporarily needed for treatment decisions. The trend graph shows the international consensus recommended target blood glucose range of 3.9–10.0 mmol/L that is used to determine the CGM glycaemic outcomes of time in range (TIR), time above range (TAR) and time below range (TBR) (Battelino et al. 2019). Glucose alert threshold lines are also displayed on the trend graph.

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Figure 4 Dexcom ONE+ optional receiver, app display on a smart phone, and all-in-one transmitter and sensor

Source: Image provided by the applicant.

As indicated in the user manual, temporary use of SMBG in parallel with Dexcom ONE+ CGM is recommended initially for treatment decisions when a person with T2D starts using Dexcom ONE+ until the user gains confidence in making treatment decisions using Dexcom ONE+ data alone. While CGM is intended to replace SMBG, limited use of SMBG is still recommended under certain circumstances (e.g. CGM readings do not match an individual's symptoms, device malfunction). SMBG is also required when a new sensor is applied to the skin as there is a 30-minute sensor warmup period when CGM is not active so readings are not received from the sensor. In the event of an interruption in transmission between the transmitter and the display device resulting in a gap in the trend graph, Dexcom ONE+ can fill in up to 3 hours of missed readings retrospectively. This does not apply if the sensor was not active due to a malfunction, sensor loss or during the warm-up period of a new sensor.

The subcutaneous CGM sensor wire measures electric currents in the interstitial fluid, which are proportional to the blood glucose concentration. These glucose concentrations are automatically converted via an algorithm to represent blood glucose levels. The level of glucose in interstitial fluid lags relative to the level observed in blood by approximately 3.5 minutes, particularly when blood glucose levels are rapidly rising or falling. While the algorithm corrects for these differences as far as possible, the accuracy of reported blood glucose assessed with CGM is lower in the hypoglycaemic and hyperglycaemic range and during periods when glucose levels are rapidly rising or falling. The readings are also less accurate at the beginning of the sensor wear period. There is also acknowledged variability in accuracy between individual sensors. This should be considered by the user during CGM use. CGM accuracy and inter-sensor variability over a physiologically relevant range of glucose concentrations are measured by the manufacturer during quality assurance using a paired comparison within and between different manufactured sensor lots, by paired comparison of sensors versus SMBG using capillary blood from a finger prick, or paired comparison of sensors to laboratory measurement of blood glucose in plasma from venous blood samples (the reference standard). Both CGM sensor accuracy and inter-sensor variability are

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considered during regulatory assessment of CGM by the TGA. This mitigates inter-sensor variability and assures that data on sensor accuracy at different glucose concentrations is reported to and documented by the regulator.

SMBG measures blood glucose at a single point in time and therefore only provides information about glycaemic control at the time of the SMBG test. CGM provides a continuous AGP of an individual's glucose level and hence glycaemic control 24 hours per day, if the system is used consistently and as recommended. Continuous measurement of glucose levels makes it easier for the user to manage their T2D through both lifestyle interventions (diet, exercise) and treatment with insulin. The goal of CGM is to improve T2D management by increasing the time in range (TIR) (i.e. time or % of CGM readings per day where glucose was between 70–180 mg/dL or 3.9–10.0 mmol/L or other agreed range) whilst also reducing time in hypoglycaemia (time below range) and hyperglycaemia (time above range) thereby reducing the risk of developing T2D-related complications (Dovc & Battelino 2021). It can also help avoid adverse events (AEs) such as severe hypoglycaemia and hyperosmolar hyperglycaemic state (HHS) requiring emergency care (MacLeod, Hepburn & Frier 1993). In the long term, maintaining glycaemic control 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 (Adler et al. 2024; Holman et al. 2008). Furthermore, users may experience quality of life (QoL) benefits including from the avoidance of the burden of daily finger prick testing of blood glucose (Matza et al. 2017; Moström et al. 2017).

The Dexcom ONE+ CGM system does not include some of the features included in other Dexcom devices (Dexcom G6 and Dexcom G7) used for T1D CGM (e.g. predictive alerts for likely hypoglycaemic excursions, or compatibility with a continuous subcutaneous insulin infusion pump in a hybrid closed loop). People with T2D utilising these features (e.g. an insulin pump) would need to consider an alternative CGM device with the required compatibility although insulin pumps are not currently reimbursed for T2D by the NDSS. The application stated that it is important for T2D patients and their clinicians to be able to differentiate and choose between different CGM systems to best suit the person's needs and abilities, as for products currently available for T1D through the NDSS. Different CGM systems report varying outcomes from clinical trials and have different functional features that could influence a person's suitability and choice.

Table 2 Comparison of the characteristics of Dexcom ONE and Dexcom ONE+

	Dexcom one+	Dexcom one
WEARABLE		
Indications	Ages 2+ with diabetes mellitus where SMBG is indicated	Ages 2+ with diabetes mellitus where SMBG is indicated
Sensor and transmitter	All-in-one sensor with transmitter	Sensor and transmitter are separate
Accuracy MARD	8.2% (when worn on back of upper arm)	9.2%
Optional calibration	Yes	Yes
Sensor wear time	Up to 10 days	Up to 10 days
Transmitter wear time	NA	90 days (reusable)
Warm-up time	30 minutes	2 hours
12-hour grace period	Yes	No
Water resistance	Waterproof - 2.4 m / 24 hours[II]	Waterproof - 2.4 m / 24 hours[II]
ALERTS & APPS		
Readings automatically sent to smartphone	Yes	Yes
Readings automatically sent to receiver without scanning	Yes	Yes
Optional low and high alerts	Yes	Yes
Delay 1st High customization	Yes	Yes
Customizable sound, volume, and vibration	Yes	Yes
Event entry	Yes	No
CONNECTIVITY		
Display devices	Smartphone iOS and Android*	Smartphone iOS and Android*
	Dexcom ONE+ receiver	Dexcom ONE receiver
Smartwatch†	Yes	No
ADDITIONAL APPS		
Remote monitoring (Follow app‡)	Yes, up to 10 followers	No
Remote data sharing (Clarity app#)	Yes	Yes
WEAR LOCATIONS		
Back of arm	Yes	Yes
Abdomen	Yes	Yes
Upper buttocks	Yes (children only 2-6 years)	Yes (children only 2-17 years)

Source: Supplied by the applicant in pre-PASC response

MARD = mean absolute relative difference

* Smartphone and receiver sold separately. Please check compatibility of your smartphone device at www.dexcom.com/compatibility. II The Dexcom ONE and Decom ONE+ sensors are waterproof and may be submerged under 2.4 meters of water for up to 24 hours without failure when properly installed. † Smartwatch must be connected to a smartphone. ‡ Internet connectivity is required for data sharing. Followers require the use of the Follow App. Followers should always confirm readings on the Dexcom App or Receiver before making treatment decisions. # Internet connectivity is required for data sharing.

PASC recognised that, although outside of the scope of the current application, short-term CGM can also be used by diabetes healthcare professionals as either a diagnostic tool to assess suboptimal glycaemic control in a patient with suspected diabetes, as an educational tool to support lifestyle changes by a person with diabetes, or to inform changes in diabetes therapeutic treatment.

Comparator

SMBG is recommended for patients with T2D who are using insulin and have been educated in appropriate alterations in insulin dose (The Royal Australian College of General Practitioners 2020). People with T2D requiring intensive insulin therapy are usually required to test their blood glucose more frequently than those receiving non-intensive insulin therapy.

In the Royal Australian College of General Practitioners guidelines for T2D (The Royal Australian College of General Practitioners 2020), SMBG is recommended for:

- People on insulin and/or sulfonylureas, which can cause hypoglycaemia
- People not on insulin who are having difficulty achieving glycaemic control
- When monitoring hypoglycaemia or hyperglycaemia caused by illness
- During pre-pregnancy and pregnancy management for established (or gestational) diabetes
- When there is a clinical need for monitoring, such as during changes in management or lifestyle, or for conditions or medications requiring data on glycaemic patterns that HbA1c cannot provide
- When HbA1c estimations are unreliable (e.g. haemoglobinopathies).

