Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1786 – FreeStyle Libre continuous glucose monitoring products for people with type 2 diabetes requiring insulin, gestational diabetes and other types of diabetes

Applicant: **Abbott Australasia Pty Ltd**

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

A resubmission requesting National Diabetes Services Scheme (NDSS) funding of the FreeStyle Libre (FSL) continuous glucose monitoring (CGM) system for people with type 2 diabetes (T2D) requiring treatment with insulin (PICO [population, intervention, comparator, outcome] Set 1), pregnant women with gestational diabetes mellitus (GDM) (PICO Set 2), and people with type 3c diabetes (T3cD) requiring insulin (PICO Set 3) was received from Abbott Australasia Pty Ltd 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 subsidisation of the Freestyle Libre 2 CGM system for people with insulin dependent T2D and gestational diabetes.

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.

Regarding the gestational diabetes population, MSAC considered that there were limited data on improvement in neonatal outcomes, with some concern of risks, and a lack of stakeholder support.

MSAC advised that a resubmission should present a revised economic model and financial impact estimates 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 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 Abbott Australasia Pty Ltd requesting public funding under the National Diabetes Services Scheme (NDSS) for the FreeStyle Libre 2 continuous glucose monitoring (CGM) system for people with type 2 diabetes requiring treatment with insulin, pregnant people with gestational diabetes, and all people aged 21 years and over with other conditions similar to type 1 diabetes requiring insulin, including type 3c diabetes. Diabetes is a condition that can cause high blood sugar (glucose), 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 FreeStyle Libre 2. This application is requesting funding for the FreeStyle Libre 2 device for people with type 2 diabetes who use insulin, people who develop diabetes while they are pregnant, and people with type 3c diabetes. An application was also considered by MSAC for another CGM device (Application 1785).

Consumer summary

MSAC considered that monitoring of blood glucose using the FreeStyle Libre 2 CGM was as safe as self-monitoring using finger prick tests. MSAC noted the application continued to claim CGM was more effective than finger-prick 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 reduce 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 fewer 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 for FreeStyle Libre 2 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 uncertainty in the effectiveness and cost-effectiveness of CGM versus finger pricking, as well as uncertainty in the financial projections submitted by the applicant. MSAC also considered that the risk of use outside of the target populations was very high, making the budgetary impact of listing potentially high.

The priority groups with type 2 diabetes using insulin that MSAC considered would receive the most benefit from CGM are:

- people with 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 these priority groups was very high, 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 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 the remaining populations, 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 Abbott Australasia was requesting National Diabetes Service Scheme (NDSS) funding of the FreeStyle Libre 2 (FSL2) and FSL2 Plus continuous glucose monitoring (CGM) system for 3 populations:

- people with type 2 diabetes (T2D) using insulin (PICO set 1)
- pregnant people with gestational diabetes (irrespective of pre-existing diabetes or need for insulin) (PICO set 2)
- people with type 3c diabetes and other types of diabetes similar to type 1 aged 21 years and over (heterogeneous group with pancreatic exocrine insufficiency) (PICO set 3).

MSAC noted that the NDSS currently funds CGM for all people with type 1 diabetes and people under 21 years of age with type 3c diabetes or other types of diabetes similar to type 1.

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 the revised assessment report include several revisions to the economic model, and focus on the subpopulations with the highest clinical need. MSAC noted that this resubmission had only partially addressed these requests.

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 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%
- those with T2D who are pregnant or 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 emphasised that CGM is the new standard of care for diabetes management, reducing the burden of glucose monitoring and helping people achieve better glycaemic control. They reiterated the findings from a recent randomised controlled trial (RCT) from the United Kingdom[1] that showed that CGM effectively reduces HbA1c, results in statistically significant improvements in time in range, and had no differences in total adverse events (AEs) or serious AEs compared with self-monitoring of

[1] 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

blood glucose (SMBG). They highlighted that CGM improves day-to-day outcomes, reduces future hospitalisations and will likely lessen long-term burden of diabetes on the healthcare system. The representatives of the applicant stated that access should be determined by need, not diabetes type.

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 1785 (Dexcom ONE+ CGM for insulin-using patients with T2D) used different definitions for the IIT and non-IIT subpopulations. MSAC recalled that, when it considered this application in July 2025, it did not define what 'intensive 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 (inclusive of premixed insulin users, who were included in the IIT population in this application) should not be included as one of the priority populations for further consideration for CGM at this time. MSAC considered that, if it is important for patients in this group to have tight control of HbA1c, it is likely they will require IIT and hence will be included in the IIT group.

MSAC considered that current NDSS funding arrangements for CGMs pose an equity of access issue for people aged 21 and over with type 3c diabetes or other types of diabetes similar to type 1 diabetes. This is because subsidised access is only available until age 21 for this population, but subsidised access is not age-restricted for those with type 1 diabetes.

MSAC noted that, although intermittent use of CGM received some support in consultation feedback, the applicant's pre-MSAC response stated that there was unlikely to be a viable role for intermittent use of CGM. The pre-MSAC response noted that 'intermittent models may be perceived as cost-containment rather than clinically appropriate care and may be inequitable for people who need continuous monitoring but cannot afford to self-fund sensors'. It also noted that 'intermittent access should not be viewed as a clinically equivalent lower-cost substitute for continuous CGM in insulin-requiring T2D'. MSAC acknowledged the validity of the argument made by the pre-MSAC response, but also acknowledged that there is intermittent use among people with T2D in Australian centres.

MSAC noted the pre-MSAC response stated that direct randomised evidence is not available for every proposed subgroup. MSAC agreed with ESC advice that evidence from the broader T2D population is likely to be applicable to the specific subpopulations with high clinical need for CGM. The pre-MSAC response also cited ESC's acknowledgement regarding the difficulty of conducting blinded studies of CGM versus SMBG as the justification for relying on the (real-world) evidence that was presented in the ADAR. MSAC considered that, although blinded comparisons may be difficult, it does not preclude other clinical study designs that are more robust than real-world evidence, and that some studies did indeed have a blinded lead-in period. MSAC noted there were also several outcomes requested in the PICOs for which no data were available or presented in the ADAR.

MSAC agreed with ESC that there are no major safety concerns with the FSL2 CGM system, but noted that ESC had identified a possible safety concern around analytical validity (i.e. where inaccurate high glucose readings could lead to excessive insulin administration). MSAC noted recent media reports of connectivity failures and incorrect insulin dosing resulting from CGM and insulin pumps, and queried whether evidence was available on device failure rates, which were not covered in the ADAR, despite this information being requested in the ratified PICO. MSAC

noted from a case report by Kogai et al. (2023)[2] and the applicant website that device failures can include:

- sensor errors, which can sometimes result in higher-than-average readings, and therefore inappropriate insulin dose and hyperglycaemia/diabetic ketoacidosis for type 1 diabetes
- sensor adhesive failures
- sensor insertion issues (bent needles) or insertion into scarred tissue (depth issue)
- software issues (updates) and signal loss.

MSAC agreed with ESC that minimum performance standards for CGM devices are required.

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 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 the collection of patient data, and that this must be appropriately managed.

MSAC noted that the widely accepted minimal clinically important difference (MCID) for HbA1c for PICO set 1 is 0.5% (recognised by the Pharmaceutical Benefits Advisory Committee [PBAC], National Institute for Health and Care Excellence [NICE] and other guidelines). However, the resubmission proposed a new MCID of 0.35%. This was justified by quoting a meta-regression of 44 RCTs (of glucose-lowering drugs) demonstrating a continuous relationship between change in HbA1C >0.25% and clinical outcomes. Overall MSAC reiterated that that there was insufficient evidence provided to reduce the accepted 0.5% MCID to claim superior effectiveness because the evidence presented lacked data on prediction bands as specified in the MSAC Guidelines. MSAC also noted recent trials on CGM devices that use an MCID of 0.5%.

MSAC noted that, when considering RCT evidence only, the basal insulin–only non-IIT population was the closest to meeting the MCID of 0.5%, with an HbA1c change of –0.46%. The subpopulation with baseline HbA1c ≥9.5% showed the greatest improvement (HbA1c change of –0.77%); however, the sample size was small and the results were imprecise, not statistically significant, and based on one trial only. No data were provided for the other subpopulations of interest.

Although MSAC did not consider the use of MCID <0.5% to be justified, it did consider that the evidence base for change in HbA1c appeared adequate. There was consistent change in HbA1c with CGM, although it did not meet the MCID of 0.5%, the studies were adequately powered (and nearly all reached statistical significance), and the studies were RCTs with low or moderate risk of bias.

MSAC noted that time in range was proposed as both an important outcome for the diabetic population and a unique feature of CGM that is not captured by SMBG. For time in hypoglycaemia (time below range) for PICO set 1, MSAC noted that CGM resulted in statistically significant but not clinically significant improvement in level 1 hypoglycaemia (<3.9 mmol), but not significant improvement for the level 2 (severe, <3.1 mmol) group. CGM also did not reach the MCID for time in range for either level.

[2] Kogai T, Sato J, Hirakata M, Iwamoto T, Nakajima K, Goto H et al., 'Diabetic ketoacidosis due to a sensor defect of FreeStyle Libre: a case report', *Journal of Diabetes Investigation*, 2023, 14(11):1321–1324, doi:10.1111/jdi.14065.

MSAC noted that the resubmission included updated hospitalisation data for PICO set 1 from a retrospective Swedish registry study (Nathanson et al. 2025[3]) that compared hospitalisation risk associated with CGM vs SMBG in patients requiring multiple daily insulin injections. The study has some risk of bias concerns including selection bias. The study showed that all-cause admissions and admissions for hypoglycaemia were significantly reduced for the T2D cohort using CGM and provided evidence of direct to health outcomes benefits of CGM use. Hospitalisation results were inconsistent across other studies – an RCT by Karter et al.[4] 2021 looked at admissions for diabetes only and found no significant difference between CGM and SMBG. MSAC noted that a meta-analysis was not attempted.

MSAC noted that the applicant requested that the population for PICO set 2 (people with gestational diabetes) should not be defined with respect to an insulin requirement. The ADAR presented meta-analyses of RCTs which initially showed no statistically significant difference in caesarean section (C-section) rates, but did show a statistically significant albeit small risk difference reduction in C-section rates when a prospective observational study[5] was added to the meta-analysis. CGM was also found to lead to a statistically significant reduction in large-for-gestational-age infants. However, there was no statistically significant difference in macrosomia, neonatal hypoglycaemic events or premature birth. MSAC noted that the stakeholder meeting had mixed views of using CGM for patients with gestational diabetes, with some stakeholders highlighting a potentially increased risk of small-for-gestational-age births as a result of mothers practising over-restriction of carbohydrate intake. Stakeholders expressed more support for CGM for pregnant people with pre-existing T2D than those with gestational diabetes.

MSAC noted that, for type 3c diabetes, comparative data were limited to one study of people post-pancreatectomy using either CGM or SMBG (Lund-Jacobsen et al. 2025)[6]. It did not support the claim of superior effectiveness, with HbA1C similar at one year follow up for the CGM and SMBG groups. The reported time in range for the CGM group did not reach the aim of 70%, while hospitalisations were less frequent for the CGM group than the SMBG group. Generalisability to the rest of the type 3c diabetes population who may have some pancreatic function is unknown. Despite this, MSAC considered there is a significant equity issue related to age, due to people with type 3c diabetes currently only having access to NDSS-funded CGM until 21 years of age. MSAC noted that feedback from the stakeholder meeting was that people with type 3c diabetes have a high clinical need and experience the most inequity of any cohort. Feedback noted that adults living with type 3c diabetes had more complex and volatile diabetes than people with type 1 diabetes and therefore should have the same access to diabetes technology as people living with type 1 diabetes.

MSAC noted that the pre-MSAC response argued that, while the applicant recognised that MSAC must prioritise decisions based on evidence rather than stakeholder views alone, stakeholder input is particularly informative because CGM is a monitoring technology supporting self-management rather than a pure therapeutic intervention. While MSAC acknowledged the importance of stakeholder feedback, it considered that such input is not sufficient on its own to

[3] Nathanson, D., Eeg-Olofsson K, Spelman T et al (2025). Intermittently scanned continuous glucose monitoring compared with blood glucose monitoring is associated with lower HbA1c and a reduced risk of hospitalisation for diabetes-related complications in adults with type 2 diabetes on insulin therapies. Diabetologia 68(1):41-51.

[4] Karter, et al. 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.

[5] Du, M., Yi, S., Wei, Y. et al. Effect of FSL-CGM on Maternal and Neonatal Outcomes in GDM: A Propensity Score Matching Study in Hangzhou, China. Diabetes Ther 16, 1385–1397 (2025). https://doi.org/10.1007/s13300-025-01749-0

[6] Lund-Jacobsen, et al. 2025. "Continuous glucose monitoring added to a standardised insulin protocol following total pancreatectomy." *Danish Medical Journal* 72 (11): 21.

form the basis of MSAC advice, and that MSAC advice must be based on sufficient clinical evidence.

MSAC noted that some issues with the economic model previously identified by MSAC had been partially addressed in the resubmission:

In model 1 (REFLECT), the time horizon was reduced from 50 years to 30 years.
In model 2 (RECODe), while there were no changes to the model, clearer model traces had been provided.
In model 3 (RECODe Frem), the Fremantle risk equations from Davis et al. 2020 were now included.

One of the models (REFLECT) did not rely on HbA1c changes.

MSAC noted that the applicant did attempt to model intermittent use and some subpopulations.

MSAC noted that the economic evaluation results for the 3 models were as follows:

- Model 1 (REFLECT): CGM is dominant
- Model 2 (RECODe): Incremental Cost Effectiveness Ratio (ICER) of $15,000 to <$25,000/quality adjusted life year (QALY)
- Model 3 (RECODe Frem): ICER of $15,000 to <$25,000/QALY.

MSAC noted that the REFLECT results were weakly supported by an observational study, and considered that the extent of cost savings seem implausible and were driving the dominant result. MSAC considered that the RECODe Frem model is likely the most reliable of the 3 models. However, it is still based on a 0.34% change in HbA1c being clinically meaningful, an overly large QALY gain from avoiding finger pricking, and modelled all insulin-dependent T2D (that is, both IIT and non-IIT patients).

MSAC considered that, although the applicant attempted to address some of MSAC's requests from the previous consideration, there is still a weak evidentiary basis to model the proposed subpopulations, and residual structural and parameter uncertainties identified by ESC remain. The key uncertainties related to whether the disutility associated with finger-prick testing and the relatively large QALY gains from avoiding finger-prick testing were overestimated, the size of cost offsets for severe hypoglycaemic events in the modelling, and the existence and extent of the translation of HbA1c levels to diabetic complications. MSAC noted that due to these uncertainties ESC had requested a multivariate respecification of the base case that involved halving the diabetes complications costs and disutilities, halving the finger-prick disutility, and halving severe hypoglycaemic event costs and disutilities.

MSAC noted that the pre-MSAC response included the multivariate analysis requested by ESC (although it strongly reiterated the argument around the 'robustness' of using a finger prick disutility of 0.3), as well as a 'hurdle analysis' in which only those individuals with improvements in HbA1c greater than 0.35% were included in the RECODe models.

Running the three models through the respecified multivariate base case analysis resulted in:

- REFLECT: CGM remained dominant
- RECODe: an increased ICER (compared with the base case) of $25,000 to <$35,000/QALY
- RECODe Frem: an increased ICER of $35,000 to <$45,000/QALY.

The hurdle analysis resulted in an ICER of $5,000 to <$15,000/QALY for RECODe and $15,000 to <$25,000/QALY for RECODe Frem. MSAC considered that the hurdle analysis could be useful if the hurdle was set at a HbA1c reduction of 0.5%.

MSAC considered that an acceptable ICER would be no more than $30,000 per QALY. This was informed by PBAC's November 2024 decision not to recommend tirzepatide for type 2 diabetes, which treated 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 respecified base cases provided in the pre-MSAC response, if any of the models used in the resubmission are accepted as a basis for decision-making, there would need to be a price reduction to bring the ICER down to no more than $30,000/QALY.

MSAC noted that the key change in the financials was the use of the PBAC Drug Utilisation Sub Committee (DUSC) estimates for the total number of patients supplied insulin, with NDSS data used to subtract non-T2D patients. However, MSAC noted that uncertainties remained relating to the derivation of the higher uptake rates that were applied in the resubmission (compared to the original submission) to estimate the number of eligible patients, and clarification on the robustness of the process used to derive the assumed market growth rates.

MSAC noted that the ADAR assumed that 27.2% of insulin-dependent T2D cases are in the non-IIT subpopulation which in turn is based on the assumption that premixed insulin users belong in the IIT subpopulation. This is the reverse of the approach that was taken by this applicant in their previous submission. However, MSAC considered that premixed insulin users should be classified as being part of the non-IIT subpopulation as this aligns with the Australian Diabetes Clinical Quality Registry (ADCQR 2024) data protocol.

MSAC noted that the estimated net financial impact of CGM inclusive of all proposed populations (T2D, gestational diabetes, T3D) was estimated at $500 million to <$600 million over 6 years (after applying $100 million to <$200 million in cost savings from reduced use of blood glucose strips). MSAC noted there were disparities in the methodology of the two CGM applications which required reconciliation.

Regarding the uptake rates in the financial estimates, MSAC noted that the pre-MSAC response argued that uptake forecasting is inherently uncertain, and that comparisons with other jurisdictions are not straightforward. The applicant then went on to cite CGM uptake rates (as a percentage of T2D insulin users) from other jurisdictions, which 'have been redacted% to redacted% (in France) and redacted% to redacted% (in Sweden) for years 1–4'. MSAC noted that these rates are lower than those applied in the resubmission. MSAC noted that the pre-MSAC response stated that the high uptake rates were aligned with Australian uptake of CGM in type 1 diabetes, based on information the applicant received including NDSS and PBAC Drug Utilisation Sub Committee (DUSC) data.

MSAC considered the risk of use outside of 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 expensive 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 did not support the staged implementation approach mentioned in the ESC report, stating that it could inadvertently delay access for those with the greatest unmet need. MSAC acknowledged the points made by the applicant, but 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 it currently did not have sufficient evidence or a reliable economic model to support public funding of CGM in the gestational diabetes or T2D populations. 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.

In the case of gestational diabetes, MSAC considered that there were scant data on improvement in neonatal outcomes, some concern of risks, and stakeholder support was limited. MSAC also noted that while the population was finite in timing, it was sizeable and recurring.

In the case of the T2D population MSAC considered that there remained significant uncertainty on the exact definition and size of the subpopulations that would most benefit and the budgetary outlay and ICER. The resubmission did not adequately address the matters raised previously by MSAC at its July 2025 meeting

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 the more broadly defined T2D population could be applied to the priority groups identified by MSAC, specifically:

- those with who require IIT (receive ≥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%
- those with T2D who are pregnant or 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 high-risk 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 its respecified multivariate base 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 short term CGM is used to identify ongoing clinical need, required further evaluation. However this should be undertaken after the consideration of the priority populations as outlined above.

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

4. Background

In July 2025, an application was submitted requesting funding for FSL CGM devices to the Medical Services Advisory Committee (MSAC) (Application 1786). After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost for people with insulin-dependent T2D, GDM and people aged over 21 years with T3cD, MSAC deferred its advice on NDSS subsidisation (July 2025 PSD p. 1).

Regarding the T2D population, MSAC considered the clinical claim that CGM leads to an overall improvement in glycaemic control measured using glycated haemoglobin (HbA1c) was not fully supported. MSAC considered that there was substantial uncertainty around estimated utilisation, and that the budget impact of subsidising CGM for the proposed populations would be very large. MSAC, therefore, advised that a revised resubmission should focus on the subpopulations who have a greater clinical need for and are more likely to benefit from CGM, as well as presenting evidence around 2 different patterns of usage (intermittent vs continuous use of CGM). The subpopulations with greater clinical need include patients who use both long-acting and short-acting insulin, people using insulin with higher levels of HbA1c (e.g. >8%), and Aboriginal and Torres Strait Islander people. More recent clinical evidence of effectiveness was also requested with a focus on comparative data (randomised or otherwise). MSAC further advised that a resubmission should present a revised economic evaluation focused on the populations with a higher clinical need and addressing the issues in the model. MSAC recommended that the resubmission should re-evaluate the applicant's suggested minimal clinically important difference (MCID).

Regarding the GDM and T3cD populations, MSAC considered that there was clinical need but noted that evidence was limited.

Table 1 summarises the key matters of concern from MSACs previous consideration of the proposed technology.

