Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1785 – Dexcom ONE+ Continuous Glucose Monitoring System

Applicant: **Australian Medical & Scientific Limited**

Date of MSAC consideration: **30 July 2026**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

This application is a resubmission of the application received in February 2025 to request National Diabetes Services Scheme (NDSS) funding of the Dexcom ONE+ real time–continuous glucose monitoring (RT-CGM) system for insulin-using patients with type 2 diabetes (T2D) with suboptimal glycaemic control. This updated application and the original Applicant Developed Assessment Report (ADAR) (Application 1785) was received from Australasian Medical & Scientific Limited (AMSL) by the Department of Health, Disability and Ageing.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC deferred its advice on NDSS (National Diabetes Services Scheme) subsidisation of the Dexcom ONE+ continuous glucose monitoring (CGM) system for people with insulin dependent type 2 diabetes (T2D).

MSAC supported NDSS subsidisation of CGM systems for people aged over 21 years with type 3c diabetes and other diabetes similar to type 1, but advised that this should be addressed as a policy issue. MSAC acknowledged that evidence was limited in this small population, but better evidence was unlikely to be available, and extrapolation of evidence from the type 1 population was reasonable. MSAC considered that clinical need is high for this patient group who also face equity of access issues, and advised that these patients should continue to have access to CGM beyond the age of 21.

Regarding the T2D population, MSAC considered that the issues it raised in its previous consideration of this application had not been adequately resolved by the resubmission. In particular, MSAC considered that there remained uncertainty as to the exact definition and size of the subpopulations likely to receive the most clinical benefit from CGM. While MSAC acknowledged that more recent evidence was promising, it considered the overall evidence base had not changed significantly since the previous submission, that the evidence base therefore remained surprisingly limited for what is a relatively common condition, and noted that the cost effectiveness and financial impact remained uncertain.

MSAC advised that a resubmission should present a reliable, transparent and editable copy of an economic model and estimates of financial impact for the groups within the T2D population that are most likely to benefit from CGM. Based on its previous advice, and reinforced by consumer

and clinical stakeholder feedback, MSAC considered these priority groups to be (i) people with T2D using intensive insulin therapy (IIT) consisting of 3 injections or more per day, (ii) First Nations people with T2D requiring insulin, (iii) those with T2D requiring insulin who are pregnant or actively planning pregnancy, and (iv) people with youth-onset T2D (i.e. diagnosed before 25 years of age) who require insulin and commence CGM before the age of 25. MSAC agreed with ESC's advice that in the absence of evidence specific to these groups, the evidence for effectiveness in the broader T2D population was accepted as applicable to these subpopulations. Intermittent use and a stepped care approach in the broader T2D population still requires further evaluation, consistent with the advice provided by MSAC in its first consideration of this application; however, this evaluation should only occur after consideration of the priority populations.

Consumer summary

This is a resubmission from Australasian Medical and Scientific Limited requesting public funding under the National Diabetes Services Scheme (NDSS) for the Dexcom ONE+ continuous glucose monitoring (CGM) system for people with insulin-dependent type 2 diabetes for self-monitoring of blood glucose.

Diabetes is a condition that can cause high blood glucose (sugar), which is when sugar builds up in the bloodstream. The most common types of diabetes are called type 1 and type 2. There are also other types of diabetes (such as type 3c), which are less common. High blood sugar (hyperglycaemia) caused by diabetes can cause a range of issues including heart disease, nerve damage and kidney damage, and can even be life-threatening. The amount of sugar in a person's bloodstream is usually controlled by a hormone called insulin. Insulin is like a key, unlocking cells to allow sugar to enter the cells from the bloodstream. People with diabetes either do not produce enough insulin (type 1) or cannot properly use the insulin they produce (type 2). Many people with diabetes use insulin injections to help keep their blood sugar levels under control, but too much insulin can cause low blood sugar (hypoglycaemia), which can also cause health problems.

People with diabetes need to regularly check their blood sugar levels, particularly around mealtimes, to help them know if they need to use insulin and how much they need. Most people check their blood sugar level by pricking their finger and placing the drop of blood onto a test strip that can measure blood glucose levels. This is called self-monitoring of blood glucose (SMBG). Some people need to do several finger prick tests over the day, which can be painful and inconvenient. Another way to test blood sugar is by using a continuous glucose monitor (CGM), which is a small device that sits on the skin (usually worn on the back of the upper arm). A sensor is inserted just under the skin and continuously measures the glucose level in the fluid under the skin. The CGM device sends the results via Bluetooth to the person's smartphone or other type of receiver, so they can monitor their blood sugar levels in real time. This information lets people with diabetes see their blood sugar at any point in time, and also lets them see trends in their blood sugar levels. This helps people understand the effects of their behaviour (such as what they eat or how much they exercise) on their blood sugar levels. Using a CGM device can also reduce the work involved in manually recording blood glucose levels (including for carers or support people), provide information to doctors to guide treatment decisions, and enable remote monitoring, which may improve access to care.

One such CGM device is called Dexcom ONE+. The Dexcom G series of CGM devices are funded under Australia's National Diabetes Services Scheme for people with type 1 diabetes. This application is requesting funding for Dexcom ONE+ for people with type 2 diabetes who have trouble controlling their blood sugar levels. A similar application was also considered by MSAC for another CGM device (Application 1786). MSAC considered that monitoring of blood glucose using the Dexcom ONE+ CGM device was as safe as self-monitoring using finger prick tests. MSAC noted the application continued to claim CGM was more effective than finger-prick

Consumer summary
self-monitoring. This claim was based on clinical trial evidence that showed CGM use resulted in a reduction in HbA1c (a blood test that measures the average blood sugar level from the past 8 to 12 weeks) around 0.3% more than monitoring via finger-prick test, which the application stated was clinically meaningful. However, MSAC noted that internationally, health technology assessment organisations (including Australia's Pharmaceutical Benefits Advisory Committee) consider that a person's HbA1c test result needs to improve by at least 0.5%, before it can be said that their diabetes is under better control. MSAC supported public funding of CGM for people aged 21 years and over with type 3c diabetes and other types of diabetes that are similar to type 1 diabetes. Although the evidence was limited, MSAC considered that better evidence was unlikely to become available, in part because these types of diabetes are rare (meaning there are less people to take part in research studies). MSAC considered that this patient group has high clinical need and, despite their conditions being similar to type 1 diabetes, they do not receive the same subsidised care as people with type 1 diabetes from the age of 21. MSAC considered this to be an equity issue and advised that it would be best addressed as a policy issue to update NDSS eligibility criteria. MSAC was of a mind to support public funding of CGM for some specific patient groups with type 2 diabetes that would likely benefit most from CGM. However, it was not able to make a decision to support public funding for these groups at this time, due to remaining uncertainties in the evidence presented in the application. There was a lack of clarity in the economic modelling and financial projections for CGM, meaning it was not clear how much it would cost over time, to fund it. The priority groups with type 2 diabetes using insulin that MSAC considered would receive the most benefit from CGM are: • people who need 3 or more daily insulin injections • Aboriginal and Torres Strait Islander people on any regimen of insulin • pregnant people or those actively planning pregnancy • people with youth-onset type 2 diabetes (i.e. those who have been diagnosed with T2D before the age of 25 years) MSAC also considered that the risk of use outside of these priority groups was very high, greatly increasing the potential budgetary impact of listing. MSAC asked the applicant to provide better economic and financial estimates focusing on the priority groups before it could make a positive recommendation. **MSAC's advice to the Commonwealth Minister for Health, Disability and Ageing** MSAC supported public funding of CGM for people aged 21 years and over with type 3c diabetes and other types of diabetes similar to type 1. MSAC deferred its decision on public funding of CGM for people with T2D, with a mind to support funding for specific groups within this population, if the issues raised by MSAC can be addressed. MSAC requested that more work be done to fix problems with the economic model to ensure that funding the device is good value for money.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this resubmission from Australasian Medical and Scientific Ltd was requesting National Diabetes Service Scheme (NDSS) funding of the Dexcom ONE+ real-time continuous glucose monitoring (RT-CGM) system for insulin-using patients with type 2 diabetes (T2D) with suboptimal glycaemic control. MSAC noted that the NDSS currently funds CGM for all people with

type 1 diabetes (T1D) and people under 21 years of age with type 3c diabetes or other types of diabetes similar to T1D.

MSAC recalled that it had previously considered this application at its July 2025 meeting, and had deferred its decision until additional information and revisions were provided. MSAC had in particular requested that the revised assessment report include several revisions to the economic evaluation, and a focus on the subpopulations with the highest clinical need. MSAC noted that this resubmission had only partially addressed these requests, with the applicant-developed assessment report (ADAR) citing a lack of evidence for many subpopulations. MSAC acknowledged that it was unlikely that detailed evidence would be available for every specific subpopulation.

To provide further information and perspectives, particularly on the patients with the highest clinical need and who may be likely to receive most benefit from CGM, MSAC welcomed a large volume of public consultation input on this application, and also undertook a targeted stakeholder meeting with clinical experts. MSAC noted that consumer and stakeholder feedback on high need populations was largely aligned with the priority groups identified by MSAC at its July 2025 consideration of this application. MSAC therefore considered that the priority subpopulations most relevant to consideration of CGM funding are insulin-dependent:

- people with T2D requiring intensive insulin therapy (IIT) and HbA1c >7.0%
- Aboriginal and Torres Strait Islander people on any regimen of insulin and HbA1c levels of >7%
- pregnant people with T2D (or those actively planning pregnancy)
- people with youth-onset T2D (i.e. diagnosed before 25 years of age)
- people aged 21 and over with type 3c diabetes or other types of diabetes similar to type 1.

MSAC noted that some subpopulations who may benefit from CGM have not been included in clinical trials: people with disability, and people with barriers to communication or sensory impairments. However, MSAC acknowledged it was likely difficult to obtain data on these specific subpopulations separate from the broader T2D population, and noted that these patients would still be included in each of the above groups, if they met the criteria for inclusion.

The applicant was granted a hearing. At the hearing, representatives of the applicant highlighted that CGM provides a fuller and more complete reading of blood glucose levels compared with finger pricking. They presented that real-world evidence shows CGM reduces HbA1c in insulin-using people with T2D. They highlighted the benefits noted through stakeholder consultation include increased safety, ease of use, and enhanced learning and agency for users, providing overall quality-of-life benefits.

MSAC considered that, for the populations identified as most likely to benefit from CGM, more certainty is needed on the population numbers, uptake rates and the incremental cost-effectiveness ratios (ICERs).

MSAC also noted that this application and concurrent application 1786 (FreeStyle Libre 2 CGM for people with insulin-dependent T2D, gestational diabetes and type 3c diabetes) used different definitions for the IIT and non-IIT subpopulations. MSAC recalled that, when it considered this application in July 2025, the committee did not define what 'intensive insulin therapy' should be. Having reviewed both applications and all provided information, MSAC considered that the IIT subpopulation should be defined as ≥3 daily insulin injections (basal–bolus regimen).

MSAC considered that the non-IIT subpopulation with HbA1c >8% should not be included as one of the priority populations for further consideration at this time. MSAC considered that, if it is

important for patients in this group to have tight control of HbA1c, or if it is necessary and appropriate to reduce their HbA1c much below 8%, it is likely they will require IIT, and hence will form part of the IIT group. MSAC also considered that pregnant people with gestational diabetes should not be included as there are concerns of associated risks, and stakeholder support was limited in the context of a sizeable, recurring population.

MSAC noted that, in the pre-MSAC response, the applicant suggested prioritising reimbursement for the IIT subgroup as they are at greatest risk of poor glycaemic outcomes, diabetes-related complications and higher healthcare costs. MSAC agreed with this suggestion but noted that the applicant did not elaborate on further reimbursement prioritisation for other subpopulations identified as at-risk or with high clinical need.

The pre-MSAC response suggested that CGM access for the subpopulation with type 3c diabetes could be implemented by changing the existing eligibility arrangements for type 1 diabetes. MSAC agreed there is an equity of access issue in this subgroup, where subsidised access is only available for the type 3c and other diabetes similar to type 1 group until age 21, but is not age-restricted for those with type 1 diabetes.

MSAC noted that, although intermittent use of CGM received some support in consultation feedback, it was not supported by the applicant in its pre-MSAC response or at the hearing. The pre-MSAC response noted that intermittent use of CGM risks delivering a partial and potentially compromised form of care, and it could still have a noticeable financial impact to the NDSS without a certainty of benefit. The pre-MSAC response also cited real-world evidence from Nemlekar et al. 2024[1] showing that adherence to CGM was associated with significant reductions in HbA1c, and people using RT-CGM had higher adherence than those using intermittent CGM. MSAC acknowledged the validity of the argument made by the pre-MSAC response, but also acknowledged that there is already some incidence of intermittent use among people with T2D.

MSAC agreed with ESC that evidence on the comparative effectiveness of CGM from suboptimally controlled T2D populations (IIT and non-IIT) presented in the ADAR such as the reported HbA1c reductions associated with CGM use for this broader population was likely applicable to the specific subpopulations with high clinical need for CGM. MSAC noted that the applicant also agreed with ESC in its pre-MSAC response.

MSAC agreed with ESC that there are no major safety concerns with the Dexcom ONE+ CGM device but noted that ESC had identified a possible safety concern around analytical validity (i.e. where inaccurate high readings could lead to excessive insulin administration). The pre-MSAC response stated that evidence supporting analytical validity was presented in its previous ADAR, and also referred to PASC's advice in the PICO confirmation that any such occurrences would be captured by the direct evidence. MSAC noted recent media reports of connectivity failures and incorrect insulin dosing resulting from CGM and insulin pumps, and queried whether data were available on device failures, which had not been provided in the application.

MSAC noted that the pre-MSAC response recommended minimum performance standards for CGM devices, which MSAC agreed with. The pre-MSAC response also argued against MSAC's previous consideration that CGM systems with similar functions can be considered collectively. MSAC maintained its view that, while some CGM systems have different functionality (e.g. insulin pump integration), systems that have similar functionality (and have appropriate quality

[1] Nemlekar PM, Hannah KL, Green CR and Norman GJ, 'Association between adherence, A1C improvement, and type of continuous glucose monitoring system in people with type 1 diabetes or type 2 diabetes treated with intensive insulin therapy', *Diabetes Therapy*, 2024, (15)3:639–636, doi:10.1007/s13300-023-01529-8.

assurance processes, analytical validity, and regulatory approvals, e.g. are listed on the Australian Register of Therapeutic Goods) are likely to have a degree of class effect. MSAC also considered there were potential privacy and cybersecurity concerns associated with collecting patient data, and that this must be appropriately managed.

MSAC noted that this resubmission provided no new direct evidence on clinical effectiveness. The claim of superior effectiveness still relies on achieving the applicant's defined minimal clinically important difference (MCID) of 0.3% reduction in HbA1c, rather than the widely accepted MCID of 0.5%. ESC had considered this less important for decision-making because the revised model used the smaller, randomised controlled trial (RCT)–based HbA1c treatment effects of 0.3% to 0.4%. Overall MSAC considered that there was insufficient evidence provided to reduce the accepted 0.5% MCID to claim superior effectiveness. MSAC also noted recent trials on CGM devices that use an MCID of 0.5%.

MSAC noted that the resubmission had made positive changes to the economic evaluation to address many of the issues identified in the first submission, including greater reliance on RCT-based evidence and more realistic HbA1c changes, and presenting results separately for different cardiovascular disease (CVD) risk equations.

MSAC noted that the economic evaluation in the resubmission used more conservative estimates, meaning the use of CGM was no longer dominant for both the IIT and non-IIT subpopulations. However, the ICER per quality adjusted life year (QALY) varied substantially depending on the risk equation used:

- For the IIT population, the ICERs were $5,000 to < $15,000/QALY when using the UK-PDS risk equation and $5,000 to < $15,000/QALY when using the Fremantle risk equation.
- For the non-IIT population, the ICERs were $35,000 to < $45,000/QALY when using the UK-PDS risk equation and $5,000 to < $15,000/QALY when using the Fremantle risk equation.

MSAC noted that QALYs were driven primarily by incremental quality of life, meaning the ICER is sensitive to the utility weights applied.

However, MSAC considered that there were numerous concerns with the economic evaluation that remained unaddressed. These included the concern that finger prick disutilities were overestimated and the potential for double-counting the quality of life decrements for finger pricking and fear of hypoglycaemia (FOH) by applying separate (additive) disutilities, the lack of justification of a different method to estimate hospitalisations for severe hypoglycaemic events (SHE) and diabetic ketoacidosis (DKA), and the existence and extent of the translation of change in HbA1c levels to longer-term diabetic complications.

MSAC noted that due to these concerns ESC had requested a respecified multivariate base case. This was to directly address the uncertainties that ESC and subsequently MSAC considered material to the cost-effectiveness results. This ESC-requested analysis is referred to as a respecified base case by the committees but should not be confused with the base case presented in the assessment. ESC requested the analysis include the convergence of HbA1c changes between years 7 and 8, halving each finger-prick disutility, removing the fear of hypoglycaemia disutility, and halving DKA and SHE costs and disutilities. MSAC noted that although the pre-MSAC response provided the result of a multivariate analysis based on these specifications, this result of $55,000 to < $75,000/QALY for the IIT population compared with $5,000 to < $15,000/QALY in the original base case was only reported for the IIT population and was reported using the version of the model that used the Fremantle risk equations rather than the version of the model that used the UK-PDS risk equations, as requested by ESC.

MSAC noted that the pre-MSAC response argued that the analysis requested by ESC is unrealistic, lacks face validity, and should not be viewed as the base case for MSAC decision-making. However, MSAC considered that the pre-MSAC response did not acknowledge the likely double counting of QALYs by including separate disutilities for finger pricking and FOH and did not provide a justification for the different approaches used in the ADAR to estimate the rates of severe hypoglycaemic events and diabetic ketoacidosis events, which is important because the claimed cost offsets for these events are very large.

MSAC considered that an acceptable incremental cost-effectiveness ratio (ICER) would be around $30,000 per quality-adjusted life year (QALY). This was informed by PBAC's November 2024 decision not to recommend tirzepatide for type 2 diabetes, which viewed an ICER of $30,000 or less as cost-effective in a large eligible population using a 0.5% HbA1c MCID.

MSAC considered that, based on the ESC-requested analysis provided in the pre-MSAC response (after accounting for the fact that it was based on the Australian risk equations rather than the UKPDS equation that was requested), and other reported sensitivity analyses, it is likely that the ICERs for both the IIT and non-IIT populations under this ESC requested analyses using the requested risk equations would exceed $30,000 per QALY (>$55,000 to < $75,000/QALY in the IIT population and >$95,000 to < $115,000 in the non-IIT population). For the IIT population MSAC estimated that a ≥**redacted**% price reduction would be required to yield an acceptable ICER of around $30,000/QALY

MSAC noted that a key improvement from the first submission for the financial estimates was some use of Pharmaceutical Benefits Schedule (PBS) data to derive financial estimates. NDSS data include anyone who has ever used insulin, so MSAC considered that the use of PBS data was more appropriate. MSAC noted that while the ADAR used NDSS estimates to estimate the total number of people with T2D, PBS estimates of the percentage of people with T2D using insulin were then applied to the NDSS estimates to derive the total number of people with T2D using insulin.

MSAC noted that the proposed population numbers in this application do not align with those in application 1786. This was because the 1785 resubmission assumed 27.2% of insulin-dependent T2D cases are in the IIT subpopulation which in turn is based on the assumption that premixed insulin users belong in the non-IIT rather than the IIT population. MSAC agreed with this assumption, noting that it aligns with the Australian Diabetes Clinical Quality Registry (ADCQR 2024) data protocols and therefore considered that the proposed population numbers in the 1785 application were more accurate.

MSAC noted that the net financial impact was estimated to be $600 million to < $700 million over 6 years, after applying $80.4 million in cost savings from the reduced use of blood glucose strips.

MSAC noted that this resubmission broke down costs for the IIT, non-IIT and Aboriginal and Torres Strait Islander populations, gestational diabetes, and other types of diabetes (including type 3c).

MSAC noted that the robustness of the process used to derive the uptake rates for all subpopulations is unknown. The pre-MSAC response argued that the same method was used in the first submission and MSAC had not raised concerns at the time. The pre-MSAC response also maintained that the uptake assumptions used in the ADAR were reasonable, possibly even an overestimate, when other reimbursed market data are analysed. However, MSAC noted that market data have never been provided to MSAC. Without details on the robustness of the estimation process, MSAC had low confidence in the estimates.

MSAC considered the risk of use of CGM outside the intended populations to be very high, which may potentially further increase the already high budgetary impact. MSAC considered that a registry-based system (underpinned by a system that supports continuity of care, such as MyMedicare) could be implemented, and that eligibility could be certified by general practitioners (GPs) who receive credentialled extra training, diabetes educators and non-GP specialists. Systems that encourage continuity of care could enhance patient engagement and remote monitoring.

MSAC considered the current pathway for accessing CGMs for type 1 diabetes through the NDSS may not be suitable for accessing CGMs for T2D. Therefore, rigorous prescribing governance will be required – for example, models used for high cost medications such as biologics with access through Provider Digital Access (PRODA). Also required is a pathway to review and cease CGM when diabetes treatment changes (for example, weight loss with GLP-1s). MSAC noted that, in the United Kingdom, patient review occurs every few months and access to CGMs is ceased if no clinically significant improvement has been observed.

MSAC noted that the pre-MSAC response supported a staged implementation approach mentioned in the ESC report. However, MSAC noted that the intention of ESC was to explore the possibility of such an approach, not to suggest it as a definite implementation approach.

Overall, MSAC considered that there was currently too much uncertainty to support public funding of CGM in the proposed T2D population . However, MSAC considered that existing funding via the NDSS of CGM for people with type 3c diabetes or other types of diabetes similar to type 1 should be extended to those 21 years and over, to ensure equity of access for this high need population. MSAC considered that current NDSS funding arrangements for CGMs in this group disadvantages people aged 21 and over. MSAC noted that, if NDSS access is extended, it will impact use of CGM devices outside the scope of this application. MSAC advised that amending the NDSS eligibility criteria to extend beyond age 21 for these subgroups was a policy decision.

For the proposed T2D population, MSAC's concerns include uncertainty on the exact definition and size of the subpopulations that would most benefit, the unmet clinical need, the budgetary outlay and the ICER. The resubmission did not adequately address the matters raised previously by MSAC at its July 2025 meeting, MSAC considered that while the economic modelling in the resubmission relied on more realistic assumptions it was still not sufficiently reliable for MSAC to advise on a cost-effective price for Dexcom ONE+. Although the financial projections are based on PBS data on use of insulin in the T2D population, MSAC does not have the analyses required for the subpopulations with the highest need. For the purposes of evaluating clinical effectiveness and cost-effectiveness MSAC accepted the assumption that the benefits of CGM (for instance in terms of the magnitude of HbA1C reduction) reported for more broadly defined populations could be applied to the priority groups identified by MSAC specifically:

- people with T2D who require IIT (≥3 daily insulin injections [basal–bolus] and HbA1c >7%)
- Aboriginal and Torres Strait Islander people on any regimen of insulin and HbA1c levels of >7%
- pregnant people with T2D (or those actively planning pregnancy) who require insulin
- people with youth-onset T2D (i.e. diagnosed before 25 years of age) who require insulin

MSAC advised that a resubmission should focus on economic modelling and financial estimates for these priority groups. MSAC advised that the resubmission economic model should: be transparent and editable; apply safety and effectiveness outcomes, and population

characteristics from the same source to ensure internal validity, and address the applicability of any non-Australian sourced data; apply Australian values/tariffs to EQ5D-5L scores; account for the concerns that motivated ESC's requests for additional analysis, and other remaining ESC and MSAC concerns; and include a multiway sensitivity analysis to examine HbA1c reduction in plausible ranges (0.3% to 0.5%) and a shorter time horizon. As noted previously, MSAC advised that an acceptable ICER for CGM would be $30,000/QALY or less.

More certain financial estimates for each specific patient cohort/use case are also crucial to MSAC's decision making.

MSAC considered that intermittent use of CGM and a stepped care model as proposed by ESC in which observation of patients using CGM continuously over a shorter period of initial use could identify those requiring longer-term continuous use also required further evaluation. However this should be undertaken after the consideration of the priority populations as outlined above.

MSAC also requested an independent validation of any future resubmission should be performed using a standardised T2D model and independently-derived financial estimates for each subpopulation.