The Royal Australian College of General Practitioners guideline states that routine SMBG for people with T2D who are considered low risk and who are using oral glucose-lowering therapies (with the exception of sulfonylureas) is not recommended (The Royal Australian College of General Practitioners 2020). The Royal Australian College of General Practitioners guideline also states that the method and frequency of monitoring should reflect individual circumstances and therapeutic aims, with SMBG most effective where the person with T2D and their healthcare providers have the knowledge, skills and willingness to incorporate SMBG and therapy adjustments into diabetes care plans (The Royal Australian College of General Practitioners 2020).

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 (The Royal Australian College of General Practitioners 2020). The American Diabetes Association (ADA) guidelines recommend for people who are using insulin that SMBG should be encouraged to check their blood glucose levels when appropriate based on their insulin regimen. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to/during/after exercise, when hypoglycaemia is suspected, after treating low blood glucose levels, when hyperglycaemia is suspected, and prior to and during critical tasks such as driving (American Diabetes Association 2024c).

Repeated SMBG can be time consuming, inconvenient, and painful, consequently leading to poor compliance and impaired quality of life (Matza et al. 2017; Moström et al. 2017). Unlike continuous monitoring, SMBG can provide only a 'snapshot' of a patient's glycaemic status at the time of testing. As

such, it may not identify all hypoglycaemic or hyperglycaemic excursions and does not provide patients with enough actionable information to support self-management (Ajjan, Slattery & Wright 2019).

In Australia, subsidised blood glucose test strips for SMBG of T2D can be purchased through the NDSS. The number of subsidised glucose test strips that a person with T2D can purchase from the NDSS in a 180-day period is 900 strips; this would only be sufficient to carry out SMBG five times per day which may not meet the needs of people with T2D using intensive insulin treatment. Typically, additional strips purchased during that period would not be subsidised, however, registrants can access more product if their limit has been reached and unique circumstances are present. This restriction on glucose testing strips may encourage people with T2D to deviate from the recommended frequency of SMBG potentially increasing the risk that glycaemic targets would not be achieved. Access to some NDSS-subsidised glucose test strips would still be required if a person with T2D is using CGM to account for those periods and circumstances when SMBG is recommended during CGM use.

Currently, there are no subsidised CGM systems for T2D available through NDSS, although some people may be able to obtain them privately or through their private healthcare insurance plan. Therefore, the appropriate comparator for CGM is SMBG as it is the current standard of care for T2D.

PASC agreed that SMBG using glucose test strips, a finger prick blood sample and glucose monitor was the appropriate comparator for CGM using Dexcom ONE+ because SMBG is recommended for people with T2D using insulin and is the current SoC for blood glucose testing included in the Australian diabetes treatment guidelines for the proposed population. PASC noted that the frequency of SMBG can vary between individuals.

Although ongoing calibration of CGMs is not required, PASC acknowledged that occasional SMBG would still be required if people are using CGM because SMBG may be required under certain conditions, such as if a person's diabetes symptoms do not match their CGM glucose readings, if their CGM malfunctions or their sensor is lost or becomes detached, and during the short sensor warm-up period following application of the sensor to the skin when CGM readings are not available. CGM is therefore expected to greatly reduce the use of SMBG in the eligible population, but not completely replace it.

Reference standard

The reference standard is laboratory measured plasma venous blood glucose testing (e.g. using a YSI [Yellow Springs Laboratory Instrument] for glucose testing or equivalent). *PASC agreed that laboratory measured plasma venous blood glucose testing was the appropriate reference standard.*

Outcomes

The following outcomes are relevant to the safety and effectiveness of CGM in the proposed subpopulations.

Safety

AEs attributable to the blood glucose monitoring may include events caused by obtaining a finger prick capillary blood sample, glucose meter or glucose test strip failure, local events (e.g. skin irritation) due to

sensor insertion or wear, sensor malfunction or detachment, and broken sensor wire left in the skin after the sensor is removed or accidently dislodged.

The psychological impact of obtaining finger prick blood samples compared to continuous monitoring of glucose readings/alerts is another relevant safety consideration, to be considered under the effectiveness of monitoring (psychological health).

PASC noted that health outcomes related to the safety of testing included broken sensor wire left in the skin after sensor removal.

Although failure of CGM or SMBG testing may be considered a safety issue, this outcome has been included under "analytical validity" to avoid double counting. The downstream implications of a monitoring failure would be considered under effectiveness.

Analytical validity

Sensor accuracy is measured relative to the reference glucose values from standard of laboratory plasma venous blood glucose testing or glucose values from SMBG. The mean absolute relative difference (MARD) is currently the most common metric used to assess the performance of CGM systems. MARD is the average of the absolute error between all CGM values and matched reference glucose values. A small percentage indicates that the CGM readings are close to the reference glucose value, whereas a larger MARD percentage indicates larger differences between the CGM and reference glucose values and lower accuracy. Although an exact cut-off for sensor accuracy has not been established, a MARD of <10% is generally considered as acceptable (Heinemann et al. 2020).

Difference in accuracy between individual sensors both within and between manufactured lots may be relevant as CGM users will use multiple sensors per year with an expectation that data is comparable between sensors. Differences in accuracy at the beginning, middle and end of the sensor wear period may also be relevant.

Accuracy is normally assessed during evaluation of investigative tests for reimbursement (Medical Services Advisory Committee). Accuracy is evaluated by the TGA during regulatory approval but these data are not available to MSAC for their subsequent consideration. The vast majority of CGM devices now have comparable and clinically acceptable accuracy (Oliver, Reddy & Leelarathna 2024). The applicant has indicated that direct evidence from RCTs for the impact of CGM on glycaemic outcomes will be presented in the assessment report. The applicant considers that the impact of accuracy is implicitly captured in the glycaemic outcomes evidence and therefore further evaluation of Dexcom ONE+ accuracy is no longer required.

PASC noted that Dexcom ONE+ CGM's accuracy was currently undergoing assessment by the TGA as part of the regulatory approval process but that data presented to the TGA was not subsequently made available to MSAC for evaluation. PASC highlighted that, in accordance with the MSAC guidelines, MSAC usually assesses the comparative diagnostic accuracy of investigative tests as part of the evaluation framework. Following discussion, PASC considered that the provision of accuracy data in the assessment report would provide additional information to support MSAC discussions when considering the relative merits of CGM versus SMBG for monitoring glycaemic control in people with T2D.

Information on concordance between CGM and SMBG at different glucose concentrations, when glucose levels are rapidly rising and falling and when blood glucose is within the hypoglycaemic and hyperglycaemic range is required to assess the relative performance of CGM and SMBG in circumstances where information would be expected to inform treatment decisions to avoid hypoglycaemic and hyperglycaemic excursions outside of the target glucose range.

Data on the proportion of sensors that are active (no sensor attenuation, termination or loss) for the 10-day period of wear and the mean and median time a sensor remains active during wear is relevant as it impacts on effective glycaemic control and availability of CGM data on which to base management decisions.

Glycaemic control

For populations with suboptimal glycaemic control, achieving glycaemic control, specifically HbA1c, by maintaining blood glucose levels within the target range using CGM or SMBG is an intermediate/surrogate clinical outcome associated with improvement in health outcomes such as reduction in microvascular and macrovascular T2D complications. The applicant has indicated that they will present evidence in the assessment report demonstrating that HbA1c is a reliable predictor of both microvascular and macrovascular outcomes for T2D. High HbA1c levels are a surrogate marker for the development of long-term diabetes complications in people with T2D, and HbA1c has been used as the primary endpoint in many CGM studies (Beck et al. 2017). However, a number of other factors beyond levels of blood glucose can influence HbA1c levels (Kaiafa et al. 2020). The minimum clinically important difference (MCID) for change in HbA1c levels is reported as a reduction of 0.5% (Kaiafa et al. 2020). *PASC noted that the minimum clinically important difference (MCID) for HbA1c in T2D reported in the published literature ranges from 0.3% to 0.5% and that supporting evidence for selection of the MCID for HbA1c would be included in the assessment report.*

PASC acknowledged that HbA1c levels are a widely-used intermediate/surrogate measure of glycaemic control and was the main effectiveness outcome included in the economic evaluation of CGM cost effectiveness. The applicant noted that existing economic models for T2D rely on HbA1c because this is the surrogate outcome with the most historical evidence around its relationship to long term health outcomes and therefore use of HbA1C as the key outcome represented the most pragmatic approach to modelling.