Table 1 Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
MCID for HbA1c	The ADAR proposed an MCID of 0.3% for change in HbA1c, which was the primary outcome to assess comparative effectiveness of CGM compared to SMBG. This was considered by MSAC to be lower than the threshold of 0.5% previously used by the PBAC. An MCID of 0.5% is also accepted by NICE (England). MSAC agreed with ESC that stronger evidence would be needed to accept an MCID of 0.3% for a superiority claim.	**Not adequately addressed** The ADAR proposed revising the MCID for HbA1c to ≥0.35%, citing a recent meta regression analysis of 44 randomised controlled trials (Diallo 2025). Diallo 2025 presents a continuous trial-level meta-regression of 44 RCTs examining the association between HbA1c reduction and clinical outcomes including MACE and all-cause mortality. While it demonstrates a continuous association between HbA1c reduction and improved health outcomes, which begin at an HbA1c reduction of approximately 0.25% and upwards (where the majority of data points cluster), the ADAR resubmission did not fully meet the explanatory requirements of Appendix 12 of the MSAC Guidelines to explain how this evidence justifies the lower proposed MCID of 0.35%. Interpretation of small HbA1c differences is further limited by heterogeneity, particularly at increments well below the 1% scale on which effects are typically estimated. Moreover, the intervention in most of the RCTs was glucose-lowering therapy (i.e. SGLT-2 inhibitors, GLP-1 receptor agonists) which may introduce a confounding effect on the relationship between HbA1c and MACE as there is a body of evidence showing that the cardiovascular benefits seen from these glucose lowering therapies may occur via mechanisms independent of glycaemic control. The case for redefining the MCID based on this evidence would therefore have benefited from a more thorough discussion instead of letting the paper speak for itself. For example, Appendix 12, p. 291 of the Guidelines states that the approach would require among other things: *Establish the biological reasoning for the link between the PSM (proposed surrogate measure) and the TCO (target clinical outcomes), including how pivotal the PSM is to the causation pathway of the TCO*. Extrapolating this relationship to derive an MCID of 0.35% as a "conservative" estimate is therefore not sufficient. Furthermore, a HbA1c reduction of at least 0.5% is the commonly accepted as an MCID for claims of superiority by PBAC, with smaller differences of 0.3--0.4% accepted for claims of non-inferiority (Semaglutide PSDs November 2019 and March 2021). Overall, a reduction in HbA1c of at least 0.5% remains appropriate for an MCID for assessing superiority.
Device-agnostic listing	PSD, p.63: Current NDSS listings do not differentiate between brands of CGM or flash glucose monitoring products. PSD, p.52: Therefore, device-agnostic funding for these products would likely be appropriate as the devices likely have a class effect.	**Addressed** Brand agnostic CGM clinical evidence is presented in the resubmission for all 3 PICO Sets and subpopulations.

Component	Matter of concern	How the current assessment report addresses it
Clinical studies limited to comparative studies only	MSAC did not consider the single arm studies presented in the ADAR as being of an equivalent evidence level to the comparative data (randomised or otherwise).	**Addressed** Evidence presented was limited to higher levels of evidence that includes comparative data (randomised or otherwise).
Focus on subgroups of patients with greater clinical need for CGM in PICO Set 1	PSD, p.2: MSAC advised that a revised resubmission should focus on the subpopulations who have a greater clinical need for CGM and are more likely to benefit from CGM, as well as presenting evidence around 2 different patterns of usage. MSAC further advised that a resubmission should present a revised economic evaluation focused on the populations with a higher clinical need and addressing the issues in the model. MSAC considered revised estimates of utilisation would be required to more accurately estimate the size of the subpopulations. MSAC noted that additional subgroups should be considered and that these may include: • People using insulin with higher baseline levels of HbA1c (e.g. > 8% and >9%). • First Nations people (e.g. with baseline HbA1c >7%). • People who use both basal and bolus insulin. • People with disability (including mental health issues and neurodivergence) for which checking BGLs creates a high burden on the individual and/or carer. Additionally, they could include Intermittent populations: • People with intercurrent illness that affects blood glucose management and requires additional short-term monitoring of BGLs. • 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 situations in which nocturnal hypoglycaemic events are suspected.	**Partially addressed** The requested population for PICO Set 1 is patients with T2D treated with insulin, with subpopulations with greater clinical need presented as requested by MSAC. Of the subpopulations identified, the ADAR considered that the evidence for people with disabilities and people with intercurrent illness was lacking. Therefore, these subpopulations are not presented. The subpopulations presented in the ADAR for PICO Set 1 are: ○ Insulin intensity ▪ All T2D on insulin ▪ T2D on insulin (IIT) ▪ T2D non-IIT ○ Level of HbA1c: ▪ Any HbA1c (same as All T2D on insulin) ▪ HbA1c ≥8.5% ▪ HbA1c ≥9.5% ○ Special T2D populations: ▪ Pregnancy ▪ First Nations ▪ Prior MACE or CKD ○ Intermittent CGM use Pertaining to these subpopulations, all the T2D subpopulations also needed to be treated with insulin. However, given the increased risk to pregnant women and neonates and that the majority of the evidence identified was not specific to patients administered insulin, the ADAR requested funding be considered insulin agnostic for this subpopulation of patients, i.e. pregnant patients with T2D need not be treated with insulin. The expected uptake in clinical practice (utilisation) was revised based on DUSC data and applicant estimates, according to MSAC's comments. However, the derivation was not provided.
Model validation A	Provide a basis to accept that the model has been validated to estimate incremental effects on the patient-relevant health states following any HbA1c improvement.	**Partially addressed** The model was provided as an Excel-based model and appeared largely editable, although some model functions incorporated Visual Basic code, which limited full transparency of certain structural components and calculations.

Component	Matter of concern	How the current assessment report addresses it
		The applicant responded that model validation work had been previously described and published. Publication of the modelling approach supports transparency and external review. The applicant also provided operational validation of model outputs, such as model traces (as described in MSAC Technical Guidance 23) presented as cumulative curves and survival curves. However, there are several issues regarding the quality and presentations of these graphs (detailed discussion in the in-line commentary in Section 3.9.3 of the resubmission).
Model validation B	Applicability of RECODe risk equations. "More evidence is needed to substantiate the ADAR's claim that RECODe reflects more recent treatment practices."	**Not adequately addressed** The RECODe risk equations were developed using data from the ACCORD study, which recruited patients from clinical sites in the United States and Canada between 2001 and 2009, approximately 17–25 years ago. The use of data from the United States and Canada has not been justified in the ADAR resubmission. MSAC questioned whether RECODe reflects the most recent treatment practices, given the time period during which data for the ACCORD study were collected. The applicant attempts to address the concerns raised about RECODe by introducing an entirely new model using REFLECT. This is not considered an appropriate response to MSAC's concerns regarding the validity of the evidence provided. The REFLECT model introduces a new set of concerns related to the employed methods and the applicability of the evidence used to inform the new model, such as the use of Swedish population data in the Australian context.
Model validation C	This should include a basis for assessing the effect of expected lags in onset of the treatment effect and less than a full epidemiological-based prediction, noting the duration of change of HbA1c levels in any of the RCTs identified in the evidence base used for the validation.	**Not adequately addressed** The applicant's response focused on the reduction in HbA1c, whereas MSAC's concern related to the timing of downstream health benefits, not merely the change in HbA1c itself. Reductions in complications are unlikely to occur immediately following a reduction in HbA1c. Therefore, MSAC requested that the model reflect the realistic timing of reductions in complications, rather than only the timing of changes in the biomarker (i.e. HbA1c). Overall, the concerns raised by MSAC and the issues addressed in the applicant's response appear to relate to different aspects of the model.
Model validation D	The ADAR did not discuss other differences between the 2 risk equations, such as why RECODe was more appropriate for the Australian population, and whether RECODe had been validated against this population. Indeed, Davis et al. (2009) found that UKPDS-OM2 was unsuitable for predicting risk in Australians with T2D, so developed an Australian-specific set of risk equations. Therefore,	**Partially addressed** In the resubmission, the applicant applied the Fremantle equations, which were derived from an Australian study. However, the use of these equations does not fully address ESC's concern that the original equations were validated only for cardiovascular events rather than for all modelled types of diabetic complications. As stated, the resubmission incorporated the Fremantle equations into the model

Component	Matter of concern	How the current assessment report addresses it
	additional uncertainty exists as to whether the model predictions are appropriate for an Australian population. Transition probability ESC noted that a key concern regarding the transition probabilities used in the model related to how the diabetes complication events were generated using Risk Equations for Complications Of T2D (RECODe) equations. ESC noted that the RECODe equations have been validated for cardiovascular events only rather than all modelled types of diabetic complications and has been superseded by more recent risk equations based on larger populations. ESC considered it unclear whether the RECODe equations had been validated in terms of disease progression only or also in terms of incremental effects across interventions.	for 4 major adverse cardiovascular events, defined as non-fatal myocardial infarction, non-fatal stroke, non-fatal heart failure, and cardiovascular death. However, the ADAR resubmission does not clearly describe how non-cardiovascular diabetic complications were modelled or whether alternative risk equations were applied to these complications. Additionally, in response, the applicant stated that ADAR 1785 (Dexcom) used a similar modelling approach. However, this may not be an appropriate example to justify, as ADAR 1785 is still under assessment in its resubmission.
Model currency	Provide a basis to accept that any such previously established model validity is still relevant despite changes to model structure (for example, that a CVD event had no impact on an individual's future risk of complications or death). The commentary considered that this assumption was clinically unrealistic.	**Partially addressed** In response, the applicant updated certain variables within the model. This included event history variables (e.g. CVD history) as events occurred, and incorporating correlations whereby blood pressure and cholesterol decline (by a small amount) when HbA1c decreases. These changes could improve the clinical plausibility of the model. However, the update of event history variables reflected the occurrence of complications rather than changes in underlying continuous risk factors over time. It remained unclear whether other continuous variables within the RECODe equations were updated.
Model Traces	ESC noted that biomarkers typically have a lag in their effect on patient outcomes and are rarely 100% predictive of an effect on subsequent clinical outcomes. ESC considered it unclear whether the model (in any form) had been validated for its incremental estimates. ESC noted that it was unclear whether the figure presented as the "base case incremental model trace" displayed cumulative results or results for each cycle. ESC considered that this trace cast doubt on the reliability of the model.	**Partially addressed** In the resubmission, the applicant added a series of cumulative curves and survival curves to address ESC's concerns regarding model traces. The inclusion of these additional outputs improves the transparency of the model. However, there are several issues regarding the quality of these graphs. Duplicate graphs were shown under different figure numbers without explanation, and inconsistent time horizons were applied across figures without justification. In addition, some survival curves for FSL and SMBG were nearly identical, suggesting no clear difference in outcomes. Model validation also remains uncertain.
	Given the difficulty in interpreting the T2D model trace provided, provide per year traces over the duration of the model for the 'Scenario 1/Step 1 version' of the model, and for each of the CGM arm, the SMBG arm, and the increment: Proportions of patients in each of the RECODe-based health states (graphed), with proportions free of complication and death in a separate graph. Modelled aggregate discounted costs, Life years and modelled discounted QALYs (graphed, accrued). Modelled discounted cost/QALY and cost/life year (increment only, graphed, accrued).	

Component	Matter of concern	How the current assessment report addresses it
Second-order PSA	For transparency, provide in a table the results of the second-order probabilistic analysis for the "Scenario 1"/"Step 1" version of the T2D model without varying the discount rate or time horizon from the first-order economic evaluation: for each of the CGM arm, the SMBG arm, and the increment: aggregate discounted costs, discounted LYs, discounted QALYs, discounted cost/LY (increment only) and discounted cost/QALY (increment only).	**Not adequately addressed** The applicant stated that, given the similarity between Step 1 and Step 2 results, only the Step 2 PSA results were provided. This does not address MSAC's request and the justification is not sufficient. The lack of Step 1 PSA results limits transparency and prevents assessment of the uncertainty associated with the model when informed by randomised trial data alone.
HRQoL	The baseline utility for all people entering the model was 0.768, informed by a meta-analysis by Niño-de-Guzmán et al. (2023). The assessment group noted that this utility was the pooled EQ-5D value associated with T2D with or without complications. It reflects the T2D population as a whole and does not account for the treatment regimen or age of the modelled population. The EQ-5D utilities also used a UK tariff; the ADAR did not convert the utility inputs to align with an Australian tariff. Age- and sex-adjusted Australian EQ-5D population norms were not applied.	**Partially addressed** The applicant argued that the utilities derived from Niño-de-Guzmán 2023 are preferable, as they represent a recent and comprehensive synthesis of the literature. The applicant also noted that the baseline utility value from this source (0.768) is highly comparable to that reported in an Australian study by Ngo 2022 (0.765). Furthermore, the applicant stated that the use of UK tariffs is appropriate according to PBAC guidelines. The justification is considered reasonable. The use of a single pooled baseline utility does not account for heterogeneity in age, sex or baseline health status, all of which may influence health-related quality of life. The absence of age- and sex-adjusted utilities therefore remains a limitation, particularly given the long-term time horizon of the model. However, this is a common simplifying assumption that may not cause a major issue.
HRQoL	The study by Niño-de-Guzmán et al. (2023) was also used to inform the utility decrements for complications. For stroke, blindness and renal failure, the ADAR assumed that the utility decrement for subsequent years would be equivalent to the first-year utility decrement, but no clinical reasoning was provided for this assumption. Long-term utility decrements were not applied to the chronic conditions of myocardial infarction and congestive heart failure. The ADAR did not provide justification for this decision, despite assuming that these have an ongoing cost impact. This is not clinically appropriate. Incorporating these would increase the incremental QALYs in favour of FSL CGM.	**Partially addressed** In response, the applicant has updated the model to incorporate disutilities for subsequent years for MI (−0.055) and CHF (−0.108). This revision is appropriate and improves the clinical plausibility of the model. The applicant also provides supporting evidence from Pinckaers 2024 to justify the assumption that post-stroke utility decrements remain relatively stable over time. However, it should be noted that the cited data from Pinckaers 2024 were up to 2 years, which may not fully capture longer-term effects. Additionally, Table 3-8 (Health utility and complication-related decrements for people with T2D) of the resubmission shows no change in the disutilities for subsequent years compared with the utility/disutility for Year 1. It is therefore unclear whether the applicant has applied the disutility values of −0.055 for MI and −0.108 for CHF in the resubmission.
Longevity of treatment effect	The ADAR did not provide any evidence to support the claim that the treatment effect was constant over time.	**Not adequately addressed** In response, the applicant provided additional clinical evidence, including updated meta-analyses incorporating follow-up data of up to 24 months, and cited

Component	Matter of concern	How the current assessment report addresses it
	ESC also requested that further information be extracted from the studies identified in the ADAR on the longevity of the treatment effect (on HbA1c levels) related to CGM use.	Nathanson 2025 as demonstrating that the HbA1c treatment effect is maintained over this period. Additionally, in the ADAR resubmission, the applicant argued that the assumption that HbA1c does not change naturally over time was conservative, as HbA1c would be expected to increase with age in clinical practice. First, it is important to note that this assumption has very different implications depending on which model is being considered. This is relevant for Model 2 and 3. However, Model 1 (REFLECT) does not use HbA1c and instead relies on directly observed event reductions. Second, given that the applicant asserts that CGM affects HbA1c, as indicated in their trial, changes in HbA1c are vital to the argument of the long-term value of CGM. The assumption that HbA1c remains constant over time, in both the treatment and comparator arms, is a structural simplification that may not reflect the natural progression of T2D.
Reduction in hypoglycaemic/ hyperglycaemic events during intercurrent illness	ESC also requested that further information be extracted from the studies identified in the ADAR regarding the impact of CGM in reducing the risk of hypo- and hyperglycaemic episodes within patients who have acute intercurrent illness (e.g. urinary tract infection).	**Partially addressed** Due to the limitations of the available data, the applicant was not able to conduct such analysis. The response from the applicant was considered reasonable, but it does not fully address MSAC's request because it does not provide further exploration of the issue, which may have included additional evidence such as indirect evidence or expert opinions.
Risk greater in first part of 10 years	ESC also noted that the 10-year risks were assumed to be distributed equally over time to generate annual risks, which ESC noted may result in events in the model occurring earlier than would occur clinically given that diabetes is a progressive disease.	**Not adequately addressed** In response, the applicant stated that risks have been adjusted to change annually rather than in 10-year intervals, using a formula to convert 10-year risks to annual risks. However, this approach assumes a constant hazard over time. As a result, risk remains evenly distributed across years, and the timing of complications in the model may still occur earlier than would be expected in clinical practice. This is considered an inappropriate assumption given the true natural progression of these risk factors, and maintaining this modelling assumption biases the analysis in favour of the intervention (FSL).
Blood pressure	ESC also noted that blood pressure, a covariate affected by HbA1c and affecting cardiovascular events, was omitted in the model. ESC noted and accepted the pre-ESC response's argument that risks of complications being fixed over time and the failure to include blood pressure as a covariate that would be reduced by a reduction in HbA1c would be conservative (against CGM) because if (for example) blood pressure reduction were to feedback into the model it would	**Partially addressed** In this resubmission, the applicant claimed that the updated model dynamically links these outcomes such that blood pressure and cholesterol decline (by a small amount) when HbA1c decreases (through covariance).

Component	Matter of concern	How the current assessment report addresses it
	reduce the risk of diabetes complications, making CGM more cost-effective. However, ESC considered that the bringing forward of the risks in the model worked to partly offset this potential conservative bias.	Although the model assumed that blood pressure and cholesterol would decline with reductions in HbA1c, the magnitude and function of these relationships were unclear, being described only as 'a small amount'.
Intermittent use (i.e. short-term use) in some subgroups	MSAC noted that evidence of intermittent vs continuous use should be presented in a resubmission: • 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 T2D 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. • Situations in which nocturnal hypoglycaemic events are suspected.	**Partially addressed** In response, the applicant stated that there was limited evidence available to inform the projected outcomes from intermittent use of CGM technology, and that the principal benefit of CGM was derived from continuous monitoring for behavioural change and ongoing patient engagement. The applicant also noted that PICO Set 2 explores gestational diabetes. Additionally, the applicant stated that, in the resubmission, no economic modelling was presented for intermittent use due to data limitations. The literature has demonstrated that using intermittent CGM in people with T2D may improve glycaemic control and patient self-management. Nevertheless, it is reasonable to claim that the available evidence is insufficient to inform robust economic modelling. Qualitative evidence or expert opinion would be useful to further explore the potential benefits of intermittent CGM use.
Decline of CGM benefit over time	MSAC further considered that the educational benefits of CGM in inducing behavioural changes may taper off over time. MSAC therefore queried whether evidence is available regarding the effectiveness of using a CGM for a limited period (e.g. 2 months in a calendar year), which may be considered as a potential option in a resubmission.	
Model stability	ESC considered that reasons for the different results between the first-order (step 2) and second-order (step 3) analyses were unclear, but this difference suggested that the model may be unstable.	**Not adequately addressed** In the resubmission, the applicant increased the number of PSA simulations (2,000 replications with 10,000 patients) and reported that the PSA ICER ($15,000 to <$25,000) is closely aligned with the deterministic base case ICER ($15,000 to <$25,000). This suggests improved numerical stability of the results. However, the applicant conducted PSA only for Model 2 (RECODe-based approach). PSA results for the other 2 models (Model 1: REFLECT and Model 3: RECODe-Fremantle) were not presented. Additionally, the 3 models used in the base case analysis produced different outcomes. Thus, it remains unclear whether the stability observed in Model 2 applies to the other model structures. These models are fundamentally different. The uncertainties of one model cannot be assumed to apply to the others. The absence of reporting the PSA for Model 1 and 3 represents a significant limitation of this ADAR, especially given the differences in the deterministic results across models.
Population data used	The 'all diabetes' population in ANDA and the data in ACCORD do not align with the population in PICO Set 1.	**Not adequately addressed** In response, the applicant stated that the mismatch was common due to the international nature of clinical trials and data limitations in Australian sources. The

Component	Matter of concern	How the current assessment report addresses it
	Given the differences in the 3 populations informing Table 3-2 in the ADAR, there is uncertainty as to whether the simulated population is clinically representative of the population of PICO Set 1.	applicant further argued that, despite these differences, the populations are broadly comparable and unlikely to introduce substantial bias, given similarities in clinical management and disease. Although some degree of mismatch between data sources may be acceptable in economic modelling, the applicant did not provide empirical evidence or validation to demonstrate that the simulated population is sufficiently representative of the PICO Set 1 population. The applicant did not extract or present relevant information from the cited references (or other sources) to demonstrate that those source populations were aligned with the Australian populations. Additionally, as noted in the original ADAR, the applicant did not seek clinical expert opinion to assess whether these populations are comparable with each other and with the population specified in PICO Set 1, nor did the applicant discuss the potential impact of using data from different populations to simulate the target population. The represents a major evidence gap because the applicant did not demonstrate the generalisability of the model results to the Australian context.
Cost offsets	MSAC noted that the model generated large cost offsets from hospitalisations but considered that the evidence to support this was poor. Overall, MSAC considered that the model produced implausible results. The annual proportion of people experiencing hospitalisation for a diabetic ketoacidosis (DKA) event and severe hypoglycaemia event (SHE) prior to and post-FSL initiation was extracted for the analysis. The study was not described in the ADAR, and the French and Australian healthcare systems and populations were also not compared to justify use of these data.	**Not adequately addressed** In response, the applicant revised the model by removing HHS and NSHE, and by replacing the evidence base for SHE (previously derived from a French study) with data from the Nathanson 2025 study. The removal of HHS and NSHE represented a structural simplification rather than addressing the underlying limitations in the evidence. Excluding these events may underestimate the true disease burden and limit the model's ability to capture meaningful differences between the intervention and comparator; sensitivity or scenario analyses would be recommended. The applicant justified the removal of HHS on the basis of avoiding reliance on French data, and instead incorporated a Swedish study. However, the appropriateness of applying Swedish data to the Australian population remained uncertain. While removing acute diabetic events may reduce the magnitude of cost offsets, it also raises uncertainty as to whether the model reflects real-world clinical practice, particularly regarding the capture of complications that would be expected to result in hospitalisation in the Australian context.
Correlation Matrix	The ADAR used a correlation matrix for baseline characteristics to ensure all individuals had a plausible set of risk factors. Matrices were from UK-based reports, published by the National Institute for Health and Care Excellence	**Not adequately addressed** MSAC noted that the ADAR used a correlation matrix, which could improve the clinical plausibility of the modelled population. However, the applicability of UK-