4. Background

At its 31 July 2025 meeting, the Medical Services Advisory Committee (MSAC) considered application 1785 submitted by AMSL in February 2025 for NDSS funding of the Dexcom ONE+ RT-CGM system for insulin-using patients with T2D. After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC deferred its advice on NDSS subsidisation of Dexcom ONE+ CGM.

MSAC had not previously considered CGM systems for people with T2D requiring insulin. In addition to Application 1785, MSAC also considered an application (1786) for NDSS funding of the FreeStyle Libre 2 (FSL) CGM system for people with T2D requiring insulin and those with gestational diabetes and other types of diabetes (including type 3c). MSAC deferred its decision on Application 1786.

No CGM system to manage T2D is currently subsidised via the NDSS in Australia.

In 2021, MSAC conducted a review of CGM products for people with type 1 diabetes (T1D) provided through the CGM initiative by the NDSS (MSAC Review 1663). After considering the available evidence, MSAC deferred advice on the clinical- effectiveness and cost-effectiveness of subsidised CGM products, concluding that further work was required to better establish the patient population, clinical effectiveness and cost-effectiveness of CGM devices for T1D.

In the Public Summary Document (PSD) for the original Dexcom ONE+ CGM submission[2], MSAC summarised the merits of the initial application and its rationale for deferring advice to the Minister. Specifically:

1. The clinical claim that CGM leads to an overall improvement in glycaemic control measured using glycated haemoglobin (HbA1c) was not fully supported. The trials were relatively small, short term, and did not report end-organ outcomes. The reduction in HbA1c was lower than the level considered a meaningful improvement by the Pharmaceutical Benefits Advisory

[2] Medical Services Advisory Committee (MSAC) 2025, Public Summary Document: Application No. 1785 – Dexcom ONE+ continuous glucose monitoring system for people with insulin-dependent type 2 diabetes. Canberra: Australian Government Department of Health, pg. 11.

Committee and regulatory agencies. However, it must be noted that MSAC stressed other benefits of CGM for patients and T2D management, including empowering patients to manage T2D and more effectively manage blood sugar levels during times of acute illness. MSAC considered that CGM could improve quality of life, and this was reflected in strong consumer support for public funding.

2. In the initial ADAR, the proposed population was large, with variable clinical need and anticipated benefits from CGM. MSAC considered that the proposed population was heterogeneous, and that CGM may be more clinically-effective and cost-effective for some subpopulations, including patients who use both long- and short-acting insulin, people with higher levels of HbA1c (e.g. > 8%) using insulin, and Aboriginal and Torres Strait Islander people.
3. Lack of transparency of the economic evaluation was an issue, which implied that the cost-effectiveness estimates were very uncertain. MSAC noted that the treatment effects appeared implausibly large and sustained. MSAC considered there was substantial uncertainty around estimated utilisation and was concerned that the budget impact of subsidising CGM for the proposed population would be very large.
4. CGM may be used intermittently, rather than continuously, to establish better glycaemic control.

In the PSD, MSAC advised it would be willing to consider a resubmission if the applicant addressed the issues raised during the evaluation of Application 1785 at the July 2025 MSAC meeting. According to the applicant, the resubmitted ADAR for Dexcom ONE+ addresses these key issues.

Table 1 outlines the key uncertainties raised by MSAC for the original Dexcom ONE+ ADAR, in addition to MSAC's proposed method to address these uncertainties, and the extent to which they have been addressed in the current ADAR.

Table 1: Summary of MSACs key uncertainties regarding the original application, MSACs proposed method to address these uncertainties, and how the resubmission addressed the uncertainties of the original ADAR, as identified by the commentary

Component	Matter of concern	How the current assessment report addresses this concern
MCID for the primary outcome assessed, mean change in HbA1c concentration (%)	In the original ADAR, the applicant used an MCID of 0.3% in the interpretation of the comparative effectiveness evidence for the primary outcome (mean change in HbA1c concentration, %, from baseline). "MSAC agreed with ESC that the evidence base presented was not sufficient to accept a MCID of 0.3%" (1785 PSD, p. 6)", which was the MCID proposed by the applicant	**Not adequately addressed** As in the original ADAR, this ADAR resubmission used an MCID of 0.3% when interpreting whether differences in HbA1c concentration between the RT-CGM and SMBG subgroups imply clinically meaningful superiority and presented no further justification for this alternative MCID. Considering that 0.5% remains the generally accepted magnitude of difference to indicate a meaningful difference, this is problematic.
Clinical evidence assessment - Population subgroup eligibility issues	MSAC considered the population assessed and proposed for funding in the original ADAR 1785 as too broad. MSAC called for any updated application to focus on subpopulations with higher clinical need, which were identified. The following section of the PSD relates this concern and directive: "MSAC considered that the proposed population was large, with variable clinical needs and anticipated benefits from CGM... considered that CGM may be more clinically effective and cost-effective for some of the subpopulations, including patients who use both long acting and short acting insulin, people using insulin with higher levels of glycated haemoglobin (e.g. > 8%) as well as Aboriginal and Torres Strait Islander people…MSAC advised that a resubmission should present a revised… evaluation focussed on the populations with a higher clinical need". (1785 PSD, MSAC's advice to the Minister, p. 1) "MSAC considered that CGM could be particularly beneficial for some groups of people with type 2 diabetes and at certain times. Such groups could include First Nations people, who may particularly benefit from this intervention and for whom finger prick testing may not be culturally appropriate; people who have a disability that increases the burden of finger prick testing on carers or on themselves; and people with baseline HbA1c levels over 8%." (1785 PSD, Consumer Summary, p. 3) "MSAC considered that alternative thresholds for baseline HbA1c to determine eligibility for CGM should be considered, to more appropriately capture the group of people for whom CGM would provide the most benefit." (1785 PSD, p. 4)	**Partially addressed** Two of the subpopulations with high clinical need proposed by MSAC for investigation are evaluated: people with T2D on IIT with HbA1c >7%; and people with T2D diabetes on basal insulin only with HbA1c levels of >8% or >9%. For the basal insulin only (non-IIT) population, HbA1c baseline level subgroups are also evaluated. The ADAR resubmission did not provide evidence for or an explanation as to why other subpopulations proposed by MSAC were not evaluated.

	The highest priority subgroups flagged by MSAC for funding consideration and assessment in the updated ADAR 1785 were: 1) "People using insulin with higher baseline levels of glycated haemoglobin (e.g. >8% and >9%); 2) First Nations people (e.g. with baseline HbA1c >7%); 3) People who use both long acting and short acting insulin; 4) People with disability (including mental health issues and neurodivergence) for which checking BGLs creates a high burden on the individual and/or carer". (1785 PSD p. 9) Other important groups MSAC highlighted as those who may benefit from short-term or intermittent CGM were: "People with intercurrent illness that affects blood glucose management and requires additional short-term monitoring of blood glucose levels; People who are pregnant and have type 2 diabetes or gestational diabetes, as high glucose levels during pregnancy can lead to abnormal development and later health problems for the child; People who are starting insulin therapy and require frequent BGL measurements; People in situations in which nocturnal hypoglycaemic events are suspected." (1785 PSD, Section 3, p. 10)	
Clinical evidence assessment – Outcome scope of the evidence analysed too narrow	MSAC pointed the applicant towards presenting additional results for the glycated haemoglobin (HbA1c) outcome and direct patient-relevant outcomes to build a stronger clinical case for NDSS subsidisation of the Dexcom ONE+ CGM. The following sections of the PSD are illustrative: "MSAC considered that the clinical claim …using glycated haemoglobin (HbA1c) was not fully supported…However, MSAC considered that CGM may have other benefits for patients and T2D diabetes management. This includes empowering patients to manage their T2D and manage blood sugar levels during times of acute illness. MSAC considered CGM could improve quality of life". (1785 PSD, p. 1) MSAC's advice to the minister stated that the trials presented in the ADAR "were relatively small, short term, and did not report end-organ outcomes" (1785 PSD, p. 1)	**Partially addressed** Difference in mean change in %HbA1c outcomes comprise the primary evidence base for the comparative effectiveness assessment. However, the applicant did introduce informative indirect evidence to address the concern of no direct patient longer term outcomes buttressing the HbA1c outcome evidence presented. This consists of a high-quality study linking use of RT-CGM to change in various longer-term health outcomes, including mortality. This large, retrospective cohort study compared a broad range of direct patient health outcomes in people with T2D who used and did not use RT-CGM, using US claims data from the US Veterans Affairs Health Care System and propensity score matching.
Clinical evidence base update	"MSAC considered… further evidence that is more up-to date and specific to…. groups is required". (1785 PSD, p. 9)	**Partially addressed** No new studies directly comparing the effectiveness of Dexcom ONE+ or other CGMs to SMBG were identified by the applicant for inclusion in the ADAR 1785 resubmission. However, two post-hoc analyses of the MOBILE trial were

		identified and deemed relevant for inclusion in this resubmission. The results of these analyses are presented along with data from the MOBILE trial in the evaluation of the non-IIT subpopulation. Additionally, during the assessment of the resubmission an additional trial was identified after the applicant's search. This was assessed and added to the evidence base. It assessed RT-CGM against SMBG in the same subpopulation (non IIT) assessed by the MOBILE trial. Evidence from this very recently published trial strengthens the clinical effectiveness claim in the non-IIT subpopulation substantially.
Clinical evidence - Validity of the comparative effectiveness superiority claim	In responding to the original ADAR 1785, MSAC questioned the appropriateness of the clinical superiority claim based on the limited strength of the comparative evidence presented for Dexcom ONE+ against SMBG. MSAC argued that based on the available data, a claim of non-inferior effectiveness is more appropriate. (1785 PSD, p. 1 and p. 6) HbA1c concentration (%), difference in mean change from baseline between groups was the primary outcome assessed to inform the conclusion of the clinical claim. The result favouring Dexcom ONE+ being less than the MCID (of 0.5%) generally accepted as sufficient to indicate a meaningful difference between groups in this outcome (including by PBAC) was the main concern raised. Imprecision was another concern for the findings not based on meta-analysis. For the meta-analysis, time points varying across included studies was highlighted as a critical issue (1785 PSD, p. 6) In the original application, no clinical comparison was conducted against FSL/FGM. This was not raised as an issue, by MSAC or the ESC. Rather, "MSAC considered there was limited evidence available to suggest a significant difference in clinical outcomes between different brands of CGM devices with comparable functionality". (1785 PSD, p. 2) MSAC, having considered the clinical evidence in the original ADAR 1785 and ADAR 1786, concluded that there was likely no difference between the FSL and Dexcom devices in terms of clinical effectiveness	**Not adequately addressed** The applicant's conclusion in the ADAR resubmission is that RT-CGM compared to SMBG is superior in clinical effectiveness for both the non-IIT and IIT subpopulations. Considering the strength of the primary outcome evidence presented in support of this claim, this conclusion is not supported. The low- to very low-certainty HbA1c outcome evidence summarised better supports a claim of non-inferior effectiveness of RT-CGM over SMBG. The uncertainties of the evidence presented for the subpopulations are consistent with those presented by MSAC and the ESC for the evidence presented for the overall population. However, it should be noted that if the results from the recently published trial had been included, the argument in support of superiority of RT-CGM over SMBG would have been stronger for the subpopulation assessed (non-IIT). The applicant asserts that Dexcom ONE+ is superior in effectiveness to other CGM devices (e.g. FSL/FGM) based on a meta-analysis of all available clinical trial. This is not supported by the results presented, which are from a methodologically flawed meta-analysis.
Economic evidence - Applicability	MSAC indicated that there is uncertainty as to whether the US claims data can be extrapolated to or is reflective of an Australian setting (1785 PSD, p. 5, 29 & 33). The ADAR did not present any clinical or economic evidence for children or adolescents (1785 PSD, p. 33).	**Not addressed** The base case parameters used RCT data (DIAMOND for IIT and MOBILE for non-IIT), although most of the parameters were informed by Karter et al. (2021). The RCTs informing the base case were conducted in US-based settings. As such, the concern regarding applicability is not fully resolved.

Economic evidence - HbA1c Treatment effects	MSAC highlighted that the ADAR assumed a treatment effect of 3 years, holding the HbA1c reduction in the RT-CGM arm constant for 3 years while the HbA1c increased by 0.15% per year in the comparator arm. After this time, it was assumed HbA1c would increase by 0.15% per year in both arms. The ADAR stated that longitudinal studies show improvements in glycaemic outcomes for up to 10 years. The commentary noted that the ADAR did not explore the length of the treatment effect in the uncertainty analysis (1785 PSD, p. 36). The commentary noted that the ADAR also did not explore the rate of HbA1c increase in an uncertainty analysis, nor did it explore a scenario in which the HbA1c of the intervention arm become equivalent to the comparator arm. This would shift the results in favour of SMBG; however, the magnitude of this shift is uncertain. Reporting on this scenario would reduce the uncertainty regarding the long-term effect of Dexcom ONE+ (1785 PSD, p. 36).	**Not adequately addressed** Upper and lower CIs were applied for both subpopulations; however, the treatment effect is still a key model driver. As such, further variation (±10%) around the treatment effects would be valuable to assess its impact and better inform decision-making. Model access was limited to a non-editable version, therefore these analyses could not be undertaken by the assessment group.
Economic evidence - Model time horizon	Time horizon needed to be at least 20 years for RT-CGM to be cost saving (dominant) vs SMBG…People enter the model at a mean age of 64.5 years, and the model assumes a 3-year treatment effect (HbA1c decrease) followed by a linear increase in HbA1c (0.15% per year). Therefore, to be cost saving, the assumption that that those with RT-CGM have a lower HbA1c than SMBG over at least 20 years is required. There are no long-term data to support this assumption. Therefore, the estimated long-term benefits are highly uncertain. Additional scenarios around treatment effect would explore this uncertainty further (1785 PSD, p. 43).	**Not adequately addressed** The applicant addressed concerns raised in the original ADAR submission; however, most QALYs were accumulated over a 20-year time horizon for both population groups. As such, a multivariate analysis using a 20-year time horizon would be valuable to assess its impact and better inform decision-making. The model was not editable by the assessment group to implement these changes.
Economic evidence - Renal complications	The ADAR did not vary renal complications nor describe how they were implemented in the model (1785 PSD, p. 42).	**Not adequately addressed** The ADAR did not vary renal complications. To better reflect disease progression and associated cost and effects, the complications of haemodialysis, peritoneal dialysis and renal transplant should be varied based on the probability of progression to ESRD, in order to estimate the total proportion of each cohort affected in both arms. Model access was limited to a non-editable version, therefore these analyses could not be undertaken by the assessment group.
Economic evidence - Risk equations	For complication and mortality, a scenario analysis was conducted using the UKPDS-82 complication risk equations with the UKPDS mortality risk equations. The ICERs in this scenario remained cost effective but became cost incurring…QALYs decreased by 1.5 for each arm, which does not make sense given the conclusions from Hayes et al. (2013) that life expectancy in the UK post-complication was higher than Australia. The ADAR did not discuss this further (1785 PSD, p. 29, 38 & 43).	**Not adequately addressed** The ADAR considered UKPDS CV complication and mortality risk and Australian adaptation of these risk equations, and presented 2 sets of base case results. However, the concern raised by MSAC in the original ADAR submission remains unaddressed.

	It is unclear what risk equations were used for the other types of diabetes complications, nor whether the model has been similarly validated when using these Australian adaptations (1785 PSD, p. 29).	
Economic evidence - Age and duration of diabetes	The baseline population were average age 64.5 with a diabetes duration of 16 years. Further, 3 populations (mean age 35 years – 1 year duration, mean age 45 years – 5 years duration and mean age 55 years – 5 years duration) were assessed. The ADAR did not state whether these populations were clinically plausible, nor did it state the reason for these choices (1785 PSD, p. 43). The ICER in this scenario remained dominant for both populations and incremental costs and QALYs increased for both populations if RT-CGM was initiated at an earlier age (1785 PSD, p. 43). The age in Karter (2021) appears to be significantly higher compared with MOBILE and Steno2tech. The duration of diabetes for Karter (2021) overlaps with the tails of the 95% confidence intervals for MOBILE and Steno2tech SMBG arm of the analysis (1785 PSD, p. 33).	**Not adequately addressed** The baseline patient/disease characteristics were informed by the pivotal trials (DIAMOND and MOBILE) where possible. However, no scenario analyses were presented in the resubmission and the original scenario was removed, creating uncertainty in the estimated outcomes.
Economic evidence - HRQoL inputs	MSAC noted that the utility decrements for all events were applied the year the event occurred. Long-term impact on HRQoL as a result of chronic complications (e.g. MI, stroke, blindness, amputation) was not included, even though long-term event-specific costs were included in the model. Beaudet (2014) used the EuroQol 5-dimension 3-level questionnaire to gather utility and decrements. Most studies in the meta-analysis used a UK tariff. The utility decrement for DKA was informed by a Chinese study in people with T1D (1785 PSD, p. 8 & 39). The ADAR did not state whether utilities were applied additively or multiplicatively. The ADAR also did not state whether any adjustments were made to align the utility decrements with the Australian population (1785 PSD, p. 39).	**Not addressed** No changes to utility were made to the base case of original ADAR submission.

Abbreviations: ADAR = applicant developed assessment report; AG = assessment group; CIs = confidence intervals; CV = cardiovascular; ESC = Economic Sub Committee; ESRD = end-stage renal disease; FSL/FGM = FreeStyle Libre/Flash Glucose Monitoring; HbA1c = glycated haemoglobin; HRQoL = health-related quality of life; ICER = incremental cost-effectiveness ratio; IIT, intensive insulin treatment; MCID = minimally clinically important difference; MSAC = medical services advisory committee; PICO = population, intervention, comparator and outcome; PSD = public summary document; QALY = quality-adjusted life year; RCT = randomised controlled trial; RT-CGM = real-time continuous glucose monitoring; SMBG = standard monitoring of blood glucose; T1D = type 1 diabetes; T2D = type 2 diabetes; UKPDS = United Kingdom prospective diabetes study.
Source: Public Summary Document for MSAC Application 1785; Tables 6 and 24, pp 32 and 74 of the MSAC 1785 ADAR + inline commentary.

5. Prerequisites to implementation of any funding advice

The Dexcom ONE+ CGM system was registered by the Therapeutic Goods Administration on 25 September 2024 (Table 2). The updated ADAR 1785 did not report any prerequisites for the Dexcom ONE+ CGM system.

Table 2: Dexcom ONE+ CGM system listed on the ARTG

Product name (sponsor)	ARTG summary	Intended purpose
Subcutaneous glucose sensor (AA-Med Pty Ltd)	**ARTG ID**: 462866 **Start date**: 25/09/2024 **Category**: Medical Device Included Class IIb **GMDN**: 59016 Subcutaneous glucose sensor	The subcutaneous glucose sensor is intended to be used as part of the CGM system. The CGM is a glucose monitoring system indicated for persons with diabetes mellitus aged 2 years and older where SMBG is indicated. The device is designed to replace finger prick BG testing for treatment decisions. Interpretation of the device results should be based on the glucose trends and several sequential readings over time. The device also aids in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments. It is intended for use by patients at home and in healthcare facilities.

Abbreviations: ARTG = Australian Register of Therapeutic Goods, BG = blood glucose, CGM = continuous glucose monitoring, GMDN = global medical device nomenclature, SMBG = self-monitoring of blood glucose.
Source: ARTG Public Summary Documents. Verified by assessment group on 25 February 2025, as reported in MSAC PSD for Application No. 1785, 31 July 2025.

6. Proposal for public funding

The ADAR for the Dexcom ONE+ CGM system proposed that NDSS funding should be provided for three T2D subpopulations with suboptimal glycaemic control requiring insulin. This funding avenue does not require a Medicare Benefits Schedule (MBS) listing.

The proposed population for NDSS funding is narrower than the indication in the ARTG listing, which is for 'persons with diabetes mellitus aged 2 years and older where SMBG is indicated'. Currently, subsidised CGM products are only available via the NDSS for people with T1D and some people <21 years with rare conditions similar to T1D. Other Dexcom RT-CGM systems (Dexcom G6 and G7) with advanced features (e.g. connectivity to pumps) are currently available through the NDSS for T1D. Dexcom ONE+ does not have these features.

The ADAR resubmission proposed three T2D populations for public funding:

- IIT subpopulation with HbA1c >7%
- non-IIT subpopulation with HbA1c levels >8% or >9%
- First Nations insulin requiring subpopulation with HbA1c >7%.

The proposed population for NDSS funding for these subpopulations are presented in Table 3, Table 4, and Table 5.

Table 3: Proposed population for NDSS funding for Dexcom ONE+ CGM System in T2D IIT users

Dexcom ONE+ CGM System
Intensive insulin using patients with T2D with a suboptimal glycaemic profile defined by the following criteria: • Aged ≥2 years • Diagnosis of T2D • Treated with ≥2 daily insulin injections, consisting of   ○ Long acting (basal) insulin and rapid acting (bolus) insulin • Suboptimal glycaemic control confirmed by laboratory measured HbA1c levels of >7.0% for adults and >6.5% for children and adolescents.

Abbreviations: CGM = continuous glucose monitoring; HbA1c = glycated haemoglobin; IIT = intensive insulin treatment; T2D = type 2 diabetes.

Table 4: Proposed population for NDSS funding for Dexcom ONE+ CGM System in T2D non-IIT users

Dexcom ONE+ CGM System
Non-intensive insulin using patients with T2D with a suboptimal glycaemic profile defined by the following criteria: • Aged ≥2 years • Diagnosis of T2D • Treated with ≥1 daily insulin injection, not otherwise included in the IIT subpopulation • Suboptimal glycaemic control confirmed by laboratory measured HbA1c levels of >8.0% or >9.0% for adults and >6.5% for children and adolescents.

Abbreviations: CGM = continuous glucose monitoring; HbA1c = glycated haemoglobin; IIT = intensive insulin treatment; T2D = type 2 diabetes.

Table 5: Proposed population for NDSS funding for Dexcom ONE+ CGM System in T2D insulin-dependent First Nations peoples

Dexcom ONE+ CGM System
Non-intensive insulin using patients with T2D with a suboptimal glycaemic profile defined by the following criteria: • Aged ≥2 years • Diagnosis of T2D • Treated with at ≥1 daily insulin injection, consisting of any insulin regimen • Suboptimal glycaemic control confirmed by laboratory measured HbA1c levels of >7.0% for adults and >6.5% for children and adolescents.

Abbreviations: CGM = continuous glucose monitoring; HbA1c = glycated haemoglobin; T2D = type 2 diabetes.

In the ADAR resubmission for the Dexcom ONE+ CGM system, the applicant states that '...Although people with a disability, pregnant women with GDM and people with other types of diabetes are not formally included in the PICO, they are recognised as subpopulations of interest in this resubmission...Dexcom is willing to work with MSAC and the Department to develop

appropriate eligibility criteria and funding arrangements for these groups, consistent with Application 1786' (ADAR 1785 Resubmission, p. 48).

The original ADAR for the Dexcom ONE+ CGM system (ADAR 1785) defined 'suboptimal glycaemic control' as laboratory-measured HbA1c levels >7.0% for adults and >6.5% for children and adolescents. The original ADAR proposed funding for two subpopulations: intensive insulin therapy (IIT) users and non-IIT users.

In responding to the original ADAR, MSAC considered that the proposed HbA1c targets represented a low threshold that would capture the vast majority of, if not all patients with diabetes on insulin. Additionally, MSAC considered that although the ideal target for HbA1c is generally <7.0%, this target should be individualised to account for factors such as patient context, age, risks, life goals and comorbidities. Thus, it may not be accurate to conclude that all patients with HbA1c >7.0% have 'suboptimal glycaemic control'. MSAC considered that alternative baseline HbA1c thresholds to determine CGM eligibility should be considered, to more appropriately capture the people for whom CGM would provide the most benefit (PSD for ADAR 1785, p. 4).

The Dexcom ONE+ CGM system is designed to replace self-monitoring of blood glucose (SMBG). The system uses a sensor to measure glucose concentrations in interstitial fluid, reporting the measurements in real time via a Bluetooth-enabled display device. To aid timely blood glucose management, the system issues alerts if the readings indicate hypo- or hyperglycaemia. Patients using the Dexcom ONE+ CGM system only require finger-prick testing if the system fails to display a blood glucose level and trend arrow or if a reading is inconsistent with symptoms or expectations (PSD for ADAR 1785, p.4).