As HbA1c reflects average glucose levels over the previous 3 months, it does not provide information about current glycaemic control, glycaemic excursions and acute complications of hypoglycaemia and hyperglycaemia. HbA1c also fails to provide information on the magnitude and frequency of glucose variability (Battelino et al. 2019). *The applicant's independent clinical expert noted that HbA1c levels do not correlate with glucose levels in approximately 20% of people with T2D.*

A list of ten core CGM metrics based on the expert opinion of an international consensus group has been developed for use in clinical practice (Table 3) (Battelino et al. 2019; Danne et al. 2017). These metrics also form the basis of outcomes reported in many clinical studies of CGM for both T1D and T2D. Some of these CGM metrics are included in the MSAC application and form the basis of the clinical claim of superiority of CGM with Dexcom ONE+ over SMBG. They have been included in the PICO as surrogate/intermediate effectiveness outcomes to be assessed for the comparison of CGM and SMBG (Table 3) (Battelino et al. 2019).

Table 3 Standardized CGM metrics for clinical care in nonpregnant individuals with T1D or T2D included as outcomes in the PICO

Metric	Interpretation	Goals
1. Number of days CGM worn		14-day wear for pattern management
2. Percentage of time CGM is active (recommend 70% of data)		70% of data from 14 days*
3. Mean glucose	Simple average of glucose values	**
4. Glucose management indicator	Calculated value approximating HbA1c (not always equivalent)	**
5. Glycaemic variability (%CV) target	Spread of glucose values	≤36% †
6. Time above range (TAR): % of readings and % of time >250mg/dL (>13.9 mmol/L)	Level 2 hyperglycaemia	<5% (most adults); <10% (older adults)
7. Time above range (TAR): % of readings and % of time 181–250mg/dL (10.1–13.9 mmol/L)	Level 1 hyperglycaemia	<25% (most adults); <50% (older adults)‡
8. Time in range (TIR): % of readings and % of time 70–180 mg/dL (3.9–10.0 mmol/L)	In range	>70% (most adults); >50% (older adults)
9. Time below range (TBR): % of readings and % of time 54–69mg/dL (3.0–3.8 mmol/L)	Level 1 hypoglycaemia	<4% (most adults); <1% (older adults)§
10. Time below range (TBR): % of readings and % of time <54mg/dL (<3.0 mmol/L)	Level 2 hypoglycaemia	<1%

Source: (American Diabetes Association 2024a; Battelino et al. 2019)
CGM = continuous glucose monitoring; %CV = percentage coefficient of variation; TAR = time above range; TBR = time below range; TIR = time in range.
* The standardised glucose metrics are for 14 days. The Dexcom ONE+ sensor has a 10-day wear period and the 70% activity would also apply to the 10-day wear period when reporting the time CGM is active. **Goals for these values are not standardized. †Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycaemia for those receiving insulin or sulfonylureas. ‡Goals are for level 1 and level 2 hyperglycaemia combined. §Goals are for level 1 and level 2 hypoglycaemia combined.

The consensus group identified "time in ranges" (i.e. TIR, TAR and TBR; see Table 3) as a metric of glycaemic control that provides more actionable information than HbA1C alone (Battelino et al. 2019). The consensus group agreed that expressing time in the various ranges can be done as the percentage (%) of CGM readings, average hours and minutes spent in each range per day, or both, depending on the circumstances (Battelino et al. 2019). Time in range (TIR) is an important metric in the evaluation of glycaemic control. The international consensus recommendations on TIR have proposed that a target glucose range of 3.9–10 mmol/L is an appropriate standard against which to assess the percentage of readings or time in range for people with either T1D or T2D, both in clinical practice and in clinical trials (Battelino et al. 2019). Percentage of TIR correlates inversely with HbA1c (Wilmot et al. 2021) and there is increasing evidence that lower TIR values are linked to macrovascular and microvascular complications (Beck, Bergenstal, Cheng, et al. 2019; Beck, Bergenstal, Riddlesworth, et al. 2019; Lu et al. 2018; Lu et al. 2021).

Although glucose targets are individualised and collaborative, the International Consensus on Time in Range established a series of target glucose ranges (TIR, time below range [TBR] and time above range [TAR]) and recommendations for time spent within these ranges for different diabetes populations including for people with T2D and older or high-risk individuals. For pregnant women with T2D or

gestational diabetes, target ranges were agreed but there was insufficient evidence to develop target times or percentages of readings within the different ranges (i.e. target TIR, TAR and TBR and % of readings within these ranges have not been developed) (Battelino et al. 2019; Danne et al. 2017). These parameters are evaluated together with the AGP for clinical decision making.

Other relevant outcomes from CGM include TBR, TAR, number of hypoglycaemic or hyperglycaemic excursions and their severity, and glycaemic variability (e.g. percentage coefficient of variation [%CV]). People with T2D generally have less glycaemic variability and hypoglycaemic excursions than people with T1D (Rama Chandran et al. 2018). Therefore, people with T2D can often achieve more TIR and less TBR compared to people with T1D. Short-term glycaemic variability is associated with the development and progression of microvascular complications, and, to a lesser extent, macrovascular complications (Ceriello, Monnier & Owens 2019). It is recommended that the percentage CV for glycaemic variability should be lower than 36% although a lower target %CV (<33%) may protect against hypoglycaemic excursions (Battelino et al. 2019).

Other consensus metrics for consideration are the number of days the CGM sensor is worn and proportion of time that CGM is active over a 14-day period. It is recommended that CGM is active (i.e. reporting glucose data) for >70% of the time over a 14-day period as lower activity has been associated with reduction in glycaemic control and ability to achieve target HbA1c levels (Battelino et al. 2019).

Treatment decisions based on information obtained from glucose monitoring (e.g. erroneous insulin titration leading to severe hypoglycaemia requiring medical intervention or hospitalisation; incidence of hyperglycaemia, severe hyperglycaemia and diabetic ketoacidosis) can impact on effectiveness.

Change in management

Effective use of data from SMBG or CGM requires that the user (or their parent/carer) or their diabetes health professional can interpret the CGM data and act upon the information appropriately to optimize their T2D treatment (i.e. guide their insulin titration or other interventions).

Other relevant outcomes include adherence to both monitoring (CGM or SMBG) and treatment, as well as the use of lifestyle interventions (e.g. diet and exercise).

Health outcomes

A reduction in diabetes complications (cardiovascular and microvascular complications), reduced mortality, improved quality of life, and improved psychological health have all been associated with improved glycaemic control. HbA1c is the most widely accepted measure of overall, long-term blood glucose control in patients with diabetes. Reduced HbA1c 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). Other relevant measures of improvements in health outcomes are reductions in the number of all-cause hospitalizations, acute diabetes-related hospitalizations and/or acute diabetes-related emergency room visits (Garg et al. 2024).

Those living with the condition continue to report not only suboptimal health metrics, but also a high burden related to care practices. Qualitative studies identified barriers to SMBG, including frustration with readings of hyperglycaemia, fear of needles, inconvenience, and feelings of a lack of self-efficacy (Ida, Kaneko & Murata 2019; Ong, Chua & Ng 2014). Patients using CGM may experience health benefits from the avoidance of daily finger prick testing and the burden of SMBG (Matza et al. 2017). In addition, the availability of CGM and option to share monitoring data may have additional psychological benefits (e.g. reduction in anxiety, hypoglycaemic confidence) for carers of older or at-risk people with T2D and parents of children with T2D.