Component	Matter of concern	How the current assessment report addresses it
	(NICE). The ADAR did not discuss the applicability of these matrices to an Australian population. However, the use of correlation matrices adds clinical plausibility to the population generated.	based correlations to an Australian population was not addressed. No empirical evidence or validation has been provided to demonstrate that the relationships between risk factors are transferable to the Australian population.
Correlation of HbA1c with other variables	Other baseline characteristics were assumed to be constant over the individual's lifetime and did not change when HbA1c was reduced. The assumption that baseline characteristics are sustained over the remainder of the time horizon is a critical area of uncertainty in diabetes modelling, highlighted in a review by Daly et al. (2022)[2]. However, other diabetes models often explore the impact of the change in other baseline variables correlated with HbA1c (e.g. SBP) to fully capture the impact of the intervention.	**Partially addressed** As noted under the component of 'Model currency' and 'Blood pressure'.
	The ADAR did not discuss whether the initial, one-time change in HbA1c was associated with any of the other continuous variables in the RECODe equations. Research suggests that HbA1c is significantly associated with changes in SBP. However, the ADAR assumed that SBP did not change while modelling the reduction in HbA1c. This assumption was not justified, and the ADAR did not explore whether HbA1c change was correlated with any of the other covariables in the RECODe equations. The commentary considered that this was a strong assumption that does not reflect clinical practice and, therefore, is a critical cause of uncertainty.	
Standard Errors	The ADAR did not elicit uncertainty estimates (standard error [SE] and/or 95% confidence intervals) from the literature, despite data being available in some studies. Instead, standard errors were assumed to be 10% of the mean.	**Not adequately addressed** In response, the applicant stated that standard errors from the literature were used where feasible, with the 10% assumption retained elsewhere. Based on Table 3-11 in the resubmission, which is a variable list, it is unclear whether literature-derived standard errors, rather than the 10% assumption, were applied in the model. Furthermore, the continued use of an assumed standard error equal to 10% of the mean for other parameters was not clearly justified.
Utilities	The Matza utility lacked face validity given that the study "had derived this value from differences in utilities elicited from members of the general public for sensor-based glucose monitoring and SMBG" p.7 PSD	**Not adequately addressed** This estimate (0.03 disutility for finger pricking) was based on preferences elicited from the general public rather than from people with T2D. It remains uncertain whether this value accurately reflects patient experience. The resubmission argued that the use of general population preferences aligned with guidance from the PBAC, MSAC, NICE and CDA-AMC, and that the use of UK tariffs is appropriate in the absence of Australian-specific data. However, the issue is not whether general population methods are allowed, but whether they are appropriate for this specific context (i.e. valuing finger pricking in people with

Component	Matter of concern	How the current assessment report addresses it
		diabetes). General population respondents may misjudge the burden of finger pricking compared with patients who routinely perform SMBG, resulting in uncertainty in the estimated disutility. Additionally, in the OWSA, the disutility associated with finger pricking was among the key drivers (the third) of the model results, with a ±20% variation, which may lead to a substantial impact on the ICER. This indicates that the model is highly sensitive to this parameter. Therefore, it should be noted that uncertainty remains regarding the use of 0.03 disutility estimate and the model is very sensitive to this assumption.
PICO Set 3 – Economic Evaluation	The ESC noted that no economic evaluation could be reasonably provided for PICO Set 3.	**Addressed** The original ADAR did not present an economic analysis for PICO Set 3, which was acknowledged and noted by MSAC in the July 2025 PSD. In the resubmission, no economic data have been presented for PICO Set 3 due to limited evidence.
ICER across subgroups	It was expressed that each PICO Set should not only be supported by clinical data but also by an accompanying ICER.	**Addressed** The applicant claimed that, where possible, an economic evaluation has been undertaken and presented but was not feasible for all subgroups. This justification is reasonable.
Uptake Rates	Uncertainty in these.	**Not adequately addressed** The applicant applied higher uptake rates in the resubmission (IIT: **redacted-redacted**%; non-IIT: **redacted-redacted**% over Years 1–6), consistent with MSAC's comments. The applicant indicated that these updated rates were based on 'T1D Australian and T2D overseas experience as well as feedback from MSAC 1786 consideration and DUSC data'. However, their derivation is unclear and not verifiable from the provided sources.
Equity Issues	PSD, p.56 MSAC may wish to consider equity issues in relation to co-payments across different diabetes types and subpopulations, noting that currently a co-payment is applicable for CGM funding for non-Aboriginal and Torres Strait Islander and non-concessional beneficiaries aged 21 years or over with T1D. Applying a full subsidy of CGM for T2D patients would therefore create an inequity in subsidy access compared to the existing NDSS subsidy co-payment arrangements for similar patients with T1D (and for blood glucose strips).	The applicant considers this to be a policy issue for government. In Table ES.2, provision is made for the equity category proposed by the applicant.
Involvement of GPs	PSD, p.56: Most patients with T2D are managed in a general practitioner (GP) setting, but GPs are currently not included in the set of health professionals who can certify eligibility for the populations eligible for CGM products through the	The applicant is in favour of the extended role of GPs. However, this again is a policy consideration.

Component	Matter of concern	How the current assessment report addresses it
	NDSS. Allowing GPs to approve the device would eliminate authorisation bottlenecks and improve equity of access. Consumer feedback also supports an extended role for GPs.	

ACCORD = Action to Control Cardiovascular Risk in Diabetes study; ADAR = applicant-developed assessment report; BGL = blood glucose level; CDA-AMC = Canada's Drug Agency–L'Agence des Medicaments du Canada; CGM = continuous glucose monitoring; CHF = congestive heart failure; CKD = chronic kidney disease; CVD = cardiovascular disease; DKA = diabetic ketoacidosis; DUSC = Drug Utilisation Sub Committee; EQ-5D = EuroQol 5 dimensions; ESC = Evaluation Subcommittee; GP = general practitioner; HbA1c = glycated haemoglobin; HHS = hyperglycaemic hyperosmolar state; ICER = incremental cost-effectiveness ratio; IIT = intensive insulin therapy; LYs = Life Years; MACE = major adverse cardiovascular event; MCID = minimal clinically important difference; MI = myocardial infarction; MSAC = Medical Services Advisory Committee; NDSS = National Diabetes Services Scheme; NICE = UK National Institute for Health & Care Excellence; NSHE = non-sever hypoglycaemic events; OWSA = one-way sensitivity analysis; PBAC = Pharmaceutical Benefits Advisory Committee; PICO = Population, Intervention, Comparator, Outcome; PSA = probabilistic sensitivity analysis; QALYs = Quality-Adjusted Life Years; RCT = randomised controlled trial; RECODe = Risk Equations for Complications Of type 2 Diabetes; T1D = type 1 diabetes; T2D = type 2 diabetes; SBP = systolic blood pressure; SE = standard error; SHE = severe hypoglycaemia event; SMBG = self-monitoring of blood glucose; UKPDS-OM2 = a patient-level simulation model for people with T2D in United Kingdom Prospective Diabetes Study
Source: FSL - Abbott - ADAR 2026 Introduction (1 of 5) F Table 2-1

5. Prerequisites to implementation of any funding advice

The FSL CGM products are listed as Class IIb medical devices on the Australian Register of Therapeutic Goods (ARTG) under a single entry for an invasive interstitial-fluid glucose monitoring system (Table 2). No prerequisites for FSL CGM were stated by the applicant. The FSL2, FSL2 Plus and FSL3 Plus devices are currently subsidised through the NDSS for all people with type 1 diabetes (T1D) and for some people under the age of 21 with rare conditions similar to T1D and requiring insulin. The requested intervention will henceforth be referred to as 'FSL products'.

Table 2 FSL products listed on the ARTG

Product name (sponsor)	ARTG summary	Intended purpose
Invasive interstitial-fluid glucose monitoring system (Abbott Australasia Pty Ltd T/A Abbott Diabetes Care)	**ARTG ID:** 233514 **Start date:** 07/02/2015 **Category:** Medical Device Included Class IIb **GMDN:** 44611 Invasive interstitial-fluid glucose monitoring system	Glucose monitoring system to assist in the determination of interstitial-fluid glucose levels in human specimens

ARTG = Australian Register of Therapeutic Goods; GMDN = Global Medical Device Nomenclature
Source: ARTG Public Summary documents

6. Proposal for public funding

The applicant-developed assessment report (ADAR) for FSL products proposed that public funding should be provided for 3 populations: people with T2D requiring insulin (PICO Set 1), pregnant women with GDM (PICO Set 2), and people aged ≥21 years with other conditions similar to type 1 diabetes which require insulin (e.g. T3cD) (PICO Set 3).

FSL CGM is designed to replace self-monitoring of blood glucose (SMBG). FSL uses a sensor to measure glucose concentrations in interstitial fluid, then reports the measurements in real time. Alerts are issued if the readings are indicative of hypoglycaemia and hyperglycaemia to aid timely blood glucose management. Patients using FSL CGM only require finger prick testing via SMBG if the FSL fails to give a reading or if a reading is inconsistent with their symptoms (July 2025 PSD p4).

The sensor can be applied to the skin on the back of the upper arm. The sensor is calibrated at the factory, negating the need for ongoing calibration of the device. The glucose readings are automatically transmitted via Bluetooth from the transmitter to the receiver/compatible smart device every minute if they are within a range of 6 metres, and no scanning is required. The all-in-one transmitter and sensor are replaced every 14 days for FSL2 and every 15 days for FSL2 Plus. FSL2 is not compatible with automated insulin delivery systems, while FSL2 Plus is.

Currently, FSL products are fully subsidised for people with T1D aged >21 years with a concession card and for people aged <21 years. It is partly subsidised for people with T1D aged >21 years without a concession card (a co-payment of $16.20 per FSL2 sensor as of 1 January 2025). For the requested populations in PICO Set 1, 2 and 3, FSL products are currently self-funded.

Funding is requested for PICO Set 1, 2 and 3 populations via the NDSS (i.e. no Medicare Benefits Schedule listing required). As consideration of subgroups with higher clinical need were requested by MSAC for patients in PICO Set 1, the proposed population for NDSS funding will vary

depending on the subgroups supported by MSAC for subsidy; this can be determined after the process has been completed.

The annual cost for FSL products (both FSL2 and FSL2 Plus) was calculated based on a monthly sensor cost of $**Redacted** (per 2 sensors, based on $**Redacted** per sensor plus standard $2 for NDSS distribution) and 24 sensors per year. With the evidence available, 2 sensors per month appears to be an appropriate estimate.

7. Population

The ADAR proposes that CGM should be subsidised for:

- patients with T2D who require insulin (PICO Set 1)
- pregnant women with GDM (PICO Set 2)
- patients aged ≥21 years with other types of diabetes (including T3cD) similar to T1D and requiring insulin (PICO Set 3)

FSL products offer comprehensive glucose data and trend information over that offered by SMBG. This could be particularly valuable during critical periods, such as pregnancy or in conditions with complex insulin requirements, and would be used in place of SMBG. However, SMBG may be required in certain scenarios, for example, when the patient's symptoms do not match the CGM reading.

Overall, the applicant considers that the PICO Sets are broadly consistent with the ratified PICO Confirmation (Table 3, Table 4 and Table 5).

Update of PICO Set 1 with the addition of new subpopulations were made at the request of MSAC, to assess subpopulations identified with high clinical need. With respect to the subpopulations, the applicant requested that for women with T2D who are pregnant the condition of concurrent insulin treatment be removed (i.e. to be insulin-agnostic) as the majority of evidence available for this subgroup were not in patients treated with insulin. For the other subpopulations, the patients are expected to be treated with insulin.

Table 3 PICO Set 1: People with T2D requiring insulin

Population	People with T2D requiring insulin (our requested population) Subpopulation: those requiring intensive insulin therapy (i.e. require multiple daily insulin injections or continuous subcutaneous insulin infusion and who are recommended to carry out frequent monitoring of their blood glucose)
Prior tests	Diagnostic tests for T2D if a. asymptomatic and at high risk (Australian T2D 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 ≥7.0 mmol/L, or • random blood glucose ≥11.1 mmol/L confirmed by a second abnormal fasting blood glucose on a separate day, or • oral glucose tolerance testing before (fasting) and 2 hours after an oral 75 g glucose load is taken Diabetes diagnosed as fasting blood glucose ≥7.0 mmol/L or 2-hour post-challenge blood glucose ≥11.1 mmol/L, or b. if symptoms of hyperglycaemia present and • patient presenting with hyperglycaemic crisis, or • single elevated fasting blood glucose ≥7.0 mmol/L, or • single HbA1c ≥6.5% (48 mmol/mol), or • random blood glucose ≥11.1 mmol/L

Intervention	FreeStyle Libre 2 or 2 Plus Continuous Glucose Monitoring (FSL products)
Comparator	SMBG with blood glucose test strips
Reference standard	Laboratory-conducted plasma venous blood glucose test

Outcomes	**Patient-relevant outcomes**
	Direct evidence for safety and effectiveness:
	Safety:
	• Local AEs associated with glucose testing
	Effectiveness:
	• T2D complications (e.g. cardiovascular and microvascular complications including kidney disease, neuropathy/nerve damage, retinopathy/eye disease, amputations/foot ulcers) (modelling)
	• Mortality (modelling)
	• QoL
	• ~~Psychological health~~
	• Hypoglycaemic or hyperglycaemic events resulting in emergency room visit/hospitalisation
	Intermediate/surrogate outcomes:
	• Glycaemic control
	  ○ HbA1c
	  ○ TIR, TBR, TAR
	  ○ number of hypoglycaemic/hyperglycaemic excursions
	  ○ glycaemic variability
	• Change in body weight/body mass index
	• Health-related QoL (modelling)
	• Patient satisfaction
	• Reducing risk of diabetic complications (modelling)
	Additional outcomes using linked evidence approach:
	Analytical validity:
	• Accuracy, concordance
	• ~~Monitoring (CGM or SMBG) failure rate~~
	Change in management:
	• ~~Uptake or alteration of lifestyle interventions (e.g. diet and exercise) and treatment (e.g. glucose-lowering therapy)~~
	• ~~Adherence to CGM or SMBG~~
	• ~~Adherence to treatments~~
	Other relevant considerations
	• Acceptability, wearability and usability of CGM vs SMBG
	• Ability to share blood glucose data with physician, relative or carer
	• Patient/carer satisfaction
	• ~~Self-efficacy (person's belief in their ability to effectively manage their T2D and achieve their clinical goals)~~
	• Work/school absenteeism and daily functioning
	Healthcare system outcomes
	• Cost, cost-effectiveness
	• Financial implications (financial impact, overall healthcare costs etc.)

Assessment questions	What is the safety, effectiveness and cost-effectiveness of FreeStyle Libre 2 or 2 Plus CGM versus SMBG in people with T2D requiring insulin therapy?

AE = adverse events; FSL = FreeStyle Libre Continuous Glucose Monitoring; HbA1c = glycated haemoglobin; QoL = quality of life; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes; TAR = time above range; TBR = time below range; TIR = time in range

Notes:

Not all outcomes in the PICO confirmation were supported by evidence in the literature. Outcomes unavailable have a ~~strikethrough~~ line. Outcomes found in modelling or added for the ADAR are coloured green.

Table 4 PICO Set 2: Pregnant women with GDM

Population	Pregnant women with GDM
Prior tests	Glycaemic assessment of pregnant mother at 24–28 weeks gestation Royal Australian College of General Practitioners criteria: • fasting plasma glucose ≥5.5 mmol/L, or • 2-hour plasma glucose ≥8.0 mmol/L (75 g OGTT) Australian Diabetes in Pregnancy Society criteria: • fasting plasma glucose 5.1–6.9 mmol/L, or • 1-hour plasma glucose (75 g OGTT) ≥10.0 mmol/L, or • 2-hour plasma glucose (75 g OGTT) 8.5–11.0 mmol/L
Intervention	FreeStyle Libre 2 or FreeStyle Libre 2 Plus CGM system
Comparator	SMBG using a finger prick capillary blood sample, glucose test strips and glucose meter
Reference standard	Laboratory-conducted plasma venous blood glucose test
Outcomes	**Patient-relevant outcomes** *Direct evidence for safety and effectiveness:* **Safety:** • Local AEs associated with glucose testing **Effectiveness for mother:** GDM complications due to diabetes and during birth • ~~GDM complications (e.g. cardiovascular complications, hypertension etc)~~ • ~~Mortality~~ • ~~Complications during birth~~ • ~~T2D post-partum and related complications~~ • ~~Quality of life~~ • ~~Psychological health~~ **Intermediate/surrogate outcomes** • Glycaemic control ○ HbA1c ○ mean fasting glucose concentration during first 4 weeks of glucose monitoring (CGM or SMBG) ○ ~~post prandial mean glycaemia~~ ○ TIR, TBR, TAR ○ number of hypoglycaemic/hyperglycaemic excursions ○ ~~glycaemic variability~~ • Change in body weight/body mass index **Effectiveness for child:** • Neonatal complications (neonatal hypoglycaemia, large for gestational age, gestational age at birth, respiratory complications, high birth weight) • ~~Complications during birth~~ • Admission to neonatal intensive care unit • ~~Long-term outcomes for child (e.g. obesity, diagnosis of T2D, heart disease)~~ *Additional outcomes using linked evidence approach:* **Analytical validity:** • Accuracy, concordance • ~~Monitoring (CGM or SMBG) failure rate~~ **Change in management:** • Uptake or alteration of lifestyle interventions (e.g. diet and exercise) and treatment (e.g. glucose-lowering therapy) • Adherence to CGM or SMBG • Adherence to treatments **Other relevant considerations** • Acceptability, wearability and usability of CGM vs SMBG • Ability to share blood glucose data with physician, relative or carer • Patient/carer satisfaction • ~~Self-efficacy (person's belief in their ability to effectively manage their GDM and achieve their clinical goals)~~ • ~~Work/school absenteeism and daily functioning~~

	Healthcare system outcomes • Cost, cost-effectiveness • Financial implications (financial impact, overall healthcare costs including cost of ongoing surveillance of mother and child post-partum for complications of GDM and development of T2D)
Assessment questions	What is the safety, effectiveness and cost-effectiveness of FreeStyle Libre 2 or FreeStyle Libre 2 Plus CGM versus SMBG in pregnant women with GDM?

AE = adverse events; FSL = FreeStyle Libre Continuous Glucose Monitoring; GDM = gestational diabetes; HbA1c = glycated haemoglobin; OGTT = oral glucose tolerance test; QoL = quality of life; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes; TAR = time above range; TBR = time below range; TIR = time in range
Notes:
Not all outcomes in the PICO confirmation were supported by evidence in the literature. Outcomes unavailable have a ~~strikethrough~~ line. Outcomes found in modelling or added for the ADAR are coloured green.

Table 5 PICO Set 3: ≥21 years with other conditions similar to T1D requiring insulin (e.g. T3cD)

Population	People aged ≥21 years with other conditions similar to T1D requiring insulin (e.g. T3cD)
Prior tests	For T3cD: fasting blood glucose, HbA1c test, imaging of pancreas, blood tests for pancreas function, blood test to exclude T1D Other rare conditions similar to T1D requiring insulin: testing as recommended by the American Diabetes Association guidelines (American Diabetes Association 2024a)
Intervention	FreeStyle Libre 2 or FreeStyle Libre 2 Plus Continuous Glucose Monitoring (FSL products)
Comparator	SMBG using a finger prick capillary blood sample, glucose test strips and glucose meter
Reference standard	Laboratory-conducted plasma venous blood glucose test

Outcomes	**Patient-relevant outcomes**
	Direct evidence for safety and effectiveness:
	Safety:
	• ~~AEs associated with glucose testing~~
	Effectiveness:
	• ~~Diabetes-related complications (e.g. cardiovascular and microvascular complications including kidney disease, neuropathy/nerve damage, retinopathy/eye disease, amputations/foot ulcers)~~
	• ~~Mortality~~
	• ~~Quality of life~~
	• ~~Psychological health~~
	• ~~Hypoglycaemic or hyperglycaemic events resulting in emergency room visit/hospitalisation~~
	Intermediate/surrogate outcomes:
	• Glycaemic control
	  ○ HbA1c
	  ○ TIR, TBR, TAR
	  ○ ~~number of hypoglycaemic/hyperglycaemic excursions~~
	  ○ glycaemic variability
	• ~~Change in body weight/ body mass index (BMI)~~
	Additional outcomes using linked evidence approach:
	Analytical validity:
	• Accuracy, concordance
	• ~~Monitoring (CGM or SMBG) failure rate~~
	Change in management:
	• Adherence to CGM or SMBG
	• Adherence to treatments
	• Uptake or alteration of lifestyle intervention or treatment (e.g. glucose-lowering therapy)
	Other relevant considerations
	• ~~Acceptability, wearability and usability of CGM versus SMBG~~
	• ~~Ability to share blood glucose data with physician, relative or carer~~
	• ~~Patient/carer satisfaction~~
	• ~~Self-efficacy (person's belief in their ability to effectively manage their diabetes and achieve their clinical goals)~~
	• ~~Work/school absenteeism and daily functioning~~

	Healthcare system outcomes • ~~Cost, cost-effectiveness~~ • Financial implications (financial impact, overall healthcare costs etc.)
Assessment questions	What is the safety, effectiveness ~~and cost-effectiveness~~ of FreeStyle Libre 2 or FreeStyle Libre 2 Plus CGM versus SMBG in people with other conditions similar to T1D requiring insulin (e.g. type 3c diabetes)?