The sensor can be applied to the skin on the abdomen or back of arm (or buttocks in children 2–6 years of age) using the inbuilt applicator. The Dexcom ONE+ CGM system is designed to replace SMBG for treatment decisions and adjunctive finger-prick SMBG testing because it is factory calibrated, negating the need for ongoing calibration of the device.

Finger prick testing is only required in the event that glucose alerts and readings from the Dexcom ONE+ CGM System do not match symptoms or expectations, or if the Dexcom ONE+ CGM System fails to display a blood glucose level and trend arrow. The Dexcom ONE+ CGM system consists of 2 main components:

- Dexcom ONE+ all-in-one transmitter and sensor (including sensor wire)
- Bluetooth-enabled display device—either a mobile phone with application and/or optional receiver.

The glucose readings are automatically transmitted to the receiver/compatible smart device every 5 minutes within a range of 10 metres. No scanning is required. The main consumables associated with the Dexcom ONE+CGM system are the all-in-one transmitter and sensor, which must be replaced every 10 days. It is anticipated that people with T2D using the Dexcom ONE+ CGM system will require 36 sensors per year, conservatively assuming 100% adherence/compliance. The ADAR stated that replacement/failure of sensors was rare and is accounted for in the conservative adherence/compliance estimate. In the absence of specific adherence/compliance data, this approach is appropriate.

The Dexcom ONE+ CGM system is incompatible with continuous subcutaneous insulin infusion pumps. As patients self-insert the sensor and attach the transmitter, no geographical barriers to

implementing the Dexcom ONE+ CGM system were described in the ADAR. The device is intended for use by people with T2D at home and in healthcare facilities.

Components of the system should not be worn during magnetic resonance imaging, computed tomography or high-frequency electrical heat (diathermy) treatment. The system should also not be exposed to scanners in an airport setting, such as an advanced imaging technology body scanner (also called a millimetre wave scanner), or scanned through a baggage X-ray machine. In these cases, the sensor would be removed and replaced with a new sensor, which does not appear to have been accounted for in the estimated average number of sensors per year used.

It is expected that patients with T2D accessing the Dexcom ONE+ CGM system will be registered on the NDSS and visit an authorised health professional to determine whether they meet the eligibility criteria for the device. Authorised health professionals include endocrinologists, certified diabetes educators and other health professionals specialising in diabetes (physicians, paediatricians or nurse practitioners) (PSD for ADAR 1785, p. 12).

The original ADAR noted that patients in the existing and proposed treatment pathways will be managed in very similar ways. For example, the Dexcom ONE+ CGM system will similarly be used in conjunction with oral and injectable medications and/or basal and rapid-acting insulin, suggesting that this will displace the need for routine SMBG. People using Dexcom ONE+ CGM will still need to be assessed by a GP or diabetes educator at least every 3 months.

In reviewing the original ADAR, MSAC noted the history of funding under the NDSS for people with T1D in Australia. Funding was initially available from April 2017 to people under 21 years of age with T1D, with access expanded in 2019 and 2022. There is a co-payment (equivalent to approximately $35.90 per month) for some groups. MSAC noted that NDSS funding is not currently available for CGM for people with T2D (PSD for ADAR 1785, p. 4).

MSAC noted that the NDSS currently funds CGM products from 3 manufacturers, 2 of whom submitted applications for consideration at the July 2025 meeting. MSAC Application 1786 sought funding for the FSL2 CGM system (PSD for ADAR 1785, p. 4).

In the PSD for the original ADAR, MSAC advised that if CGM for any of the identified populations is supported in future, co-payment arrangements for these populations should align with existing co-payments for people with T1D, to ensure equity of access. Based on the evidence presented, MSAC considered that different CGM systems with similar features were likely to be equivalent and unlikely to yield differences in magnitude or type of benefit. MSAC thus considered that, if funding is supported, it would be appropriate to fund different brands of CGM systems with comparable functionality in a device-agnostic manner, noting that further consideration should be given as to whether devices with specific features should be considered equivalent (PSD for ADAR 1785, p. 10).

7. Population

In the ADAR resubmission, there is one PICO set with 3 subpopulations (Table 6).

There are two differences between the PICO of the original ADAR and that of the resubmitted ADAR. The first relates to the population component: the updated PICO includes an additional subpopulation, which is the insulin-dependent First Nations subpopulation. The second relates to the outcomes component: unlike in the original ADAR, where a range of patient relevant outcomes were specified, ‘patient relevant outcomes’ for assessment are not specified in the resubmission.

Considering the scope of the clinical claim in the ADAR resubmission (Section 9), it is important to highlight the systematic review question in the PICO (Table 6):

What is the safety, effectiveness and cost-effectiveness of the Dexcom ONE+ CGM system versus SMBG in people aged ≥2 years with T2D and suboptimal glycaemic control who require insulin therapy?

Table 6: PICO criteria for assessing Dexcom ONE+ for patients with T2D that have suboptimal glycaemic control on insulin therapy in the ADAR resubmission

Component	Description
Population	The subpopulations requested consists of patients aged ≥2 years with T2D and a suboptimal glycaemic profile defined by the following criteria: **IIT subpopulation**: treated with ≥2 daily insulin injections (basal–bolus) and HbA1c levels of >7.0% for adults and >6.5% for children and adolescents. **non-IIT subpopulation:** treated with ≥1 insulin injection (not otherwise included in the IIT subpopulation) and HbA1c levels of >8% or >9% for adults and >6.5% for children and adolescents. **Insulin-dependent First Nations subpopulation**: treated with ≥1 daily insulin injection (any regimen) and HbA1c levels of >7% for adults and >6.5% for children and adolescents.
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 2 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 2 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+ CGM System.
Comparator	SMBG using a finger prick blood sample.
Reference standard	Laboratory conducted plasma venous blood glucose test.
Outcomes	**Patient relevant outcomes** *Direct evidence for safety and effectiveness:* **Intermediate/surrogate outcomes:** • glycated haemoglobin (HbA1c) **Healthcare system outcomes** • Cost, cost-effectiveness • Financial implications (financial impact, overall healthcare costs, etc.)
Systematic review question: What is the safety, effectiveness and cost-effectiveness of the Dexcom ONE+ CGM system versus SMBG in people aged ≥2 years with T2D and suboptimal glycaemic control who require insulin therapy?	

Abbreviations: AUSDRISK = Australian type 2 diabetes risk assessment tool; CGM = continuous glucose monitoring; FBG = fasting blood glucose; HbA1c = glycated haemoglobin; IIT = intensive insulin therapy; OGTT = oral glucose tolerance test; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes.

8. Comparator

The nominated comparator is SMBG, as in the original ADAR. This comparator was assessed by MSAC as appropriate during assessment of the original ADAR and is the current standard of care for blood glucose testing for the proposed populations in Australia (PSD for ADAR 1785, p. 16).

In the PSD for the original ADAR, MSAC highlighted other aspects of the comparator to bear in mind when considering the merits of the application for Dexcom ONE+ CGM system funding:

- The frequency of SMBG is individualised, but international guidelines suggest that SMBG is needed 6–10 times per day for people with IIT regiments. People with T2D requiring IIT are usually required to test their blood glucose more frequently than those not receiving IIT. The ADAR quotes evidence to suggest an increased frequency of SMBG correlates with improved HbA1c in T1D and T2D.
- The NDSS provides subsidised blood glucose monitoring strips for SMBG for a 6-month period after initial diagnosis of T2D. Ongoing access, in 6-monthly increments, is available when assessed as clinically necessary and authorised by a GP or diabetes educator. Subsidised SMBG products vary substantially in cost.
- 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 is sufficient to perform SMBG 5 times per day, which may not meet the needs of people with T2D using IIT. Typically, additional strips purchased during that period would not be subsidised, although 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 NDSS-subsidised glucose testing strips would still be required for people with T2D using CGM, to account for those circumstances when SMBG is recommended during CGM use (e.g. diabetes symptoms do not match CGM glucose readings, CGM malfunctions, or sensor becomes lost or detached).

Regarding current funding for the comparator, there are no subsidised CGM systems for T2D available via the NDSS in Australia. Some people with T2D may be able to obtain CGM systems privately or via their private health insurance plan (e.g. public or private hospital, MBS, other funding source) (PSD for ADAR 1785, p. 16).

9. Summary of public consultation input

Consultation input was welcomed from:

1785 – Dexcom ONE continuous glucose monitoring system for people with insulin dependent type 2 diabetes	Inputs Received
Organisations (12)	
I am providing input on behalf of a consumer group or organisation. Consumer organisations are not-for-profit organisations representing the interests of healthcare consumers, their families and carers.	4
I am providing input on behalf of a medical, health, or other (non-consumer) organisation. For example, input on behalf of a group of clinicians, research organisation, professional college, or from an organisation that produces a similar service or technology.	8
Individual input *	
I am a health professional or health academic working in the area.	44
I have the health condition that this health service or technology is for.	120
I have the health condition that this health service or technology is for and have experience with the proposed health service or technology.	368
I am a parent, partner or another person caring for someone from the above two groups.	48
I am an interested individual who does not fall into any of the above categories.	26
Total number of inputs received	**573**
*NOTE: Approximately half (52%) of respondents selected more than one category so the totals for each individual category when added together will be greater than the total number of inputs. That is, some of the people who indicated that they have the health condition will also have been counted as parents, health workers etc.	

The Medical Services Advisory Committee (MSAC) received consultation input from 12 organisations (4 consumer organisation and 8 health organisations) and 561individuals. Approximately half of respondents (52%) selected multiple response categories. For example, they indicated that they had the condition of interest and were also a health practitioner or academic and/or a parent or carer of someone with diabetes. Approximately 87% of individual respondents identified as having diabetes and around three quarters of these had used a continuous glucose monitor (CGM). In addition, ~9% indicated that they were a parent or carer of someone with diabetes; ~8% indicated that they were a health practitioner or health academic; and ~4% indicated that they were another interested party. Many respondents who selected one or more individual respondent types also indicated that they were submitting on behalf of an organisation. In many cases this was because they were acting in response to email advice they received from the applicant about the MSAC consultation. For the purposes of this summary, these inputs have been treated as input from individuals.

The organisations that provided input were:

- DPV Health
- Cystic Fibrosis Qld, which noted its submission was informed by direct engagement with people living with cystic fibrosis, families, service providers and clinicians
- Western Sydney Diabetes[1]
- Queensland Diabetes Clinical Network
- Diabetes Australia

- Australasian Diabetes in Pregnancy Society
- The Prince Charles Hospital, Queensland Lung Transplant Service and Advanced Heart Failure and Heart Transplant Unit
- CF Together (2 inputs)
- Australian Diabetes Society
- Medtronic
- Diabetes Health Network, WA

A tailored survey was used for the consultation, seeking stakeholder views on issues raised by the MSAC when it considered the application in July 2025. Survey responses included opinions, reflections and insights informed by lived and practice-based experiences.

Responses were overwhelmingly supportive of expanded NDSS access to continuous glucose monitoring (CGM) for people with diabetes, particularly those using insulin. Contributors described CGM as a practical, preventative tool that reduces the burden and pain of frequent finger-prick testing, improves day-to-day decision-making about food, activity and medication, and provides real-time trend information and alerts that can be responded to, to prevent dangerous hypoglycaemia and hyperglycaemia. A recurrent theme was that cost should not be a barrier to safety, and people experiencing financial hardship / low-income households cannot afford to pay privately for CGM.

A summary of responses against each survey question is provided below.

Type 2 diabetes requiring insulin – groups who may benefit more from CGM

Approximately 76% of respondents agreed that some groups of people with type 2 diabetes requiring insulin would benefit more than others from CGM. Many still advocated for universal eligibility, arguing that all people with type 2 on insulin (and even those not on insulin) would benefit from the educational, monitoring, and safety aspects of a CGM. However, respondents highlighted groups who they believed would benefit most, including:

- People who require multiple daily insulin injections or both long and short-acting insulin.
- People with high HbA1c or other indicators of poorly controlled diabetes such as recurrent hypo- or hyperglycaemic episodes.
- Young people (not necessarily on insulin) who develop type 2 diabetes, to help establish lifelong preventive habits.
- Older people, or people with disability, who have reduced vision, dexterity or cognitive or communication impairments or differences;
- Neurodivergent people, people with complex comorbidities or mental health conditions who have impairments in memory and/or other cognitive functions that make it challenging to recognise and communicate about symptoms of concern, and/or manage the work of monitoring and recording blood glucose levels without CGM.

The benefits of CGM identified as most significant for people in these groups, and for carers of people in these groups, included:

- Safety – CGM makes it is easier to avoid/identify/communicate about and/or respond to hypo- or hyperglycaemic episodes and achieve improved overall diabetes control.
- Ease – CGM reduces how much work it takes, and how hard and/or complex and/or demanding this work is, of monitoring, record keeping, and, when needed, communicating about one's data to carers and health professionals.

- Enhanced learning – CGM can provide accessible, effective learning experiences for people who might otherwise find it challenging to learn how to manage their blood glucose levels or provide support to someone else.
- Agency – Some people who need to rely on a carer without CGM are, or can become able to manage independently with CGM, or can be supported to participate in these processes with a carer.

Relevant examples include:

- A respondent who provides disability support to a client who is non-verbal explained the client may not be able to readily communicate symptoms of concern to staff between finger prick tests, but CGM could provide alerts.
- A parent of a person with intellectual disability described how access to CGM and the real time data could support their daughter to learn about how to manage her diabetes independently, or together with support workers.
- Working parents with busy lives reported it's difficult to manage or prioritise regular finger prick testing.
- Elderly people reported that age-related vision-impairments and arthritis make it physically difficult to finger prick.

Some respondents also identified people with type 3c diabetes, including cystic fibrosis related and other atypical forms of diabetes, and gestational diabetes as particularly benefiting from CGMs. The Australian Cystic Fibrosis Data Registry was cited as an important source of real-world evidence that could support identification of people with Cystic Fibrosis who could most benefit from CGM. People in safety-critical roles, such as drivers, frontline workers and shift-workers; and those at risk of nocturnal hypoglycaemia were also identified as groups that may benefit from more access to CGM, due to the serious risks associated with severe glycaemic events and complications.

Around 13% of respondents did not agree that some groups would benefit from a CGM more than others, stating that 'all people with diabetes' or 'anyone on insulin' would benefit. Many also said targeting only certain groups would be inequitable, could unfairly exclude people who are managing well (or create perverse incentives not to manage well) and ignores the fact that cost is a major barrier for many who could benefit. A small number expressed the view that funding would be better directed towards insulin pumps or enhanced subsidy for people with type 1 diabetes. MSAC was encouraged to consider how registry data could be more formally incorporated into evaluation frameworks.

Short term or intermittent use

Most respondents (~97%) answered the question about whether people would still benefit from intermittent or short-term use of a CGM. Approximately 58% of these respondents agreed people would still benefit; ~ 20% did not agree; and the remainder (~ 19%) were unsure. Many respondents stressed that ongoing CGM access would be preferable but still viewed intermittent CGM as 'better than no access.' Respondents considered intermittent or short-term CGM use beneficial because it provides continuous, real-time glucose data that can reveal patterns not captured by finger-prick testing, including overnight high and low glucose levels, post-meal spikes, hypoglycaemia, hyperglycaemia and glycaemic variability. Respondents said this can support safer insulin initiation and titration, guide medication use, diet and exercise changes, and help clinicians tailor treatment during periods of change such as new diagnosis, illness, pregnancy or hospital discharge. It was also viewed as a useful educational tool that helps

people understand how food, activity, stress and medication affect their glucose levels, motivating behaviour change, improving self-management, reducing finger-prick burden and diabetes distress, and offering a more affordable or practical option for people who may not need or cannot sustain continuous CGM use.

In terms of the duration of short-term use, health practitioners noted that this would vary for different groups. For example, a pregnant person with diabetes may only need a CGM for the duration of the pregnancy, while someone on steroid treatment may only need it while taking the steroid. A needs-based eligibility framework rather than one restricted by diabetes classification alone was suggested to ensure CGM is used where it has the greatest impact. The most common periods cited by both health practitioners and other respondents was three or six months, on the basis that it gives enough time for people to learn how to use CGM, understand glucose patterns, adjust treatment or behaviour, and demonstrate whether the technology is clinically useful. Some people with diabetes felt that even a fortnight of use would be beneficial, supporting targeted education, allowing the effectiveness of treatment or behaviour changes to be monitored, and supporting periodic treatment reviews.

For intermittent use, the most common suggestions were for regular intermittent use tied to quarterly or six-monthly review cycles, followed by blocks of around two to three months per year. Many respondents proposed one month every three months (quarterly) or every six months because these intervals align with HbA1c testing, routine clinical reviews, and the need to reassess glucose patterns after changes in diet, activity or medication. Respondents said these schedules would help people “stay on track”, check whether blood glucose was remaining stable, and provide enough data to identify patterns, troubleshoot problems and adjust treatment before the next review period. Some respondents preferred smaller, repeated blocks across the year rather than one long period, to capture seasonal, lifestyle, and health changes over time.

Many emphasised that the optimal duration would vary by individual and clinical need, with higher-risk groups—such as people using insulin, experiencing hypoglycaemia, pregnancy or unstable diabetes—often seen as needing more frequent or continuous access rather than intermittent use. Some respondents described their lived or practice-based experiences to demonstrate how short-term or intermittent use may be very beneficial for some people, but not for others, due to other personal or clinical factors. For example, for someone with ADHD, or another condition that impairs executive functioning, intermittent use may have little or no durable benefits, but continual use may.

Respondents who did not see benefit in intermittent or short-term CGM use noted that glucose levels can be impacted by multiple factors and fluctuate daily, so effective management may require ongoing rather than episodic monitoring. Several people expressed that it felt cruel, and could exacerbate stress-related conditions, to grant people who otherwise could not afford it, the ability to view real-time data about their ‘full time health condition’ for a short term, then take it away again.

Most respondents (~ 79%) agreed that the groups of people identified by MSAC as benefiting from short term or intermittent use would do so. Approximately nine percent did not agree that these groups would benefit, and the remainder were unsure (~ 9%) or did not answer the question (~3%). Responses frequently referred to the benefits of short-term of intermittent CGM for people with type 2 diabetes not requiring insulin, especially where glucose levels are poorly controlled, multiple medications are required, or where insulin use is being considered as the next step. Other groups cited in responses about intermittent or short-term CGM included people newly diagnosed, those starting insulin for the first time, people with pre-diabetes or insulin resistance, pregnant people with diabetes and those who develop gestational diabetes, and people with impairments related to ageing or disability that make finger-prick testing difficult.

Respondents said short-term or intermittent CGM could support early education and safer treatment adjustment, help people review the impact of diet and lifestyle before diabetes progresses, improve glucose control during pregnancy, and increase safety and independence for people at risk of unnoticed highs or lows or who cannot self-monitor.

Co-payments

Approximately 80% of respondents agreed that, if funded, the approach to co-payments should reflect current arrangements for people with type 1 diabetes who are eligible to access a CGM through the National Diabetes Services Scheme (NDSS). Respondents who provided comment noted that this approach would provide fairness, consistency and equity across people with similar clinical needs. Many respondents said that a co-payment would make CGM substantially more affordable and accessible, compared with current out-of-pocket costs, which were often described as prohibitive. Several also argued that improved access could reduce long-term complications and health system costs.

Around 8% of respondents did not support a co-payment that reflected the funding available to people with type 1 diabetes, ~9% were unsure, and ~3% did not answer the question. A small number of respondents noted that people with type 1 diabetes do not produce insulin at all and therefore are at higher clinical risk and should receive a greater subsidy. Others argued that CGM was a 'life saving' tool and should be provided free of charge to everyone on insulin.

Affordability remained a key concern of respondents, regardless of whether they supported a copayment. There were responses that supported concessional rates, means testing, or waived co-payments for higher-risk or financially vulnerable groups. Many respondents stressed that a co-payment could disproportionately impact access and have long-term financial impacts for people on low incomes, including those who don't qualify for concessions but have very high costs related to medical treatment of multiple conditions or for multiple family members. Many respondents who did not agree with a co-payment said that the current type 1 rate would still mean CGM is too expensive for many people. Many raised that the financial impact would be greatest for groups experiencing multiple other forms of intersecting marginalisation, including First Nation's people, pensioners, and people who need to travel long distances to see their specialists and argued CGM should be fully subsidised when clinically recommended.

Role of general practitioners (GPs)

Approximately 87% of respondents were supportive of GPs being able to certify eligibility for CGM products through the NDSS. This dropped to ~ 66% of those who identified as health practitioners or health academics. Around 7% of respondents did not support GP involvement, while ~4% were unsure and ~2% did not answer the question.

The most common reasons for supporting GP involvement in CGM certification was improved access and reduced delays. Respondents noted that it can take months to see an endocrinologist, especially in rural, regional, and remote Australia, and the cost may be prohibitive, creating unnecessary barriers to access. Access to diabetes educators can also be limited. Allowing GPs to certify CGM access was seen as reducing out-of-pocket costs and administrative hurdles, making access faster, simpler and more equitable.

Many respondents also noted that their GP manages their diabetes day to day, monitors test results, prescribes insulin and medications, and understands their broader health needs and circumstances better than a specialist who is seen only occasionally. Supporters argued that allowing GPs to certify eligibility would better reflect how diabetes care is delivered in Australia, improve continuity of care, and ease pressure on specialist services. However, respondents noted the need for appropriate training, clear guidance, and referral pathways for complex cases.

Respondents who did not support GP involvement generally argued that GPs may lack the specialist expertise, time, and up-to-date knowledge needed to assess CGM eligibility and support effective use. Many preferred certification to remain with endocrinologists and diabetes educators, who were seen as better placed to provide appropriate oversight, education, and ongoing management, while also reducing the risk of inappropriate access or misuse.

In terms of additional training that GPs may require to certify eligibility for CGM products through the NDSS, most respondents noted that GPs were experienced in managing diabetes, especially type 2 diabetes, and would only require targeted, practical training in CGMs. The main areas of training identified were:

- training on the use of CGMs, including how the device works, how to apply it, how to read and interpret the results and how to explain the results to patients.
- refresher training on diabetes subtypes, insulin management, glucose variability, and the benefits and limitations of CGMs.
- clear, simple guidance on how to assess eligibility for a CGM, with respondents wanting standardised criteria, decision tools, and straightforward information on available products, policies and referral thresholds.

In addition, respondents noted that GPs should have ready access to support from specialists and diabetes educators. Many favoured shared care with, or referral pathways to, endocrinologists, diabetes educators/nurses and dietitians/nutritionists. A small number of respondents felt that GPs were too time poor to take on this role and had poor understanding of managing people with insulin dependent diabetes.

Additional comments/themes

Several key themes emerged from comments received by MSAC on this application. The first theme relates to people's experiences using a CGM, with many describing it as 'life-changing' or 'lifesaving'. Benefits that respondents highlighted include improved glucose control, better understanding of how food, exercise and medication affect blood glucose, and greater ability to detect and prevent hypoglycaemic events, especially overnight.

The second major theme concerns affordability and equity. Many respondents indicated that the current cost of continuous glucose monitoring (CGM) devices is unsustainable, particularly for pensioners, low-income households, older adults, and individuals with multiple health conditions. Some reported being forced to ration their usage, forgo access entirely, or make significant personal sacrifices to maintain access. Additionally, there was a strong perception that existing eligibility criteria are unfair and discriminatory, as people with similar clinical needs may be treated differently due to an 'outdated classification system'. Criteria based on diabetes type were seen as potentially excluding high-risk individuals with complex clinical needs from receiving subsidised CGM access.

Respondents also frequently argued that broader access would be a preventive investment, reducing hospitalisations and long-term complications, although a smaller number raised concerns about cost-effectiveness, evidence of benefit for some groups, supply capacity, and the influence of manufacturers.

10. Characteristics of the evidence base

The updated literature search did not identify any new comparative studies, as acknowledged by the applicant in the section of the ADAR resubmission describing the results of the search and study selection (ADAR 1785 resubmission, p. 52).

The clinical claim in the ADAR resubmission is based on: 1) Hba1c outcomes from 2 RCTs (not pooled)—one assessing the non-IIT population, the other the IIT population—which constitutes the primary evidence base; and 2) results of a meta-analysis performed specifically for the ADAR resubmission, which pooled HbA1c outcomes from various studies, including a subset of studies previously included in the original ADAR and studies included in application 1786 (FSL).