Other relevant considerations

- Acceptability, wearability and usability of CGM versus SMBG
- Impact on daily life and work attendance
- User or carer satisfaction/perceived qualitative benefits and disadvantages of CGM
- Motivation to initiate use of CGM and factors contributing to or impacting on continued use of CGM
- Continuity of supply (sensors etc)
- Impact of CGM on self-management and the model of T2D care for insulin users (e.g. patient empowerment, education and support, change in care location, frequency of routine follow-up, use of telehealth support, remote monitoring of patient's glycaemic control)

PASC noted that the outcome of 'Adherence to glucose testing' should be amended to 'Adherence to CGM or SMBG'. PASC considered that 'adherence to CGM or SMBG and 'acceptability, wearability and usability of CGM versus SMBG' were intermediate outcomes for health or change in management with the latter under the subheading of 'other relevant considerations'

The following outcomes are relevant to the safety and effectiveness of CGM in the proposed subpopulations and are included in the PICO:

Patient relevant outcomes
Direct evidence for safety and effectiveness
Safety:
- Local adverse events (AEs) associated with glucose testing

Intermediate outcomes:
- Glycaemic control
    - glycated haemoglobin (HbA1c)
    - time in range (TIR), time below range (TBR) and time above range (TAR)
    - number of hypoglycaemic/hyperglycaemic excursions
    - glycaemic variability
- Change in body weight/body mass index (BMI)

Effectiveness:
- T2D complications (e.g. cardiovascular and microvascular complications, kidney disease, neuropathy/nerve damage, retinopathy/eye disease, amputations/foot ulcers)
- Mortality
- Quality of life

- Psychological health
- Hypoglycaemic or hyperglycaemic events resulting in emergency room visit/hospitalisation

Additional outcomes using linked evidence approach
Analytical validity:
- Accuracy, concordance
- Monitoring failure rate

Change in management
- Adherence to CGM or SMBG
- Adherence to treatments
- Uptake or alteration of lifestyle interventions (e.g. diet and exercise) and treatment (e.g. glucose-lowering therapy)

Other relevant considerations
- Acceptability, wearability and usability of CGM versus SMBG
- Ability to share blood glucose data with physician, relative or carer
- Patient/carer satisfaction
- Self-efficacy (person's belief in their ability to effectively manage their T2D and achieve their clinical goals)
- Work/school absenteeism and daily functioning

Healthcare system outcomes
- Cost, cost-effectiveness
- Financial implications (financial impact, overall healthcare costs, etc.)

PASC noted that uptake of exercise is a separate measure from body weight/BMI which is not a measure of uptake directly and that the latter needs to be recategorized.

PASC noted that the outcome of QoL is a different concept from the outcome of psychological health. PASC advised that it was therefore important to avoid any double counting of benefits in the assessment when discussing QoL versus psychological health and other related outcomes (e.g. self-efficacy). Self-efficacy was considered to be an "other relevant consideration" rather than a direct health outcome.

Severe hypoglycaemia and hyperglycaemia are relevant health outcomes that may be measured by the rate of hospitalisations and emergency room visits. The applicant's independent clinical expert noted that hypoglycaemia could be just as important as Hb1AC levels as a predictor of glycaemic control and therefore as a proxy for longer term health outcomes, but there was a scarcity of long-term studies of CGM use which focused on hypoglycaemia.

Assessment framework

The clinical claim is that CGM using Dexcom ONE+ results in superior health outcomes compared to SMBG based on improvement in measures of glycaemic control and QoL.

A limited number of studies have investigated the use of CGM in children, adolescents and young adults with T2D. There was no supporting evidence for the effectiveness of CGM in women with T2D during pregnancy; effectiveness and safety of CGM would be inferred from use in pregnant women with T1D.

The effectiveness of CGM in both subpopulations proposed in MSAC Application 1785 is supported by studies that can broadly be categorised based on the intensity of their insulin regimens as supporting use of CGM in either Subpopulation 1 or Subpopulation 2. The MSAC application considers that for patients with uncontrolled diabetes (HbA1c >7%), the risks of long-term complications are the same irrespective of what type of insulin or pharmacological regimen a person with T2D is receiving. Therefore, both intensive insulin users and non-intensive insulin users could benefit from the use of CGM to lower their HbA1c levels and improve time in their target glycaemic range.[1] There is comparative clinical evidence for CGM versus SMBG in terms of improving glycaemic control (surrogate/intermediate clinical outcome) for both proposed subpopulations (Bao et al. 2022; Beck et al. 2017; Billings, Parkin & Price 2018; Davis et al. 2022; Karter et al. 2021; Lever et al. 2024; Lind et al. 2024; Martens et al. 2021). However, evidence would be required to demonstrate that improving glycaemic control (considered a surrogate/intermediate clinical outcome in the assessment framework) results in clinically significant improvements in health outcomes (e.g. microvascular and macrovascular complications) and other diabetes-relevant qualitative outcomes (e.g. QoL, diabetes distress, patient satisfaction, self-efficacy) for both proposed subpopulations.

It may be particularly important to demonstrate that glycaemic control is a valid surrogate for health outcomes in vulnerable populations with T2D (e.g. Aboriginal and Torres Strait Islander adults and children, people with poor social support, and people with multiple comorbidities) with suboptimal glycaemic control. These populations are considered to have a high unmet need but direct evidence for improvement in health outcomes from use of CGM versus SMBG for these populations is likely to be very limited.

PASC noted that the applicant has included studies in the application providing direct evidence for change in HbA1c, which PASC considered to be an intermediate/surrogate health outcome. PASC noted that there were no data from comparative studies direct from test to health outcomes such as mortality and other relevant outcomes such as QoL.

PASC confirmed that the proposed alternative assessment framework which omits consideration of evidence on analytical validity and change in management is acceptable because these elements are already implicitly captured in direct evidence for an impact of the test on clinical (albeit surrogate) outcomes. This is subject to the condition that evidence is also provided that demonstrates that the observed change in HbA1c (or other measure of glycaemic control) is associated with clinically significant improvements in more direct and long term health outcomes and other relevant outcomes (e.g. QoL) . PASC noted that it would also be important to document such evidence for groups with high unmet needs (e.g. Indigenous people, pregnant women, children, people with low social support and individuals with multiple comorbidities) where possible although PASC acknowledged that data specific to these groups may be limited.

While PASC accepted that the proposed alternative assessment framework could be used as the basis for the economic modelling in the applicant developed assessment report (ADAR) for the reasons discussed above, PASC's preference was that analytic validity data should also be presented in the clinical section of the ADAR to allow comparison across CGM systems.

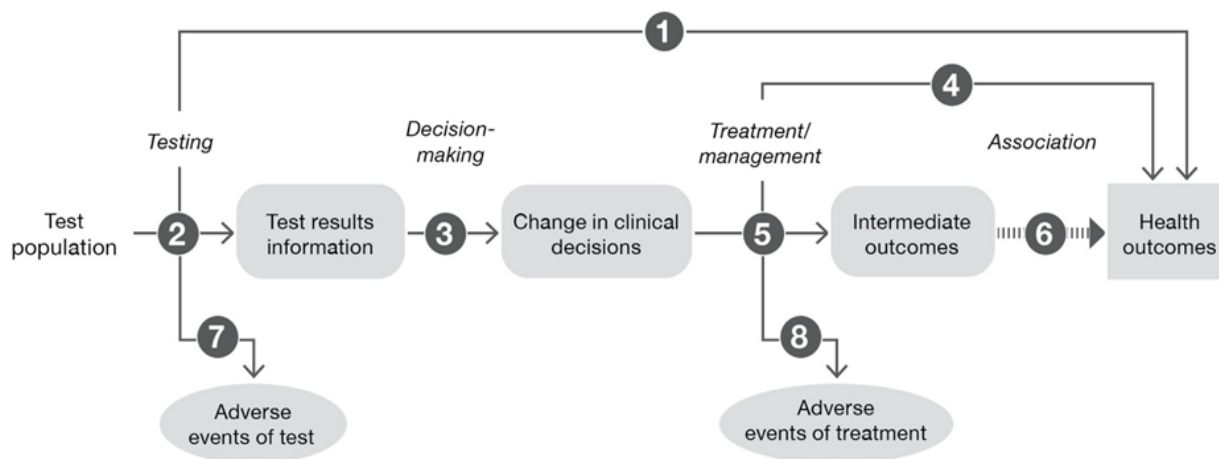The standard assessment framework used for assessment of investigative tests is shown in Figure 5.