AE = adverse events; CGM = continuous glucose monitoring; FSL = FreeStyle Libre Continuous Glucose Monitoring; HbA1c = glycated haemoglobin; QoL = quality of life; SMBG = self-monitoring of blood glucose; T1D = type 1 diabetes; T2D = type 2 diabetes; T3cD = type 3c diabetes; TAR = time above range; TBR = time below range; TIR = time in range
Notes:
Not all outcomes in the PICO confirmation were supported by evidence in the literature. Outcomes unavailable have a ~~strikethrough~~ line. Outcomes found in modelling or added for the ADAR are coloured green.

8. Comparator

The nominated comparator for all 3 PICO Sets is SMBG; that is, blood glucose monitoring using finger pricking method with a blood glucose monitor. The blood glucose monitoring strips required for SMBG are currently subsidised by the NDSS. SMBG is an appropriate comparator across all 3 PICO Sets as it is the standard of care for blood glucose testing across all of the proposed diabetes populations.

In the PSD from its July 2025 consideration, MSAC highlighted the following aspects of the comparator to bear in mind when considering the merits of the application for FSL funding (July 2025 PSD for ADAR 1786, p. 18):

- The frequency of SMBG is individualised, but international guidelines suggest that SMBG is needed 6 to 10 times per day for people with intensive insulin therapy (IIT) regiments. People with T2D requiring IIT are usually required to test their blood glucose more frequently than those receiving non-IIT.
- The number of subsidised glucose test strips that a person with T2D can purchase from the NDSS in a 180-day period is 900 strips; this would only be sufficient to carry out SMBG 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. However, registrants can access more product if their limit has been reached and unique circumstances are present. This restriction on glucose testing strips may encourage people with T2D to deviate from the recommended frequency of SMBG, potentially increasing the risk that glycaemic targets would not be achieved.
- Access to some NDSS-subsidised glucose test strips would still be required if a person with T2D is using CGM to account for those periods and circumstances when SMBG is recommended during CGM use. For example, if a person's diabetes symptoms do not match their CGM glucose readings, if their CGM malfunctions, or if their sensor becomes lost or detached.

9. Summary of public consultation input

Consultation input was welcomed from:

1786 – FreeStyle Libre 2 continuous glucose monitoring system	Inputs Received
Organisations (31)	
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.	7
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.	24
Individual input *	
I am a health professional or health academic working in the area.	583
I have the health condition that this health service or technology is for.	1620
I have the health condition that this health service or technology is for and have experience with the proposed health service or technology.	5288
I am a parent, partner or another person caring for someone from the above two groups.	739
I am an interested individual who does not fall into any of the above categories.	217
Total number of inputs received	**7942***

* NOTE: Almost half (47%) 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 31 organisations (7 consumer organisation, one of whom submitted two pieces of input, and 24 health organisations) and 7911 individuals. Almost half of respondents (47%) 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 (76.5%) had used a continuous glucose monitor (CGM). In addition, ~ 9% indicated that they were a parent or carer of someone with diabetes; ~ 7% indicated that they were a health practitioner or health academic; and ~ 3% 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 about the MSAC consultation from the applicant. For the purposes of this summary, these inputs have been treated as input from individuals. The organisations that provided input are listed at Attachment A.

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.

Respondents were overwhelmingly supportive of expanded NDSS access to continuous glucose monitoring (CGM) for people with diabetes, particularly those using insulin, arguing that cost should not determine safety. Contributors describe 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 prevent dangerous hypoglycaemia and hyperglycaemia.

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

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

The survey asked people to indicate if they agreed there are certain groups of people with type 2 diabetes requiring insulin who would benefit more than others from access to a CGM. Approximately 74% of respondents agreed. Respondents framed CGM as an essential monitoring tool that supports safer insulin use, better glucose control, shared data with clinicians and/or carers, and reduced long term harm.

While many still advocated for universal eligibility, respondents highlighted groups who may benefit most, including:

- People whose diabetes is clinically complex or who belong to a group more at risk of poor diabetes-related outcomes. For example, people on multiple daily injections or basal–bolus regimens, those with high HbA1c or marked glucose variability, those with recurrent or unrecognised hypoglycaemic episodes ('hypos') (especially overnight), First Nations people, pensioners and people from low-income households, people with kidney disease, or transplant-related steroid use, and older adults.
- People for whom monitoring with regular finger prick testing is challenging or inaccessible. For example, people with relevant impairments in physical, sensory, cognitive or communication functioning due to disability, neurodivergence, mental health conditions or ageing (especially if living alone) or needle aversion.
- People who are unable to read traditional monitors but can manage with the voice to text functions of the mobile application.
- People for whom recognising and communicating about symptoms of concern is challenging, (e.g. people with communication, cognitive or sensory impairments, people with learning or intellectual disabilities, people with low health literacy).
- People who need to travel long distances or wait a long time to see specialists, such as people who live in rural or remote areas (as CGM facilitates remote monitoring and medical consultations).
- People who have safety-critical jobs (e.g. drivers, shift workers).

Around 15% of respondents did not agree that some groups would benefit more than others, expressing the view that everyone on insulin would benefit from CGM access. Many supported expanding subsidised access to all people with diabetes, not just those who are insulin-dependent, arguing that this could prevent disease progression and ultimately lower healthcare costs.

Gestational Diabetes

Around 97% of respondents expressed a view on use of CGMs for gestational diabetes, with around three quarters (~74%) agreeing that this would be beneficial. Several health practitioners noted that tight glycaemic control in gestational diabetes is essential for optimal outcomes for both mother and baby and that CGM provides clear, actionable information that allows women and their clinicians to adjust diet, activity and treatment in real time, making it a particularly appropriate time-limited intervention for achieving optimal maternal and neonatal outcomes.

Around 3% of those who expressed a view disagreed, with the remainder (23%) unsure. Respondents who did not support CGM use for gestational diabetes asserted that while people with gestational diabetes may gain some convenience and reduced stress from CGM, the condition is usually short term and can generally be managed adequately with finger-prick monitoring and clinical support. If funding is limited, they argued, it should be directed to people experiencing diabetes long-term. Some respondents also noted that there is insufficient evidence to support CGM use for gestational diabetes.

Type 3c diabetes requiring insulin

Around 97% of respondents expressed a view on whether public funding of CGM should be extended to people aged ≥ 21 years with type 3c diabetes requiring insulin. Approximately 80% of these respondents agreed that public funding should be extended to this group, with 1% not agreeing and the remaining 19% unsure. Several respondents noted that type 3c diabetes poses unique and significant risks due to impaired pancreatic function from conditions such as pancreatitis, cystic fibrosis, pancreatic surgery or cancer treatment. This leads to unpredictable glucose swings, reduced glucagon production which increases the risk of severe hypoglycaemia, and more complex insulin requirements. CGM was therefore viewed as extremely valuable in this group, providing continuous visibility of glucose patterns that allows both patients and clinicians to manage insulin therapy more safely and effectively. It was further argued that the population with type 3c diabetes is small so extending CGM funding to this group would not have a huge financial impact. For example, Cystic Fibrosis Australia cited data from the Australian Cystic Fibrosis Registry, indicating that in 2025 there were 450 people with cystic fibrosis aged >21 years, who used insulin.

The main reason given for not extending funding for CGMs to people with type 3c diabetes was that it was discriminatory to fund CGMs for some groups on insulin and not others. Several respondents also disagreed on the basis that access to CGM for people with type 3c diabetes should be available before the age of 21 (i.e. they were unaware this was already the case).

Short term or intermittent use

Most respondents (98%) answered the question about whether people would still benefit from intermittent or short-term use of a CGM. Approximately 61% of these respondents agreed people would still benefit; ~ 17% did not agree and the remainder (~ 22%) were unsure. Key benefits of intermittent or short-term use identified by respondents included:

- improved self-management through real-time feedback. Many noted that even brief CGM exposure can create lasting behaviour change by making glucose patterns visible in a way that finger-prick testing does not.
- better clinical decision-making and safer treatment adjustment. Short-term CGM was commonly seen as most useful during periods of treatment change or instability, such as starting insulin, titrating doses, changing non-insulin therapies, illness, steroid use, pregnancy, or unexplained hyperglycaemia or hypoglycaemia. In these situations, respondents considered CGM valuable for identifying overnight trends, post-prandial excursions and otherwise unrecognised lows, allowing clinicians and patients to make more informed/safer management decisions.

Recommended CGM use patterns varied. Numerous respondents expressed the view that continuous use was preferable but if CGM was only available for short-term or intermittent use, then common suggestions were:

- targeted, time-limited periods of wear (eg.10-15 days) before a specialist or quarterly diabetes review.

- short blocks of use at diagnosis or when initiating or adjusting therapy, and repeat intermittent use every 2 to 3 months, quarterly, or when control deteriorates or circumstances change. Respondents often framed intermittent CGM as a structured review and learning tool with greatest value when paired with clinician input and education.

Some health practitioners and organisations indicated that if CGM is only funded for intermittent use, the timing of use should be determined collaboratively by clinicians and consumers, rather than mandated. This would allow users to decide when to utilise their subsidised CGMs based on individual needs and circumstances. Some respondents highlighted that losing access to CGM after becoming accustomed to its benefits could lead to feelings of anger and frustration.

Those who did not see benefit in intermittent or short-term CGM use considered that diabetes management requires ongoing rather than episodic monitoring, particularly for people using insulin or at risk of hypoglycaemia. These respondents suggested that limiting access to short-term or intermittent use may reduce the safety, clinical, behavioural and quality-of-life benefits associated with continuous access to CGM. Cost and equity were also noted, with short-term access seen as inadequate for people with ongoing clinical needs who cannot afford continuous use.

Most respondents (~ 77%) agreed that the groups of people identified by MSAC as benefiting from short term or intermittent use would do so. Eight percent did not agree that these groups would benefit, ~ 13% were unsure and ~2% did not answer the question.

In terms of other groups who might benefit from short-term or intermittent use of CGM, the most frequently cited groups were people:

- with type 2 diabetes managing with oral medication/lifestyle measures
- with pre-diabetes or insulin resistance
- newly diagnosed with diabetes learning how food, activity and medication affect their glucose levels
- people with obesity, metabolic syndrome, or polycystic ovary syndrome.

Those listed previously as particularly benefiting from CGM use were also noted as priority groups for intermittent CGM if that was all that was available.

Co-payments

Approximately 83% 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 comments argued that this would be a fairer and more consistent approach for people with insulin-treated type 2, type 3c and other forms of diabetes who face similar risks and monitoring needs. While many accepted a modest co-payment as reasonable and sustainable, a significant number also argued for full subsidy or additional concessions for those experiencing financial hardship, with several emphasising that access should be based on clinical need rather than diabetes type.

Around 4% of respondents did not agree that the approach to co-payments should reflect current arrangements under the NDSS for people with type 1 diabetes. The remainder were unsure (~10%) or did not answer the question (~2%). Many respondents who did not agree said a co-payment at the current type 1 rate would still be too expensive for many people, with some noting that the financial impact would be greatest for groups experiencing multiple forms of intersecting marginalisation, including First Nation's people, pensioners, concession card holders, and those

already facing multiple health-related costs. They felt this could reduce access to CGM and lead to worse health outcomes and higher costs to the health system over time.

Others argued that the same co-payment model is not appropriate for all groups, because CGM need varies by clinical circumstances, duration of use and financial vulnerability. Instead, they favoured lower or no co-payments for people at higher clinical risk or with limited ability to pay. One respondent noted that people with Type 1 diabetes are generally at higher clinical risk because they do not produce any insulin, so they should receive a higher subsidy then people with type 2 diabetes dependent on insulin.

Multiple respondents shared their own lived experiences or observations of others' experiences of the financial stress of accessing CGM whilst living on or below the poverty line. These respondents reported valuing the benefits of CGM so much that they had made trade-offs to continue to pay for it, like skipping meals or essential medications, letting insurance policies lapse, reducing social activities, and one person had given up their companion pet.

Role of general practitioners (GPs)

Approximately 91% of respondents were supportive of GPs being able to certify eligibility for CGM products through the NDSS (this dropped to ~ 73% of those who identified as health practitioners or health academics). Around 4% of respondents did not support GP involvement, while 4% were unsure and 1% did not answer the question. Amongst health practitioners/academics 16% did not support GP involvement, 10% were unsure and 1% did not answer the question.

Supporters of GP involvement emphasised access, timeliness and practicality as good reasons for GPs being able to certify CGM access. Many respondents said GPs already manage most diabetes care for people with type 2 diabetes, know the patient's broader clinical and social circumstances, and are often the most accessible clinician—especially in rural, regional and outer-metro areas where endocrinologists and credentialled diabetes educators are scarce, costly, or involve long wait times. They argued that allowing GPs to authorise CGM would reduce delays, lower out-of-pocket costs, ease pressure on specialist services, and better reflect how diabetes care is delivered in practice.

Those who did not support GP involvement noted that GPs lack the time and specialised knowledge needed to assess eligibility, initiate CGM appropriately, interpret data, and provide the education and follow-up required for patients to use the technology effectively. A common view was that CGM works best when introduced through diabetes-specific providers such as credentialled diabetes educators, nurse practitioners or endocrinologists, who can provide structured education, troubleshooting and ongoing support. Others were concerned that expanding GP authorisation without safeguards could lead to inappropriate certification, missed referrals to specialist diabetes support, poorer patient outcomes, and inefficient use of public resources.

In terms of additional training that GPs may require to certify eligibility for CGM products through the NDSS, most respondents who provided comment thought GPs would need only targeted, practical training rather than extensive new qualifications. The main areas identified were understanding how different CGM devices work, how to apply and set them up, how to use associated apps and software, and how to interpret CGM data. It was considered that this training could be provided through short online modules or CPD-style education, with some suggesting this should include regular updates as technology and evidence evolve. A smaller group felt GPs already have enough diabetes knowledge and would need little or no extra training beyond practical product-specific information.

Beyond training, respondents frequently raised the need for ongoing support structures around GPs, including access to diabetes educators, endocrinologists, practice nurses, and decision-

support tools. Many emphasised that GPs would need clear eligibility criteria for access to CGMs, referral pathways, practical patient education materials, access to CGM data and reporting systems, and streamlined NDSS or administrative processes. Several respondents also stressed that CGM prescribing should be embedded within coordinated, multidisciplinary care, rather than relying on the GP alone.

Additional comments/themes

Several themes emerged from comments received by MSAC on this application. The strongest was people's positive experiences of using CGM. Many respondents described CGM as 'life-changing' for managing diabetes and related conditions. They said it helped them improve day-to-day glucose control, lower HbA1c, better understand patterns and triggers, and receive alerts when blood glucose levels were too high or too low. Many also said CGM provided important safety benefits compared with finger-prick testing alone, especially through overnight alerts, trend data, and easier monitoring during work, driving, pregnancy, illness and other complex situations. Respondents also described broader quality-of-life benefits, including less anxiety, less pain and burden from frequent finger pricks, greater confidence, agency and independence, and better-informed decisions about diet, exercise and medication. Carers said remote monitoring helped them support children or older family members and respond quickly to hypoglycaemic episodes.

Another strong theme was equity and affordability. Many respondents said CGM is too expensive at current prices, especially for pensioners, people on low incomes, and those managing several health-related expenses. A common view was that access should be based on clinical need rather than diabetes type. Many argued that people with insulin-treated type 2 diabetes, gestational diabetes, type 3c diabetes and other complex conditions, such as nocturnal ketotic hypoglycaemia, face similar risks to those with type 1 diabetes and should have similar access to support. Some respondents with type 2 diabetes said they felt their lives were valued less than those of other people with diabetes. They also felt they were blamed for developing the condition, and that this had contributed to discrimination in access to CGM.

A third theme was the potential for long-term benefits across the health system. Many respondents emphasised the likely downstream savings to the health system. They argued that supporting better prevention and self-management by subsidising CGMs would result in fewer emergency presentations, hospitalisations, long-term complications and overall healthcare costs.

10. Characteristics of the evidence base

PICO Set 1

The clinical evidence presented for PICO Set 1 is presented in Table 6. A total of 22 studies were included, 5 of which have been carried over from the original ADAR and 17 that are new additions. Of the total number of studies, 14 studies are for the general T2D population (10 randomised controlled trials [RCTs], 4 retrospective cohort studies), 4 are for the pregnancy population (3 RCTs, 1 retrospective cohort study), 2 for the intermittent CGM use population (1 RCT, 1 retrospective cohort study) and 2 are for the First Nations population (1 qualitative, 1 retrospective cohort study). The systematic literature review (SLR) was appropriate in addressing MSAC's request for device-agnostic comparative data. Note that the data presented for FreeDM2 in the ADAR were obtained from a conference abstract. The full publication for FreeDM2 has since been published (Wilmot 2026). FreeDM2 presented evidence for the general T2D population, and no results were available from the study for the subpopulations of interest.

Notably the new studies included Nathanson 2025[7], which provided direct to health outcomes data via T2D hospitalisation rate reporting for CGM vs SMBG use and was used as inputs into the REFLECT model (see Section 10).

The use of the RoB 2 (revised Cochrane risk-of-bias tool for randomized trials) tool in the ADAR for evaluating RCTs and ROBINS-I (risk of bias in non-randomized studies of interventions) tool for non-randomised studies was appropriate. The reporting of the risk of bias assessments based on RoB 2 is a strength of this application. Reassessment found the same quality/risk of bias concerns, with a few exceptions. The exceptions are as follows: Haak 2017 and MOBILE 2022 were found to have bias related to randomisation process and was deemed to be of some concern (ADAR assessed as low). These changes have been reflected in Table 6.

[7] Nathanson, D., Eeg-Olofsson K, Spelman T et al (2025). Intermittently scanned continuous glucose monitoring compared with blood glucose monitoring is associated with lower HbA1c and a reduced risk of hospitalisation for diabetes-related complications in adults with type 2 diabetes on insulin therapies. Diabetologia 68(1):41-51.