Primary evidence – HbA1c outcomes evaluating RT-CGM vs SMBG in the non-IIT (1 RCT) and IIT subpopulations (1 RCT)

In the ADAR resubmission, results for the primary outcome (change in %HbA1c) reported in 2 RCTs (DIAMOND and MOBILE) constitute the primary evidence base underpinning the clinical effectiveness claim. The DIAMOND trial contributed the outcomes data for evaluation of comparative effectiveness for the IIT subpopulation (i.e. those who require treatment with basal insulin and bolus insulin). The MOBILE trial contributed data for assessment of the non-IIT subpopulation.

No studies evaluated the comparative effectiveness of the Dexcom ONE+ CGM system compared to SMBG in the First Nations subpopulation proposed for public funding.

Key characteristics of the trials included to inform the comparative effectiveness claim are presented in Table 7.

Table 7: Key features of the primary evidence used to assess comparative effectiveness in the ADAR resubmission

References	Eligibility criteria (N)	Setting	Design/duration	Risk of bias *	Patient population	Outcome(s)	Use in modelled evaluation
Dexcom ONE+ CGM vs SMBG							
DIAMOND trial (Beck 2017 [primary publication]; Billings 2018 [post-hoc analysis]) Protocol registration at ClinicalTrials.gov: NCT02282397	Age ≥25 years, T2D treated with multiple daily injections of insulin for at least 1 year, central laboratory measured HbA1c levels of 7.5% to 10.0%, stable diabetes medication regimen and weight over the prior 3 months, self-reported BGM averaging 2 or more times per day and estimated glomerular filtration rate of at least 45 mL/min/1.73 m^2. (N=158 randomised, Dexcom ONE+ arm 79, SMBG arm 79)	25 endocrinology practices in North America (22 US, 3 Canada), of which 19 were community-based and 6 were academic centres (4 additional sites screened but did not enrol patients).	RCT (OL, referred to as DIAMOND trial)	Low	IIT subpopulation (i.e. those who require treatment with basal insulin and bolus insulin)	Difference in mean change in %HbA1c HbA1c categories, including <7.0% and <7.5% Reduction in HbA1c level, various categories, including ≥10%, ≥1%, ≥0.5% Reduction in HbA1c level ≥1% or HbA1c level <7% Follow up at 3 months and 6 months	Used (point effect estimate of −0.3% change in HbA1c was used for the IIT subpopulation in the cost effectiveness modelling)

References	Eligibility criteria (N)	Setting	Design/duration	Risk of bias *	Patient population	Outcome(s)	Use in modelled evaluation
MOBILE trial (Martens 2021 [primary publication]; Martens 2025 [post-hoc analysis]; Davis 2022 [post-hoc analysis]) Protocol registration at ClinicalTrials.gov: NCT03566693	Age ≥30 years, diagnosis of T2D treated with 1 or 2 daily injections of long- or intermediate-acting basal insulin for at least 6 months, locally measured HbA1c level of 7.8–11.5% (lower limit changed during study from 8.0–7.8% to enhance recruitment), self-reported BGM testing averaging ≥3 per week, and availability of a smart phone compatible with the CGM device for data uploading. Participants could be using any other antidiabetic medication in addition to basal insulin (provided the regimen had been stable for at least 3 months), but not prandial insulin. (N=175 randomised, Dexcom ONE+ arm 116, SMBG 59)	15 sites in US	RCT (OL, referred to as MOBILE trial)	Some concerns	Non-IIT subpopulation (those who require treatment with basal insulin (including pre-mixed regimens)	Difference in mean change in %HbA1c Follow up at 3 months and 8 months for all outcomes	Used (point effect estimate of −0.4% change in HbA1c was used for the non-IIT subpopulation in the cost effectiveness modelling)

Abbreviations: BGM = blood glucose monitoring; CGM = continuous glucose monitoring; DB = double blind; HbA1c = glycated haemoglobin; IIT = intensive insulin therapy; MC = multicentre; OL = open label; RCT = randomised controlled trial; SMBL = self-monitoring of blood glucose; T2D = type 2 diabetes.
Note: *Assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2) by the commentary.

Two trials (Steno2tech (Lind 2024) and 2GO-CGM (Lever 2024)), included in the original ADAR were excluded from the synthesis/results of the ADAR resubmission. The applicant reported the reasons for these study exclusions as follows.

- Steno2tech: "MSAC raised concerns relating to the magnitude of HbA1c benefit and statistical power of this trial in their evaluation of Application 1785" (ADAR 1785 resubmission, p. 56).
- 2GO-CGM: "The overall trial population (~50% of patients were using basal insulin only while ~50% were using basal-bolus insulin) was deemed not applicable to proposed subpopulations (Section 1) as subgroup analyses were not reported for intensive and non-intensive cohorts. It was not applicable to the proposed use of RT-CGM in Australia, as patients in this study were generally younger and had higher baseline HbA1c levels than is likely to be observed in Australian clinical practice. This study is predominantly (54%) in an Indigenous Māori population" (ADAR 1785 resubmission, p. 56)

Secondary evidence – Meta-analysis of HbA1c outcomes assessing RT-CGM vs SMBG across IIT and non-IIT subpopulations

In the ADAR resubmission, results of a meta-analysis that pooled change in %HbA1c outcomes from RCT and real-world evidence (RWE) studies (n=9 in total) to assess RT-CGM against SMBG across both IIT and non-IIIT subpopulations were also presented. Four of the included studies reported change in HbA1c results from comparisons of Dexcom RT-CGM against SMBG, while 5 reported these outcomes from comparisons of FSL/Flash Glucose Monitoring (FGM) against SMBG. The studies were identified from the original ADAR 1785 and original ADAR 1786 (as discussed in the 1786 PSD), respectively. The length of follow-up prior to HbA1c assessment varied across the studies included in the meta-analysis (10 weeks to 3–6 months). Five of the studies were IIT population assessments, and 4 were non-IIT population assessments (or mostly).

Outcomes of subsets of the studies were also pooled to investigate whether the treatment effect is greater for Dexcom ONE+ than for FSL/FGM.

Table 8 provides the ADAR resubmission's description of the studies in these meta-analyses, including the point effect estimates of the summary HbA1c measures. The forest plot of the meta-analyses presented in the resubmission is provided in Figure 1.

Table 8: Scenario analyses presented in meta-analysis for Dexcom RT-CGM and FSL/FGM

Study ID	Evidence type	Timepoint	T2D population	Change in HbA1c	Scenario analyses								
					#1	#2	#3	#4	#5	#6	#7	#8	#9
Dexcom RT-CGM													
DIAMOND	RCT	3 months	IIT	−0.3%	✓	✓	x	x	✓	✓	x	x	x
MOBILE	RCT	8 months	Non-IIT	−0.4%	x	x	x	x	x	x	✓	x	✓
Steno2tech	RCT	12 months	Non-IIT (83%)	−0.9%	x	x	x	x	x	x	✓	x	✓
Karter (2021)	RWE	12 months	IIT	−0.56%	x	✓	x	x	x	✓	x	x	x
FSL/FGM													
Haak (2017)	RCT	6 months	IIT	0.03%	x	x	✓	✓	✓	✓	x	x	x
Yaron (2019)	RCT	10 weeks	IIT	−0.49%	x	x	✓	✓	✓	✓	x	x	x
Bosi (2022)	RWE	3–6 months	Non-IIT	−0.3%	x	x	x	x	x	x	x	✓	✓
Nathanson (2025a)	RWE	24 months	IIT	−0.33%	x	x	x	✓	x	✓	x	x	x
Nathanson (2025a)	RWE	24 months	Non-IIT	−0.34%	x	x	x	x	x	x	x	✓	✓
Total number (N) of studies included				9	1	2	2	3	3	5	2	2	4
Meta-analysed result of change in %HbA1c				−0.35%	−0.30%	−0.45%	−0.22%	−0.25%	−0.24%	−0.33%	−0.60%	−0.34%	−0.37%

Abbreviations: FSL/FGM = FreeStyle Libre/Flash glucose monitoring; IIT = intensive insulin treatment; RCT = randomised controlled trial; RWE = real-world evidence; RT-CGM = real-time continuous glucose monitoring; T2D = type 2 diabetes.

11. Comparative safety

No comparative safety data were included for assessment in the ADAR resubmission. The ADAR resubmission stated this is because the conclusion that Dexcom ONE+ compared to SMBG has non-inferior safety was not disputed by the ESC or MSAC.

12. Comparative effectiveness

The main comparative effectiveness outcomes presented in the ADAR resubmission (described as the 'primary evidence') are summarised in Table 9 and Table 10. The quality of the evidence was reevaluated by the assessment group using the GRADE approach and is incorporated into the interpretation of the evidence (see Section 2A.3).

Application of the GRADE framework was informed by MSAC guidance, alongside recently published GRADE guidance on rating imprecision.[3] [4] The rationale that informed the downgrading of the certainty of evidence (from high to low or very low) is detailed in notes accompanying each of the tables presenting the primary outcome results which are presented directly below.

RT-CGM versus SMBG

IIT subpopulation

The DIAMOND trial change in %HbA1c results suggest that compared to SMBG, RT-CGM may lead to a greater reduction in HbA1c at 3 months and possibly a similar treatment effect at 6 months in the IIT subpopulation. However, it must be noted that the differences indicated are lower than that generally accepted by PBAC in the past as sufficient to imply clinical significance (0.5% difference) – as noted in Table 1, the ADAR resubmission did not supply any justification for adopting a lower MCID of 0.3%. Additionally, there is imprecision in the results, due to the small sample sizes included in the analysis. Accordingly, the evidence supporting these findings is rated as low to very low certainty by the commentary (Table 9).

Another finding from the DIAMOND trial is that a greater proportion of patients using RT-CGM achieved an improvement in HbA1c of ≥0.5% (assessed at 6 months) than patients using SMBG. In the DIAMOND trial, 73% (n=56/79) of patients in the RT-CGM arm achieved an improvement in HbA1c of ≥0.5% compared with only 49% (n=37/79) of patients in the SMBG arm (p=0.007). This means an additional 24% of patients managed with RT-CGM (compared with SMBG) achieved a clinically important improvement in health outcomes measured by HbA1c change. However, this finding is subject to uncertainty as it is based on one small trial (n=79 in each arm).

Non-IIT population

The MOBILE trial results indicate that RT-CGM compared to SMBG may result in a greater reduction in HbA1c at 3 months and 8 months in the non-IIT subpopulation. Concerns underlying the certainty of the evidence are the same as those in the IIT subpopulation; however, in the

[3] Zeng L, Brignardello-Petersen R, Hultcrantz M, Mustafa RA, Murad MH, Iorio A, et al. GRADE Guidance 34: update on rating imprecision using a minimally contextualized approach. Journal of clinical epidemiology 2022;150: 216–24.

[4] Schünemann HJ, Neumann I, Hultcrantz M, Brignardello-Petersen R, Zeng L, Murad MH, et al. GRADE guidance 35: update on rating imprecision for assessing contextualized certainty of evidence and making decisions. Journal of clinical epidemiology 2022;150: 225–42.

MOBILE trial (non-IIT population) bias due to imbalance between the groups is a low-level additional concern. Assessed using GRADE, this evidence is very low certainty (Table 9).

The change in HbA1c for RT-CGM versus SMBG (i.e. ≥8.5%, ≥9.5%) gives the impression of a small superior treatment effect at 8 months favouring RT-CGM, which increases as baseline HbA1c increases. While this is encouraging, and could be useful to inform targeting of funding, confidence in this finding is still affected by imprecision relating to small sample sizes (Table 10).

Table 9: Clinical trial results for change in HbA1c for RT-CGM vs SMBG (DIAMOND and MOBILE)

Timepoint	RT-CGM [Dexcom ONE+ system]	SMBG	Mean (95% CI) adjusted difference; p value	Quality of evidence [Reassessment] **
IIT subpopulation: DIAMOND (ITT)				
Baseline	8.5 (0.6) (n=79)	8.5 (0.7) (n=79)	-	
3 months	−1.0 (−1.2, −0.8) (n=77)	−0.6 (−0.8, −0.4) (n=75)	−0.3 (−0.6, −0.1); p=0.005	⊕⊕⊙⊙ LOW [a]
6 months	−0.8 (−1.0, −0.7) (n=77)	−0.5 (−0.7, −0.3) (n=75)	−0.3 (−0.5, 0.0); p=0.022	⊕⊙⊙⊙ VERY LOW [b]
Non-IIT subpopulation: MOBILE (primary analysis set)				
Baseline	9.1 (1.0) (n=115)	9.0 (0.9) (n=58)	-	
3 months *	−1.2 (1.2) (n=108)	−0.6 (1.2) (n=57)	−0.5 (−0.9, −0.3); p<0.001	⊕⊙⊙⊙ VERY LOW [c]
8 months	−1.1 (1.5) (n=105)	−0.6 (1.2) (n=51)	−0.4 (−0.8, −0.1); p=0.02	⊕⊙⊙⊙ VERY LOW [d]

Abbreviations: CI = confidence interval; IIT = intensive insulin therapy; ITT = intention-to-treat; RT-CGM = real-time continuous glucose monitoring; SMBG = standard monitoring of blood glucose.
Notes: * analyses conducted post-hoc.
** The applicant rated the evidence quality for all outcomes as MODERATE in the ADAR 1785 resubmission and stated that "RCTs were graded as per the ESC evaluation of Application 1785" (refer to p. 69 of the current ADAR). During evaluation, the quality of evidence was reassessed.
Reasons for downgrading:
[a] Risk of bias: lack of blinding of participants may have resulted in performance bias (although this is a low-level concern), no downgrading; Imprecision (−2): 1 trial only with few participants. The magnitude of the difference indicated by the point effect estimate is less than the level (0.5%) generally accepted (including by PBAC) as sufficient to indicate a meaningful difference between groups in this outcome, and the confidence interval included the MCID threshold value Indirectness of evidence: follow-up time is relatively short, however we have not downgraded for this concern.
[b] Risk of bias: lack of blinding of participants may have resulted in performance bias (although a low-level concern); Imprecision (−3): 1 trial only with few participants, the magnitude of the difference indicated by the point effect estimate is less than the level (0.5%) generally accepted as sufficient (including by PBAC) to indicate a meaningful difference between groups in this outcome, and the confidence interval included the MCID threshold value. Indirectness of evidence: follow-up time is relatively short, however we have not downgraded for this concern.
[c] Risk of bias (−1): lack of blinding of participants may have resulted in performance bias (although this is a low-level concern). Imbalance in the number of participants randomly assigned to the groups (CGM n=116, SMBG n=59) is a concern. Imprecision (−2): 1 trial only with few participants, while the difference indicated by the point effect estimate is sufficient to indicate a meaningful difference, upper CI value less than MCID value, signalling uncertainty about whether the magnitude of difference required for a clinically important effect is indicated for the general population. Indirectness of evidence: follow-up time is relatively short, however we have not downgraded for this concern.
[d] Risk of bias (−1): lack of blinding of participants may have resulted in performance bias (although a low-level concern) and imbalance in the number of participants assigned to the groups is a concern. Imprecision (−2): 1 trial only with few participants. The magnitude of the difference indicated by the point effect estimate is less than the level (0.5%) generally accepted as sufficient (including by PBAC) to indicate a meaningful difference between groups, and the upper CI value is less than the commonly accepted MCID value (0.5%).

Table 10: Clinical trial results conducted post-hoc and stratified by baseline %HbA1c change for RT-CGM vs SMBG at 8 months (MOBILE)

Baseline HbA1c	Mean change from baseline		Mean (95% CI) adjusted difference*; p value	Quality of evidence [Reassessment] **
	RT-CGM	SMBG		
Non-IIT subpopulation: MOBILE (8 months)				
≥8.5%	−1.4 (n=74)	−0.9 (n=35)	−0.4 (−0.8, 0.1); p=0.10	⊕⊙⊙⊙ VERY LOW [a]
≥9.0%	−1.4 (n=53)	−1.0 (n=27)	−0.3 (−0.8, 0.3); p=0.37	⊕⊙⊙⊙ VERY LOW [a]
≥9.5%	−1.7 (n=39)	−0.9 (n=13)	−0.8 (−1.6, 0.1); p=0.06	⊕⊙⊙⊙ VERY LOW [b]
≥10.0%	−2.1 (n=22)	−0.4 (n=8)	−1.5 (−2.6, −0.5); p=0.005	⊕⊙⊙⊙ VERY LOW [c]

Abbreviations: CI = confidence interval; IIT = intensive insulin therapy; RT-CGM = real-time continuous glucose monitoring; SMBG = standard monitoring of blood glucose.

Notes:

* Adjusted for baseline HbA1c and clinical site. Analyses conducted post-hoc.

** The applicant assessed the first 3 outcomes listed in the table as LOW quality and the last as VERY LOW quality and made a note that: "post-hoc analyses have been regraded due to low sample sizes and post-hoc nature of the analyses" (p. 70, Table 23). During evaluation, the quality of evidence was reassessed, and the overall assessment was similar.

Reasons for downgrading:

[a] Risk of bias (-1): imbalance in number randomised to groups is a concern, and lack of blinding of participants may have resulted in performance bias (although the latter is a low level concern); Imprecision (-2): one trial only with few participants, the magnitude of the difference indicated by the point estimate is less than the level (of 0.5%) generally accepted as sufficient to indicate a meaningful difference between groups in this outcome (including by PBAC), the wide confidence interval includes the MCID threshold value and null value.

[b] Risk of bias (-1): imbalance in number randomised to groups is a concern, and lack of blinding of participants may have resulted in performance bias (although the latter is a low-level concern); Imprecision (-2): one trial only with few participants, the wide confidence interval includes the MCID threshold value and null value.

[c] Risk of bias (-1): imbalance in number randomised to groups is a concern, and lack of blinding of participants may have resulted in performance bias (although the latter is a low-level concern); Imprecision (-2): one trial only with very few participants.

Overall T2D population (non-IIT or IIT subpopulations)

In the T2D population with suboptimal glucose control (IIT or non-IIT subpopulations) the overall pooled effect from 9 studies favoured CGM (Dexcom and Flash) over SMBG, with a mean HbA1c reduction of −0.35% (95% CI: −0.45, −0.25; I^2 = 66%) (Figure 1, Table 11).

The methods of the meta-analysis and details of the studies included in the meta-analysis are poorly reported in the ADAR. The summary results produced should be interpreted as being supported by very low certainty evidence and there is limited confidence in the presented results. This is due to the pooling of RWE and RCT HbA1c outcomes, the number of participants contributing data to each individual study estimate is not provided, the lack of information on whether or how analyses of RWE/observational studies adjusted for potential confounders (or what were considered to be the main prognostic factors that needed adjustment by the studies to ensure groups compared were similar across the included studies), and no reporting of risk of bias assessments for the included studies.

Table 11: Summary result for change in HbA1c for RT-CGM vs SMBG (9 studies)

Time point	RT-CGM [Dexcom ONE+ or other type of CGM device]	SMBG	Mean (95% CI) adjusted difference; p value	Heterogeneity (Cochrane I^2 statistic)	Method	Quality of evidence *
IIT or non-IIT subpopulation						
Up to 2 years	Not reported	Not reported	−0.35 (−0.45 to −0.25)	66%	Random effects	⨁⊙⊙⊙ VERY LOW [a]

Abbreviations: Assessment Group = AG; CI = confidence interval; IIT = intensive insulin therapy; RT-CGM = real-time continuous glucose monitoring; SMBG = standard monitoring of blood glucose.

Notes:

* Assessed by the AG.

Reasons for downgrading:

[a] Risk of bias (−1): possible performance bias is a concern due to lack of blinding of participants in the trials (all were open label trials). In 3 trials (MOBILE, Yaron 2019, Haak 2017) bias related to imbalance between the groups is a concern. In the Steno2tech trial bias due to missing outcome data is a concern. For the RWE observational studies, adjustment was poorly reported and no details were provided about how the groups compared were selected, therefore selection bias and confounding are concerns. Imprecision (−1): point estimate of effect is less than the value generally accepted as sufficient to indicate a clinically meaningful difference. Inconsistency (−1): I^2 >50%. Indirectness of evidence (−1): length of follow-up highly variable across the studies included, and lack of clarity about similarities/differences in key characteristics of the T2D subpopulations included. Publication bias (−1): search reported in the ADAR 1785 resubmission states clearly that RCTs that evaluated Dexcom ONE+ vs SMG were sought.

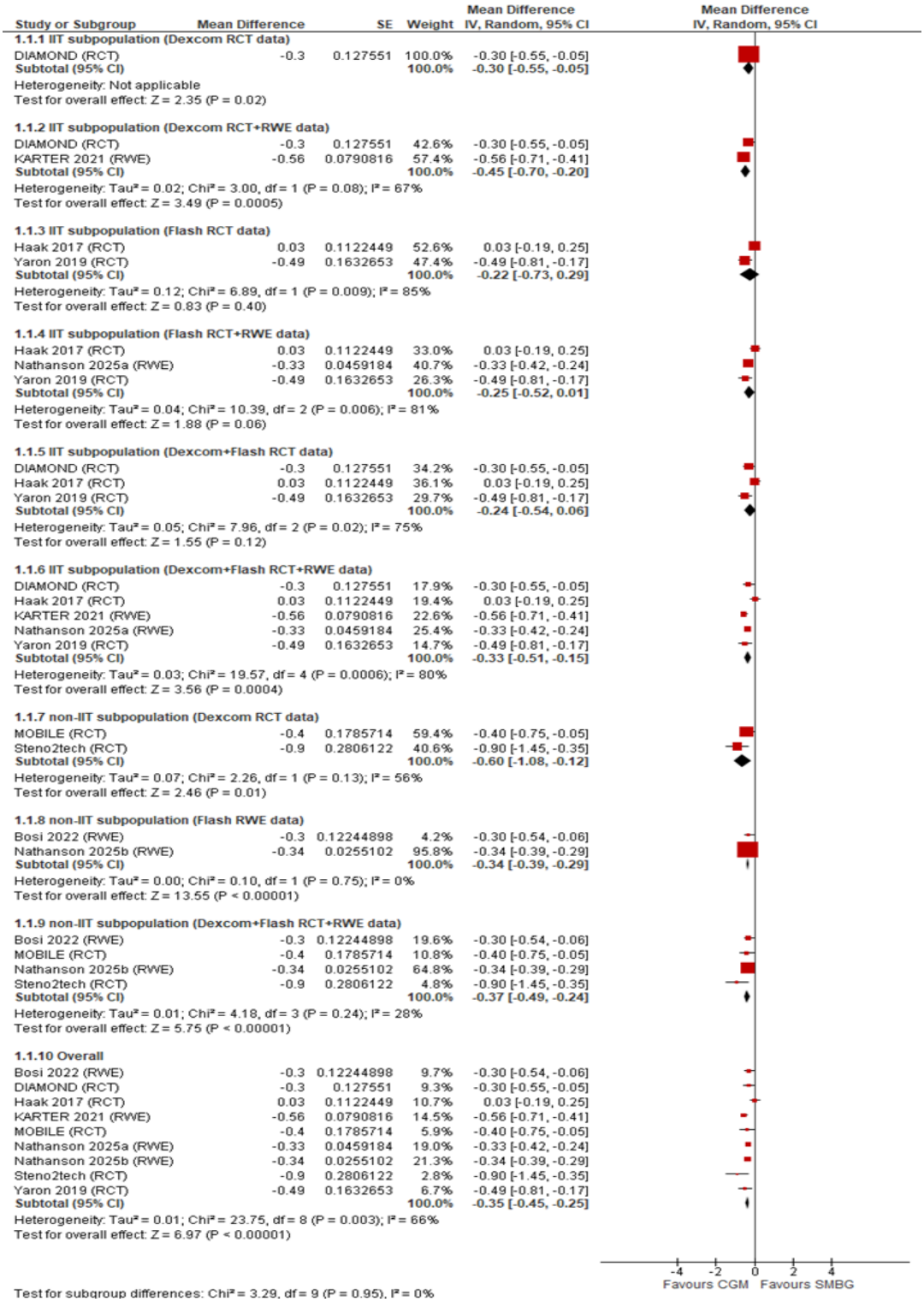


Figure 1: Forest plot of meta-analysis assessing RT-CGM vs SMBG

Abbreviations: FSL/FGM, FreeStyle Libre/Flash Glucose Monitoring; IIT, intensive insulin treatment; RCT, Randomised Controlled Trial; RWE, Real-World Evidence; RT-CGM, Real-Time Continuous Glucose Monitoring; T2D, Type 2 Diabetes.
Source: ADAR 1785 Resubmission, p. 67 (Attachment 2 - Note that this attachment is a RevMan file that is zipped, which the assessment group was unable to open, but were able to source from the ADAR resubmission document).