Figure 5 Standard assessment framework used for assessment of investigative tests including full linked evidence approach

Figure notes: 1: direct from monitoring to health outcomes evidence; 2: monitory accuracy; 3: change in management (lifestyle interventions such as diet, exercise; insulin treatment regimen); 4: influence of change in management on health outcomes; 5: influence of the change in management on glycaemic measures; 6: association of intermediate outcomes (e.g. glycaemic control) with health outcomes; 7: adverse events due to monitoring (e.g. psychological impact, serious hypoglycaemic event, hyperosmolar hyperglycaemic states; 8: adverse events due to treatment (e.g. impact on glycaemic control; psychological impact; quality of life; hypoglycaemic or hyperglycaemic events)

Questions for the standard assessment framework that are applicable to both test subpopulations, i.e. people with T2D who have suboptimal glycaemic control and are intensive insulin users (Subpopulation 1) or non-intensive insulin users (Subpopulation 2), are as follows:

1. What is the effectiveness of blood glucose monitoring using CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood results (e.g. macrovascular and microvascular complications, mortality, quality of QoL, psychological health)?
2. What is the accuracy of CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood for monitoring blood glucose? What is the concordance between CGM and SMBG testing? What patient-related, device-related or environmental factors could influence accuracy and concordance of CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood for monitoring blood glucose?
3. What is the effectiveness of blood glucose monitoring using CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood in terms of changing clinical decision-making?
4. Are observed changes in clinical management associated with changes in health outcomes (e.g. macrovascular and microvascular complications, mortality, quality of life, psychological health)?
5. Are observed changes in clinical management associated with changes in glycaemic control?
6. Are observed changes in glycaemic control associated with changes in health outcomes (e.g. macrovascular and microvascular complications, mortality, quality of life, psychological health), i.e. is glycaemic control an appropriate surrogate outcome for patient-relevant health outcomes?
7. What is the safety of CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood for monitoring blood glucose?
8. Is the method of blood glucose monitoring associated with differences in diabetes treatment-related AEs?

The assessment framework proposed for Dexcom ONE+ evaluation is shown in Figure 6.
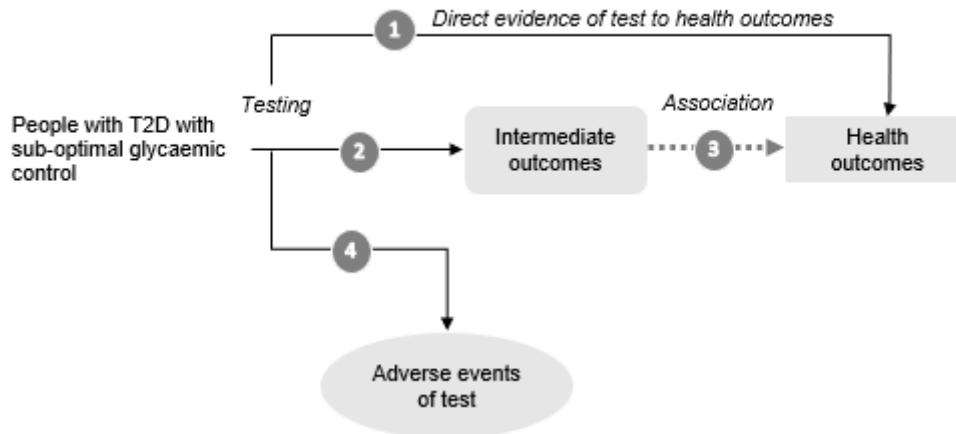
Figure 6 Proposed alternative assessment framework

Figure notes: 1: direct from monitoring to health outcomes evidence (e.g. quality of life); 2: influence of monitoring on intermediate outcomes (e.g. glycaemic control); 3: association of intermediate outcomes with health outcomes (e.g. serious hypoglycaemic event, hyperosmolar hyperglycaemic states, mortality due to severe hypoglycaemia or hyperglycaemia); 4: adverse events due to monitoring (e.g. finger prick injuries, psychological impact)

Questions for the proposed assessment framework that are applicable to both test subpopulations are:

1. What is the effectiveness of blood glucose monitoring using CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood results (e.g. macrovascular and microvascular complications, mortality, quality of QoL, psychological health)?
2. What is the effectiveness of blood glucose monitoring with Dexcom ONE+ CGM versus SMBG in terms of maintaining glycaemic control?
3. Are observed changes in glycaemic control associated with changes in health outcomes (e.g. macrovascular and microvascular complications, mortality, quality of life, psychological health), i.e. is glycaemic control an appropriate surrogate outcome for patient-relevant health outcomes?
4. What is the safety of CGM with Dexcom ONE+ versus SMBG using finger prick capillary blood for monitoring blood glucose?

Clinical management algorithms

Current management algorithm for blood glucose testing

People with T2D who have suboptimal glycaemic control and are intensive insulin users (Subpopulation 1) or non-intensive insulin users (Subpopulation 2) are recommended to carry out SMBG testing using a finger prick capillary blood sample (The Royal Australian College of General Practitioners 2020). The current clinical management algorithm for SMBG for the proposed subpopulations is shown in Figure 7. Comprehensive education regarding blood glucose monitoring, nutrition, and the avoidance and appropriate treatment of hypoglycaemia are considered as critically important for any person using insulin (American Diabetes Association 2024b).

SMBG measures blood glucose levels at a single point in time with testing frequency based on an individual's clinical need as advised by their diabetes healthcare professional. People with T2D and suboptimal glycaemic control receiving intensive insulin therapy, i.e. basal insulin and bolus rapid-acting

insulin (Subpopulation 1) are at increased risk of a hypoglycaemic events and therefore frequently carry out SMBG (on average 6 – 10 times daily or as recommended by their diabetes healthcare professional). People with T2D and suboptimal glycaemic control receiving non-intensive insulin treatment, i.e. basal insulin only (Subpopulation 2) usually carry out SMBG at a lower frequency (on average three times a day or as recommended by their diabetes healthcare professional) as they have a slightly lower risk of hypoglycaemia particularly if their fasting glucose is consistently above the target range i.e. in the hyperglycaemic range (The Royal Australian College of General Practitioners 2020). The target blood glucose range for people with T2D carrying out SMBG is generally 4–7 mmol/L for fasting blood glucose or pre-prandial blood glucose, and 5–10 mmol/L for postprandial blood glucose although these targets may be individualised (The Royal Australian College of General Practitioners 2020).

PASC noted that people with T2D using intensive insulin therapy often need SMBG at a higher frequency than those using basal insulin alone reflecting their increased risk of hypoglycaemic events. These people may have a higher unmet need for more effective blood glucose monitoring and therefore may derive greater benefit from CGM than those on non-intensive insulin regimens.

For adults with T2D who SMBG using finger prick capillary blood samples, a structured assessment at least annually should include (The Royal Australian College of General Practitioners 2024):

- the person's self-monitoring skills
- the quality and frequency of testing
- checking that the person knows how to interpret the blood glucose results and what action to take
- the impact on the person's quality of life
- the continued benefit to the individual
- the equipment used.

The blood glucose reading obtained from the meter is displayed in mmol/L blood and is stored in the meter's memory for future reference including the date and time of the blood sample test. This allows the person with T2D or their diabetes healthcare professional to review their readings.