Table 6 Key features of the included evidence for CGM in T2D on insulin

References	N	Design/ Follow-up	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
CGM vs SMBG						
Population: T2D on insulin						
Ajjan 2023	CGM: 36 SMBG: 34	RCT, MC, OL 90 days	Low	Adult T2D with recent onset MI. Includes insulin-using subpopulation	HbA1c mean change from baseline, % Time in hypoglycaemia QoL [b]	Not used
Bosi 2022	CGM: 109 SMBG: 213	Matched RC, MC 3–6 months	Some concerns	Adult T2D using basal-bolus insulin	HbA1c mean change from baseline, % Hospital admissions (T2D related)	Not used
FreeDM2	CGM: 198 SMBG: 105	RCT, MC, OL 32 weeks	NR	Adult T2D using basal-only insulin	HbA1c mean change from baseline, %	Not used
Haak 2017	CGM: 149 SMBG: 75	RCT, MC, OL 6 months	Some concerns [a]	Adult T2D using insulin (bolus, basal-bolus, CSII)	HbA1c mean change from baseline, % Time in hypoglycaemia Treatment satisfaction (DTSQ) QoL	0.3 and 3.8 test strips used for FSL and SMBG, respectively*
Kim 2024	CGM: 52 SMBG: 47	RCT, MC, OL 24 weeks	Low	Adult T2D using insulin (basal-bolus, CSII)	HbA1c mean change from baseline, % Time in hypoglycaemia Treatment satisfaction (DTSQ)	Not used
Nathanson 2025	CGM: 2,876 (MDI), 2,292 (Basal) SMBG: 33,584 (MDI matched), 43,424 (Basal matched)	Matched RC, MC 24 months	Some concerns [a]	Adult T2D using insulin (basal or MDI)	HbA1c mean change from baseline, % Hospital admissions (T2D related)	The REFLECT-based model structure
Yaron 2019	CGM: 53 SMBG: 48	RCT, MC 10 weeks	Some concerns	Adult T2D using insulin basal-bolus	HbA1c mean change from baseline, % Treatment satisfaction (DTSQ) QoL	Not used
2GO-CGM (Lever 2024)	CGM: 33 SMBG: 34	RCT, MC, OL 3 months	Low	Adolescents/adults with T2D using insulin	HbA1c mean change from baseline, % Time in hypoglycaemia Adverse events	Not used

References	N	Design/ Follow-up	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
Bergenstal 2022	CGM: 28 SMBG: 23	RCT, SC, OL 16 weeks	Some concerns	Adults with T2D using insulin (subpopulation)	HbA1c mean change from baseline, %	Not used
DIAMOND (Beck 2017)	CGM: 105 SMBG: 53	RCT, MC, OL 6 months	Low	Adult T2D treated with basal-MDI insulin	HbA1c mean change from baseline, % Time in hypoglycaemia QoL Adverse events	Not used
Karter 2021	CGM: 344 SMBG: 35,736	Matched RC, MC 12 months	Some concerns	T2D treated with insulin	HbA1c mean change from baseline, % Time in hypoglycaemia Hospital admissions (T2D related)	Not used
MOBILE (Martens 2021)	CGM: 116 SMBG: 59	RCT, MC, OL 8 months	Some concerns [a]	Aged ≥30 years with T2D treated with 1–2 daily injections of insulin with HbA1c of 7.8–11.5% and SMBG averaging ≥3 times per week	HbA1c mean change from baseline, % Time in hypoglycaemia Adverse events	Not used
Reaven 2023	CGM: 15,706 SMBG: 29,912	Matched RC, MC 12 months	Low	T2D treated with insulin	HbA1c mean change from baseline, % Hospital admissions (T2D related)	Not used
Steno2tech (Lind 2024)	CGM: 40 SMBG: 36	RCT, SC, OL 12 months	Some concerns	Aged ≥18 years with insulin-treated T2D with HbA1c ≥7.5%	HbA1c mean change from baseline, % QoL Hospital admissions (T2D related) Adverse events	Not used
Population: First Nations						
Eer 2023	8	Thematic qualitative feasibility study	NR	First Nations people from regional locations with T2D using insulin	Feasibility and acceptability of CGM via qualitative interviews	Not used
McLean 2023	57	Prospective observational	NR	Australian high-risk pregnant women with T2D in regional/remote areas	Time in range LGA	Not used
Population: T2D in pregnancy						
Liu 2025	CGM: 17 SMBG: 15	RCT, OL, SC 14 days	Low	Pre-GDM who all had T2D (also included GDM subpopulation)	**Maternal** Treatment satisfaction	Not used

References	N	Design/ Follow-up	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
Nunlee-Bland 2024	CGM: 14 SMBG: 10	RCT, OL, SC 34 weeks post-delivery	Some concerns	Pre-GDM with T2D on insulin	**Maternal** HbA1c change (%) Caesarean delivery Preterm birth **Neonatal** Neonatal hypoglycaemia LGA SGA Birthweight (g) NICU admission	Not used
Padgett 2024	CGM: 82 SMBG: 278	Retr. Cohort, SC Post-delivery	Some concerns	Pregnant with T2D	**Maternal** HbA1c change (%) Caesarean delivery Preterm birth **Neonatal** Neonatal hypoglycaemia LGA SGA NICU admission	Not used
Secher 2013	CGM: 16 SMBG: 14	RCT Post-delivery	Some concerns	Pregnant with T2D	**Maternal** HbA1c change (%) Caesarean delivery Preterm birth **Neonatal** Neonatal hypoglycaemia LGA Birthweight (g)	Not used

References	N	Design/ Follow-up	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
Population: Intermittent CGM use						
Hirsch 2025	Continuous CGM: 4,629 total Subpopulations by CGM frequency: ≥1 to ≤90 days): 1,081 >90 to ≤180 days: 523 >180 to ≤270 days): 540 >270 days: 2,485 SMBG: 4,629	Propensity matched RC, MC 12 months	Some concerns	Adults with T2D on basal or prandial insulin	HbA1c mean change from baseline, %	Not used
Aleppo 2021	Continued CGM (from Phase 1): 51 Continued SMBG (from Phase 1): 57 Commenced SMBG (after CGM use in Phase 1): 53	RCT, MC 6 months	NR	Adults with T2D on 1 or 2 daily insulin injections	HbA1c mean change from baseline, % Time in range, hr/day	Not used

AE = adverse event(s); AG = assessment group; CGM = continuous glucose monitoring; CSII = continuous subcutaneous insulin infusion; Retr. Cohort = retrospective cohort study; DTSQ = Diabetes Treatment Satisfaction Questionnaire; FSL = flash glucose monitoring; GDM = gestational diabetes mellitus; HbA1c = glycated haemoglobin; LGA = large for gestational age; MC = multicentre; MDI = multiple daily injections; MI = myocardial infarction; NICU = neonatal intensive care unit; NR = not reported; OL = open label; Propensity matched RC = propensity score matched retrospective cohort; QoL = quality of life; RC = retrospective cohort; RCT = randomised controlled trial; SC = single centre; SGA = small for gestational age; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes; TIR = time spent within target glucose range

Notes:

* Study applied in both economic and financial models

** Risk of bias was assessed by the applicant and AG, in the case where the AG disagreed with the applicant's assessment, the AGs judgement was included.

[a] Was downgraded by assessment group from low to some concerns

[b] Data not presented for clinical section

Source: FSL - Abbott - ADAR 2026 PICO Set 1 (2 of 5)

PICO Set 2

The characteristics of the evidence base for PICO Set 2 are presented in Table 7. In total, 8 studies provided outcomes data on the use of CGM vs SMBG in GDM, including 5 RCTs and 3 cohort studies. Of these studies, 3 studies (Bastobbe 2023, Majewska 2023 and Won 2025) were identified in the original ADAR. The remaining studies are new for this resubmission. The SLR was appropriate in addressing MSAC's request for device-agnostic comparative data.

The use of the RoB 2 tool in the ADAR for evaluating RCTs and ROBINS-I tool for non-randomised studies was appropriate. The ADAR assessed all RCTs as low risk of bias except Wei 2016, which was judged to have some concerns. The assessment group (AG) undertook an independent assessment for RCTs only, and assessed all trials as having some concerns, except for Elkind-Hirsch 2026, which was assessed as high risk of bias. These judgements primarily reflected the open-label design of the trials. Behavioural changes arising from knowledge of intervention allocation may differ for different interventions, affecting blood glucose levels and subsequent maternal and neonatal outcomes. In Elkind-Hirsch 2026, patients randomised to the control arm also received advice based on blinded CGM results, which would not form part of standard care. Therefore, this study was judged to be at high risk of bias.

One prospective cohort study, Du 2025, was identified in the ADAR via manual searching just prior to ADAR resubmission and could not be included in the meta-analyses conducted by the University of Melbourne Statistical Consulting Centre, due to the lack of time. Meta-analyses were redone by the applicant using RevMan v5.3 to include outcomes from Du 2025. However, results were only presented in the ADAR resubmission if the result became statistically significant following addition of Du 2025. Given the sample size of Du 2025 (CGM = 466; SMBG = 932), which was substantially larger than the other studies (CGM = 25 to 190; SMBG = 40 to 185), the impact of Du 2025 in the meta-analyses for other outcomes is unclear as the results are not presented in the ADAR resubmission. The commentary considered it would be informative to view the results of the meta-analyses with this study included, even if its addition did not alter the statistical significance of the outcomes.

Table 7 Key features of the included evidence for CGM in GDM

References	N		Design	Follow-up	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
	CGM	SMBG						
Amylidi-Mohr 2025	156	143	RCT, SC	Visits every 2 weeks from enrolment, 6–8 weeks post-partum	Some concerns*	GDM diagnosed week 24–28, enrolled week 24–32	Caesarean delivery Preterm birth Gestational age at birth Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000g), LGA NICU admission	Not used
Bastobbe 2023	37	74	Cohort with matched controls, Retr, SC	Visits every 4 weeks, or every 2 weeks with insulin treatment	High^	GDM requiring insulin or high risk for requiring insulin	HbA1c change (%) Caesarean delivery Preterm birth Gestational age at birth Neonatal hypoglycaemia LGA Birthweight (g) NICU admission	Not used
Du 2025	466	2,596	Cohort with matched controls, Pros., SC	Visits every 2–4 weeks until 28 weeks, every 2 weeks until 36 weeks, weekly thereafter until birth	Moderate^	GDM diagnosed week 24–28	Caesarean delivery Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000g), Birthweight (g) NICU admission	Not used
Elkind-Hirsch 2026	80	40	RCT, SC	Monthly visits and post-partum	High*	Early diagnosed GDM (week 8–26)	HbA1c change (%) Caesarean delivery Preterm birth Gestational age at birth Neonatal hypoglycaemia LGA Birthweight (g) NICU admission	Not used

References	N		Design	Follow-up	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
	CGM	SMBG						
Lindner 2025	190	185	RCT, MC	Run-in prior to randomisation, next visit 8–10 days, then every 2 weeks	Some concerns*	GDM diagnosed week 24–31	HbA1c change (%) Caesarean delivery Preterm birth Gestational age at birth Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000 g), LGA SGA Birthweight (g) NICU admission	Not used
Majewska 2023	49	50	RCT, SC	visits every 2 weeks	Some concerns*	GDM diagnosed week 24–28	HbA1c change (%) Caesarean delivery Gestational age at birth Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000 g), LGA SGA Birthweight (g) NICU admission	Not used
Wei 2016	58	62	RCT, SC	4-week FSL/SMBG treatment assessment, plus post-partum follow-up [a]	Some concerns*	GDM diagnosed week 24–28, singleton pregnancy	Gestational age at birth Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000 g), LGA SGA Birthweight (g)	Not used
Won 2025	25	164 (non-FSL)	Cohort, Pros., SC	Randomised to CGM either in 2nd or 3rd trimester	Moderate^	Diagnosed GDM, singleton or multiple pregnancies included	Neonatal hypoglycaemia Macrosomia (birthweight ≥4,000 g), LGA SGA Birthweight (g) NICU admission	Not used

ADAR = applicant-developed assessment report; AG = assessment group; CGM = continuous glucose monitoring; FSL = flash glucose monitoring; GDM = gestational diabetes; HbA1c = glycated haemoglobin; LGA = large for gestational age; MC = multicentre; NICU = neonatal intensive care unit; NS = not specified; pros = prospective; RCT= randomised controlled trial; retr = retrospective; SC = single cohort; SGA = small for gestational age; SMBG = self-monitoring of blood glucose

Notes:

* Risk of bias for RCTs was assessed by the applicant as low for all studies except for Wei 2016 which was judged to have some concerns. RCTs were reassessed by the AG and judged to have some concerns for all RCTs except Elkind-Hirsch 2026, which was judged to have high risk of bias.

^ Assessed by applicant as low risk of bias.

[a] Follow-up meetings were set every 2 to 4 weeks until 28 gestational weeks, fortnightly until 32 gestational weeks and weekly thereafter.

Source: FSL - Abbott - ADAR 2026 PICO Set 2 (3 of 5) F Table 2-2

PICO Set 3

In total, 6 studies provided outcomes data on the use of CGM in T3cD (Table 8). Four of the 6 studies were published as abstracts only. One of 2 full study publications (Lee 2022) reports a single result for the glycaemic outcomes, not a change value. The other full study population (Lund-Jacobsen 2025) compared CGM vs SMBG in 2 cohorts that had undergone total pancreatectomy and were given both glucose monitoring devices over different time periods. Of these studies, only Lund-Jacobsen 2025 is new for this resubmission. The other studies were previously reported in the original ADAR.

A risk of bias assessment in the ADAR rated all studies as being of moderate to high risk of bias (in the context of the body of evidence for efficacy and safety of CGM vs SMBG in T3cD). An overall GRADE assessment judged the body of evidence as low quality, given the limited study evidence available.

The ADAR used the National Heart, Lung, and Blood Institute (NHLBI) tool to assess the risk of bias for the non-comparative studies and the ROBINS-I tool for Lund-Jacobsen 2025, which was considered appropriate. The ADAR judged the risk of bias for Lund-Jacobsen 2025 to be moderate, although the rationale for this assessment was not provided. As Lund-Jacobsen 2025 is new for this ADAR resubmission, a risk of bias assessment was also performed by the AG for this study. The AG judged it to be at serious risk of bias, noting the large number of exclusions relating to death and missing CGM data.

Table 8 Key features of the included evidence for CGM in T3cD

References	N	Design	Study duration	Risk of bias*		Patient population	Outcome(s)	Use in modelled evaluation
				ADAR	AG			
Evans 2024	125	Retrospective cohort, single centre	Not reported	High	-	T3cD with subgroup using insulin	HbA1c, glycaemic measures	NA
Hagan 2020	12	Prospective observational cohort, single centre	3–9 months	High	-	CFRD using insulin	HbA1c change from baseline	NA
Lee 2022	21	Prospective observational cohort, single centre	Results taken from CGM data within one year of use	High	-	T3cD using insulin (also T1D, T2D patients)	Glycaemic variability TIR HbA1c	NA
Lund-Jacobsen 2025	CGM: 40 SMBG: 30	Retrospective comparative cohorts, single centre	12 months	Moderate	Serious	T3cD, had total pancreatectomy, using insulin (4% with T1D, 23% with T2D preoperatively)	HbA1c TBR (<3.9 mmol/L) Severe hypoglycaemia events Days in hospital postoperatively	NA
Rahman 2020	30	Prospective, observational cohort, single centre	3–6 months	High	-	CFRD (insulin use not specified)	HbA1c change from baseline Infective exacerbation rate	NA
Shimmin 2020	78	Retrospective, observational cohort, single centre	3 months	High	-	CFRD using insulin	HbA1c change from baseline TIR	NA

ADAR = applicant-developed assessment report; AG = assessment group; CFRD = cystic fibrosis-related diabetes; CGM = continuous glucose monitoring; HbA1c = glycated haemoglobin; SMBG = self-monitoring of blood glucose; T1D = type 1 diabetes; T2D = type 2 diabetes; T3cD = type 3c diabetes; TBR = time below range; TIR = time in range
Note:

* Risk of bias was assessed by the applicant and AG, in the case where the AG disagreed with the applicant's assessment, the AGs judgement was noted.

Source: FSL - Abbott - ADAR 2026 PICO Set 3 (4 of 5) F Table 2-2

11. Comparative safety

PICO Set 1

Safety outcomes were reported only for the full PICO Set 1 population and not for subpopulations. Outcomes were reported by trial and were not meta-analysed (Table 9). The ADAR did not provide an assessment of the comparability between the studies. Therefore, it is unclear if confounding factors had contributed to the differences in the incidence of AEs observed between studies. For all outcomes reported, the number of safety events across the studies were small. A discrepancy was identified in the DIAMOND study presented in the ADAR, where the total population in each arm of the DIAMOND trial was reported as 79 in both arms for safety outcomes (Table 9), while this was reported as 105 (CGM) and 53 (SMBG) in the key features of the comparative studies (Table 6).

Adverse events (AE) were generally higher with CGM than SMBG, while serious AEs and severe AEs were similar between the 2 interventions. Serious or severe hypoglycaemic AEs were also largely similar between the CGM and SMBG. Device-related AEs were higher with CGM than SMBG, while discontinuation due to AEs were similar between CGM and SMBG. Safety outcomes were also reported in FreeDM2 (Wilmot 2026), which were reported in a similar proportion of patients on CGM and SMBG for any AE (75% vs 74%), serious AEs (7% vs 8%) and severe hypoglycaemic events (0% vs 1%). Device-related AEs were higher with CGM (18%) than SMBG (8%). The safety results from FreeDM2 are largely similar to the results observed in the other RCTs (Table 9).

The incidence of AEs reported to the TGA for FSL products was low (0.0002% to 0.0221%). These rates are substantially lower than AE frequencies reported in RCTs; however, direct comparison is inappropriate. RCTs involve active surveillance and therefore report higher event frequencies than passive post-market systems reporting. While these data do not support a claim of superior safety, they do not indicate a meaningful safety issue. In the absence of comparative evidence demonstrating significant harm, a conclusion of non-inferiority safety is considered reasonable, and is consistent with the position previously accepted by MSAC.

Table 9 Summary of AEs for CGM vs SMBG reported in the RCTs for PICO Set 1

	Ajjan 2023 [a]		Haak 2017		Kim 2024		2GO-CGM		DIAMOND		MOBILE	
	CGM	SMBG	CGM	SMBG	CGM	SMBG	CGM	SMBG	CGM	SMBG	CGM	SMBG
N	**69**	**72**	**149**	**75**	**52**	**53**	**33**	**34**	**79**	**79**	**116**	**59**
CGM device	FSL	-	FSL	-	FSL	-	Dexcom G4	-	Dexcom G6	-	Dexcom G6	-
AEs	NR	NR	114 (77)	47 (63)	15 (29)	25 (48)	NR	NR	1 (1)	0	29 (25)[b]	8 (14) [b]
Serious AEs	NR	NR	16 (11)	12 (16)	NR	NR	0	2 (6)	NR	NR	14 (12)	7 (12)
Severe AEs	0	0	NR	NR	3 (6)	2 (4)	NR	NR	NR	NR	NR	NR
Hypoglycaemic serious or severe AEs	NR	NR	10 (7)	1 (1)	NR	NR	0	0	0	0	1 (1)	1 (2)
Device-related AEs	14 (20)	4 (6)	6 (4)	0	NR	NR	1 (3)	0	NR	NR	NR	NR
Discontinuation due to AEs	0	0	1 (1)	2 (3)	NR	NR	NR	NR	NR	NR	NR	NR

AE = adverse event; CGM = continuous glucose monitoring; FSL = Freestyle Libre; NR = not reported; RCT = randomised control trial; SMBG = self-monitoring of blood glucose
Notes:
[a] Includes insulin and non-insulin-using patients, as AE data not reported separately for these populations.
[b] AEs reported as non-serious AEs, rather than total AEs, with serious AEs reported separately.
Source: FSL - Abbott - ADAR 2026 PICO Set 1 (2 of 5) F Table 2-25

PICO Set 2

A summary of the safety outcomes reported for PICO Set 2 is presented in Table 10. Safety outcomes were only reported in 2 studies and not reported consistently between studies. Nevertheless, where reported, no statistically significant differences were observed between CGM and SMBG.

Overall, evidence for the comparative safety of CGM in patients with GDM is limited, and a claim of non-inferior safety is not well supported.

Table 10 Summary of AEs for CGM vs SMBG in GDM

Study ID	AE	CGM		SMBG		CGM vs SMBG
		N	n (%)	N	n (%)	
Amylidi-Mohr 2025	Skin reactions and discomfort	156	6 (4)	143	11 (8)	NR *
Lindner 2025	Any AE	190	33 (17)	185	20 (11)	OR 1·73 (95% CI 0·96, 3·19), p=0.067
	Serious AE	190	23 (12)	185	28 (15)	OR 0·77 (95% CI 0·42, 1·40), p=0.39

AE = adverse event; CGM = continuous glucose monitoring; NR = not reported; OR = odds ratio; SMBG = self-monitoring of blood glucose
Notes:
* Calculated by assessment group using RevMan v5.3 for the commentary: OR 0.48 (95% CI: 0.17, 1.33)
Source: FSL - Abbott - ADAR 2026 PICO Set 2 (3 of 5) F Table 2-14

PICO Set 3

Safety outcomes for CGM were not reported for PICO Set 3. Therefore, it is not possible to reach a conclusion on the claim of non-inferior safety.

12. Comparative effectiveness

PICO Set 1

A summary of the comparative effectiveness for CGM vs SMBG is presented in Table 11 and Table 12 for change in glycaemic parameters and hospitalisation for any reason, respectively. For the comparative change in HbA1c from baseline, statistically significant differences were observed between CGM and SMBG in favour of CGM irrespective of (sub)population. The exception is for patients with baseline HbA1c ≥9.5%, although the high level of imprecision for this subpopulation limits the clinical relevance of the results. Despite statistical significance, none of the point estimates exceed a presumptive MCID of 0.5%.

It is unclear if HbA1c changes included in the meta-analyses were taken at different timepoints, with study follow-up ranging from 10 weeks to 24 months. The level of adherence to CGM or SMBG over the study follow-up was also not reported. A comparison of the studies was also not presented; therefore, it is uncertain if confounders may be present that may explain any differences in effectiveness between studies. There are also inconsistencies in the data presented in the ADAR between the tabulated results and the forest plots presented for the meta-analyses. The point estimates (mean change) for the cohorts in Nathanson 2025, 2GO-CGM, and MOBILE were different to those reported in Table 2-21 and Table 2-22 of the main body for PICO Set 1, with no explanations provided for the discrepancies.

Time in hypoglycaemia was only reported for the general T2D population and not by subpopulation. CGM led to significantly shorter time in level 1 hypoglycaemia (<3.9 mmol/L) than SMBG. However, there was no statistically significant difference for level 2 hypoglycaemia (<3.1 mmol/L). Heterogeneity was high in both meta-analyses (I^2: 82.2–86.6%). The difference between interventions in time in hypoglycaemia between CGM and SMBG also did not exceed the proposed MCID of 58 minutes/day for level 1 hypoglycaemia or 14 minutes/day for level 2 hypoglycaemia (ADA. 2026).

Of note, when all studies were considered, the differences in HbA1c between CGM and SMBG was similar irrespective of insulin intensity (subpopulations 1 and 2) with the point estimates for mean difference between −0.34% and −0.35%. This suggests that the benefit from CGM versus SMBG was not different between people requiring different insulin intensities and the general T2D population. In contrast, when only RCTs were considered, patients on basal insulin only achieved greater benefit with CGM over SMBG (mean difference −0.46%) compared with the general T2D population (mean difference −0.34%) and those on intensive insulin therapy (mean difference −0.27%).