RT-CGM using Dexcom ONE+ versus FreeStyle Libre/Flash Glucose Monitoring

As the applicant reported, across the pooled analyses, RT-CGM was consistently associated with greater reductions in HbA1c compared with FSL/FGM across both IIT and non-IIT T2D populations.

When analyses were restricted to studies directly comparing RT-CGM (Dexcom) with FSL/FGM (refer to Table 8 for the scenarios), the pooled estimates consistently favoured RT-CGM (Dexcom), in terms of HbA1c reduction across both insulin-treated subgroups:

- In the IIT population, combining RCT and RWE evidence for RT-CGM (DIAMOND; Karter 2021) vs FSL/FGM (Haak 2017; Nathanson 2025a; Yaron 2019) yields a numerical HbA1c benefit in favour of Dexcom RT-CGM (MD: −0.45% [Scenario #2] vs −0.25% [Scenario #4]), equating to a HbA1c difference of 0.2%.
- In the non-IIT population, comparing RCT for Dexcom RT-CGM (MOBILE; Steno2tech) vs RWE evidence for FSL/FGM (Bosi 2022; Nathanson 2025b) resulted in a numerical HbA1c benefit in favour of Dexcom RT-CGM (MD: −0.60% [Scenario #7] vs −0.34% [Scenario #8]), equating to a HbA1c difference of 0.26%.

(ADAR 1785 resubmission, p. 66).

However, the commentary considered that there were two main reasons why these results should not be interpreted as supporting the claim that Dexcom ONE+ is superior to FSL. Firstly, the meta-analyses underpinning the results are subject to methodological flaws, including pooling of outcomes from studies with different designs and assessment at different timepoints. These methodological flaws are acknowledged in the resubmission (p. 64 of ADAR 1785 resubmission). Secondly, this is indirect (not direct) pooled comparative evidence. Specifically, effects shown by sets of studies that compared RT-CGM Dexcom ONE+ against SMBG were pooled to produce summary effect measures, and effects observed by studies comparing RT-CGM FSL/FGM against SMBG were pooled to produce summary effect measures; which were subsequently compared to draw conclusions about the relative effectiveness of one device type over another. This use of indirect comparative evidence is problematic, in that there is unclear risk of confounding by other factors.

Interpretation – clinical claim

The applicant states that, based on the presented evidence and in answer to the systematic review question, it is reasonable to conclude RT-CGM has superior efficacy compared to SMBG in IIT and non-IIT patients aged ≥2 years with T2D who have suboptimal glycaemic control.

The commentary considered two aspects of this claim to be of concern:

1. The ‘superior efficacy/effectiveness’ clinical claim is not justified based on the comparative evidence presented to support it. Considering the effect measures and quality of the evidence for each outcome (low to very low quality), a non-inferiority clinical claim is appropriate for both Dexcom ONE+ vs SMBG and RT-CGM vs SMBG, along with a cautionary interpretive note of low-level confidence in the comparative effectiveness findings.
2. The clinical claim is silent on comparative effectiveness among one high-priority population group included in the PICO and funding proposal, namely the First Nations T2D subpopulation. A statement is made that the results are generalisable to this population; however, this is questionable, considering unique features of this population that may imply differences in utilisation and adherence compared to other populations.

Additional evidence to inform the clinical claim

Other evidence evaluating the clinical claim (additional to the HbA1c outcomes data presented) is important to note.

A high-quality observational study by Reaven et al. (2025) was included by the applicant in the ADAR 1785 resubmission.[5] Reaven et al. (2025) presents indirect evidence linking RT-CGM to improvement in long-term direct, critical patient outcomes from a large observational study. This population-based retrospective study analysed US claims data from the Veterans Affairs Health Care System. The study used propensity score matching of data from 12,729 patients with T2D who used insulin plus RT-CGM compared to those who used insulin without RT-CGM, to assess the effect of RT-CGM on mortality. The data showed a significant reduction in risk of mortality for RT-CGM users (hazard ratio [HR]: 0.79; 95% CI: 0.73, 0.86) This analysis also showed RT-CGM use was associated with lower all-cause hospitalisation, severe cardiovascular disease, and admissions related to hyperglycaemia. The study showed a modest but significant difference in HbA1c between groups.

Another relevant study identified is the recently published %HbA1c results for CGM versus SMBG from the FreeDM2 trial in individuals with T2D on basal insulin plus modern therapies (published after the applicant's literature search date).[6] Modern therapies included sodium-glucose co-transporter 2 (SGLT-2) inhibitors and/or glucagon-like peptide (GLP)-1 and/or dual gastric inhibitor polypeptide/GLP-1 agonist. The primary outcome differed between groups in %HbA1c concentrations in this trial. The treatment effect favoured RT-CGM over SMBG. Importantly, the magnitude of the mean differences in %HbA1c between groups (indicated by the point estimate of effects) was greater than that seen in the MOBILE trial's measurement of this relative effect in the non-IIT T2D population with suboptimal glucose control (adjusted mean difference between groups in HbA1c concentration from baseline to week 32 was −0.5; 95% CI −0.7 to −0.2). The incidence of non-device-related adverse events in both groups was similar, and there were 2 instances of severe hypoglycaemia in the control group. This HbA1c outcome result from the FreeDM2 trial presents important additional evidence in support of RT-CGM offering improved glycaemic control versus SMBG during self-management and under clinician-supported management in people with T2D on basal insulin plus modern therapies.

The trial's authors summarised the implications of the FreeDM2 trial, stating:

> The FreeDM2 trial provides robust evidence that real-time CGM statistically and clinically significantly improves glycaemic control in people with type 2 diabetes and suboptimal glucose concentrations, despite treatment with basal insulin, SGLT2 inhibitors, GLP-1 receptor agonists, or dual GIP/GLP-1 receptor agonists. Improvements were achieved through self-management and sustained after clinician intervention with additional therapies. This randomised controlled trial establishes the utility of real-time CGM in the management of type 2 diabetes and provides rationale for updating treatment guidelines to support wider use of the technology.[7]

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[5] Reaven PD, Macwan S, Newell M, Arani G, Norman GJ, Miller DR, Zhou JJ. Initiation of Continuous Glucose Monitoring and Mortality in Type 2 Diabetes. Diabetes Technol Ther. 2025 Oct;27(10):778-789. doi: 10.1089/dia.2025.0227. Epub 2025 May 28. PMID: 40432529.

[6] Wilmot EG, Moore P, Sathyapalan T, Choudhary P, Lim JZM, Neupane S, et al. FreeDM2 Study Group. Continuous glucose monitoring versus self-monitoring of blood glucose in individuals with type 2 diabetes: a randomised, multicentre, open-label, superiority trial. Lancet Diabetes Endocrinol. 2026 Apr 23:S2213-8587(26)00076-8. doi: 10.1016/S2213-8587(26)00076-8. Epub ahead of print. PMID: 42035781.

[7] Wilmot EG, Moore P, Sathyapalan T, Choudhary P, Lim JZM, Neupane S, et al. FreeDM2 Study Group. Continuous glucose monitoring versus self-monitoring of blood glucose in individuals with type 2 diabetes: a randomised, multicentre, open-label, superiority trial. Lancet Diabetes Endocrinol. 2026 Apr 23:S2213-8587(26)00076-8. doi: 10.1016/S2213-8587(26)00076-8. Epub ahead of print. PMID: 42035781.

Overall, this evidence strengthens the case for RT-CGM being superior in effectiveness to SMBG in the non-IIT T2D subpopulation with suboptimal glucose control.

13. Economic evaluation

A revised economic evaluation was presented to address uncertainties associated with the cost-effectiveness of Dexcom RT-CGM identified at the July 2025 MSAC meeting. A cost-utility analysis was conducted comparing Dexcom RT-CGM to SMBG for the management of suboptimally controlled insulin-dependent T2D in Australia.

Overview of cost-utility analysis

The cost-utility analysis presented in the resubmission compared Dexcom RT-CGM to SMBG for the management of T2D among IIT and non-IIT subpopulations over a lifetime horizon from an Australian healthcare system perspective. This approach is considered reasonable, given the clinical claim of superior efficacy and non-inferior safety. A IQVIA core diabetes model (CDM) (version 10) was applied to estimate the incremental cost per quality-adjusted life year (QALY) gained for T2D patients treated with insulin. The IQVIA CDM is a generic web-based microsimulation model designed to estimate the cost-effectiveness of diabetes care interventions with adaptability to rural and regional care-specific settings. The IQVIA CDM has been extensively evaluated and validated, and its reliability in informing reimbursement decisions has been internationally tested and accepted. Therefore, the commentary considered that the IQVIA CDM is appropriate for modelling diabetes care interventions such as CGM; however, for the purposes of MSAC evaluations, it is limited by access/editing restrictions, so was unable to be fully evaluated by the commentary.

The ADAR resubmission revised the definition of subpopulations to be IIT and non-IIT and performed health economic evaluations across each subpopulation. T2D patients treated with both basal and bolus insulin who exhibit suboptimal glycaemic control (as confirmed by laboratory-measured HbA1c levels >7.0% for adults and >6.5% for children and adolescents) were classified as the IIT subpopulation. T2D patients treated with insulin who did not meet the criteria for inclusion in the IIT subpopulation, but exhibit suboptimal glycaemic control (as confirmed by laboratory-measured HbA1c levels >8.0% for adults and >6.5% for children and adolescents) were classified as the non-IIT subpopulation.

In the resubmission, baseline characteristics for the IIT and non-IIT subpopulations were informed by the DIAMOND[8] and MOBILE[9] trials, respectively. This revision was made to improve the internal consistency of the clinical evidence and cost-effectiveness evaluation for these subpopulations, and to address applicability issues to the Australian patient populations as raised by MSAC in the original submission (1785 PSD; p. 33). Nevertheless, these trials may not reflect the Australian setting as they were conducted in a US setting. Further, the PICO clearly stated that patients aged ≥2 years with T2D and with a certain glycaemic profile were eligible for the application, whereas most of the model inputs were derived from the trial, which included an

[8] Beck, RW, Riddlesworth, TD, Ruedy, K, Ahmann, A, Haller, S, Kruger, D, McGill, JB, Polonsky, W, Price, D, Aronoff, S, Aronson, R, Toschi, E, Kollman, C & Bergenstal, R 2017, 'Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial', Ann Intern Med, vol. 167, no. 6, pp. 365-74.

[9] Martens, T, Beck, RW, Bailey, R, Ruedy, KJ, Calhoun, P, Peters, AL, Pop-Busui, R, Philis-Tsimikas, A, Bao, S, Umpierrez, G, Davis, G, Kruger, D, Bhargava, A, Young, L, McGill, JB, Aleppo, G, Nguyen, QT, Orozco, I, Biggs, W, Lucas, KJ, Polonsky, WH, Buse, JB, Price, D & Bergenstal, RM 2021, 'Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial', Jama, vol. 325, no. 22, pp. 2262-72.

adult population. Therefore, the concern raised by MSAC in the original ADAR regarding the lack of applicability to the broader population inclusive of paediatric patients remains unaddressed.

No economic evaluation was conducted for the proposed First Nations subpopulation, nor for pregnant women with GDM or other types of diabetes, due to the lack of clinical evidence. However, the ADAR indicated that reductions in HbA1c observed among individuals with comparable glycaemic profiles, insulin regimens and disease burden, particularly those receiving IIT, support the generalisability of these outcomes to First Nations people, which was not considered a reasonable assumption by the assessment group.

A brief overview of the model elements appears in Table 12.

Table 12: Summary of economic evaluation

Component	Description
Perspective	Australian healthcare system perspective
Population	Insulin-dependent T2D patients • IIT: T2D patients treated with both basal insulin and bolus insulin, with suboptimal glycaemic control confirmed by laboratory measured HbA1c levels >7.0% for adults and >6.5% for children and adolescents. • non-IIT: T2D patients treated with insulin not otherwise included in the IIT subpopulation, with suboptimal glycaemic control confirmed by laboratory measured HbA1c levels >8.0% for adults and >6.5% for children and adolescents.
Intervention	RT-CGM using the Dexcom ONE+ CGM system
Prior testing	Not relevant to the economic model
Comparator	SMBG
Type(s) of analysis	Cost-utility analysis
Outcomes	Life years and quality-adjusted life years gained
Time horizon	Lifetime for the base case; 10, 20 and 30 years in sensitivity analysis
Computational method	Microsimulation
Generation of the base case	A modelled approach using the IQVIA CDM
Health states	As specified in CDM; 17 interdependent sub-models inform the modelling of complication incidences (MI, congestive heart failure, stroke, neuropathy, ulcer/amputation/hypoglycaemia, ketoacidosis, lactic acidosis, angina, peripheral vascular disease, retinopathy, macular oedema, cataract, neuropathy, depression, oedema, and non-specific mortality)
Cycle length	Annual
Transition probabilities	HbA1c reductions offered by RT-CGM vs SMBG result in less complication risks as modelled by CDM
Discount rate	5% for both costs and effects
Software	IQVIA CDM (CDM, v10)

Abbreviations: CDM = CORE diabetes model; HbA1c = glycated haemoglobin; IIT = intensive insulin therapy; MI = myocardial infarction; SMBG = self-monitoring of blood glucose; RT-CGM = real-time continuous glucose monitoring; T2D = type 2 diabetes; v10= version 10.
Source: Adapted from Table 25, p78 of the MSAC 1785 ADAR + in-line commentary.

The use of Dexcom ONE+ was based on data from the G4-Platinum (DIAMOND trial[8]) and G6 RT-CGM (MOBILE trial[9]), which are Dexcom CGM systems that offer broader integration with insulin pumps and automated insulin delivery systems. Dexcom ONE+ is primarily focused on CGM without advanced connectivity options. This may introduce uncertainty in terms of treatment effectiveness. As such, the outcome should be interpreted with caution when informing decision making.

Transition probabilities and extrapolation

The revised base case analysis for both subpopulations used the UKPDS-82 cardiovascular (CV) risk equation as well as the Fremantle CV risk equation[10] and presented the base case results separately. Similarly, mortality risk equation includes the UKPDS risk equation for mortality (in combination with the UKPDS-82 CV risk equation) as well as the risk equation published by Hayes et al in 2013[11] (in combination with the Fremantle CV risk equation). Additional descriptions of these risk calculations were included in the resubmission, which the commentary considered reasonable.

For the IIT subpopulation, the revised base case analysis used clinical data from the DIAMOND trial,[8] from which the adjusted mean difference between RT-CGM and SMBG—HbA1c reduction of −0.3% (net change in HbA1c) in the RT-CGM arm—was applied. The duration of the RT-CGM treatment effect is sustained for 7 years, as indicated by the COMISAIR trial,[14] while HbA1c progression in the SMBG arm remains constant over the same period. The long-term increase of HbA1c (0.05%) in the SMBG and RT-CGM arms after 7 years is assumed to be identical. However, long-term data are unavailable in the T2D population. The HbA1c effect of RT-CGM has been shown to be maintained for upwards of 7 years in at least 2 different T1D populations,[12,13] with the COMISAIR study[14] reporting similar characteristics to the proposed IIT subpopulation. Further, two hypothetical scenarios were evaluated: a constant treatment effect for 7 years followed by a decline (converging to 0) in treatment effect at years 8 and 14 (resulting in incremental cost effectiveness ratio [ICER] increases of 18.71% and 13.27%, respectively); and a variation in HbA1c treatment effects within the 95% CI (−0.8% to 0.0%), which resulted in ICER changes ranging from −26.6% to 53.72%. These findings indicate HbA1c treatment effect is a key driver of the model.

For the non-IIT subpopulation, the revised base case analysis used clinical data from the MOBILE trial,[9] from which the adjusted mean difference between RT-CGM and SMBG—HbA1c reduction of −0.4% (net change in HbA1c) in the RT-CGM arm and same duration of HbA1c treatment effect and annual HbA1c re-increase as for the IIT subpopulation—was applied (7 years; 0.05% increase). Similarly to the IIT subpopulation, two hypothetical scenarios were evaluated: a constant treatment effect for 7 years followed by a decline (converging to 0) in treatment effect at years 8 and 14 – these resulted in ICER increases of 26.46% and 17.33%, respectively; and a variation in HbA1c treatment effect within the 95% CI (−0.8% to −0.1%), which resulted in ICER changes ranging from −53.49% and 57.64%. These findings indicate HbA1c treatment effect is a key driver of the model.

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[10] Davis, WA, Khuman, MW & Davis, TM 2010, 'An Australian cardiovascular risk equation for type 2 diabetes: the Fremantle Diabetes Study', Intern Med J, vol. 40, no. 4, pp. 286-92.

[11] Hayes, AJ, Davis, WA, Davis, TM & Clarke, PM 2013, 'Adapting and validating diabetes simulation models across settings: accounting for mortality differences using administrative data', J Diabetes Complications, vol. 27, no. 4, pp. 351-6.

[12] Champakanath, A, Akturk, HK, Alonso, GT, Snell-Bergeon, JK & Shah, VN 2022, 'Continuous Glucose Monitoring Initiation Within First Year of Type 1 Diabetes Diagnosis Is Associated with Improved Glycemic Outcomes: 7-Year Follow-Up Study', Diabetes Care, vol. 45, no. 3, pp. 750-3.

[13] J., S 2023, 'Comparison of Different Treatment Modalities in 7 Years of Follow-up.', paper presented to EASD 2023, Hamburg, Germany, October 2, 2023.

[14] Šoupal, J, Petruželková, L, Flekač, M, Pelcl, T, Matoulek, M, Daňková, M, Škrha, J, Svačina, Š & Prázný, M 2016, 'Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study', Diabetes Technol Ther, vol. 18, no. 9, pp. 532-8.

Similarly to the original ADAR, the risk of severe hypo- and hyperglycaemia events was informed by US claims data of Karter et al, 2021.[15] No change was made in the resubmission. As such, the concerns raised in the original ADAR by MSAC remain unaddressed.

Health outcomes

In the resubmission, baseline utility score and utility decrement due to associated complications were informed by a published systematic review and meta-analysis,[16] supplemented by a study by Zhao et al, 2021.[17]

The applicant assumed an equivalent baseline utility value in both IIT and non-IIT subpopulations. This may be inappropriate, given that patients receiving intensive treatment in the IIT group may have more severe disease and be at high risk of complications. These utility values may differ from that of patients in the non-IIT group.

The key concerns raised by MSAC in the original ADAR submission remain unaddressed. For instance, none of the referred studies applied the Australian tariff, which may be significantly different to UK and US population norms. Further, the ADAR lacks detail on how the decrement was applied for a person who has more than one event per year.

Healthcare resource use and costs

The resubmission had no major updates on healthcare resource use costs, although the price of glucose test strips ($15 per pack of 100 strips i.e. $0.15 per strip in the original ADAR submission) was changed to $19.10 per pack. The estimated annualised SMBG cost was $264.92 and $139.43 per patient for the IIT and non-IIT subpopulations, respectively (based on assumed daily test frequency of 3.8 and 2, respectively).

The annual treatment cost of RT-CGM is $**redacted**. The same cost was applied to each subpopulation.

No change was made in the resubmission for the cost of diabetes-related complications. These costs were informed by Australian publications on the modelled cost-effectiveness of RT-CGM,[18,19] supplemented by a study by Zhang et al, 2023[20] for peripheral arterial disease of the lower extremities (i.e. ulcer and amputation). Therefore, concerns raised by MSAC in the original ADAR submission remain unresolved.

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[15] Karter, AJ, Parker, MM, Moffet, HH, Gilliam, LK & Dlott, R 2021, 'Association of Real-time Continuous Glucose Monitoring with Glycaemic Control and Acute Metabolic Events Among Patients with Insulin-Treated Diabetes', Jama, vol. 325, no. 22, pp. 2273-84.

[16] Beaudet, A, Clegg, J, Thuresson, PO, Lloyd, A & McEwan, P 2014, 'Review of utility values for economic modeling in type 2 diabetes', Value Health, vol. 17, no. 4, pp. 462-70.

[17] Zhao, X, Ming, J, Qu, S, Li, HJ, Wu, J, Ji, L & Chen, Y 2021, 'Cost-Effectiveness of Flash Glucose Monitoring for the Management of Patients with Type 1 and Patients with Type 2 Diabetes in China', Diabetes Ther, vol. 12, no. 12, pp. 3079-92.

[18] Isitt, JJ, Roze, S, Sharland, H, Cogswell, G, Alshannaq, H, Norman, GJ & Lynch, PM 2022, 'Cost-Effectiveness of a Real-Time Continuous Glucose Monitoring System Versus Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Therapy in the UK', Diabetes Ther, vol. 13, no. 11-12, pp. 1875-90.

[19] Pease, A, Callander, E, Zomer, E, Abraham, MB, Davis, EA, Jones, TW, Liew, D & Zoungas, S 2022, 'The Cost of Control: Cost-effectiveness Analysis of Hybrid Closed-Loop Therapy in Youth', Diabetes Care, vol. 45, no. 9, pp. 1971-80.

[20] Zhang, Y, Carter, HE, Lazzarini, PA, Cramb, S, Pacella, R, van Netten, JJ, Cheng, Q, Derhy, PH, Kinnear, EM & McPhail, SM 2023, 'Cost-effectiveness of guideline-based care provision for patients with diabetes-related foot ulcers: A modelled analysis using discrete event simulation', Diabet Med, vol. 40, no. 1, p. e14961.

Results

In the resubmission, the base case outcomes for both subpopulations (IIT and non-IIT) using the UKPDS and Fremantle risk equations were presented separately.

ITT subpopulation

Based on the UKPDS risk estimations, the ICER for the use of Dexcom RT-CGM compared with SMBG was $5,000 to < $15,000 per QALY gained, with an additional 0.511 QALYs and $**redacted** in costs for the T2D IIT subpopulation over a lifetime horizon (Table 13).

Based on the Fremantle risk estimations, the ICER for the use of Dexcom RT-CGM compared with SMBG was $5,000 to < $15,000 per QALY gained, with an additional 0.579 QALYs and $**redacted** in costs for the T2D IIT subpopulation over a lifetime horizon.

Table 13: Results of economic evaluation for IIT subpopulation

Parameter	UKPDS			Fremantle		
	RT-CGM	SMBG	Incremental	RT-CGM	SMBG	Incremental
Costs	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**
LYs	9.979	9.924	0.055	11.897	11.857	0.04
QALYs	7.497	6.986	0.511	8.828	8.249	0.579
Incremental costs per QALY gained	**$Redacted**[1]			**$Redacted**[1]		

Abbreviations: IIT= intensive insulin therapy; LY = life year; QALY = quality-adjusted life year; RT-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose; UKPDS = UK prospective diabetes study.
Source: Adapted from Tables 31 and 32, pp. 96-98 of the MSAC 1785 ADAR + in-line commentary.
The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000

The disaggregated base case costs for the IIT subpopulation are presented in Table 14.

Table 14: Disaggregated base case cost for RT-CGM vs SMBG for IIT population

Base case costs & outcomes	UKPDS				Fremantle			
	RT-CGM	SMBG	Difference	*% of incremental cost*	RT-CGM	SMBG	Difference	*% of incremental cost*
Glucose monitoring costs	**$Redacted**	**$Redacted**	**$Redacted**	***Redacted%***	**$Redacted**	**$Redacted**	**$Redacted**	***Redacted%***
Management (preventative screening, medication) costs	$2,873	$2,856	$17	***Redacted%***	$3,439	$3,423	$16	***Redacted%***
CV complications	$78,315	$78,489	−$174	***-Redacted%***	$139,244	$140,931	−$1,687	***-Redacted%***
Renal complications	$23,726	$25,112	−$1,386	***-Redacted%***	$43,519	$47,164	−$3,645	***-Redacted%***
Ulcer/amputation/neuropathy complications	$8,656	$8,877	−$221	***-Redacted%***	$13,818	$14,217	−$399	***-Redacted%***
Ophthalmic complications	$27,303	$28,663	−$1,359	***-Redacted%***	$35,667	$37,738	−$2,071	***-Redacted%***
Severe hypoglycaemia (req. medical assistance)	$0	$3,710	−$3,710	***-Redacted%***	$0	$4,369	−$4,369	***-Redacted%***
Hyperglycaemia & DKA	$0	$3,083	−$3,083	***-Redacted%***	$0	$3,630	−$3,630	***-Redacted%***
Total direct (medical) cost	**$Redacted**	**$Redacted**	**$Redacted**	***100%***	**$Redacted**	**$Redacted**	**$Redacted**	***100.00%***

Abbreviations: CV = cardiovascular; DKA = diabetic ketoacidosis, IIT = intensive insulin therapy; RT-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose
Note: additional analyses conducted during the commentary are presented in *italics*.
Source: Adapted from Tables 31 and 32, pp. 100-101 of the MSAC 1785 ADAR + in-line commentary.