If their blood glucose levels are outside of the target range, their insulin treatment (or other glucose-lower therapies included in their treatment regimen) may need to be adjusted, as insulin has a very narrow therapeutic range. Some people with T2D can self-manage their own insulin treatment by titrating the amount of insulin required to correct their blood glucose levels or are able to administer other management such as rapid acting oral carbohydrate if their blood glucose is in the hypoglycaemic range. Alternatively, they may seek advice from a diabetes healthcare professional about adjusting their insulin regimen based on the monitoring results on their glucose meter. If their blood glucose readings suggest they require an urgent clinical intervention (e.g. their glucose reading indicates they are at risk of severe hypoglycaemia or hyperglycaemia), they may seek emergency care by calling emergency services or going to an emergency department. Regular follow-up consultation with their diabetes healthcare professional at ~3 to 6 monthly intervals, which includes clinical assessment and HbA1c testing, provides additional information about the effectiveness of the T2D treatment regimen over the previous 3 months. This guides ongoing treatment and frequency of SMBG if insulin treatment is intensified.
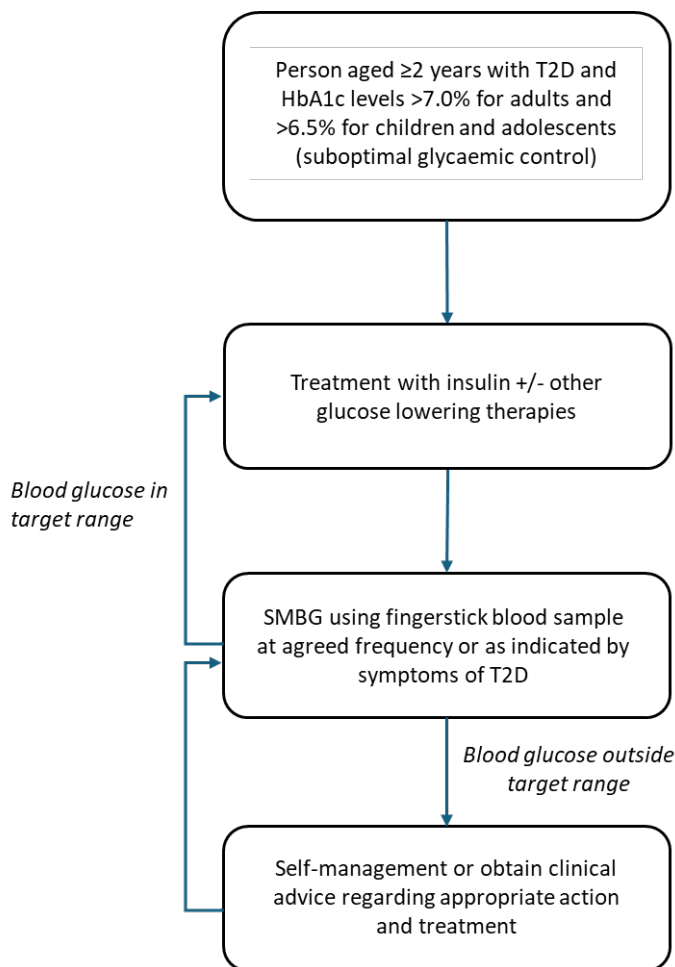
Figure 7 Current clinical management algorithm of SMBG for a person with T2D and suboptimal glycaemic control requiring insulin treatment

Source: Adapted from Figure 6, p.16 of MSAC Application 1785 PICO Set 1.
HbA1c = glycated haemoglobin; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes.
Note: The agreed frequency of SMBG is individualised and is based on a patient's clinical need and advice from their diabetes healthcare professional.

Proposed management algorithm for blood glucose testing

The proposed management algorithm for people with T2D who have suboptimal glycaemic control and are intensive insulin users (Subpopulation 1) or non-intensive insulin users (Subpopulation 2) is shown in Figure 8.

A person with T2D and suboptimal glycaemic control receiving either intensive insulin treatment (Subpopulation 1) or non-intensive insulin treatment (Subpopulation 2), either with or without other glucose lowering therapies, will continue to monitor their blood glucose levels. Instead of carrying out SMBG, they will have the option to use CGM. Even though CGM provides more information than SMBG, not all people with T2D requiring insulin treatment may wish to use CGM to check their blood glucose. People with T2D using insulin who choose to continue SMBG will follow the current management algorithm in Figure 7.

CGM with Dexcom ONE+ provides a AGP of glucose levels and hence glycaemic control over the whole 24-hour period, if the system is being used consistently and correctly. The CGM also provides the user with information about how rapidly their blood glucose is rising or falling and alerts when the blood glucose levels exceed or fall below individualised prespecified blood glucose thresholds which helps to detect episodes of hyperglycaemia and hypoglycaemia facilitating both acute management (e.g. insulin titration or administration of rapid acting oral carbohydrate) and long-term adjustments to therapy. CGM provides glucose level data in real-time to allow the person or their parent/carer to make decisions about insulin titration to prevent their glucose becoming too high (hyperglycaemia) or falling too low (hypoglycaemia). If CGM indicates that the person's glucose level is relatively stable and is within the target range, then no changes to the insulin dose or frequency are likely to be required. If the person's glucose levels are outside the target range, the person can follow prior clinical advice about the appropriate action to take or seek further advice from their diabetes healthcare professional if they are unsure. If the glucose levels indicate that they require urgent medical assistance, they may call emergency services or attend an emergency department. Because CGM provides an AGP of their glucose level, more information is available to guide acute and long-term treatment decisions by the user and their diabetes healthcare professional; treatment decisions based on CGM may be different than those based on SMBG because more information is available at the point of decision making. As CGM data from Dexcom ONE+ can be shared with a diabetes healthcare professional via an app, the diabetes healthcare professional is able to provide appropriate advice based on the AGP. CGM data can also be shared via an app with a parent or carer which is essential for use of CGM in young children included in the proposed subpopulations, people with disabilities who are unable to self-manage their T2D treatment and frail or elderly people with T2D who may need additional assistance in interpreting their CGM data and managing their insulin treatment.

A person using CGM would not usually need to carry out SMBG using a glucose meter. However, if the person with T2D experiences acute diabetes-related symptoms that are not aligned with the blood glucose readings from CGM, they would need to check that their CGM glucose readings are correct by carrying out SMBG from a finger prick capillary blood sample using a glucose test strip. If the CGM glucose readings are incorrect and the person's glucose levels are in the hypoglycaemic or hyperglycaemic range, they can follow prior clinical advice about the appropriate action to take or seek further medical advice regarding the most appropriate course of action including titration of their insulin dose or administration of rapid acting oral carbohydrate. If they require urgent medical attention, they can call the emergency services or attend the emergency department. Subpopulation 1 that includes people with T2D requiring intensive insulin treatment are at increased risk of hypoglycaemic excursions requiring interventions such as self-titration of their insulin dose, administration of rapid acting oral carbohydrate or consultation with their diabetes healthcare professional. They may require assistance from a diabetes healthcare professional or emergency services and treatment in an emergency department, depending upon the severity of the hypoglycaemia. The risk of hypoglycaemia is likely to be lower for Subpopulation 2 using basal insulin only.

Regular follow-up consultation with their diabetes healthcare professional at ~3 to 6 monthly intervals would continue in the proposed management algorithm.

PASC noted that the current and proposed management algorithms were similar and included management of blood glucose levels (glycaemic control) rather than long term health outcomes. The proposed algorithm for CGM included occasional use of SMBG to confirm blood glucose levels when a person's diabetes symptoms did not match their CGM blood glucose readings.
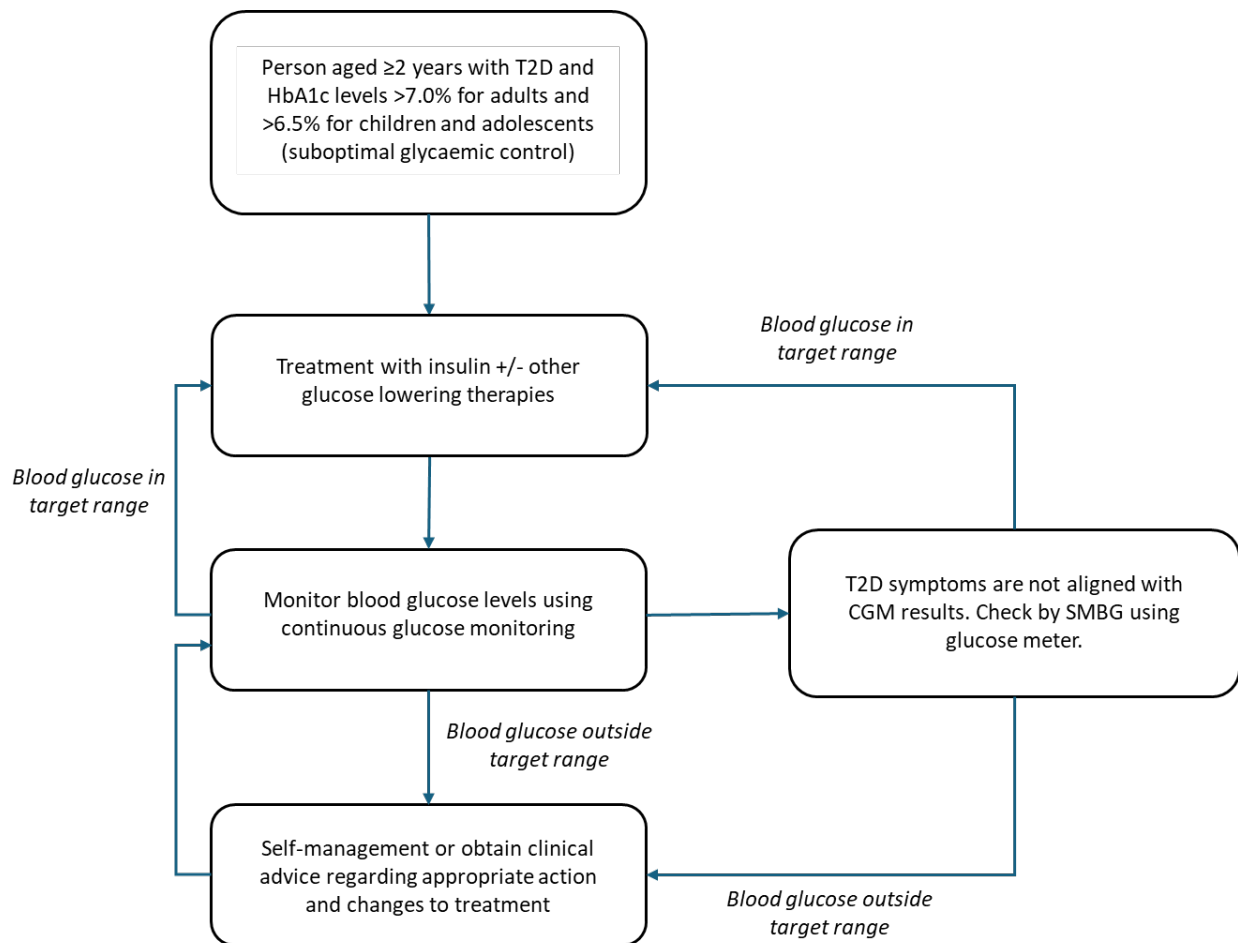
Figure 8 Clinical management algorithm for CGM of a person with T2D and suboptimal glycaemic control requiring insulin treatment