For subpopulations 3 and 4 (i.e. different baseline HbA1c), those with a higher baseline HbA1c (⩾9.5%) achieved greater improvement in HbA1c with CGM than SMBG (mean difference −0.77%) compared with the general T2D population (mean difference −0.34%), and patients with baseline HbA1c ⩾8.5% (mean difference −0.40%). The results should be interpreted with caution as the sample size for patients with baseline HbA1c ⩾9.5% was small (CGM = 39, SMBG = 13).

For subpopulations 5 and 6 (history of CVD or CKD or history of event, note that the nature of the 'event' was not clear to the commentary) no data was provided for change in HbA1c so no subpopulation analyses could be conducted.

In the First Nations population (subpopulation 7), limited outcome data were reported in the studies identified in the ADAR, which does not adequately cover the outcomes outlined in the PICO. While a 9% increase in TIR reported in McLean 2023 is important, due to the non-representative population sample of the study, this finding is not clearly generalisable to the entire First Nations T2D subpopulation proposed for funding.

In subpopulation 8 (pregnant women with pre-existing T2D) mean HbA1c change for the mother was only reported within groups by one study, with no comparative data between CGM and SMBG. Maternal outcomes were reported in 3 studies (Table 13). Caesarean delivery showed no significant differences between groups in any study and preterm birth was statistically significant (in favour of CGM) for one study but not for the other 2. Neonatal hypoglycaemia showed a statistically significant difference in favour of CGM for one study; however, larger trials did not show significant difference between CGM and SMBG for this outcome. NICU admission was significantly lower in 2 studies. However, one of those studies had a small sample size and a low number of total events. The other study showing statistical significance in favour of CGM had a reasonable sample size and, therefore, may suggest some potential reductions in NICU admissions for neonates whose mother is using CGM vs SMBG.

In subpopulation 9 (intermittent CGM use) within-group trends suggest a potential worsening of HbA1c following CGM discontinuation and stability with continued use, but no comparison between groups was reported. As such, it is not possible to draw meaningful conclusions about the comparative effectiveness of continuing versus discontinuing CGM.

Overall, considering the effects indicated and strength of the evidence (very low quality assessed using GRADE) the claim of superior efficacy is not well supported for the whole T2D population or any of the subpopulations evaluated. A claim of non-inferior efficacy is more appropriate.

Table 11 Summary of efficacy outcomes: glycaemic outcomes

Outcome	Number of studies	CGM vs SMBG Mean difference (95% CI)	Heterogeneity (I^2)
Change in HbA1c (%) from baseline			
Whole T2D population			
All comparative studies	**14**	**−0.35 (−0.44, −0.27)**	47.8%
RCTs only	**9**	**−0.34 (−0.51, −0.16)**	53.0%
Subpopulation 1 and 2: insulin intensity			
All comparative studies			
Intensive insulin therapy	**7**	**−0.34 (−0.49, −0.19)**	68.5%
Basal insulin only	**3**	**−0.35 (−0.41, −0.29)**	0%
RCTs only			
Intensive insulin therapy	**4**	**−0.27 (−0.52, −0.03)**	67.3%
Basal insulin only	**2**	**−0.46 (−0.70, −0.22)**	0%
Subpopulation 3 and 4: baseline HbA1c			
≥8.5%	**2**	**−0.40 (−0.68, −0.12)**	0%
≥9.5%	1	−0.77 (−1.58, 0.05)	NA
Subpopulation 5 and 6: history of CVD or CKD		NR	NR
Subpopulation 7: First Nations		NR	NR
Subpopulation 8: pregnancy in T2D		NR	NR
Subpopulation 9: intermittent or continuous CGM use		NR	NR
Time in hypoglycaemia (level 1)*			
Whole population	**5**	**−0.16 (−0.31, −0.01)**	82.2%
Time in hypoglycaemia (level 2)*			
Whole population	4	−0.05 (−0.12, 0.02)	86.6%

CGM = continuous glucose monitoring; CI = confidence interval; CKD = chronic kidney disease; CVD = cardiovascular disease; GDM = gestational diabetes; HbA1c = glycated haemoglobin; NA = not applicable; NR = not reported; RCT = randomised controlled trial; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes

Notes:

* Level 1 hypoglycaemia is when the patient's blood glucose is <3.9 mmol/L and level 2 hypoglycaemia is when the patient's blood glucose is <3.1 mmol/L; the lower the blood glucose the worse the hypoglycaemia.

Bolded results indicate statistical significance.

Source: FSL - Abbott - ADAR 2026 PICO Set 1 (2 of 5) F Figure 2-7, Figure 2-8, Figure 2-9, Figure 2-10, Figure 2-11, Figure 2-12

Any hospitalisations were not reported consistently across the studies, and a meta-analysis was not presented. Instead, the results from each study were reported separately (Table 12). In Nathanson 2025, CGM led to significantly fewer hospitalisations for any reason vs SMBG. Reaven 2023 also reported significant reductions in hospitalisations for people using CGM compared to those using SMBG. However, no statistically significant difference between CGM and SMBG was reported for Karter 2021 for any hospitalisation. The inability to compare across or combine studies restricts interpretation and limits the strength of conclusions regarding the effect of CGM on hospitalisation risk. Nevertheless, a reduction in the risk of any hospitalisation was generally reported across the studies.

Table 12 Summary of efficacy outcomes: hospitalisation due to any reason

Outcome	CGM vs SMBG
Nathanson 2025	
Whole population	**RR 0.71 (95% CI: 0.67, 0.75); p < 0.001**
MDI cohort	**RR 0.84 (95% CI: 0.77, 0.90); p < 0.001**
Basal insulin cohort	**RR 0.76 (95% CI: 0.69, 0.84); p < 0.001**
Karter 2021	RD −3.4 (95% CI: −8.5, 1.6); p = 0.19
Reaven 2023	**HR 0.89 (95% CI: 0.82, 0.97); p = 0.004**

CGM = continuous glucose monitoring; CI = confidence interval; HR = hazard ratio; MDI = multiple daily injection; RD = risk difference; RR = risk ratio; SMBG = self-monitoring of blood glucose

Bolded results indicate statistical significance.

Source: Nathanson et al. 2025 Table 2 p 6; FSL - Abbott - ADAR 2026 PICO Set 1 (2 of 5) F Table 2-15

Apart from glycaemic outcomes, specific maternal and neonatal outcomes are also important in the pregnancy in T2D subpopulation (subpopulation 8). The results were not meta-analysed in the ADAR but reported separately for each study.

Table 13 Key maternal and neonatal outcomes for subpopulation 8: pregnant women

	Nunlee-Bland 2025			Padgett 2024			Secher 2013		
	CGM	SMBG	P value	CGM	SMBG	P value [d] OR or MD (95% CI)	CGM	SMBG	P value
N	**14**	**12**		**82**	**278**		**16**	**14**	
Maternal outcomes									
Caesarean delivery, n (%)	9 (64)	4 (40)	P = 0.41	54 (65.9)	179 (64.4)	P = 0.81	8 (50)	6 (43)	P = 0.70
Preterm birth, n (%)	3 (21)	4 (40)	P = 0.39	28 (34.2)	136 (48.9)	**P = 0.02 OR 0.54 (0.32, 0.90)**	3 (19%)	0 (0%)	P = 0.23
Gestational age at birth, weeks									
Mean (SD)	37.21 (1.65)	32.63 (9.51)	P = 0.09	-	-	-	-	-	-
Median (IQR)	-	-	-	37.1 (35.9, 38.0)	37.0 (33.9, 38.0)	**P = 0.04** MD: −0.10 (−1.31, to 1.11)	262 (range 206, 280) days	267 (range 259, 277) days	P = 0.17
Neonatal outcomes									
Neonatal hypoglycaemia, n (%)	0 (0)	8 (80)	**P = 0.0001**	22 (27.5)	85 (31.6)	P = 0.49 OR 0.85 (0.42, 1.71)	4 (31)	2 (14)	P = 0.39
LGA, n (%)	2 (14)	3 (30)	P = 0.61	16 (19.5)	54 (19.4)	P = 0.99 OR 0.65 (0.28, 1.54)	4 (25)	4 (29)	P = 1.00
SGA, n (%)	3 (21)	0 (0)	P = 0.24	12 (14.6)	37 (13.3)	P = 0.76 OR: 0.86 (0.22, 3.41)	NR	NR	-
Birthweight, g									
Mean (SD)	3,113 (626)	2,985 (778)	P = 0.661	-	-	-	-	-	-
Median (IQR)	-	-	-	3,013 (2,540, 3,450)	2,845 (2,160, 3,480)	P = 0.12 MD: 42 (−332, 415)	3,371 (range 1,070, 4,260)	3,343 (range 2,773, 3,818)	P = 0.70
NICU admission, n (%)	0 (0)	8 (80)	**P = 0.0001**	27 (33.8)	128 (47.6)	**P = 0.03 OR 0.56 (0.33, 0.95)**	NR	NR	-

CGM = continuous glucose monitoring; CI = confidence interval; LGA = large for gestational age; MD = mean difference; NICU = neonatal intensive care unit; NR = not reported; OR = odds ratio; SGA = small for gestational age; SMBG = self-monitoring of blood glucose

Notes: P values are reported for CGM vs SMBG treatment differences (unless reported otherwise).

a. Reported at 34 weeks. P values are within group comparisons using paired t test.
b. Reported as a percentage change from baseline, rather than as a HbA1c % value.
c. Values at different timepoints reported in Secher 2013 supplementary Table 1, change values not reported.
d. P values are from Table 2 in Padgett 2024, adjusted ORs and mean differences are reported in Table 3.

Bolded text indicates statistically significant difference.

Source: FSL - Abbott - ADAR 2026 PICO Set 1 (2 of 5) F Table 2-17

Additional evidence to inform the clinical claim

A 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.[8] For the general, T2D population, data presented for FreeDM2 in the ADAR were obtained from a conference abstract; however, the full study has since been published. No subgroup analyses for the subpopulations of interest for the 1786 ADAR were reported in the FreeDM2 trial.

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.[9]

PICO Set 2

A summary of the results for use of CGM vs SMBG in patients with GDM is presented in Table 14 and Table 15. The resubmission has addressed some of MSAC's concerns by presenting comparative data. However, not all relevant outcomes were included despite being available in the studies. Several potentially relevant studies were not included in the evidence base without clear reasoning as to why this was so. Meta-analysis results included Du 2025 only when the study changed the overall findings to statistical significance. Therefore, the extent of selective reporting is unclear and limits interpretation of the overall evidence base.

Glycaemic outcomes were limited to the mean change in HbA1c, which was not statistically significantly different between CGM and SMBG. Although time in range was also reported in the studies, this was not presented in the ADAR.

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[8] 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.

[9] 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.

Other maternal outcomes, caesarean delivery and preterm birth, were not statistically significantly different between CGM and SMBG. Caesarean delivery achieved statistical significance in favour of CGM only when the results of Du 2025 were included in the meta-analysis.

For neonatal outcomes, statistically significant differences were observed for LGA and NICU admission in favour of CGM. There were no statistically significant differences observed for other neonatal outcomes.

Overall, there is insufficient evidence to support the comparative effectiveness of CGM vs SMBG in patients with GDM. The point estimates for the majority of outcomes are in favour of CGM, although the majority of results were not statistically significant. The claim of superior effectiveness was not well supported.

Table 14 Summary of results for CGM vs SMBG in GDM: categorical outcomes

Outcome - Incidence of:	N studies (k)	N patients (N)	Study type	Risk difference	(95% CI)	I^2	Risk ratio	(95% CI)	I^2
Neonatal outcomes									
Neonatal hypoglycaemia	5	875	RCTs	–0.024	–0.075, 0.028	47.0%	0.75	0.556, 1.010	0.0%
	7	1,164	All	0.003	–0.027, 0.033	33.6%	0.807	0.606, 1.076	18.1%
Macrosomia (birthweight >4,000 g)	5	849	RCTs	–0.026	–0.095, 0.042	62.5%	0.791	0.361, 1.732	48.5%
	7	994	All	–0.012	–0.053, 0.029	50.3%	0.838	0.406, 1.731	34.8%
LGA [a]	5	917	RCTs	**–0.067**	**–0.126, –0.008**	**36.9%**	**0.63**	**0.450, 0.883**	**33.4%**
	7	1,215	All	**–0.057**	**–0.101, –0.014**	**30.9%**	**0.675**	**0.468, 0.974**	**34.3%**
SGA [b]	3	550	RCTs	0.013	–0.042, 0.067	29.7%	1.338	0.849, 2.11	0.0%
	4	695	All	0.014	–0.029, 0.056	0.0%	1.338	0.857, 2.088	0.0%
NICU admission	4	857	RCTs	–0.054	–0.147, 0.039	72.6%	**0.535**	**0.345, 0.83**	**0.0%**
	6	1,105	All	–0.058	–0.117, 0.001	60.2%	**0.522**	**0.347, 0.785**	**0.0%**
Maternal outcomes									
Caesarean delivery	5	963	RCTs	–0.036	–0.099, 0.027	0.0%	0.927	0.816, 1.054	0.0%
	6	1,066	All (without Du 2025 [c])	–0.047	–0.107, 0.013	0.0%	0.914	0.806, 1.036	0.0%
	7	2,464	All (including Du 2025 [c])	**–0.05**	**–0.09, –0.01**	**0.0%**	**0.91**	**0.85, 0.98**	**0%**
Preterm birth	3	761	All	–0.008	–0.045, 0.029	51.30%	0.661	0.311, 1.404	32.6%
	4	863	RCTs	0	–0.025, 0.024	27.50%	0.685	0.352, 1.335	6.5%

CGM = continuous glucose monitoring; CI = confidence interval; LGA = large for gestational age; NICU = neonatal intensive care unit; RCT = randomised controlled trials; SGA = small for gestational age; SMBG = self-monitoring of blood glucose

Notes:

I^2 is the heterogeneity statistic reported for each meta-analysed outcome.

[a] Defined as weight >90th percentile for gestational age and sex.

[b] Defined as weight <10th percentile for gestational age and sex.

[c] The meta-analyses were conducted by University of Melbourne Statistical Consulting Centre (on behalf of the applicant) prior to the identification of the matched cohort study Du 2025. To investigate whether the addition of Du 2025 to the 'All studies' meta-analyses, the meta-analyses were redone including Du 2025. The only analysis where adding Du 2025 altered the statistically significance of the result was with 'Caesarean delivery'.

Bolded results indicate statistical significance.

Source: FSL - Abbott - ADAR 2026 PICO Set 2 (3 of 5) F Table 2-3

Table 15 Summary of results for CGM vs SMBG in GDM: continuous outcomes

Outcome	N studies (k)	N patients (N)	Studies	Mean difference	(95% CI)	I^2
Neonatal outcomes						
Birthweight, g	4	668	RCTs	−68.9	−143.7, 6.0	0.0%
	6	916	All studies	−54.8	−123.4, 13.9	0.0%
Maternal outcomes						
Gestational age, weeks	5	966	RCTs	0.07	−0.23, 0.38	63.7%
	6	1,069	All studies	−0.05	−0.48, 0.39	75.2%
HbA1c mean change	2	299	All studies	0.03	−0.07, 0.14	75.9%

CI = confidence interval; HbA1c = glycated haemoglobin; RCT = randomised controlled trials.
Source: FSL - Abbott - ADAR 2026 PICO Set 2 (3 of 5) F Table 2-4

PICO Set 3

Comparative data were limited to one full publication, Lund-Jacobsen 2025, which enrolled patients with T3cD who had undergone total pancreatectomy. In the CGM group, approximately half the time over a 12-month period (43-58%) glucose level was within target range, and the remaining time was above range. Since a comparison of data is not available, it is unclear how this compares with the SMBG group. Considering that the goals of treatment based on the American Diabetes Association (ADA. 2026) were for TIR >70%, and TAR <5% for most adults, Lund-Jacobsen 2025 did not meet the goals of therapy for glycaemic control. No statistically significant differences between CGM and SMBG were observed for hospitalisation due to hypoglycaemia and days spent in hospital.

Adherence to CGM relative to SMBG was not reported.

As all patients in Lund-Jacobsen 2025 had undergone total pancreatectomy, the patients would be completely deficient in insulin and glucagon. They are, therefore, not representative of the majority of T3cD patients, the majority of whom would have some level of pancreatic function. Overall, the claim of superior effectiveness is not supported.

Table 16 Summary of results for patients with T3cD

Variable	Lund-Jacobsen 2025	
	CGM	SMBG
N	**40**	**30**
HbA1c	Baseline: NR 3 months after discharge, mean (SD): 8.1% (1.0) 12 months after discharge: 8.5% (1.0)	Baseline: NR 3 months after discharge, mean (SD): 7.9% (1.1) 12 months after discharge: 8.6% (1.2)
TIR (3.9–10.0 mmol/L/), % time	43–58% during 12-month observation period	Not measured
TBR (<3.9 mmol/L), % time	0% during 12-month observation period	Not measured
Hospitalisations due to severe hypoglycaemia, n (%)	0 (0%), in 12-month period (p = 0.21 vs SMBG)	4 (13%), in 12-month period
Mean (SD) number of days in hospital	Number of days in hospital after discharge from TP to 12 months 4.0 (7.7) (p = 0.13 vs SMBG)	Number of days in hospital after discharge from TP to 12 months 15.5 (39.6)
Study endpoint	12 months	

CGM = continuous glucose monitoring; NR = not reported; SD = standard deviation; SMBG = self-monitoring of blood glucose; TBR = time below range; TIR = time in range; TP = total pancreatectomy
Source: FSL - Abbott - ADAR 2026 PICO Set 3 (4 of 5) F Table 2-3

Clinical claim

The claim of superior effectiveness and non-inferior safety is not well supported for all 3 PICO Sets.

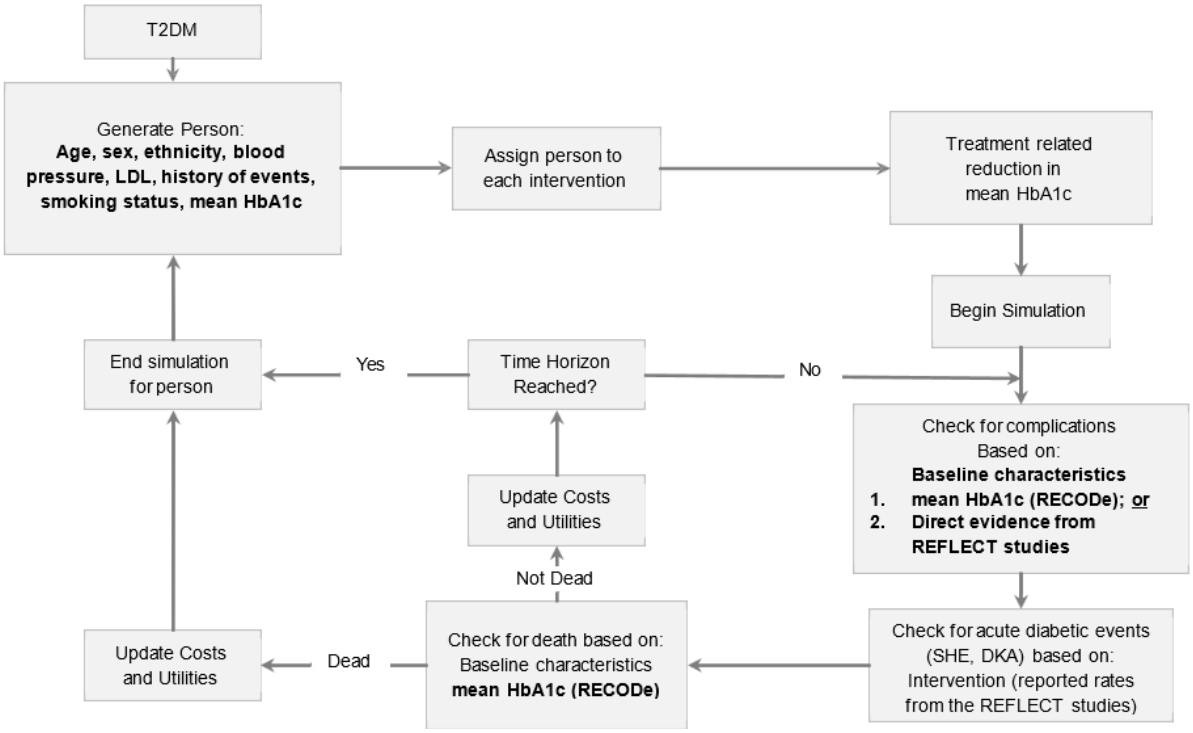
13. Economic evaluation

Cost-effectiveness analysis for people with T2D treated with insulin (PICO Set 1)

The cost-effectiveness analysis (CEA) compared the FSL system with SMBG, leveraging the clinical claim of superior efficacy (glycaemic control) and non-inferior safety in people with T2D treated with insulin.

To conduct the CEA, the applicant used the Determination of Diabetes Utilities, Costs and Effects (DEDUCE) patient-level microsimulation model (Szafranski 2024), developed in Microsoft Excel. The model structure is presented in Figure 1, obtained from Section 3.3.5 of the ADAR resubmission 1786. The model simulated 10,000 unique patients, reduced from 50,000 in the original ADAR. Table 17 summarises the economic evaluation and provides an overview of the model parameters, derived from Section 3.3.1 of the ADAR resubmission 1786.