Non-ITT subpopulation

Based on the UKPDS risk estimations, the ICER for the use of Dexcom RT-CGM compared with SMBG was $35,000 to < $45,000 per QALY gained with an additional 0.287 QALYs and $5,000 to < $15,000 in costs for the T2D non-IIT subpopulation over a lifetime horizon (Table 15).

Based on the Fremantle risk estimations, the ICER for the use of Dexcom RT-CGM compared with SMBG was $5,000 to < $15,000 per QALY gained with an additional 0.314 QALYs and $0 to < $5,000 in costs for the T2D non-IIT subpopulation over a lifetime horizon.

Table 15: Results of economic evaluation for non-IIT subpopulation

Parameter	UKPDS			Fremantle		
	RT-CGM	SMBG	Incremental	RT-CGM	SMBG	Incremental
Costs	$Redacted	$Redacted	$Redacted	$Redacted	$Redacted	$Redacted
LYs	9.950	9.878	0.072	12.076	12.036	0.04
QALYs	7.231	6.944	0.287	8.677	8.363	0.314
Incremental costs per QALY gained	$Redacted[1]			$Redacted[2]		

Abbreviations: IIT= intensive insulin therapy; LY = life year; QALY = quality-adjusted life year; RT-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose; UKPDS = UK prospective diabetes study.
Source: Adapted from Tables 33 and 34, pp. 103-105 of the MSAC 1785 ADAR + in-line commentary.
The redacted values correspond to the following ranges:
[1] $35,000 to <$45,000
[2] $5,000 to < $15,000

The disaggregated base case costs for the IIT subpopulation are presented in Table 16.

Table 16: Disaggregated base case cost for RT-CGM vs SMBG for non-IIT population

Base case costs & outcomes	UKPDS				Fremantle			
	RT-CGM	SMBG	Difference	*% of incremental cost*	RT-CGM	SMBG	Difference	*% of incremental cost*
Glucose monitoring costs	**$Redacted**	**$Redacted**	**$Redacted**	***Redacted%***	**$Redacted**	**$Redacted**	**$Redacted**	***Redacted%***
Management (preventative screening, medication) costs	$2,863	$2,839	$24	***Redacted%***	$3,478	$3,458	$20	***Redacted%***
CV complications	$84,638	$84,648	−$10	***- Redacted%***	$148,613	$151,217	−$2,604	***- Redacted%***
Renal complications	$27,882	$30,388	−$2,506	***- Redacted%***	$53,998	$61,205	−$7,207	***- Redacted%***
Ulcer/amputation/neuropathy complications	$9,135	$9,322	−$187	***- Redacted%***	$15,063	$15,617	−$554	***- Redacted%***
Ophthalmic complications	$29,934	$31,738	−$1,804	***- Redacted%***	$40,728	$43,966	−$3,239	***- Redacted%***
Severe hypoglycaemia (req. medical assistance)	$0	$1,848	−$1,848	***- Redacted%***	$0	$2,221	−$2,221	***- Redacted%***
Hyperglycaemia & DKA	$0	$2,053	−$2,053	***- Redacted%***	$0	$2,454	−$2,454	***- Redacted%***
Total direct (medical) cost	**$Redacted**	**$Redacted**	**$Redacted**	***100%***	**$Redacted**	**$Redacted**	**$Redacted**	***100%***

Abbreviations: CV = cardiovascular; DKA = diabetic ketoacidosis, IIT = intensive insulin therapy; RT-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose
Note: additional analyses conducted during the commentary are presented in *italics*.
Source: Adapted from Tables 33 and 34, pp. 103-105 of the MSAC 1785 ADAR + in-line commentary.

Model impacts using UKPDS risk equations are further explored and key drivers summarised in Table 17.

Table 17: Key drivers of the model

IIT subpopulation		
Description	**Method/Value**	**Impact** **Base case: $Redacted[1]/QALY gained**
Time horizon	Lifetime time horizon was applied for the base case model. The time horizons on 10-year, 20-year and 30-year were varied. The 20-year and 30-year time horizons reported favorable outcomes. Extrapolation on short-term (i.e. 10-year) time horizons remains uncertain.	*High, favours Dexcom ONE+ RT-CGM procedure.* *The base case, 30-year and 20-year extrapolation may favour RT-CGM, yielding **redacted**% higher ICER ($**Redacted**[2] per QALY gained) and **redacted**% higher ICER ($$**Redacted**[2]per QALY gained) compared to base case, respectively. Use of 10-year time horizons generates higher ICER of **redacted**% ($**Redacted**[2]per QALY gained) compared to base case.*
HbA1c treatment effects	Resubmitted base case applied −0.3% as informed by DIAMOND[8] clinical trial. The effect of 95% CIs for base case (i.e. upper (−0.0%) and lower (−0.5%)) estimates was explored in sensitivity analysis.	*Potentially high impact; direction of effect unclear; limited uncertainty in the inputs.* *Use of upper CI value generates higher ICER by **redacted**% ($**Redacted**[2]per QALY gained) and lower CI generates lower ICER by **redacted**% ($**Redacted**[1] per QALY gained) compared to base case.*
Duration of HbA1c effects	The duration of RT-CGM treatment effect was sustained for 7-years and increased steadily by 0.05% beyond 7-year in the base case. For SMBG, the duration of treatment effect remains constant up to 7-year and long-term increase was identical to RT-CGM. Alternative scenarios analyses with constant effect for 7-years and converging to zero at 8-year and 14-year, resulted in higher costs and lower effects.	*Moderate, favours Dexcom ONE+ RT-CGM procedure.* *Use of 7-year constant and converging to zero at 8-year and 14-year increased ICER by **redacted**% ($**Redacted**[2] per QALY gained) and **redacted**% ($**Redacted**[2]per QALY gained), respectively.*
Fear of hypoglycaemia (FoH) utility	Disutility associated with FoH was 0.0155, which was indicated by Soriano and Polonsky[21] for the base case. Alternative scenarios based on DIAMOND[8] trial data (0.025) and exclusion of FoH was explored.	*High, favours Dexcom ONE+ RT-CGM procedure.* *Use of alternative disutility for FoH as indicated by DIAMOND trial (0.025) reduced the ICER by **redacted**% ($**Redacted**[1]per QALY gained) compared to base case. However, exclusion of FoH generated around **redacted**% higher ICER ($**Redacted**[2] per QALY gained) compared to base case.*
DKA and severe hypoglycaemic events (SHE incidence and FoH	Similar to original ADAR submission, risk of DKA and SHE for base case was 2.5% and 4%, respectively. This evidence was informed by Kater et al (2021)[15].	*High, favours SMBG arm.* *Use of 50% reduction of DKA and SHE in SMBG arm and FoH in the RT-CGM arm increased the ICER by **redacted**%*

[21] Soriano, EC & Polonsky, WH 2023, 'The Influence of Real-Time Continuous Glucose Monitoring on Psychosocial Outcomes in Insulin-Using Type 2 Diabetes', J Diabetes Sci Technol, vol. 17, no. 6, pp. 1614-22.

	An alternative scenario was tested by assuming 50% reduction of incidence on DKA and SHE in SMBG arm and FoH in the RT-CGM arm. Another scenario was tested with the exclusion of incidence on DKA, SHE and FoH in the RT-CGM arm.	*($**Redacted**[2]per QALY gained) compared to base case.* *An alternative scenario with the exclusion of those events increased the ICER by **redacted**% ($**Redacted**[3] per QALY gained) compared to base case.*
Renal complications	Similar to the original ADAR submission, the renal complication was not tested in the uncertainty analysis. The relative risk of end stage renal disease was 15% lower in RT-CGM arm compared to SMBG arm; however, the incremental cost of renal complications was $1,386 (i.e. 19.03% of total incremental cost), instrumental in offsetting the higher cost of RT-CGM.	*Potentially high impact; direction of effect unclear. Risk of renal complication and incremental cost are directly associated (i.e. with each increasing incidence of renal complication, estimated cost saving increases), indicating renal complications could be significant drivers.*
Non-IIT subpopulation		
Description	**Method/Value**	**Base case: $Redacted[3]/QALY gained**
Time horizon	Lifetime time horizon was applied for the base case model. The time horizons on 10-year, 20-year and 30-year were varied. The 20-year and 30-year time horizons reported favorable outcomes. Extrapolation on short-term (i.e. 10-year) time horizons remain uncertain.	*High, favours Dexcom ONE+ RT-CGM procedure.* *The base case, 30-year and 20-year extrapolation may favour RT-CGM, yielding equivalent ICER ($**Redacted**[3]per QALY gained) and **redacted**% higher ICER ($**Redacted**[3]per QALY gained) compared to base case, respectively.* *Use of 10-year time horizons generates higher ICER of **redacted**% ($**Redacted**[4] per QALY gained) compared to base case.*
HbA1c treatment effects	Resubmitted base case applied −0.4% as informed by MOBILE[9] clinical trial. The effect of 95% CIs for base case (i.e. lower (−0.8%) and upper (−0.1%)) estimates was explored in sensitivity analysis.	*Potentially high impact; direction of effect unclear; limited certainty in the inputs.* *Use of upper CI value generates higher ICER by **redacted**% ($**Redacted**[5]per QALY gained) and lower CI generates lower ICER by **redacted**% ($**Redacted**[2] per QALY gained) compared to base case.*
Duration of HbA1c effects	The duration of RT-CGM treatment effect was sustained for 7-year and increased steadily by 0.05% beyond 7-year in the base case. For SMBG, the duration of treatment effect remains constant up to 7-year and long-term increase was identical to RT-CGM. Alternative scenarios analyses with constant effect for 7-years and converging to zero at 8-year and 14-year, resulted in higher cost and lower effects.	*Moderate, favours Dexcom ONE+ RT-CGM procedure.* *Use of 7-year constant and converging to zero at 8-year and 14-year increased ICER by **redacted**% ($**Redacted**[3]per QALY gained) and **redacted**% ($**Redacted**[3] per QALY gained), respectively.*
FoH utility	The disutility associated to FoH was 0.00775, which was half of IIT subpopulation for the base case. Alternative scenarios based on the DIAMOND[8] trial data (0.025) and exclusion of FoH was explored.	*High, favours Dexcom ONE+ RT-CGM procedure.* *Use of alternative disutility for FoH as indicated by DIAMOND trial (0.025) reduced the ICER by **redacted**% ($**Redacted**[6] per QALY gained) compared to base case. However, exclusion of FoH generated **redacted**%*

		*higher ICER ($**Redacted**[4] per QALY gained) compared to base case.*
DKA and SHE incidence and FoH	Similar to the original ADAR submission, risk of DKA and SHE for base case was 1.25% and 2%, respectively. This evidence was assumed to be half of the IIT subpopulation. Alternative scenario was tested by assuming 50% reduction of incidence on DKA, and SHE in SMBG arm and FoH in the RT-CGM arm. Another scenario was tested with the exclusion of incidence on DKA, SHE and FoH in the RT-CGM arm.	*High, favours SMBG arm.* *Use of 50% reduction of DKA and SHE in SMBG arm and FoH in the RT-CGM arm increased the ICER by **redacted**% ($**Redacted**[4] per QALY gained) compared to base case.* *Alternative scenario with the exclusion of those events increased the ICER by **redacted**% ($**Redacted**[5] per QALY gained) compared to base case.*
Renal complications	Similar to the original ADAR submission, renal complication was not tested in the uncertainty analysis. The relative risk of end stage renal disease was 18% lower in RT-CGM arm compared to SMBG arm; however, the incremental cost of renal complications was $2,506 (i.e. 25% of total incremental cost), instrumental in offsetting the higher cost of RT-CGM.	*Potentially high impact; direction of effect unclear. Risk of renal complication and incremental cost are directly associated (i.e. with each increasing incidence of renal complication, estimated cost saving increases), indicating renal complications could be significant drivers.*

Abbreviations: CIs = confidence intervals; DKA, diabetic ketoacidosis; FoH = fear of hypoglycaemia; HbA1c = glycated haemoglobin; ICER = incremental cost-effectiveness ratio; IIT = intensive insulin therapy; LCL = lower control limit; non-IIT = non-intensive insulin therapy; SMBG = self-monitoring of blood glucose; RT-CGM = real-time continuous glucose monitoring; QALY = quality-adjusted life year; SHE, severe hypoglycaemic event; UCL = upper control limit.
Source: Adapted from Tables 37 and 38, pp. 107-109 of the MSAC 1785 ADAR + in-line commentary and generated during the evaluation.
The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000
[2] $15,000 to < $25,000
[3] $35,000 to < $45,000
[4] $45,000 to < $55,000
[5] $55,000 to < $75,000
[6] $25,000 to < $35,000

Overall, higher baseline risk is associated with slightly greater treatment effects, corresponding to higher ICERs. For instance, among the non-IIT subpopulation, which had a higher baseline HbA1c of 9.1%, the treatment effect was −0.40%, resulting in an ICER of $35,000 to < $45,000 per QALY gained (based on UKPDS risk equations). In contrast, the IIT subpopulation had a lower baseline HbA1c of 8.5% and treatment effect of −0.3%, with a comparatively lower ICER of $5,000 to < $15,000 per QALY gained using the same risk equations.

Some uncertainties and missing evidence exist within the model-based cost-utility analysis. The disutility associated with the fear of hypoglycaemia (FoH) had a minor impact on QALYs in the RT-CGM arm; however, it had no impact on the SMBG arm, indicating the assumption made to inform transition probability on the RT-CGM arm only (i.e. disutility of 0.0155) may have considerable influence over the cost-utility outcomes. The model implicitly applied no change in the psychological burden of SMBG users, which may bias the incremental QALY gain in favour of RT-CGM.

The assumed duration of HbA1c treatment effects (maintained up to 7 years, with gradual waning to zero at 8–14 years) impact only the RT-CGM arm. There was no impact on the SMBG arm, which introduces structural uncertainty. As such, the model outcomes are sensitive to the assumed duration of effects. The uncertainty analyses were conducted using more conservative UKPDS-based risk equations (Table 18).

Table 18: Scenario analyses

Analyses	Incremental cost	Incremental QALY	ICER ($/QALY gained)	% change from base case
IIT subpopulation				
Base case	**$Redacted**	**0.511**	**$Redacted**[1]	—
Time horizon (base case lifetime)*				
10 years	**$Redacted**	0.320	**$Redacted**[2]	***redacted*%**
20 years	**$Redacted**	0.448	**$Redacted**[2]	***redacted*%**
30 years	**$Redacted**	0.496	**$Redacted**[2]	***redacted*%**
HbA1c treatment effect (base case −0.3%)				
HbA1c treatment effect −0.5% (95% LCL)	**$Redacted**	0.536	**$Redacted**[1]	***redacted*%**
HbA1c treatment effect −0.0% (95% UCL)	**$Redacted**	0.459	**$Redacted**[2]	***redacted*%**
Duration of HbA1c effects (base case 7 years constant and increased steadily by 0.05% beyond 7 years)				
7 years constant converging at 8 years	**$Redacted**	0.485	**$Redacted**[2]	***redacted*%**
7 years constant converging at 14 years	**$Redacted**	0.490	**$Redacted**[2]	***redacted*%**
FoH utility (base case 0.0155)				
DIAMOND[8] FoH utility (0.025)	**$Redacted**	0.607	**$Redacted**[1]	***redacted*%**
No FoH utility	**$Redacted**	0.360	**$Redacted**[2]	***redacted*%**
DKA, SHE incidence and FoH (base case 2.5%, 4% and 0.0155)				
50% reduction for all DKA and SHE in SMBG arm and FoH utility in RT-CGM arm	**$Redacted**	0.426	**$Redacted**[2]	***redacted*%**
No DKA or SHE in SMBG arm and no FoH utility for RT-CGM	**$Redacted**	0.341	**$Redacted**[3]	***redacted*%**
Non-IIT subpopulation				
Base case	**$Redacted**	**0.287**	**$Redacted**[3]	—
Time horizon (base case lifetime)*				
10 years	**$Redacted**	0.168	**$Redacted**[4]	***redacted*%**
20 years	**$Redacted**	0.250	**$Redacted**[3]	***redacted*%**
HbA1c treatment effect (base case −0.4%)				
HbA1c treatment effect −0.8% (95% LCL)	**$Redacted**	0.348	**$Redacted**[2]	***redacted*%**
HbA1c treatment effect −0.1% (95% UCL)	**$Redacted**	0.243	**$Redacted**[5]	***redacted*%**
Duration of HbA1c effects (base case 7 years constant and increased steadily by 0.05% beyond 7 years)				
7 years constant converging at 8 years	**$Redacted**	0.265	**$Redacted**[3]	***redacted*%**
7 years constant converging at 14 years	**$Redacted**	0.273	**$Redacted**[3]	***redacted*%**
FoH utility (base case 0.00775)				
DIAMOND[8] FoH utility (0.025)	**$Redacted**	0.335	**$Redacted**[3]	***redacted*%**
No FoH utility	**$Redacted**	0.212	**$Redacted**[4]	***redacted*%**
DKA, SHE incidence and FoH (base case 1.25%, 2% and 0.00775)				
50% reduction for all DKA and SHE in SMBG arm and FoH utility in RT-CGM arm	**$Redacted**	0.212	**$Redacted**[4]	***redacted*%**

No DKA or SHE in SMBG arm and no FoH utility for RT-CGM	$**Redacted**	0.200	$**Redacted**[5]	***redacted***%

Abbreviations: DKA = diabetic ketoacidosis; FoH = fear of hypoglycaemia; HbA1c = glycated haemoglobin; ICER = incremental cost-effectiveness ratio; IIT = intensive insulin therapy; LCL = lower control limit; non-IIT = non-intensive insulin therapy; QALY = quality-adjusted life year; RT-CGM = real-time continuous glucose monitoring; SHE = severe hypoglycaemic events; SMBG = self-monitoring of blood glucose; UCL = upper control limit
Note: additional analyses conducted during the commentary are presented in *italics*.
*Lifetime was modelled using a 50-year time horizon applied from cohort entry (mean age 60 years for IIT subpopulation; 59.9 years for non-IIT subpopulation).
Source: Adapted from Tables 37 and 38, pp. 107-109 of the MSAC 1785 ADAR + in-line commentary.
The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000
[2] $15,000 to < $25,000
[3] $35,000 to < $45,000
[4] $45,000 to < $55,000
[5] $55,000 to < $75,000

Although the model was described as fully editable and login access was provided, the version provided was 'public but not modifiable,' which restricted modification of input parameters and limited the ability to conduct additional uncertainty analysis during the evaluation. Nevertheless, existing scenarios could be rerun to validate the model outcomes.

The commentary requested the following additional information from the applicant (if possible in its pre-ESC response):

1. *The ADAR resubmission performed sensitivity analyses based on the UKPDS risk equation and presented results for both IIT and non-IIT populations. However, the base case analysis was presented based on both UKPDS and Fremantle risk equations. To maintain consistency to the base case results and explore the economic impact based on Australian risk equations (i.e. Fremantle equations), additional sensitivity analyses for both populations would be valuable.*
2. *Variations (±10%) for the key cost drivers, such as renal and ophthalmic complications.*
3. *Further variation (±10%) around the treatment effects, as indicated in Table 1.*

Sensitivity analyses show that most of the QALYs gained were accumulated within a 20-year time horizon for both populations. As such, performing multivariate analyses considering the following parameters over a 20-year time horizon may provide more precise estimates for decision-making.

1. *Upper and lower limits of HbA1c*
2. *Mean diabetes duration to 14.1 years*
3. *Omit FoH utilities in RT-CGM arm*

The applicant provided the requested sensitivity analyses in Tables 19 and 20.

Table 19: Additional sensitivity analyses requested on the Fremantle base-case - IIT and non-IIT subpopulation

Analysis	Total costs, AUD			QALY			ICER per QALY gained
	RT-CGM	SMBG	Difference	RT-CGM	SMBG	Difference	
IIT subpopulation							
Base-case (Fremantle)	**$Redacted**	**$Redacted**	**$Redacted**	**8.828**	**8.249**	**0.579**	**$Redacted**[1]
Discount Rate							
3.50%	**$Redacted**	**$Redacted**	**$Redacted**	10.121	9.452	0.669	**$Redacted**[1]
0.00%	**$Redacted**	**$Redacted**	**$Redacted**	14.979	13.964	1.015	**$Redacted**[2]
HbA1c Effect							
HbA1c treatment effect −0.5% (95% LCL)	**$Redacted**	**$Redacted**	-**$Redacted**	8.850	8.249	0.601	Dominant
HbA1c treatment effect −0.0% (95% UCL)	**$Redacted**	**$Redacted**	**$Redacted**	8.797	8.249	0.547	**$Redacted**[3]
Duration of Hba1c Effect (e.g., 7 years constant converging to zero at 8 years)							
7 years constant converging at 8 years	**$Redacted**	**$Redacted**	**$Redacted**	8.808	8.249	0.558	**$Redacted**[1]
7 years constant converging at 14 years	**$Redacted**	**$Redacted**	**$Redacted**	8.817	8.249	0.568	**$Redacted**[1]
FoH Utility							
DIAMOND FoH utility (0.025)	**$Redacted**	**$Redacted**	**$Redacted**	8.940	8.249	0.691	**$Redacted**[1]
No FoH utility	**$Redacted**	**$Redacted**	**$Redacted**	8.653	8.249	0.403	**$Redacted**[1]
DKA And SHE Incidence And FoH							
-50% DKA and SHE in SMBG arm and -50% FoH utility in RT-CGM arm	**$Redacted**	**$Redacted**	**$Redacted**	8.741	8.269	0.471	**$Redacted**[3]
No DKA or SHE in SMBG arm and no FoH utility for RT-CGM	**$Redacted**	**$Redacted**	**$Redacted**	8.653	8.282	0.370	**$Redacted**[4]
Time Horizon							
10 years	**$Redacted**	**$Redacted**	**$Redacted**	5.441	5.100	0.341	**$Redacted**[3]
20 years	**$Redacted**	**$Redacted**	**$Redacted**	7.814	7.315	0.498	**$Redacted**[1]
30 years	**$Redacted**	**$Redacted**	**$Redacted**	8.619	8.063	0.557	**$Redacted**[1]
Non-IIT subpopulation							
Base-case (Fremantle)	**$Redacted**	**$Redacted**	**$Redacted**	**8.677**	**8.363**	**0.314**	**$Redacted**[1]
Discount Rate							
3.50%	**$Redacted**	**$Redacted**	**$Redacted**	9.971	9.606	0.365	**$Redacted**[1]
0.00%	**$Redacted**	**$Redacted**	-**$Redacted**	14.875	14.310	0.566	Dominant
HbA1c Effect							
HbA1c treatment effect −0.8% (95% LCL)	**$Redacted**	**$Redacted**	-**$Redacted**	8.727	8.363	0.364	Dominant
HbA1c treatment effect −0.1% (95% UCL)	**$Redacted**	**$Redacted**	**$Redacted**	8.651	8.363	0.289	**$Redacted**[5]
Duration of Hba1c Effect (e.g., 7 years constant converging to zero at 8 years)							
7 years constant converging at 8 years	**$Redacted**	**$Redacted**	**$Redacted**	8.655	8.363	0,292	**$Redacted**[6]