Source: Adapted from Figure 7, p.16 of MSAC Application 1785 PICO Set 1
HbA1c = glycated haemoglobin; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes.

Proposed economic evaluation

The clinical claim is that the use of the Dexcom ONE+ CGM system by the proposed subpopulations results in superior health outcomes and non-inferior safety compared to self-monitoring of blood glucose (SMBG). There was no claim in the application for the relative safety of CGM versus SMBG for either of the proposed subpopulations with T2D requiring insulin treatment. *PASC noted that the clinical claim for use of the Dexcom ONE+ CGM by the proposed subpopulations was for superior health outcomes and non-inferior safety compared to SMBG.*

Based on the clinical claim that CGM is more effective than SMBG, the most suitable economic analysis would be a cost effectiveness analysis or cost-utility analysis (Table 4). *PASC considered that that the most appropriate economic evaluation would be a cost-utility analysis.*

Table 4 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	**Uncertain[a]**	**Noninferior[b]**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
b An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

Proposal for public funding

This MSAC application is requesting NDSS funding for subsidised Dexcom ONE+ CGM products for people aged ≥2 years with T2D that have suboptimal glycaemic control (uncontrolled T2D) who require either treatment with basal insulin and rapid acting insulin (intensive insulin users; Subpopulation 1) or require treatment with basal insulin only (non-intensive insulin users; Subpopulation 2). *PASC confirmed that for people with T2D the proposed source of public funding for CGM was the NDSS, as for T1D (i.e. no MBS listing is being requested).*

Currently, all people with T1D can apply for subsidised access to CGM products if they meet the eligibility criteria. As for people with T1D accessing CGM products through the NDSS, it is anticipated that people with T2D applying to access Dexcom ONE+ CGM products will be required to be registered with the NDSS and see an authorised health professional to determine whether they meet the NDSS 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 to include GPs who currently prescribe and/or titrate insulin may be beneficial by reducing the treatment burden on secondary care.

PASC considered the diabetes support networks for CGM were in place, however a staged introduction of CGM for people with T2D, could be considered by Government should there be an expansion to eligibility to ensure demand can be met. PASC indicated that adding GPs to the list of authorising healthcare professionals for NDSS-funded CGM was not a matter for MSAC consideration.

A Dexcom ONE+ sensor is disposable and can be worn for a maximum period of 10 days. The cost of CGM is the same for both proposed subpopulations (i.e. regardless of intensity of insulin use). Therefore, each eligible person would require 36 sensors per year. The applicant has not currently provided the cost of the Dexcom ONE+ sensor. The total cost of the Dexcom ONE sensor plus reusable transmitter provided in the application was AUD $REDACTED per year (equivalent to AUD $REDACTED/month); this cost was used for

the Dexcom ONE+ estimates in the absence of a price for the Dexcom ONE+ sensor. This figure does not include the cost of a receiver if the eligible person prefers to use a receiver or is unable to access/utilise the Dexcom app on a smart device for their CGM with Dexcom ONE+. The estimates assume optimal use of the Dexcom ONE+ system (i.e. no sensors become detached or malfunction and that the sensors and transmitter remain fully operational for the maximum duration). The applicant confirmed in their pre-PASC response that updated cost estimates for Dexcom ONE+ CGM would include the cost of providing replacement sensors to the user (e.g. due to sensor malfunction).

The MSAC application included utilisation estimates based on extrapolation of annual NDSS data for people with T2D using insulin for the period June 2017 to June 2023. Data for the proportion of people with T2D with uncontrolled T2D (71%) and for the proportion of people with T2D who require intensive insulin treatment (70%) or non-intensive insulin treatment (27%) was obtained from the ANDA in 2022. The uptake of CGM in both Subpopulation 1 and Subpopulation 2 was estimated as REDACTED%, REDACTED%, REDACTED% and REDACTED% in Year 2025, 2026, 2027, and 2028, respectively.

Estimated CGM uptake and total cost over the first 4 years of funding via the NDSS for the proposed subpopulations are:

Subpopulation 1 (intensive insulin users)

Table 5 Estimated total annual cost of CGM with Dexcom ONE+ for Subpopulation 1 (intensive insulin users)

	2025	2026	2027	2028	Source / description
Patients with type 2 diabetes	1,348,427	1,379,517	1,410,608	1,441,784	Extrapolated based on NDSS: Diabetes data snapshots (July 2017; July 2018; July 2019; July 2020; July 2021; July 2022; July 2023)
Insulin users with type 2 diabetes	331,044	339,290	347,535	355,803	Extrapolated based on NDSS: Diabetes data snapshots (July 2017; July 2018; July 2019; July 2020; July 2021; July 2022; July 2023)
T2D intensive insulin users, %	70%	70%	70%	70%	Australian National Diabetes Audit
T2D intensive insulin users, n	231,730	237,503	243,274	249,062	
Uncontrolled T2D, %	71%	71%	71%	71%	Australian National Diabetes Audit
Uncontrolled T2D, n	164,528	168,627	172,725	176,834	
Uptake of CGM, %	REDACTED%	REDACTED%	REDACTED%	REDACTED%	Applicant assumption
CGM use, n	REDACTED%	REDACTED%	REDACTED%	REDACTED%	
Annual cost of Dexcom ONE+ per person, AUD $	$REDACTED	$REDACTED	$REDACTED	$REDACTED	Based on current price of Dexcom ONE CGM sensor plus reusable transmitter supplied in the application. Proposed cost of Dexcom ONE+ CGM sensor (combined sensor and transmitter) to be provided in assessment report.
Total annual cost of CGM for Subpopulation 1, AUD $ *	**$REDACTED**	**$REDACTED**	**$REDACTED**	**$REDACTED**	

Source: MSAC Application 1785 utilisation and cost estimates
AUD $ = Australian dollars, CGM = continuous glucose monitoring, T2D = type 2 diabetes
* It should be noted that these estimates assume that the cost of Dexcom ONE+ per year is the same as Dexcom ONE, the price remains the same between 2025 and 2028, the estimated uptake of CGM is accurate, that all people started using Dexcom ONE+ CGM at the beginning of that year (rather than staged uptake of CGM throughout the year), that all people continued using CGM for a complete 12 months and that nobody discontinued use of CGM between 2025 to 2028.