Figure 1 DEDUCE (RECODe-based & REFLECT-based model schematic)



DKA = diabetic keto-acidosis; HbA1c = glycated haemoglobin A1c; LDL = low density lipoprotein; SHE = severe hypoglycaemia event; T2D = type 2 diabetes mellitus

Table 17 Summary of the economic evaluation

	Scope of decision problem
Economic analysis	CEA
Population	T2D people living with diabetes treated with insulin
Intervention	FSL CGM products
Comparator	SMBG
Outcomes	Hypoglycaemia events avoided LYG QALYs ICER
Costs	Glucose monitoring costs Diabetes-related complications costs ADE costs
Perspective	Australian publicly funded healthcare system
Primary target audience	Australian public payers
Time horizon	The model horizon has been reduced to 30 years in the base case from the previous 50 years.
Computational method	Patient-level microsimulation
Generation of the base case	There are 3 model variations that can be utilised to generate base case analyses: 1. Using the REFLECT-based approach in which the Nathanson 2025 study events observed are utilised to estimate patient outcomes directly; that is, using direct high-quality comparative evidence (RWE)

	data on the reduction of diabetes complications. In this approach there is therefore no user specified HbA1c reduction. 2. Using the RECODE-based risk equations that link HbA1c to patient outcomes, which is the same approach utilised in the original ADAR. In this approach, an immediate one-time absolute reduction in the HbA1c level in the first year of treatment initiation is used to indirectly extrapolate reduction in diabetes complications. 3. Using the RECODE-based risk equations incorporating the Fremantle CVD risk equations as presented by Davis 2020 (Davis et al. 2020). Modelled approach, which assigns costs and utilities based on the spectrum of complications and ADEs that a simulated person experiences. In each model cycle that a simulated person remains alive, the incidence and history of diabetes complication events are updated (thereby providing a model memory). Any appropriate decrement in health utility is applied together with any costs associated with treatment and complications (including acute and subsequent costs).
Health states	Alive, dead, various complications.
Cycle length	1-year with half-cycle correction
Transition probabilities	For the RECODe versions of the model, the complications within DEDUCE for T2D are based on the RECODe risk engine regardless of maintenance therapy. For the REFLECT/Nathanson version of the model, the complications rates/probabilities are user assigned (prepopulated using Nathansen 2025). Both macrovascular (i.e. myocardial infarction, stroke, congestive heart failure) and microvascular (renal failure and blindness) complications are included. Multiple covariates act as predictor variables for complications, and HbA1c levels are covariates across all complications.
Discount rate	5% for both costs and outcomes
Software	Excel

ADE = acute diabetic event; CEA = cost-effectiveness analysis; CGM = continuous glucose monitoring; FSL = Freestyle Libre; HbA1c = glycated haemoglobin; ICER = incremental cost-effectiveness ratio; LYG = life years gained; QALYs = quality-adjusted life years; SMBG = self-monitoring of blood glucose; T2D = type 2 diabetes

Model

In the resubmission, the applicant presented 3 models to evaluate the cost-effectiveness of treatments for people with T2D receiving insulin:

- Model 1 – REFLECT-based model: complication risks were derived from those observed in the REFLECT trial (reported in Nathanson 2025). This model is different from the others because it incorporates relative risks (RR) and the baseline rates from Nathanson 2025, which reports observed patient outcomes from use of CGM rather than via surrogate outcomes linked to final patient outcomes.
- Model 2 – RECODe (HbA1c) based model: similar to that presented in the original ADAR, with additional features including annual risk adjustments and dynamically updated risk factors.
- Model 3 – RECODe-Fremantle (HbA1c) based model: incorporates the Fremantle cardiovascular disease (CVD) risk equations (Davis 2020).

<u>RECODe risk equations</u>

The RECODe risk equations were developed using data from the ACCORD study, which recruited patients from clinical sites in the United States and Canada between 2001 and 2009, approximately 17–25 years ago. In the PSD for the original ADAR, MSAC questioned whether

RECODe reflects the most recent treatment practices, given the time period during which data for the ACCORD study were collected.

The resubmission attempts to address the concerns raised about RECODe by introducing an entirely new model using REFLECT. This is not considered an appropriate response to MSAC's concerns regarding the validity of the evidence provided. The REFLECT model introduces a new set of concerns related to the employed methods and the applicability of the evidence used to inform the new model, such as the use of Swedish population data in the Australian context (detailed discussion is provided below).

It may not be appropriate for a resubmission to introduce multiple new models that produce significantly different conclusions and rely on a different set of assumptions as a way to strengthen the argument. In fact, this approach highlights the extent to which the evidence base is highly uncertain, with conclusions varying substantially depending on the modelling structure used.

Dynamic risk factors

In the PSD for the original ADAR, MSAC noted that baseline characteristics were assumed to remain constant over a patient's lifetime and did not change in response to reductions in HbA1c. This was considered a key source of uncertainty, as risk factors in T2D typically evolve over time and are often correlated. In particular, the original ADAR did not explore whether changes in HbA1c were associated with changes in other continuous variables within the RECODe equations.

In response, the applicant updated certain variables within the model. This included event history variables (e.g. CVD history) as events occurred, and incorporated correlations whereby blood pressure and cholesterol decline by 'a small amount' when HbA1c decreases. These changes could improve the clinical plausibility of the model. However, the update of event history variables reflected the occurrence of complications rather than changes in underlying continuous risk factors over time. It remains unclear whether other continuous variables within the RECODe equations were updated.

Additionally, although the model assumed that blood pressure and cholesterol would decline with reductions in HbA1c, these relationships were described as "a small amount", which may not provide sufficient quantitative detail for describing model assumptions.

Model validation

When a treatment lowers HbA1c, the associated health benefits, such as reductions in complications (e.g. cardiovascular events), may not occur immediately. In the PSD for the original ADAR, MSAC asked the applicant to demonstrate whether the model appropriately reflects the timing of treatment effects, based on how HbA1c changed in the clinical trials.

However, the applicant's response focused on the reduction in HbA1c, whereas MSAC's concern related to the timing of downstream health benefits, not merely the change in HbA1c itself. Reductions in complications are unlikely to occur immediately following a reduction in HbA1c. Therefore, MSAC requested that the model reflect the realistic timing of reductions in complications, rather than only the timing of changes in the biomarker (i.e. HbA1c). Overall, the concerns raised by MSAC and the issues addressed in the applicant's response appear to relate to different aspects of the model.

Model traces

In this resubmission, the applicant added a series of cumulative curves and survival curves to address ESC's concerns regarding model traces. The inclusion of these additional outputs

improves the transparency of the model. However, there are several issues regarding the quality of these graphs.

First, some of the curves are duplicated but presented under different figure numbers. For example, the figure of cumulative complication events reduction for step 1 - REFLECT and the figure of cumulative adverse events reduction for base case - REFLECT are the same (Figures 3-6 and 3-24 in the main body of ADAR resubmission), using the same graphs and descriptions. No explanation is provided for why identical graphs are presented with different figure descriptions.

Second, the graphs are based on different time horizons (e.g. 20, 21 and 30 years). It is unclear why different time horizons were used across these figures.

Third, some of the survival curves are almost completely overlapping between FSL and SMBG (e.g. the complication free survival curves and the death rate curves for RECODe-Fremantle (Figures 3-19 and 3-20 in the main body of ADAR resubmission)), meaning that no clear difference in survival, either complication free or overall, can be identified between the intervention and comparator. However, formal statistical analysis may be needed to confirm this.

10-year risks conversion

ESC previously noted that the model assumed 10-year risks were distributed equally over time to generate annual risks, which may result in events occurring earlier than would be expected clinically, given the progressive nature of T2D. ESC's concern was about how 10-year risks were converted into annual risks.

In response, the applicant stated that annual risks have been adjusted to change annually rather than in 10-year intervals, using the following formula to convert 10-year risks to annual risks:

Equation 2 1-year risk = 1 − (10-year risk)^(1/10)

However, this approach assumes a constant hazard over time. As a result, risk remains evenly distributed across years, and the timing of complications in the model may still occur earlier than would be expected in clinical practice. This is considered an inappropriate assumption given the true natural progression of these risk factors, and maintaining this modelling assumption biases the analysis in favour of the intervention (FSL).

Amputation

In the PSD for the original ADAR, MSAC raised concerns about the omission of amputation from the model. Amputation is a chronic complication associated with T2D and has a substantial impact on both costs and HRQoL. It was included in the UKPDS-OM2 and BRAVO risk equations. Additionally, amputation was associated with one of the largest utility decrements reported in Niño-de-Guzmán 2023.

In this resubmission, the applicant did not discuss the potential impact of this omission, nor did they justify the exclusion of amputation from the model or acknowledge the assumption underlying its exclusion.

Population

PICO Set 1 defines the population as people with T2D requiring insulin. In the resubmission, 9 subpopulations were identified (not all of which are mutually exclusive, see Table 11 for subpopulation definitions) and of these 9, funding was requested for 2 over-arching subpopulations: people with T2D using only basal insulin (subpopulation 1), and people with T2D using IIT (including premixed insulin), also referred to as MDI (subpopulation 2).

Mismatched population

In the PSD for the original ADAR, MSAC noted that the 'all diabetes' population in ANDA and the population in ACCORD do not align with the population specified in PICO Set 1, raising concerns regarding whether the simulated population is clinically representative.

In response, the applicant stated that the mismatch was common due to the international nature of clinical trials and data limitations in Australian sources. The applicant further argued that, despite these differences, the populations are broadly comparable and unlikely to introduce substantial bias, given similarities in clinical management and disease.

Although some degree of mismatch between data sources may be acceptable in economic modelling, the applicant did not provide empirical evidence or validation to demonstrate that the simulated population is sufficiently representative of the PICO Set 1 population. The applicant did not extract or present relevant information from the cited references (or other sources) to demonstrate that those source populations were aligned with the Australian populations. Additionally, as noted in the commentary for the original ADAR, the applicant did not seek clinical expert opinion to assess whether these populations are comparable with each other and with the population specified in PICO Set 1, nor did the applicant discuss the potential impact of using data from different populations to simulate the target population.

Swedish and Australian population

The applicant stated that a new model was added in the resubmission, namely REFLECT-based modelling using more recent data. This study is based on a Swedish population. Swedish risk equations may be used as proxies for Australian populations due to similarities in healthcare systems and diabetes management. However, the results should be interpreted cautiously and ideally validated using Australian data.

The applicant argued that the healthcare systems of Sweden and Australia are comparable, by claiming the availability of publicly subsidised hospital care in both countries, their ranking among the top 20 healthcare systems globally, and their delivery of similar health outcomes. However, healthcare system ranking or the presence of universal healthcare does not ensure that epidemiological risk relationships are transferable between populations. Additional evidence is required, such as comparisons of age distribution, socioeconomic profiles and disease epidemiology.

The applicant also developed an additional analysis comparing the Swedish and Australian healthcare systems in the context of T2D management, to demonstrate similarities between the 2 countries (e.g. system structure and financing, models of care for T2D, governance and national guidelines). However, this comparison does not address several key issues, including the statistical comparability of patient populations and the validation of REFLECT risk equations in the Australian context.

Treatment effect

HbA1c

A reduction of 0.35% in HbA1c was used in the resubmission. However, in the PSD for the original ADAR, MSAC noted that a reduction in HbA1c of 0.5% has previously been accepted as the smallest difference needed to show better clinical outcomes by international committees.

MSAC noted that the original ADAR did not provide evidence to support the assumption that the treatment effect of CGM on HbA1c was maintained over time and requested further information on the durability of this effect based on the available clinical evidence.

In response, the applicant provided additional clinical evidence, including updated meta-analyses incorporating follow-up data of up to 24 months, and cited Nathanson 2025 as demonstrating that the HbA1c treatment effect is maintained over this period. Additionally, in the resubmission, the applicant argued that the assumption that HbA1c does not change naturally over time was conservative, as HbA1c would be expected to increase with age in clinical practice.

First, it is important to note that this assumption has very different implications depending on which model is being considered. This is relevant for Model 2 and 3. However, Model 1 (REFLECT) does not use HbA1c and instead relies on directly observed event reductions. Second, given that the applicant asserts that CGM affects HbA1c, changes in HbA1c are vital to the argument of the long-term value of CGM. The assumption that HbA1c remains constant over time, in both the treatment and comparator arms, is a structural simplification that may not reflect the natural progression of T2D.

Complications

In the PSD for the original ADAR, ESC raised concerns regarding the use of RECODe equations to generate complication risks in the model. These equations were validated primarily for cardiovascular events rather than for all types of diabetic complications included in the model. ESC also noted that RECODe may not represent the most up-to-date risk model. In addition, it was unclear whether the RECODe equations had been validated only for disease progression or also for estimating incremental effects across interventions. As noted, UKPDS-OM2 was considered unsuitable for predicting risk in Australians with T2D, and an Australian-specific set of risk equations was suggested.

In the resubmission, the applicant then applied the Fremantle equations, which were derived from an Australian study. However, the use of these does not fully address ESC's concern that the original equations were validated only for cardiovascular events rather than for all modelled types of diabetic complications. As stated in the ADAR, the resubmission incorporated the Fremantle equations into the model for 4 major adverse cardiovascular events, defined as non-fatal myocardial infarction, non-fatal stroke, non-fatal heart failure, and cardiovascular death. However, the report does not clearly describe how non-cardiovascular diabetic complications were modelled or whether alternative risk equations were applied to these complications.

Additionally, in response, the applicant stated that ADAR 1785 (Dexcom) used a similar modelling approach. However, this may not be an appropriate example to justify use of the approach, as ADAR 1785 is still under assessment in its resubmission.

Hospitalisation

In the PSD for the original ADAR, MSAC raised concerns that the model generated large cost offsets from reduced hospitalisations for diabetic ketoacidosis (DKA) and severe hypoglycaemia event (SHE), but the supporting evidence was poorly described and based on non-Australian data without adequate justification. In response, the applicant revised the model by removing hyperosmolar hyperglycaemic state (HHS) and non-severe hypoglycaemic event (NSHE) from the analysis, For SHE, the evidence base was updated using data from Nathanson 2025, replacing the previous French study.

In the original ADAR, the applicant used the annual percentage of DKA events as a surrogate for the annual percentage of HHS events. As HHS events are generally more common in T2D than DKA events, this assumption may not reflect clinical practice. The removal of HHS from the resubmission also removed reliance on this surrogate assumption, which reduces uncertainty associated with the previous assumption.

However, excluding HHS and NSHE may also reduce the capture of downstream complications, hospitalisations and associated cost offsets, potentially resulting in conservative estimates of the intervention effect. The commentary considered that additional scenario analyses, such as reintroducing HHS using alternative assumptions or including NSHE, may help assess the impact of these structural assumptions on model outcomes.

The applicant justified the removal of HHS on the basis of avoiding reliance on French data and instead utilised a Swedish study. However, the appropriateness of applying Swedish data to the Australian population remains uncertain and was not adequately justified by the applicant.

Utility inputs

Utility decrements for complications

In the PSD for the original ADAR, MSAC raised concerns regarding the application of utility decrements for diabetes-related complications, noting inconsistencies in how short- and long-term disutilities were applied. Specifically, while the study by Niño-de-Guzmán 2023 was used to inform utility decrements, the original ADAR assumed that for stroke, blindness and renal failure, the disutility in subsequent years was equivalent to that in the first year without providing clinical justification. In addition, no long-term disutility was applied for complications, such as myocardial infarction (MI) and congestive heart failure (CHF), despite ongoing costs being included. As stated in the PSD, the commentary considered this approach to be clinically inappropriate and noted that incorporating long-term disutilities would likely increase incremental quality-adjusted life years (QALYs) in favour of FSL.

In response, the applicant has updated the model in the resubmission to incorporate disutilities for subsequent years for MI (−0.055) and CHF (−0.108). This revision is appropriate and improves the clinical plausibility of the model. The applicant also provided supporting evidence from Pinckaers 2024 to justify the assumption that post-stroke utility decrements remain relatively stable over time.

However, it should be noted that the cited data from Pinckaers 2024 were up to 2 years, which may not fully capture longer-term effects. Additionally, Table 3-8 (Health utility and complication-related decrements for people with T2D) in the resubmission shows no change in the disutilities for subsequent years compared with the utility/disutility for Year 1. It is therefore unclear whether the applicant has applied the disutility values of −0.055 for MI and −0.108 for CHF in the resubmission.

Disutility for finger pricking

In the PSD for the original ADAR, MSAC raised concerns regarding the appropriateness of applying a 0.03 disutility for finger pricking derived from Matza 2017. This estimate was based on preferences elicited from the general public rather than from people with T2D. It remains uncertain whether this value accurately reflects patient experience.

The resubmission argued that the use of general population preferences aligned with guidance from the Pharmaceutical Benefits Advisory Committee (PBAC), MSAC, National Institute for Health and Care Excellence (NICE) and Canada's Drug Agency–L'Agence des Medicaments du Canada (CDA-AMC), and that the use of UK tariffs is appropriate in the absence of Australian-specific data. However, the issue is not whether general population methods are allowed, but whether they are appropriate for this specific context (i.e. valuing finger pricking in people with diabetes). General population respondents may misjudge the burden of finger pricking compared with patients who routinely perform SMBG, resulting in uncertainty in the estimated disutility.

Additionally, in the one-way sensitivity analysis, the disutility associated with finger pricking was among the key drivers (the third) of the model results, which may lead to a substantial impact on the ICER. Therefore, it should be noted that uncertainty remains regarding the use of 0.03 disutility estimate and the model is very sensitive to this assumption.

Cost inputs

Number of sensors/strips

As noted in the PSD for the original ADAR, the estimate of 3.8 strips per person per day in the SMBG arm was derived from an RCT conducted across 26 European centres involving 75 intensive insulin users (Haak 2017). This value was assumed to apply equally to both intensive and non-intensive insulin users. However, estimates in France (8 sites in Haak 2017) and Germany (10 sites in Haak 2017) indicated that intensive insulin users required at least 4 strips per day, compared with approximately 2 strips per day for non-intensive insulin users. Therefore, the number of strips used may be underestimated in both the SMBG and FSL CGM arms. This issue was not addressed or justified in the resubmission.

Additional sensors

As noted in the commentary for the original ADAR, the applicant did not discuss whether additional sensors would be required due to device failure or early removal. The resubmission also did not explore scenario analyses relating to compliance or variation in the number of sensors used. The one-way sensitivity analysis indicated that the cost of FSL (labelled as 'FGM Drug Cost annual' as the variable) is a key driver of cost-effectiveness, ranking as the second most influential parameter. Increasing the cost of FSL results in a higher incremental cost-effectiveness ratio (ICER). This issue was not addressed or justified in the resubmission.

Renal failure cost

As noted in the commentary for the original ADAR, the costs that the applicant selected for renal disease ($30,828 in the year of event occurrence; and $16,986 in the subsequent year) were relatively small for end-stage renal disease. The RECODe risk equations predict end-stage renal disease, which is stage 5 of chronic kidney disease (CKD). According to Chen 2024, the overall annual per-person cost for CKD stage 5 was $67,117. The cost used by the applicant is more reflective of CKD stage 4. This issue was not addressed or justified in the resubmission.

Cost from a Tasmanian study

As noted in the commentary for the original ADAR, the applicant did not discuss whether the complication costs which were based on a Tasmanian study are representative of those observed in mainland Australia, or whether Tasmania's remoteness affects these estimates (e.g. costs of heart failure). The state's geographic isolation may influence costs due to limited access to specialist services and the need for travel. This issue was not addressed or justified in the resubmission.

Results

The results of first-order economic analysis are presented in Table 18, developed from the modelled costs and health gains for FSL versus SMBG monitoring using the RCT results and the comparative results (Table 3-12 and Table 3-15 in the main body of ADAR resubmission). Additionally, the results of subpopulation economic analyses are presented in Table 19, developed based on the information from Table 3-18 in the main body of ADAR resubmission (the deterministic subpopulation analyses).