Analysis	Total costs, AUD			QALY			ICER per QALY gained
	RT-CGM	SMBG	Difference	RT-CGM	SMBG	Difference	
IIT subpopulation							
Base-case (Fremantle)	**$Redacted**	**$Redacted**	**$Redacted**	**8.828**	**8.249**	**0.579**	**$Redacted**[1]
7 years constant converging at 14 years	**$Redacted**	**$Redacted**	**$Redacted**	8.662	8.363	0.299	**$Redacted**[4]
FoH Utility							
DIAMOND FoH utility (0.025)	**$Redacted**	**$Redacted**	**$Redacted**	8.733	8.363	0.371	**$Redacted**[1]
No FoH utility	**$Redacted**	**$Redacted**	**$Redacted**	8.588	8.363	0.225	**$Redacted**[3]
DKA And SHE Incidence And FoH							
-50% DKA and SHE in SMBG arm and -50% FoH utility in RT-CGM arm	**$Redacted**	**$Redacted**	**$Redacted**	8.632	8.373	0.260	**$Redacted**[3]
No DKA or SHE in SMBG arm and no FoH utility for RT-CGM	**$Redacted**	**$Redacted**	**$Redacted**	8.588	8.380	0.208	**$Redacted**[6]
Time Horizon							
10 years	**$Redacted**	**$Redacted**	**$Redacted**	5.292	5.112	0.180	**$Redacted**[6]
20 years	**$Redacted**	**$Redacted**	**$Redacted**	7.633	7.367	0.266	**$Redacted**[4]
30 years	**$Redacted**	**$Redacted**	**$Redacted**	8.452	8.149	0.304	**$Redacted**[3]

The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000
[2] $0 to < $5,000
[3] $15,000 to < $25,000
[4] $25,000 to < $35,000
[5] $45,000 to < $55,000
[6] $35,000 to < $45.000

Table 20: Additional sensitivity analyses requested based on varying complication costs (#1), varying treatment effects (#2) and multivariate analysis – IIT and non-IIT subpopulations

Analyses	Incremental cost	Incremental QALY	ICER ($/QALY gained)
Sensitivity analysis #1 [a]			
IIT subpopulation			
Base case (UKPDS)	**$Redacted**	**0.511**	**$Redacted**[1]
-10% eye and kidney complication costs	**$Redacted**	0.511	**$Redacted**[1]
+10% eye and kidney complication costs	**$Redacted**	0.511	**$Redacted**[1]
Base case (Fremantle)	**$Redacted**	**0.579**	**$Redacted**[1]
+10% eye and kidney complication costs	**$Redacted**	0.579	**$Redacted**[1]
+10% eye and kidney complication costs	**$Redacted**	0.579	**$Redacted**[1]
Non-IIT subpopulation			
Base case (UKPDS)	**$Redacted**	**0.287**	**$Redacted**[2]
-10% eye and kidney complication costs	**$Redacted**	0.287	**$Redacted**[2]
+10% eye and kidney complication costs	**$Redacted**	0.287	**$Redacted**[3]
Base case (Fremantle)	**$Redacted**	**0.314**	**$Redacted**[1]
-10% eye and kidney complication costs	**$Redacted**	0.314	**$Redacted**[4]
+10% eye and kidney complication costs	**$Redacted**	0.314	**$Redacted**[1]
Sensitivity analysis #2 [b]			
IIT subpopulation			
Base case - HbA1c treatment effect −0.3% (UKPDS)	**$Redacted**	**0.511**	**$Redacted**[1]
HbA1c treatment effect +10% of upper CI (= -0.55%)	**$Redacted**	0.539	**$Redacted**[1]

Base case - HbA1c treatment effect −0.3% (Fremantle)	$**Redacted**	**0.579**	$**Redacted**[1]
HbA1c treatment effect +10% of upper CI (= -0.55%)	-$**Redacted**	0.605	Dominant
Non-IIT subpopulation			
Base case - HbA1c treatment effect −0.4% (UKPDS)	$**Redacted**	**0.287**	$**Redacted**[2]
HbA1c treatment effect +10% of upper CI (= -0.88%)	$**Redacted**	0.362	$**Redacted**[1]
HbA1c treatment effect −10% of lower CI (= -0.09%)	$**Redacted**	0.245	$**Redacted**[5]
Base case - HbA1c treatment effect −0.4% (Fremantle)	$**Redacted**	**0.314**	$**Redacted**[1]
HbA1c treatment effect +10% of upper CI (= -0.88%)	-$**Redacted**	0.367	Dominant
HbA1c treatment effect −10% of lower CI (= -0.09%)	$**Redacted**	0.290	$**Redacted**[5]
Multivariate analysis [c]			
IIT subpopulation			
Base case (UKPDS)	$**Redacted**	**0.511**	$**Redacted**[1]
Baseline HbA1c of 8.3% & 14.1 years & no FoH & 20 yrs duration	$**Redacted**	0.355	$**Redacted**[4]
Base case (Fremantle)	$**Redacted**	**0.579**	$**Redacted**[1]
Baseline HbA1c of 8.3% & 14.1 years & no FoH & 20 yrs duration	$**Redacted**	0.401	$**Redacted**[1]
Non-IIT subpopulation			
Base case (UKPDS)	$**Redacted**	**0.287**	$**Redacted**[2]
Baseline HbA1c of 8.3% & 14.1 years & no FoH & 20 yrs duration	$**Redacted**	0.213	$**Redacted**[5]
Base case (Fremantle)	$**Redacted**	**0.314**	$**Redacted**[1]
Baseline HbA1c of 8.3% & 14.1 years & no FoH & 20 yrs duration	$**Redacted**	0.216	$**Redacted**[2]

[a] Eye and Kidney cost items included: Haemodialysis each year; Peritoneal Dialysis, Year of Onset; Peritoneal Dialysis, each Subsequent Year; Renal transplant, Year of Event; Renal transplant, Each Subsequent Year; Laser treatment ; Severe Vision Loss/Blindness, Year of Onset; Severe Vision Loss/Blindness, Subsequent Year; Cataract surgery; Cataract, each subsequent year; Neuropathy each year. b HbA1c treatment effect −10% of lower CI for the IIT subpopulation were not considered as it crosses 0% (negative effect). c Other scenarios were considered non-informative.

The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000
[2] $35,000 to < $45,000
[3] $25,000 to < $35,000
[4] $15,000 to < $25,000
[5] $45,000 to < $55,000

14. Financial/budgetary impacts

This ADAR presents associated financial implications to expand the subsidisation coverage of Dexcom ONE+ RT-CGM among people living with insulin-dependent T2D. An epidemiological approach was taken due to the absence of reliable usage data for SMBG for the market share approach. The RT-CGM is assumed to substitute SMBG. Estimated utilisation was calculated for the following populations: IIT, non-IIT, First Nations, GDM and other diabetes, using epidemiological data from the Australian Diabetes Clinical Quality Registry (2024),[22] the

[22] Monash University, School of Public Health & Preventive Medicine, 2025, Australian Diabetes Clinical Quality Registry Annual Report 2024, Monash University, Australia, <https://www.monash.edu/medicine/sphpm/adcqr/publications>.

Australian Institute of Health and Welfare and the National Indigenous Australians Agency (2023),[23] and the Australian Bureau of Statistics (2021),[24] which is reasonable.

In the resubmission, the number of T2D patients requiring insulin treatment was estimated using Prospection data analysis (2022)[25]. A proportion of 15.9% was estimated by dividing the number of people with T2D (NDSS 2022 data) by the number of T2D patients receiving insulin treatment (based on Prospection data for 2022 (1786 PSD, p. 63)). This source is considered appropriate, and consistent with MSAC advice that the PBS data are more accurate than the NDSS data. However, assuming this proportion (15.9%) remains constant from 2022 to 2032 may be unrealistic.

NDSS T2D data from 2017–2024 were used to derive a linear equation to estimate the future prevalence of insulin-dependent T2D. The applicant-estimated uptake of RT-CGM ranges from 18–60% in year 1 increasing to 35–80% in year 6; however, no expert consultation was undertaken to inform these estimates.

The resubmission estimated the daily number of test strips to be 3.8 for IIT, 2 for non-IIT, 4 for GDM populations, and 2.5 for First Nations and other diabetes patients if Dexcom ONE+ is not used (SMBG arm). Although wastage was considered and the cost per pack of 100 strips was applied to calculate cost offsets, Dexcom ONE+ users may still require some glucose test strips at follow-up. However, the applicant assumed zero test strip use in the Dexcom ONE+ arm without justification. This uncertainty may result in an overestimation of the overall financial impact.

As indicated in the original ADAR submission, each patient would require 12.17 packs of sensors annually, with packs containing 3 sensors and each sensor lasting 10 days. However, annual pack numbers may be overestimated, as the Evaluation Subcommittee (ESC) previously noted that a 90% adherence rate is more appropriate than 100%. This was not addressed in the resubmission. The cost of Dexcom ONE+ was estimated to be $redacted per annum. In the resubmission, based on the estimated cost to the NDSS, the cost of glucose test strips was updated from $15 to $19.10 per 100 strips. The total annual cost of the test strips for each population was estimated to be $264.92, $139.43, $173.56, $68.76, $13.56 for IIT, non-IIT, First Nations, GDM and other diabetes patients, respectively. Furthermore, based on PBS data on insulin usage, 67% of patients accessing subsidised use of Dexcom ONE+ are assumed to be concessional card holders and the remaining 33% assumed to be eligible for co-payment. Co-payment was $35.90, as indicated by MSAC in the original ADAR submission (1785 PSD, p. 60). First Nations populations were eligible for a full concession.

The concern regarding broader healthcare cost savings in the original ADAR submission has been addressed by using model-based estimates of average 6-year healthcare cost savings associated with complication avoidance ($726.30 for IIT and First Nations; $487.95 for non-IIT) following introduction of RT-CGM vs SMBG. However the ADAR resubmission took the conservative approach of omitting cost savings for the GDM and other diabetes populations (due to the lack of relevant evidence).

[23] Australian Institute of Health and Welfare & National Indigenous Australians Agency 2023, Measure 1.09 Diabetes, Aboriginal and Torres Strait Islander Health Performance Framework Australian Government, viewed 18 December 2025.

[24] Australian Bureau of Statistics 2021, Estimates of Aboriginal and Torres Strait Islander Australians, Australian Government, viewed 18 December 2025.

[25] Prospection, 2022, Report on Australian insulin using type 2 diabetes patients 2022.

Financial implications to the NDSS resulting from the proposed listing of RT-CGM, including expected uptake and costs for each subgroup, are summarised in Table 21.

Table 21: Net financial implications of RT-CGM use to NDSS

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated use and cost of the proposed health technology						
IIT subpopulation						
Number of people eligible for RT-CGM	43,035	43,980	44,925	45,870	46,815	47,759
Number of people who receive RT-CGM	15,062	19,791	24,709	27,522	30,429	33,432
Number of Dexcom ONE+ sensor packs	183,258	240,790	300,622	334,849	370,225	406,751
Cost in millions to the NDSS (without co-payment)	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[5]
Cost in millions to the NDSS (with co-payment adjusted)	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[4]	**$Redacted**[4]
Change in use and cost of other health technologies						
Total 100-strip pack replaced	208,914	274,501	342,709	381,728	422,057	463,696
Total cost saving (cost in millions)	$3.9	$5.2	$6.5	$7.3	$8.1	$8.9
Net financial impact to the NDSS (cost in millions)	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]
Overall net impact to NDSS (including complication avoidance cost saving)* (cost in millions)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[1]
Non-IIT subpopulation (HbA1c>8%)						
Number of people eligible for RT-CGM	74,691	76,331	77,971	79,611	81,251	82,891
Number of people who receive RT-CGM	13,071	17,175	21,442	23,883	26,407	29,012
Number of Dexcom ONE+ sensor packs	159,030	208,957	260,879	290,580	321,280	352,977
Cost in millions to the NDSS (without co-payment)	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[4]	**$Redacted**[4]
Cost in millions to the NDSS (with co-payment adjusted)	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[4]
Change in use and cost of other health technologies						
Total 100-strip pack replaced	95,418	125,374	156,527	174,348	192,768	211,786

Total cost saving (millions)	$1.8	$2.4	$2.9	$3.3	$3.7	$4.1
Net financial impact to the NDSS (cost in millions)	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[2]	**$Redacted**[2]	**$Redacted**[3]	**$Redacted**[3]
Overall net impact to NDSS (including complication avoidance cost saving)* (cost in millions)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[2]
First Nations						
Number of people eligible for RT-CGM	16,821	17,190	17,560	17,929	18,298	18,667
Number of people who receive RT-CGM	5,887	7,736	9,658	10,757	11,894	13,067
Number of Dexcom ONE+ sensor packs	71,629	94,116	117,502	130,880	144,708	158,984
Cost in millions to the NDSS (without co-payment)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[1]
Cost in millions to the NDSS (with co-payment adjusted)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[1]	**$Redacted**[1]	**$Redacted**[1]
Change in use and cost of other health technologies						
Total 100-strip pack replaced	53,498	70,294	87,760	97,752	108,079	118,742
Total cost saving (millions)	$1.0	$1.3	$1.7	$1.9	$2.1	$2.3
Net financial impact to the NDSS (cost in millions)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[1]	**$Redacted**[1]
Overall net impact to NDSS (including complication avoidance cost saving)* (cost in millions)	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
GDM						
Number of people eligible for RT-CGM	33,405	33,405	33,405	33,405	33,405	33,405
Number of people who receive RT-CGM	20,043	22,715	24,052	25,054	26,390	26,724
Number of Dexcom ONE+ sensor packs	60,129	68,146	72,155	75,161	79,170	80,172
Cost in millions to the NDSS (without co-payment)	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Cost in millions to the NDSS (with co-payment adjusted)	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]
Change in use and cost of other health technologies						

Total 100-strip pack replaced	20,043	22,715	24,052	25,054	26,390	26,724
Total cost saving (millions)	$1.4	$1.6	$1.7	$1.7	$1.8	$1.8
Net financial impact to the NDSS (cost in millions)	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[7]
Other Diabetes						
Number of people eligible for RT-CGM	9,325	9,859	10,394	10,928	11,462	11,996
Number of people who receive RT-CGM	5,595	6,704	7,483	8,196	9,055	9,597
Number of Dexcom ONE+ sensor packs	68,074	81,570	91,048	99,716	110,169	116,763
Cost in millions to the NDSS (without co-payment)	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Cost in millions to the NDSS (with co-payment adjusted)	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Change in use and cost of other health technologies						
Total 100-strip pack replaced	5,595	6,704	7,483	8,196	9,055	9,597
Total cost saving (millions)	$1.0	$1.2	$1.3	$1.4	$1.6	$1.7
Net financial impact to the NDSS (cost in millions)	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Overall (all subpopulations combined)						
Overall total cost in millions to NDSS	**$Redacted**[8]	**$Redacted**[9]	**$Redacted**[11]	**$Redacted**[11]	**$Redacted**[11]	**$Redacted**[11]
Overall total cost saving (millions)	**$Redacted**[7]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Overall net financial impact to the NDSS (cost in millions)	**$Redacted**[5]	**$Redacted**[10]	**$Redacted**[11]	**$Redacted**[11]	**$Redacted**[11]	**$Redacted**[11]

Abbreviations: GDM = gestational diabetes mellitus; HbA1c = glycated haemoglobin; IIT = intensive insulin therapy; non-IIT = non-intensive insulin treatment; NDSS = National Diabetes Services Scheme; RT-CGM = real time continuous glucose monitoring; T2D = type 2 diabetes.

*Applied model-based estimates of average 6-year healthcare cost savings associated with complication avoidance following introduction of RT-CGM vs SMBG. The average 6-year estimated saving for the IIT population and the First Nations subpopulation was $726.30 and for non-IIT was $487.95.

Source: Adapted from Tables 55-63, pp. 125-133 of the MSAC 1785 ADAR + in-line commentary

The redacted values correspond to the following ranges:

[1] $20 million to < $30 million
[2] $30 million to < $40 million
[3] $40 million to < $50 million
[4] $50 million to < $60 million
[5] $60 million to < $70 million
[6] $10 million to < $20 million
[7] $0 to < $10 million
[8] $70 million to < $80 million
[9] $90 million to < $100 million
[10] $80 million to < $90 million
[11] $100 million to < $200 million

Overall, most of the concerns raised by MSAC in the original ADAR submission have been resolved in the resubmission; however, some uncertainties remain and certain aspects of the calculations presented lack sufficient supporting evidence in the financial impact analysis. For instance, uptake rate was assumed without consultation with experts. The criteria underlying this assumption and the robustness of the estimation process were not clearly described by the applicant.

In the analysis within the ADAR, the annual incidence of GDM was assumed decline in 2026 and then remain stable at 33,405 cases from 2026 to 2032. However, the trend in GDM cases varies rather than consistently declining. For instance, cases increased in 2020 and 2021, followed by a slight decrease in 2022, then rose again in subsequent year before declining again in 2025. This pattern indicates fluctuations over time rather than a sustained declining trend. Given this, the assumption in the ADAR of a sharp 27% reduction in 2026, followed by a constant rate (plateau) through 2032, is not plausible. The reduction rate in the ADAR sensitivity analysis during the evaluation is arbitrary, which may exert higher uncertainties on the budget impact.

Omitting users of pre-mixed insulin from the IIT definition reduced the IIT proportion of the proposed population from 70.1% (assumed in the original ADAR submission) to 27.2%, a reduction of 42.9%. This reduction may introduce uncertainty into the estimates. To address this, a sensitivity analysis using an arbitrary 50% value was performed during the evaluation. However, the absence of robust empirical evidence to support these assumptions may increase uncertainty in the budget impact model results.

15. Other relevant information

ESC considered that it would be informative for MSAC to consider a respecified multivariate base case based on the UK-PDS risk equations with the following elements:

- Convergence of HbA1c levels between 7 and 8 years
- Halving of finger-prick disutility
- Removing the fear of hypoglycaemia disutility
- Halving of DKA and SHE costs and disutilities

An estimate of the analysis requested by ESC using previously generated outputs of sensitivity and scenario analyses is presented below with the caveat that this is an approximation which is not based on directly inputting changes into the model. The results of the analyses up to but excluding the change in device cost is presented separately from the results including the change in device cost. The applicant is invited to comment on the former.

Table 22: IIT subpopulation (UK-PDS risk equations)

	1. Incremental cost ($)	2. Incremental QALY
A. 7 years constant converging at 8 years [1]	**Redacted**	0.485
B. Base case	**Redacted**	0.511
C. Contribution of convergence of HbA1C between Y7 and Y8 to base case (0.5*B-A)	**-Redacted**	0.013
D. FOH set to zero[1]	**Redacted**	0.360
E. Contribution of FOH to base case (B-D)	**Redacted**	0.151
F. No DKA, SHE offset or FOH utility[1]	**Redacted**	0.341
G. Contribution of DKA, SHE and FOH to base case (B-F)	**-Redacted**	0.170
H. Contribution of DKA and SHE only to base case (G-E)	**-Redacted**	0.019
I. HbA1C treatment effect[1]	**Redacted**	0.459
J. Contribution of HbA1C to base case (B-I)	**-Redacted**	0.052
K. Contribution of skin-prick disutility to base case (B2-E2-H2-J2)	n.a.	0.289

Abbreviations: QALY= Quality Adjusted Life Years; FOH=fear of hypoglycemia; DKA= diabetic ketoacidosis; SHE=severe hypoglycaemic events

1. Table 37 of ADAR

Incremental cost of ESC-requested analysis = B1-C1-(0.5*H1))=$**Redacted**

Incremental QALY of ESC-requested analysis =B2-C2-D2-(0.5*H2)-(0.5*K2)=0.193 QALY

Revised ICER = $55,000 to < $75,000 per QALY

Table 23: Non-IIT subpopulation (UK-PDS risk equations)

	1. Incremental cost ($)	2. Incremental QALY
A. 7 years constant converging at 8 years [1]	**Redacted**	0.265
B. Base case	**Redacted**	0.287
C. Contribution of convergence of HbA1C between Y7 and Y8 to base case (0.5*B-A)	**-Redacted**	0.011
D. FOH set to zero[1]	**Redacted**	0.212
E. Contribution of FOH to base case (B-D)	**Redacted**	0.075
F. No DKA,SHE offset or FOH utility[1]	**Redacted**	0.200
G. Contribution of DKA, SHE and FOH to base case (B-F)	**-Redacted**	0.087
H. Contribution of DKA and SHE only to base case (G-E)	**-Redacted**	0.012
I. HbA1C treatment effect[1]	**Redacted**	0.243
J. Contribution of HbA1C to base case (B-I)	**-Redacted**	0.044
K. Contribution of skin-prick disutility to base case (B2-E2-H2-J2)	n.a.	0.156

Abbreviations: QALY= Quality Adjusted Life Years; FOH=fear of hypoglycemia; DKA= diabetic ketoacidosis; SHE=severe hypoglycaemic events

1. Table 38 of ADAR

Incremental cost of ESC-requested analysis = B1-C1-(0.5*H1))=$**Redacted**

Incremental QALY of ESC-requested analysis =B2-C2-D2-(0.5*H2)-(0.5*K2)=0.117 QALY

Revised ICER = $95,000 to < $115,000 per QALY

16. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- The comparative effectiveness of real-time continuous glucose monitoring (CGM) versus self-monitoring of blood glucose (SMBG) for type 2 diabetes (T2D) was assessed in 2 subpopulations with suboptimal glycaemic control: people with T2D on intensive insulin therapy (IIT) with glycated haemoglobin (HbA1c) >7%, and people with T2D on basal insulin only with HbA1c levels of >8% or >9% (non-IIT). According to the resubmission, other higher clinical need subgroups suggested by MSAC were not included in the resubmission Applicant Developed Assessment Report (ADAR) due to lack of subpopulation-specific data. ESC considered that the evidence presented on effectiveness in broader patient populations is likely to be applicable to specific subpopulations.
- ESC noted the consultation advice received for the current and previous consideration of this application, and from the recently convened clinical stakeholder meeting, was broadly aligned with MSAC's suggestions for identifying subpopulations of patients with T2D with the highest clinical need for CGM.
- Clinical stakeholders were broadly supportive of intermittent CGM and limited evidence from the MOBILE trial extension suggests there is a possible benefit of intermittent CGM against SMBG.
- The resubmission presented evidence that the applicant stated demonstrates individual CGM systems should be assessed based on their own outcomes data (rather than considered collectively). This was based on a meta-analysis of randomised and non-randomised studies presented as secondary evidence, which the commentary considered to be methodologically flawed.
- HbA1c level subgroup results (derived post-hoc from the MOBILE trial) suggest that people with non-IIT T2D and higher levels of baseline HbA1c could possibly have a greater treatment effect (favouring CGM over SMBG). Small sample sizes in the analysis make this finding uncertain. An RCT in people with non-IIT T2D published since the applicant's search for evidence also reported a difference between groups in HbA1c change from baseline favouring CGM over SMBG. This difference was greater than that observed in the MOBILE trial and strengthens the case for superior efficacy of CGM compared to SMBG in the non-IIT subpopulation.
- Other relevant evidence includes a large population-based observational study (n = 12,792 participants) included in the ADAR resubmission linking CGM use to improvements in various longer-term patient outcomes and reductions in mortality in the T2D population. However, ESC noted there was a modest difference in HbA1c (0.15%) between the CGM and SMBG groups and queried the plausibility of the estimated size of effects on clinical outcomes, and whether residual confounding might be an alternative explanation for the observations.

Economic issues:

- ESC remained concerned about (i) whether the disutilities associated with finger-prick testing and with the linked fear of hypoglycaemia both generating the relatively large quality adjusted life year (QALY) gains from avoiding finger-prick testing were overestimated, (ii) a lack of justification of use of a different method to estimate hospitalisations for severe hypoglycaemic events (SHE) and diabetic ketoacidosis (DKA), and (iii) the existence and extent of the translation of HbA1c levels to diabetic complications. ESC recommended that the applicant address these uncertainties by reporting a respecified multivariate base case including convergence of HbA1c between years 7 and 8, halving each finger-prick disutility,

removing the fear of hypoglycaemia disutility, and halving diabetic ketoacidosis and severe hypoglycaemic event costs and disutilities.

Financial issues:

- The exclusion of premixed insulin users from the definition of IIT reduced the estimated IIT subpopulation by 43% compared to the original ADAR (2025) submission. Given that the IIT subpopulation is a key cost driver in the model, this assumption is likely to underestimate the financial impact of CGM. Nevertheless, there remains substantial uncertainty for the appropriate definition and size of the IIT population.
- The robustness of the process used to derive the uptake rates for all subpopulations is unknown. Without details on the robustness of the estimation process, there is low confidence in the estimates.

Other relevant information:

- Regarding a potential staged approach to implementation, ESC cautioned that the subpopulations who are most likely to benefit from access to CGM are also the least likely to have a strong evidence base to inform access.