The estimated total annual cost of Dexcom ONE+ to the NDSS would be $REDACTED in 2025 (Year 1) rising to $REDACTED in 2028 (Year 4).

Subpopulation 2 (non-intensive insulin users)

Table 6 Estimated total annual cost of CGM with Dexcom ONE+ for Subpopulation 2 (non-intensive insulin users)

	2025	2026	2027	2028	Source / description
Patients with type 2 diabetes	1,348,427	1,379,517	1,410,608	1,441,784	Extrapolated based on NDSS: Diabetes data snapshots (July 2017; July 2018; July 2019; July 2020; July 2021; July 2022; July 2023)
Insulin users with type 2 diabetes	331,044	339,290	347,535	355,803	Extrapolated based on NDSS: Diabetes data snapshots (July 2017; July 2018; July 2019; July 2020; July 2021; July 2022; July 2023)
T2D non-intensive insulin users, %	27%	27%	27%	27%	Australian National Diabetes Audit
T2D non-intensive insulin users, n	89,382	91,608	93,834	96,066	
Uncontrolled T2D, %	71%	71%	71%	71%	Australian National Diabetes Audit
Uncontrolled T2D, n	63,461	65,041	66,622	68,207	
Uptake of CGM, %	REDACTED%	REDACTED%	REDACTED%	REDACTED%	Applicant assumption
CGM use, n	REDACTED%	REDACTED%	REDACTED%	REDACTED%	
Annual cost of Dexcom ONE+ per person, AUD $	$REDACTED	$REDACTED	$REDACTED	$REDACTED	Based on current price of Dexcom ONE CGM sensor plus reusable transmitter supplied in the application. Proposed cost of Dexcom ONE+ CGM sensor (combined sensor and transmitter) to be provided in assessment report.
Total annual cost of CGM for Subpopulation 2, AUD $ *	**$REDACTED**	**$REDACTED**	**$REDACTED**	**$REDACTED**	

Source: MSAC Application 1785 utilisation and cost estimates
AUD $ = Australian dollars, CGM = continuous glucose monitoring, T2D = type 2 diabetes
* It should be noted that these estimates assume that the cost of Dexcom ONE+ per year is the same as Dexcom ONE, the price remains the same between 2025 and 2028, the estimated uptake of CGM is accurate, that all people started using Dexcom ONE+ CGM at the beginning of that year (rather than staged uptake of CGM throughout the year), that all people continued using CGM for a complete 12 months and that nobody discontinued use of CGM between 2025 to 2028.

The estimated total annual cost of Dexcom ONE+ to the NDSS would be $REDACTED in 2025 (Year 1) rising to $REDACTED in 2028 (Year 4).

PASC agreed that the source of the applicant's figures for CGM uptake over the first four years in the proposed populations was unclear and therefore current estimates of cost for each subpopulation provided in the MSAC application were uncertain. PASC noted that the applicant confirmed in their pre-PASC response that updated cost estimates would be provided in the assessment report.

Application 1785 – Dexcom ONE+ continuous glucose monitoring system for people with insulin dependent type 2 diabetes

Summary of public consultation input

PASC noted and welcomed consultation input from 5 organisations and 3 individuals, 1 of whom was a consumer and 2 health professionals.

The organisations that submitted input were:

- Australian Diabetes Society
- Medtronic Australasia
- Pharmaceutical Society of Australia (PSA)
- Primary Care Diabetes Society of Australia (PCDSA)
- Royal Australian College of General Practitioners (RACGP)

The consultation input received was predominantly supportive of public funding for Dexcom ONE CGM system for people with insulin dependent T2D. *PASC noted that there was stakeholder support for broad use of CGMs in people with T2D.*

Medtronic and PCDSA were supportive of public funding for CGM for people with diabetes but not as proposed in the application (please see 'Additional Comments' section below for further information). The consultation input raised a number of concerns, primarily in relation to difficulty accessing CGM devices and services via the NDSS and the need to broaden the proposed eligible population.

Consumer Input

Consumer input stated that people with T2D felt blind about what was going on inside their body and that CGM technology is amazing as it allows people to see the data and truly understand how diet, exercise and stress affected blood glucose levels. For some people, in the absence of CGM, the fear of medications causing hypoglycaemic events dissuaded them from using insulin and impeded them from taking the optimal dose. Currently the cost of CGM is a barrier for people with T2D.

Benefits and Disadvantages

The main benefits of public funding received in the consultation input included dramatically improving glycaemic control, alarms for high or low glucose levels, the ability for people to monitor food choices and increased engagement in diabetes management. PCDSA stated that CGM is beneficial for people with T2D who have cognitive impairment, as carers are able to monitor glycaemic levels and be alerted to approaching hypoglycaemic events, allowing carers to take preventive action. Input also stated that long term use of CGM contributed to optimally controlled blood glucose levels and prevented future complications from diabetes including retinopathy, amputations, cardiovascular events, kidney damage and neuropathy.

The main disadvantages of public funding received in the consultation input included difficulty accessing CGM via the NDSS and the RACGP had concerns about the lack of long-term efficacy data related to the use of CGM. The RACGP queried whether the benefits of CGM would be sustained in practice given the request for permanent ongoing funding (i.e. would real-world data demonstrate the same extent of benefit observed in trials over time?).

Population, Comparator (current management) and Delivery

The consultation input ranged from disagreeing to agreeing with the proposed population. Medtronic and PCDSA advocated to expand the population to all people with insulin dependent diabetes, with PCDSA stating that the population should include people regardless of HbA1c levels. A health professional stated that the population should include people with type 3c diabetes, maturity-onset diabetes of the young (MODY) and gestational diabetes. The RACGP and PSA stated that CGM is most beneficial in people commencing insulin regimes as it allows titration of insulin doses and information on stabilising glycaemia.

The consultation input mostly agreed with the proposed comparator. One health professional stated that there is no comparator as SMBG has limited benefit and does not provide alerts for hypoglycaemic events. Consumer input included that some people were unable to perform SMBG themselves as it can be difficult to perform for older patients with arthritis or it makes them light-headed and sick.

Other services identified in the consultation input as being needed to be delivered before or after the intervention included patient management and support through a multi-disciplinary team and diabetes education. Most of the input raised the issue of difficulty accessing CGM due to limited professionals who can sign the NDSS forms authorising subsidised CGM. The Australian Diabetes Society support the RACGP position that GPs should be included in the authorised certifier group to provide patients with access to subsidised CGM, as removing patients from the GP setting would increase costs, fragment care and burden patients and carers, particularly in regional and remote areas. Medtronic noted that access and workforce issues are an important policy consideration, especially if there is an increased burden on parts of the workforce without the capacity to support ongoing management of diabetes with the insights from CGM.

Additional Comments

Medtronic stated that CGM alone is investigative not therapeutic, and that it was important to consider the relationship between CGM and insulin use, and whether the CGM is paired with an insulin delivery device. Medtronic considered that the MSAC evaluation should be device agnostic and evaluate CGM as an intervention more broadly, noting that the outcomes are tied to insulin delivery, and that specific devices should be considered through the NDSS.

PASC noted there was some stakeholder feedback that PASC consideration of CGM should be device agnostic but though PASC supported this in principle this was a moot point given the specific applications under consideration.

Next steps

The applicant confirmed at the PASC meeting that an ADAR will be submitted for MSAC consideration.

Applicant Comments on Ratified PICO

AMSL acknowledges the PASC's comment that there is "*likely to be a hierarchy of clinical need within the T2D population requiring insulin*". Whilst PASC may consider that certain subpopulations may be have a greater need for CGM, the benefits of Dexcom CGM are supported by studies (predominantly high-quality RCTs) conducted in the intensive and non-intensive T2D populations. As such, AMSL is of the view that should there be a need to establish a hierarchy of clinical need for CGM in more narrowly defined

populations than those in the PICO, this should be done in close consultation with all stakeholders including clinicians and patient organisations representing people living with T2D.

Since this application was prepared for consideration at the December 2024 PASC meeting, Dexcom ONE+ CGM system has been approved by the TGA.

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