ESC discussion

ESC noted that this resubmission from Australasian Medical & Scientific Limited requested National Diabetes Services Scheme (NDSS) funding for the Dexcom ONE+ continuous glucose monitoring (CGM) system for people with insulin-dependent type 2 diabetes (T2D).

MSAC previously considered this application at its July 2025 meeting but deferred its advice at that time (see the public summary document for Application 1785 from July 2025). MSAC advised that a resubmission should present a revised economic evaluation focused on the populations with higher clinical need, 2 different patterns of usage (continuous and intermittent), and any more recent clinical evidence of effectiveness, as well as addressing issues identified in the economic model. MSAC also considered revised estimates of utilisation would be required to more accurately estimate the size of the subpopulations. MSAC considered there was limited evidence available to suggest a significant difference in clinical outcomes between different brands of CGM devices with comparable functionality, and that further consideration should be given as to whether devices that have similar features should be considered equivalent.

In addition to Application 1785, MSAC also considered Application 1786 for NDSS funding of the FreeStyle Libre 2 (FSL) CGM system for people with T2D requiring insulin and those with gestational diabetes and other types of diabetes (including type 3c) in July 2025. MSAC also deferred its advice on Application 1786.

ESC noted and welcomed public consultation on this application from 561 individuals and 12 organisations. Consultation input noted benefits for subgroups including people with multiple daily insulin injections, bolus regimens, high levels of glycated haemoglobin (HbA1c), marked glucose variability, high risk of hypoglycaemia (especially overnight), disability, neurodivergence, people living alone, drivers and shift workers, and people in rural and remote areas who may lack access to specialist care. Key benefits identified included real-time feedback leading to behaviour change, safer titration of insulin, identification of overnight trends to inform management, and the educational value of constant monitoring. A large proportion of respondents supported access to CGM for gestational diabetes, noting that time-limited access during pregnancy could have benefits for maternal and neonatal outcomes. Consultation feedback overwhelmingly preferred continuous access to CGM, although around half of respondents said people would benefit from intermittent or short-term use. ESC noted the consultation advice received for the current and previous consideration of this application, and from the recently convened clinical stakeholder meeting, was broadly aligned with MSAC's

suggestions for identifying subpopulations of patients with T2D with the highest clinical need for CGM.

Respondents noted that current costs for CGM can be prohibitive for many people, and access based on diabetes type is perceived as inequitable. Around 80% of respondents supported copayments consistent with existing NDSS arrangements for people with T1D, noting that this would be fair, consistent and equitable. However, respondents also noted that Aboriginal and Torres Strait Islander people and people managing multiple expenses may need different considerations regarding copayments.

Consultation inputs overall indicated strong support for the role of general practitioners (GPs) in certifying eligibility for CGM, noting that this would reduce out-of-pocket costs, GPs have deeper knowledge of patients both clinically and personally, and access to specialists can be slow, costly and geographically limited. However, this support was substantially lower in respondents who identified as health professionals or health academics. These respondents noted that GPs lack specialist knowledge to interpret CGM data and provide adequate patient education, GP access may constitute a missed referral to diabetes-specific support services, and that patient education is optimally provided through credentialled diabetes educators.

ESC noted that MSAC members attended a meeting with clinical stakeholders regarding Applications 1785 and 1786 on 20 May 2026. Participants broadly supported intermittent use of CGM, noting that intermittent access was preferable to no access. Participants also raised the option of a stepped care model in which observation of patients using CGM continuously over a shorter period of initial use could identify those requiring longer-term continuous use. Participants had concerns around using HbA1c levels to determine eligibility, but could not identify an appropriate alternative. ESC considered that, in the absence of another suitable biomarker, HbA1c level remains the most appropriate way to determine eligibility. Participants considered that subpopulations should be identified on the basis of those who might benefit most from intensified treatment (such as people with diabetic foot or kidney disease, or other clinical factors indicating severity) or those most at risk of harm from hypoglycaemic episodes (such as people with a higher risk of hypoglycaemic episodes due to higher doses of insulin, or people with intercurrent illness). Stakeholders had mixed opinions on the type of clinician who could authorise access to CGM. ESC noted that GP involvement had been raised but remained unresolved and was characterised by the applicant as a policy issue.

ESC recalled that MSAC had considered there was insufficient evidence to support the applicant's use of a 0.3% reduction in HbA1c as the minimal clinically important difference (MCID). MSAC had noted that this was lower than the generally accepted MCID of 0.5% reduction in HbA1c, which is used by the Pharmaceutical Benefits Advisory Committee and regulatory agencies. ESC noted that the applicant did not address this issue in the resubmission and no further justification for an MCID of 0.3% was provided. However, ESC considered that this issue was less central to decision-making than in the previous submission because the revised model used the smaller RCT-based HbA1c treatment effects of −0.30% and −0.40%, and because the broader evidence base suggested potential patient-relevant benefits beyond HbA1c alone.

ESC recalled that MSAC had advised that the resubmission should focus on subpopulations with higher clinical need. These included people using insulin with higher baseline levels of HbA1c (e.g. >8% and >9%); Aboriginal and Torres Strait Islander people (e.g. with baseline HbA1c >7%); people who use long-acting and short-acting insulin; people with disability; people with intercurrent illness; people who are pregnant and have type 2 diabetes or gestational diabetes; people who are starting insulin therapy and require frequent blood glucose level measurements; and people in whom nocturnal hypoglycaemic events are suspected. The applicant partially addressed this request in the resubmission by including evaluation of people with T2D on

intensive insulin therapy (IIT) with HbA1c >7%, and people with T2D on basal insulin only with HbA1c levels of >8% or >9%. The applicant stated that other populations were not evaluated due to the lack of comparative studies in these groups. However, the applicant noted in its pre-ESC response that it is reasonable to expect that CGM will provide similar clinical benefits in all these subgroups. ESC noted that there was little incentive to collect such data and considered that the evidence presented on the effectiveness in the broader population is likely to be applicable specific subpopulations.

ESC noted that many subgroups who are likely to benefit involve small numbers of patients (such as people with type 3c diabetes (T3cD) and other types of diabetes similar to type 1, Aboriginal and Torres Strait Islander people, and people with youth-onset T2D (i.e. those diagnosed at age <25 years)). ESC considered that it may be reasonable to extrapolate the overall effect size to these groups, given there are no reasons to expect that effectiveness will be substantially less in these groups. ESC considered that the groups with the greatest clinical need, who often have worse outcomes from diabetes, may not be those with the strongest direct evidence, and that this would need to be taken into account in any staged implementation approach.

ESC recalled that MSAC had advised that the resubmission should include patient-relevant outcomes, including quality of life (QoL) and end-organ outcomes. The applicant had included a large retrospective cohort study using data from the United States Veterans Affairs Health Care System and propensity score matching to link use of real-time CGM to change in longer-term health outcomes, including mortality. The results showed lower mortality risk for CGM users, as well as lower all-cause hospitalisation, severe cardiovascular disease and admissions related to hyperglycaemia. However, ESC considered that residual confounding could not be excluded and noted that the observed between-group difference in HbA1c was modest. ESC queried the plausibility of the estimated size of effects on clinical outcomes given the small HbA1c difference undermining the postulated mechanism of action.

ESC noted that public consultation and the clinical stakeholder meeting provided qualitative input of perceived quality-of-life benefits, including reduced burden of finger-prick testing, and improved confidence in self-management.

The applicant stated that no new studies on comparative clinical effectiveness were available. The core comparative evidence remained the DIAMOND and MOBILE randomised trials, supplemented by post-hoc analyses, a pooled meta-analysis, and observational evidence, including the large propensity-matched Veterans Affairs cohort study discussed above.

ESC noted that the post-hoc analyses of the MOBILE trial for the non-IIT subpopulation results suggested a statistically significant mean reduction in HbA1c for people using Dexcom ONE+ compared with SMBG at 3 months and 8 months, with greater reductions seen in people with higher baseline HbA1c levels. However, ESC noted that the commentary had assessed the quality of this study and these analyses as very low. The commentary also identified an additional trial that assessed CGM against SMBG in the same subpopulation (non-IIT) in the MOBILE trial. The commentary considered that evidence from this very recently published trial strengthens the clinical effectiveness claim in the non-IIT subpopulation.

ESC noted that this trial was a randomised controlled trial (RCT) evaluating the FreeStyle Libre 2 CGM device (FreeDM2 trial, published since the applicant's literature search). This reported an adjusted mean difference in HbA1c between the CGM group and the SMBG group of −0.5%. ESC considered that this evidence was directionally consistent with MOBILE and strengthened the case for superior effectiveness of CGM compared with SMBG in the non-IIT subpopulation.

The resubmission also included a meta-analysis of real-time CGM compared with SMBG, but ESC noted there were methodological flaws in pooling studies with different designs and timepoints

for outcome measurement. The commentary also noted the issues with indirect comparisons and risk of confounding in this analysis. The applicant's pre-ESC response included real-world evidence on the use of CGMs that suggested a larger mean reduction in HbA1c of 1.31%. However, ESC noted that the included studies were single-arm (non-comparative) studies, mostly using administrative data and before-and-after analysis, and therefore had a high risk of bias.

The applicant's pre-ESC response also noted a range of international guidelines and funding decisions that support CGM use.

ESC noted the applicant's claim that Dexcom ONE+ was superior to other CGM devices. In its previous consideration of this application, MSAC did not consider that this claim was supported by the evidence in the original submission, and the commentary did not consider that this was supported by the methodologically flawed meta-analysis in the resubmission. ESC noted the applicant's clarification in its pre-ESC response that the meta-analysis was intended to demonstrate that individual brands of CGMs differ from one another and should be assessed on their own outcomes data.

ESC noted the applicant's statement that intermittent use of Dexcom ONE+ was not a viable option, while continuous use of CGM systems is clinically justified to maintain glycaemic outcomes. Data were provided on mean time in range and mean HbA1c from a 6-month extension phase of the MOBILE trial, in which 53 participants continued CGM and 53 participants discontinued and returned to SMBG. ESC noted the small numbers of participants and overlapping confidence intervals in these data but considered that the extension study could be interpreted as demonstrating a benefit of intermittent CGM compared with SMBG.

ESC noted the resubmission did not include comparative safety data, as the Applicant Developed Assessment Report (ADAR) stated that the claim of non-inferior safety had previously been accepted by MSAC. ESC considered there may be a potential safety concern relating to the analytical performance of CGM devices, in that if observed blood glucose (according to CGM) overestimates the true level, then patients may self-administer a higher dose of insulin than needed and cause a hypoglycaemic event. The applicant's pre-ESC response referred to the Australian Diabetes Society's statement on the need for minimum quality standards for CGMs and noted that current TGA processes may fall short of this. ESC agreed that a robust quality assurance system should be in place, while also noting that each sensor is only worn for up to 2 weeks before being replaced, helping to minimise potential safety risks associated with the performance of individual sensors. ESC further noted that the safety concern regarding analytical performance of continuous glucose monitoring devices had not been incorporated into the economic analyses, despite the potential for overestimation of glucose values to result in accidental insulin overdosing and hypoglycaemic events. ESC considered that, if the application progressed, quality assurance and minimum performance standards for subsidised devices would remain an important implementation consideration.

For the original ADAR, MSAC had noted multiple issues with the economic model. ESC considered that only some issues had been adequately addressed in the resubmission. These were as follows:

- The ADAR presented the results using the Western Australia (Fremantle) risk equations separately to the model-validated UKPDS risk equations.
- The result of using a shorter HbA1c treatment effect had been addressed in sensitivity analyses. ESC also noted that the applicant now used smaller randomised controlled trial–based HbA1c treatment effects rather than observational study estimates.
- The applicant had reduced the background increase in HbA1c to a more plausible rate of 0.05% per year (compared to 0.15% per year in the previous ADAR).

- The applicant had reduced the hospital-related cost offsets assumed from CGM use, which MSAC had previously considered overestimated.

ESC noted the applicant's reasoning that data were not available for many of the subpopulations proposed by MSAC, and so these groups were not included in the economic analysis. ESC considered that the changes to the economic modelling led to results for the previously proposed subpopulations that were more realistic than those presented in the previous ADAR.

However, ESC also noted that several residual structural and parameter uncertainties in the model remained unaddressed, leading to overall uncertainty in the economic value of the proposal for NDSS funding of Dexcom ONE. These were as follows:

- The change in model structure from 17 health states to 10 health states required validation or clarification.
- Concerns with utility estimates identified in the previous ADAR were unaddressed - in particular, the assumed finger-prick testing disutilities (as discussed further below) and the failure to multiply EQ5D-5L scores by Australian values.
- The effect of expected lags in onset of the treatment effect on diabetic complications was not assessed.
- There was a lack of justification of use of a different method to estimate hospitalisations for severe hypoglycaemic events (SHE) and diabetic ketoacidosis (DKA).
- There was a lack of justification for applying US-sourced data to populate baseline characteristics.
- No sensitivity analyses using a shorter base case time horizon were conducted.
- The lack of sensitivity analyses varying the subtypes of renal complications avoided.
- The life expectancy anomaly across the 2 sets of risk equations was unexplained.
- No sensitivity analyses of the age and duration of T2D were conducted.

ESC considered that the direction and magnitude of these multiple sources of uncertainty were mostly unclear, leading to little confidence in the model outputs.

ESC noted the model presented a cost-utility analysis using patient-level microsimulations. ESC considered that this type of analysis was appropriate if MSAC was to accept the claim of superior effectiveness. The IIT subpopulation was treated with ≥2 daily insulin injections (basal–bolus) and had HbA1c levels of >7.0% for adults and >6.5% for children and adolescents. ESC noted that this population now excluded those using premixed insulin, which affected the financial estimates. The non-IIT subpopulation was treated with ≥1 daily insulin injection (not otherwise included in the IIT subpopulation) and had HbA1c levels of >8% or >9% for adults and >6.5% for children and adolescents. ESC noted that the HbA1c thresholds for adults in the non-IIT population were higher than in the previous submission.

Modelling was not conducted for the subpopulation of Aboriginal and Torres Strait Islander people, and the ADAR assumed that this would be similar to the IIT population, although no evidence was provided to support this. The model did not include short-term use of CGM except for gestational diabetes or pregnant people with T2D. ESC noted that the applicant's pre-ESC response stated that, despite the lack of available evidence, it was reasonable to expect that CGM would provide similar clinical benefits for gestational diabetes, First Nations people, people with a disability, and those with T3cD and other types of diabetes. ESC agreed that it was reasonable to assume a similar treatment effect in these populations to the broader T2D population.

ESC also noted that the economic evaluations, consistent with use of RCT-based treatment effects, now used RCT-based population characteristics in preference to those from the US-based

retrospective cohort study (Karter 2021)[26] where possible. ESC noted that this improved the internal validity of diabetic complication-related costs and quality-adjusted life-years (QALYs), but made it difficult to discern the drivers from these multiple changes to the results of the economic evaluation. ESC also noted that using RCT data may still overestimate the HbA1c treatment effects; however, the reduction in HbA1c remained smaller in the IIT population than in the non-IIT population, which MSAC may consider more plausible if it accepts that this is due to the increased baseline HbA1c in the non-IIT model.

ESC noted that, for the IIT population, based on the UKPDS risk estimations, the incremental cost-effectiveness ratio (ICER) for the use of Dexcom ONE+ CGM compared with SMBG was $5,000 to < $15,000 per QALY gained, with an additional 0.511 QALYs and $redacted in costs over a lifetime horizon. Based on the Fremantle risk estimations, the ICER for the use of Dexcom ONE+ CGM compared with SMBG was $5,000 to < $15,000 per QALY gained, with an additional 0.579 QALYs and $redacted in costs over a lifetime horizon.

ESC noted that, for the non-IIT population, based on the UKPDS risk estimations, the ICER for the use of Dexcom ONE+ CGM compared with SMBG was $35,000 to < $45,000 per QALY gained with an additional 0.287 QALYs and $redacted in costs over a lifetime horizon. Based on the Fremantle risk estimations, the ICER for the use of Dexcom ONE+ CGM compared with SMBG was $5,000 to < $15,000 per QALY gained with an additional 0.314 QALYs and $redacted in costs over a lifetime horizon.

In the base case results of the economic evaluation, ESC noted that incremental QALYs for each population were driven by incremental changes in QoL rather than life-years. ESC remained concerned that the disutility associated with finger-prick testing and with the linked fear of hypoglycaemia both generating the relatively large QALY gains from avoiding finger-prick testing were overestimated. ESC noted that using the general population to derive these utilities, rather than people with diabetes, may overestimate the QALY loss relating to finger-prick testing. This is because the general population is poor at estimating a *loss* of QoL in worse health states that they have not experienced. The general guidance from HTA agencies to use the general population is appropriate for minimising a patient's incentive to overestimate the *gain* of QoL in better health states. ESC also considered that this may overlap with the disutility associated with fear of hypoglycaemia. ESC noted that simply halving the finger-prick QALY gain increased the ICER to $15,000 to < $25,000 per QALY gained for the IIT subpopulation[27].

ESC noted that the sensitivity analyses showed that, even where the HbA1c treatment effect converged over time or a reduced time horizon was applied, the model continued to generate divergent risks of diabetes complications and other sources of incremental QALYs. ESC noted that, by partitioning the incremental QALY (0.511 for the IIT subpopulation using the UKPDS model), the drivers were mainly the avoidance of finger-prick testing (approximately 0.289 QALYs) and reduced fear of hypoglycaemia (0.151 QALYs), with smaller contributions from avoidance of SHE and DKA (0.019 QALYs) and diabetes complications (0.052 QALYs). ESC also noted that, with reference to the same IIT subpopulation and UKPDS model, incremental glucose monitoring costs (+$redacted) were partly offset by reductions in SHE costs (−$3,710), DKA costs (−$3,083) and diabetes complication costs (−$3,140), but that the SHE and DKA estimates were generated separately from a United States–based retrospective cohort study, adding uncertainty about

[26] Karter, A. J., Parker, M. M., Moffet, H. H., Gilliam, L. K., & Dlott, R. (2021). Association of real-time continuous glucose monitoring with glycemic control and acute metabolic events among patients with insulin-treated diabetes. Jama, 325(22), 2273-2284.

[27] Estimated as $7284/0.367 QALY where 0.367 QALY = base case incremental QALY of 0.511 minus 0.1445 (half of finger prick disutility estimated at approximately 0.289 QALYs).

residual bias and applicability to the Australian setting. Similar conclusions were drawn by partitioning the non-IIT UKPDS model.

ESC noted that a re-estimate of the ICERs which (a) ignored any changes in hospitalisation and complications costs and (b) focused only on the benefit of avoiding finger-prick disutility resulted in ICERs of $55,000 to < $75,000 per QALY[28] for the IIT subpopulation and $115,000 to < $135,000 per QALY[29] for the non-IIT subpopulation.

ESC suggested that a respecified multivariate UKPDS base case, including convergence of HbA1c between years 7 and 8, halving each finger-prick disutility, removing the fear of hypoglycaemia disutility, and halving diabetic ketoacidosis and severe hypoglycaemic event costs and disutilities would be beneficial for MSAC's consideration. ESC considered that this analysis would help address the following remaining key uncertainties in the modelling already discussed: (i) whether the disutility associated with finger-prick testing and the relatively large QALY gains from avoiding finger-prick testing was overestimated and double-counted with the fear of hypoglycaemia disutility, (ii) lack of justification of use of a different method to estimate hospitalisations for SHE and DKA, and (iii) the existence and extent of the translation of decreases in HbA1c levels to decreases in diabetic complications. ESC noted that an approximation of these ICERs generated indirectly by relying on results from previously reported sensitivity analyses indicated that an ICER of around $55,000 to < $75,000 per QALY for the IIT subpopulation and around $95,000 to < $115,000 per QALY for the non-IIT subpopulation would be generated.[30]

ESC noted the revised financial analysis. ESC noted that the epidemiological estimates for utilisation continue to rely on NDSS data to estimate the number of people living with T2D although they now more appropriately also use the MSAC-preferred number of people with T2D using insulin as per Pharmaceutical Benefits Scheme utilisation (PBS; 201,880 people in 2022 who had used insulin over the previous 12 months), rather than NDSS data to estimate the percentage of people with T2D who had used insulin.

ESC noted the reassignment of premixed insulin users from the IIT subpopulation to the non-IIT subpopulation reduced the estimated IIT subpopulation by 43% compared to the original ADAR (2025) submission. Given that the IIT subpopulation is assumed to generate larger diabetes strip cost offsets, this reassignment may overestimate the financial implications of CGM. Nevertheless, there remains substantial uncertainty for the appropriate definition and size of the IIT subpopulation. ESC considered the robustness of the process used to derive the uptake rates for all subpopulations is also unknown, which also reduces confidence in the assumed estimates. ESC considered that the uncertainty in uptake rates could be better evaluated by presenting observed uptake rates in Australia for T1D or in any other market(s) with similar subsidy support for T2D. ESC noted that the ADAR then added on top of this main T2D population estimates associated with other subpopulations (First Nations with T2D, gestational diabetes mellitus (GDM), and other types of diabetes) but accounted for the overlap between First Nations with T2D subpopulation and other T2D subpopulations by assuming (applying various data sources) that 10.63% of patients with T2D are First Nations people.

ESC noted that, for all subpopulations combined, the net financial impact to the NDSS for subsidising CGM would be $60 million to < $70 million in year 1, increasing to $100 million to < $200 million by year 6. ESC noted that the net financial impact over six years increased by 36%

[28] This was estimated by dividing the incremental cost of testing ($**redacted**) by the residual incremental QALY solely attributable to avoided finger prick-disutility after excluding other QALY benefits (0.052).

[29] This was estimated by dividing the incremental cost of testing ($**redacted**) by the residual incremental QALY solely attributable to avoided finger prick-disutility after excluding other QALY benefits (0.156).

[30] Refer to Section 12 for the steps used in this calculation.

when higher uptake rates were assumed, as presented in a sensitivity analysis by the commentary[31]; increased by 22% when the IIT to non IIT split was amended to 50%/50%; increased by 11% when the percentage of patients with insulin dependent T2D assumed to be First Nations was increased by 10%; and reduced by 15% when there is assumed to be a reduction in the GDM population over time. ESC considered that the appropriate assumption on reduction in the GDM population over time was uncertain given the impact of the new definition of GDM in recent Australian clinical guidelines.

ESC noted that implementation issues, if CGM funding were to be supported for the identified subpopulations, were the same as those raised for application 1786 and included whether any implementation should be staged, whether an open tender process should apply, whether price reductions from a tender process would apply to current CGM populations subsidised by the NDSS, and how any future access arrangements should be designed to target those most likely to benefit while remaining practical to administer.

ESC noted that people with T2D generally undergo HbA1c testing 4 times each year to coincide with clinical appointments. ESC considered whether a staged approach might include 4 CGM sensor packs per year for most patients who are not high risk, and potentially additional packs for patients at high risk. These options would need to be explored in the financial estimates.

17. Applicant comments on MSAC's Public Summary Document

AMSL / Dexcom agree with the MSAC that there are inequities in the access to subsidised CGMs in Australia. We commend the MSAC in supporting that patients with conditions similar to Type 1 diabetes have access to CGMs on the NDSS past their 21st birthday. However, the inequity extends beyond age; all patients requiring the use of multiple daily insulin injections should have equitable access and choice of a CGM that meets the ANZ quality use of CGM standards.

Dexcom has addressed MSAC's concerns and requests for hypothetical modelling scenarios (such as the convergence of CGM treatment effect to that of fingerprick testing at 8 years or 14 years). However, we do not endorse a model of diabetes that reduces the QoL benefits from avoiding finger prick testing and removes the disutility of fear of hypoglycaemia as well as arbitrary reducing the costs and disutility of the clinical aspects of the condition that define the disease (that of hypoglycaemia and hyperglycaemia). Dexcom considers that ESC's requested multivariate sensitivity analyses relies on clinically implausible and deliberately conservative assumptions that lack face validity, are not reflective of the disease state, do not reflect the evidence presented in the ADAR and are contrary to what consumers stated they valued in CGMs during the feedback process. As such, these analyses were only provided as sensitivity analyses to satisfy the request of the ESC and are not a base-case for decision-making.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website

[31] From 35%, 45%, 55%, 60%, 65% and 70% to 60%, 68%, 72%, 75%, 79% and 80% in years 1 to 6, respectively.