Table 18 Results of first-order economic analysis

Parameter	FSL	SMBG	Increment	ICER
Step 1: RCT trial data only				
Model 1: Model 1: REFLECT				
Cost	**$Redacted**	**$Redacted**	**-$Redacted**	
QALY	6.728	6.227	0.501	Dominant
LY	9.955	9.952	0.003	Dominant
Model 2: RECODe				
Cost	**$Redacted**	**$Redacted**	**$Redacted**	
QALY	7.201	6.772	0.429	**$Redacted**[1]
LY	10.153	10.022	0.131	**$Redacted**[2]
Model 3: RECODe + Fremantle				
Cost	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**[1]
QALY	7.264	6.850	0.414	
LY	10.153	10.022	0.132	**$Redacted**[3]
Step 2: Base case analysis (all comparative trials)				
Model 1: Model 1: REFLECT				
Cost	**$Redacted**	**$Redacted**	**-$Redacted**	
QALY	6.728	6.227	0.501	Dominant
LY	9.955	9.952	0.003	Dominant
Model 2: RECODe				
Cost	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**[1]
QALY	7.203	6.772	0.431	
LY	10.155	10.022	0.133	**$Redacted**[4]
Model 3: RECODe + Fremantle				
Cost	**$Redacted**	**$Redacted**	**$Redacted**	**$Redacted**[1]
QALY	7.265	6.850	0.416	
LY	10.155	10.022	0.134	**$Redacted**[3]

FSL = FreeStyle Libre continuous glucose monitoring products, ICER = incremental cost-effectiveness ratio; LY = life year; SMBG = self-monitoring of blood glucose; QALY= quality-adjusted life year
Notes: All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] $15,000 to < $25,000
[2] $55,000 to < $65,000
[3] $65,000 to < $75,000
[4] $45,000 to < $55,000

Table 19 Results of subpopulation economic analyses

Subpopulation	Model 1: REFLECT			Model 2: RECODe			Model 3: RECODe + Fremantle		
	Δ Costs	Δ QALYs	($/QALY)	Δ Costs	Δ QALYs	($/QALY)	Δ Costs	Δ QALYs	($/QALY)
Base case	-$**Redacted**	0.501	Dominant	$**Redacted**	0.431	$**Redacted**[1]	$**Redacted**	0.416	$**Redacted**[1]
Subpopulation 1: All T2D Basal Insulin patients	-$**Redacted**	0.501	Dominant	$**Redacted**	0.429	$**Redacted**[1]	$**Redacted**	0.414	$**Redacted**[1]
Subpopulation 2: All T2D Intensive Insulin patients	-$**Redacted**	0.501	Dominant	$**Redacted**	0.428	$**Redacted**[1]	$**Redacted**	0.414	$**Redacted**[1]
Subpopulation 3: All T2D Insulin patients with HbA1c >=8.5%	-$**Redacted**	0.485	Dominant	$**Redacted**	0.442	$**Redacted**[2]	$**Redacted**	0.425	$**Redacted**[1]
Subpopulation 4: All T2D Insulin patients with HbA1c >=9.5%	-$**Redacted**	0.468	Dominant	$**Redacted**	0.570	$**Redacted**[3]	$**Redacted**	0.531	$**Redacted**[1]
Subpopulation 5/6: T2D CVD/CKD	-$**Redacted**	0.485	Dominant	$**Redacted**	0.433	$**Redacted**[1]	$**Redacted**	0.417	$**Redacted**[1]
Subpopulation 7: T2D First Nations	-$**Redacted**	0.613	Dominant	$**Redacted**	0.470	$**Redacted**[1]	$**Redacted**	0.463	$**Redacted**[1]
Subpopulation 8: Pregnancy	No feasible economic modelling								
Subpopulation 9: Intermittent	No feasible economic modelling								

FSL = FreeStyle Libre continuous glucose monitoring products; HbA1c = haemoglobin A1c; ICER = incremental cost-effectiveness ratio; LY = life year, QALY= quality-adjusted life year.
All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] $15,000 to < $25,000
[2] $5,000 to < $15,000
[3] $0 to < $5,000

According to the resubmission, ICERs across most subpopulations were generally similar to the base case across the 3 modelling approaches. Under the REFLECT model, CGM remained dominant in subpopulations 1 to 7. Under Models 2 and 3, ICERs were generally within a similar range to the base case; however, lower ICERs were observed in the higher HbA1c subgroups (≥8.5% and ≥9.5%), particularly in Model 2. No economic modelling was presented for the pregnancy (subpopulation 8) or intermittent use populations (subpopulation 9).

In general, populations with higher baseline HbA1c appeared to have more favourable ICERs, which may reflect greater absolute reductions in diabetes-related complications and healthcare utilisation. However, the relationship between baseline HbA1c and ICER is likely multifactorial and may also depend on model assumptions. For example, where a model captures larger reductions in downstream complications and hospitalisations in populations with higher baseline HbA1c, greater cost offsets may have contributed to more favourable ICERs.

The results of the one-way sensitivity analysis (Table 20) in the resubmission differ from those in the original ADAR. For example, the disutility associated with finger pricking (0.03) was not identified as a key driver previously but is now ranked among the key drivers in the tornado diagram of the resubmission (Figure 2).

This disutility was derived from the general public rather than from people with T2D. The concern of this assumption has been discussed in the utility inputs section. The one-way sensitivity analysis indicates that variation in this parameter has a substantial impact on the ICER, suggesting that the model is highly sensitive to this parameter. Therefore, uncertainty remains regarding the use of this value, and this assumption has a significant influence on the model results.

Table 20 Key drivers of the model

Description	Method/value	Impact Base case (Model 2, all comparative trials) : $Redacted[1]/QALY gained
FSL one-time absolute HbA1c reduction	The one-time, absolute HbA1c reduction for FSL was explored in the one-way sensitivity analysis (Figure 2) with a mean of 0.55% (SE = 0.001147959) (Source: *FSL Aust CEM - Step 2 - BaseCase - RECODe - OneWay - Final*). However, in the report, they varied ±20% of the mean (Table 3-11 in Section 3.8.2 of the resubmission). It is unclear which method they used in the analysis.	High value, favours FSL Low value, favours SMBG
FSL and SMBG annual costs	Costs of FSL and SMBG were explored in the one-way sensitivity analysis (Figure 2) and varied ±20% of the mean.	For FSL cost High value, favours SMBG Low value, favours FSL For SMBG cost High value, favours FSL Low value, favours SMBG
Finger stick disutility	The disutility of finger stick was explored in the one-way sensitivity analysis (Figure 2) and varied ±20% of the mean.	High value, favours FSL Low value, favours SMBG
Baseline utility	The baseline utility was explored in the one-way sensitivity analysis (Figure 2) and was varied ±20% of the mean.	High value, favours FSL Low value, favours SMBG
Diabetes-related complications costs	Costs of diabetes-related complications (MI, CHF, renal and stroke) were explored in the one-way sensitivity analysis (Figure 2) and was varied ±20% of the mean.	High value, favours FSL Low value, favours SMBG

CHF = congestive heart failure; FSL = FreeStyle Libre Continuous Glucose Monitoring; HbA1c = glycated haemoglobin; MI = myocardial infarction; QALY = quality-adjusted life year; SMBG = self-monitoring of blood glucose.

The redacted values correspond to the following ranges:
[1] $15,000 to < $25,000

Figure 2 One-way sensitivity analyses, tornado diagram from the ADAR resubmission

[Figure redacted]

FSL = FreeStyle Libre Continuous Glucose Monitoring; HbA1c = glycated haemoglobin; ICER = incremental cost-effectiveness ratio; QALY= quality-adjusted life year.

In the PSD of the original ADAR, ESC noted that the reasons for the differences between the first-order (deterministic) and second-order (PSA) analyses were unclear, with the PSA ICER ($15,000 to <$25,000) differing from the base case ICER ($5,000 to <$15,000), likely due to differences in simulation size. This discrepancy raised concerns regarding model stability, and no justification was provided to demonstrate that the number of simulations was sufficient for convergence.

In the resubmission, as in the original ADAR, the applicant conducted PSA only for Model 2 (RECODe-based approach). PSA results for the other 2 models (Model 1: REFLECT and Model 3: RECODe-Fremantle) were not presented. The applicant increased the number of PSA simulations (2,000 replications with 10,000 patients) and reported that the PSA ICER ($15,000 to <$25,000) (Table 21) is closely aligned with the deterministic base case ICER ($15,000 ro <$25,000). This suggests improved numerical stability of the results.

Table 21 Results of second-order probabilistic analysis

Parameter	FSL	SMBG	Increment	ICER
Cost	$**Redacted**	$**Redacted**	$**Redacted**	$**Redacted**[1]
QALY	7.2032	6.7719	0.431	
LY	10.156	10.024	0.13263	$**Redacted**[2]

FSL = FreeStyle Libre continuous glucose monitoring products, ICER = incremental cost-effectiveness ratio; LY = life year; QALY = quality-adjusted life year; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.

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

However, the 3 models used in the base case analysis produced different outcomes, with Model 1 indicating that FSL dominated SMBG, Model 2 producing an ICER of $15,000 to <$25,000, and Model 3 producing an ICER of $15,000 to <$25,000. Thus, it remains unclear whether the stability observed in Model 2 applies to the other model structures.

These models are fundamentally different. The uncertainties of one model cannot be assumed to apply to the others. The absence of reporting of the PSA for Model 1 and 3 represents a significant limitation of this ADAR, especially given the differences in the deterministic results across models. *The pre-ESC response provided these results which are reproduced below in Figure 3.*

The deterministic scenario analyses, derived from Table 3-17 in the main body of the resubmission, are summarised in Table 22. These explore uncertainties including discounting, exclusion of all diabetes-related complication costs, disutility of finger pricking, and time horizon.

Figure 3 – PSA Scatterplots (Model 1: REFLECT (left), Model 3: RECODe with Fremantle adjustment (right))

[Figure redacted]

Table 22 Deterministic scenario analyses

	Model 1: REFLECT			Model 2: RECODe			Model 3: RECODe + Fremantle		
Analyses	**Incremental cost**	**Incremental QALY**	**ICER**	**Incremental cost**	**Incremental QALY**	**ICER**	**Incremental cost**	**Incremental QALY**	**ICER**
Base case	-$**Redacted**	0.501	Dominant	$**Redacted**	0.431	$**Redacted**[1]	$**Redacted**	0.416	$**Redacted**[1]
No discounting	-$**Redacted**	0.903	Dominant	$**Redacted**	0.760	$**Redacted**[1]	$**Redacted**	0.730	$**Redacted**[1]
Exclude all diabetes-related complication costs	-$**Redacted**	0.501	Dominant	$**Redacted**	0.431	$**Redacted**[2]	$**Redacted**	0.416	$**Redacted**[2]
50% finger prick disutility	-$**Redacted**	0.349	Dominant	$**Redacted**	0.278	$**Redacted**[2]	$**Redacted**	0.262	$**Redacted**[3]
Shorter horizon (5 years)	-$**Redacted**	0.152	Dominant	$**Redacted**	0.141	$**Redacted**[1]	$**Redacted**	0.138	$**Redacted**[2]

FSL = FreeStyle Libre Continuous Glucose Monitoring; ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year
Note:
All results involved 10,000 microsimulations.
All currencies represent AUD.

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

Cost-consequence analysis for gestational diabetes (PICO Set 2)

The cost-consequence analysis (CCA) compared the FSL system with SMBG, leveraging the clinical claim of superior efficacy (glycaemic control) and non-inferior safety in pregnant women with GDM. A summary of the GDM economic evaluation is presented in Table 23.

Table 23 Summary of the economic evaluation

Component	Description
Perspective	Australian publicly funded healthcare system
Population	Women with GDM
Prior testing	Diagnosis of GDM in weeks 24 to 28
Comparator	SMBG
Type(s) of analysis	Cost-consequence analysis
Outcomes	Cost of glucose monitoring Reduction in NICU admission Reduction in caesarean births
Time horizon	12 weeks (scenario with 50 weeks)
Computational method	Simple cost calculator
Generation of the base case	Applicant estimated the total cost of glucose monitoring for FSL and SMBG by estimating resource use Incidence (%) of reduction in NICU admission and reduction in caesarean births and cost estimates applied to them
Cycle length	Time of treatment
Discount rate	0%
Software	Microsoft Excel

FSL = FreeStyle Libre Continuous Glucose Monitoring; GDM = gestational diabetes; NICU = neonatal intensive care; SMBG = self-monitoring of blood glucose

Parameters

In the original ADAR, the applicant used macrosomia as the main clinical evidence for the cost consequence analysis. In this resubmission, the applicant incorporated additional clinical evidence, including meta-analyses demonstrating statistically significant reductions in LGA infants. The reported risk difference (–0.057) and number needed to treat (17.54) suggest a clinically meaningful benefit. The applicant also noted that LGA is a more appropriate outcome than macrosomia, as it accounts for gestational age and maternal characteristics (however the ADAR resubmission cites an example that is not epidemiologically accurate; birthweight is mediated by maternal anthropometric and metabolic characteristics rather than ethnicity per se). This is an appropriate update.

The applicant also incorporated reductions in NICU admissions and caesarean births. These outcomes are relevant drivers of healthcare costs and are appropriate inclusions in a short-term economic analysis.

Costs associated with NICU admissions and caesarean births were derived using Australian Refined Diagnosis Related Groups (AR-DRGs) and National Efficient Cost Determinations. This is appropriate and aligns with an Australian healthcare payer perspective.

In the resubmission, the estimated costs of FSL and SMBG were consistent with those presented in the original ADAR. As noted in the commentary on the original ADAR, the applicant assumed no wastage, such that the payer would pay for each individual SMBG strip rather than per pack.

However, given the co-payment associated with SMBG strips, it is more likely that patients would purchase packs of 100 strips, rather than 25.2 or 319.2 as noted in the resubmission. As a result, some degree of wastage would be expected, which would increase the cost. This issue was not addressed or justified in the resubmission nor was any scenario analysis performed as part of the submission.

Results

The CCA compared the FSL system with SMBG, leveraging the clinical claim of superior efficacy (glycaemic control) and non-inferior safety in pregnant women with GDM. A summary of the GDM economic evaluation is presented in Table 24.

Table 24 Results of cost-consequence analysis

Step	FSL	SMBG	Increment
Base case (12 weeks)			
Cost of glucose monitoring	**$Redacted**	**$Redacted**	**$Redacted**
Change in admission to NICU	Not presented	Not presented	−$412
Change in caesarean births	Not presented	Not presented	−$729
Total cost	Not presented	Not presented	-**$Redacted**
Scenario (50 weeks)			
Cost of glucose monitoring	Not presented	Not presented	**$Redacted**
Change in admission to NICU	Not presented	Not presented	−$412
Change in caesarean births	Not presented	Not presented	−$729
Total cost	Not presented	Not presented	**$Redacted**

FSL = FreeStyle Libre Continuous Glucose Monitoring; NICU = neonatal intensive care; SMBG = self-monitoring of blood glucose
Note: All currencies represent AUD.

In the resubmission, the applicant presented a cost-consequence analysis similar to the original ADAR, but included cost offsets from reductions in NICU admissions and caesarean births and removed those associated with macrosomia. This approach is considered appropriate given the limited evidence. However, there is limited exploration of parameter uncertainty, such as variation in unit costs.

In addition, consideration of hyper- or hypoglycaemia was not included, and the cost-saving conclusion was driven by reductions in NICU admissions and caesarean births among infants of people with gestational diabetes.

The 50-week scenario appeared to represent a threshold analysis intended to demonstrate the duration of FSL use at which the intervention would remain cost-neutral, rather than a clinically plausible duration of CGM use during pregnancy. However, this was not clearly explained in the resubmission and may cause confusion, given that GDM is typically diagnosed at 24–28 weeks gestation and pregnancy generally lasts 38–40 weeks.

Other diabetes (PICO Set 3)

The applicant did not present any economic evidence for FSL in other diabetes populations.

14. Financial/budgetary impacts

The ADAR presented a financial analysis to expand the subsidisation coverage of FSL among people living with T2D. It adopted an epidemiological approach to estimate the anticipated 6-year financial implications of FSL to the federal NDSS budget in the 3 PICO populations:

- PICO Set 1: People with T2D requiring insulin
- PICO Set 2: People with GDM
- PICO Set 3: People with other types of diabetes.

In PICO Set 1 of the resubmission, the applicant listed 9 subpopulations, including:

- Subpopulation 1: T2D basal only
- Subpopulation 2: T2D IIT (excluding basal)
- Subpopulation 3: T2D HbA1c ≥8.5%
- Subpopulation 4: T2D HbA1c ≥9.5%
- Subpopulation 5: T2D CVD CKD
- Subpopulation 6: T2D CVD CKD events
- Subpopulation 7: T2D First Nations
- Subpopulation 8: T2D pregnancy
- Subpopulation 9: Intermittent CGM use.

The resubmission stated that the applicant seeks funding for all T2D patients requiring insulin, with the exception of subpopulation 7 (First Nations peoples with T2D) and subpopulation 8 (pregnant women with T2D). The resubmission presented the outcomes of these 2 subpopulations separately because they represent a small number of patients with a particularly high clinical need and are likely to significantly benefit from CGM use.

Subpopulation 9 (intermittent CGM use) was excluded from the financial analysis in the resubmission without justification.

FSL2 vs FSL2 Plus

The ADAR applied the Dispensed Price for Maximum Quantity (DPMQ) for FSL2 ($**Redacted** per sensor; i.e. $**Redacted** per sensor plus standard $2 for NDSS distribution) across all PICO Sets 1, 2 and 3. This was calculated based on a monthly sensor cost of $**Redacted** per 2 sensors, which appears to be an appropriate estimate. In the commentary for the original ADAR, MSAC noted that 'cost and uptake data focused on FSL2 and did not consider FSL2 Plus'. In the resubmission, the applicant assumed that the unit cost of FSL2 Plus are equivalent to FSL2. This is reasonable as FSL2 Plus will be covered by the same ARTG item. FSL2 and FSL2 Plus will henceforth be referred to as 'FSL products'. (Section 5, PSD)

However, the resubmission did not clearly state whether FSL2 Plus is intended to replace FSL2 or to be used concurrently, given that FSL2 Plus has been available in Australia since 1 April 2025. This is not expected to significantly affect the analysis results, as any differences have been minimised by grouping both under the term 'FSL products'.

FSL uptake rate:

Compared to the original ADAR, the ADAR resubmission applied higher uptake rates (IIT users: **redacted-redacted**%, non-IIT users: **redacted-redacted**%), in line with MSAC's comments. The applicant indicated that these updated rates were based on 'T1D Australian and T2D overseas experience as well as feedback from MSAC 1786 consideration and [Drug Utilisation Sub Committee] DUSC data' (Table 4-1 in the main body of the resubmission).

However, the updated rates were not aligned with the Australian T1D data provided by MSAC (Table 4-3 in the main body of the resubmission) or the overseas T2D data (Table 4-2 in the main body of the resubmission). The derivation was not clear and could not be verified. The magnitude and direction of the bias introduced by this unverified uptake rate are uncertain, and its impact on the base case findings is unclear.

Number of sensors

For insulin users in PICO Set 1, and populations in PICO Set 3, each patient was estimated to require 24 FSL sensors per year, whereas women with GDM in PICO Set 2 were estimated to require 6 sensors per year. As noted in the commentary on the original ADAR, the applicant did not explore uncertainties related to adherence/compliance or the number of sensors. This issue has not been addressed or discussed in the resubmission, either in the clinical or economic/financial sections.

The base case financial analysis, in the resubmission, assumed that 'patients are rarely fully compliant in practice' and considered 24 sensors per year to be a conservative upper estimate. However, no sensitivity analyses were conducted to test lower adherence or reduced sensor utilisation. Reduced adherence or fewer sensors used would reduce overall costs. Consequently, omission of this uncertainty may result in an overestimation of financial impact estimates.

Strips

The ADAR estimated the daily number of the test strips to be 0.3 and 3.8 for FSL and SMBG, respectively. Wastage was identified as a concern and raised by MSAC for the original ADAR. However, this issue has not been addressed or justified in the resubmission. The applicant assumed no wastage, with unit costs based on per strip rather than per pack (100 strips).

This assumption is likely to underestimate costs due to unaccounted wastage, as the healthcare payer (NDSS) is expected to fund full packs rather than individual strips for both the SMGB and FSL arms.

Additionally, in the resubmission, test strip use associated with FSL and SMBG was derived from Haak 2017. However, the T2D population in Haak 2017 comprised IIT users only. In the resubmission, the number of test strips for non-IIT users was assumed to be equivalent to that of IIT users. MSAC previously noted that this assumption was inappropriate, as test strip utilisation is expected to be higher in IIT than in non-IIT populations.

Furthermore, the number of strips in both the FSL and SMBG arms may be underestimated. As discussed by the commentary in the July 2025 PSD, recommendations from France suggest a minimum of 4 and 2 strips per day for IIT and non-IIT users, respectively. This was not addressed in the resubmission.

PICO Set 1

The ADAR noted a significant difference in terms of the definitions used between MSAC 1785 and 1786. The applicant noted that 'premixed insulin' was included in MSAC 1785 (Dexcom) but was not included in the original FSL ADAR (MSAC 1786). In the resubmission, it was incorporated into the 'intensive insulin' category. However, in the Dexcom resubmission, 'premixed insulin' was classified within the non-IIT subpopulation. This inconsistency does not facilitate comparison, which was claimed by the applicant in the resubmission.

In the original ADAR (MSAC 1786), the number of T2D patients using insulin was estimated using Prospection data. This source was considered appropriate and consistent with the department's advice that PBS data were more accurate than NDSS data, according to ESC's comments. In the

resubmission, however, the data source was changed to NDSS and DUSC data, instead of Prospection analysis.

The number of T2D patients in 2026 was calculated using an annual growth rate of 1.3%, which was calculated based on DUSC data from 2020 to 2025. The applicant then used a 1% annual growth rate to estimate the number of T2D patients from Year 1 to Year 6. There are uncertainties associated with the use of both the 1.3% and 1% growth rates:

- 1.3%: The annual growth data show a fluctuation, including a notable increase between 2022 and 2023, followed by a decline from 2023 to 2024. This fluctuation may not accurately reflect the underlying trend and could introduce additional uncertainty into the estimates.
- 1%: In the resubmission, the applicant suggested that this growth rate was informed by the Prospection analysis. However, no relevant information on population growth (neither annual numbers nor growth rates) was identified in the Prospection analysis.

Based on the results presented in the resubmission, the financial implications of PICO Set 1 to the NDSS resulting from the proposed listing of FSL are summarised in Table 25 and Table 26. Only subpopulations 1 (basal-only insulin patients) and 2 (ITT users) are presented in the executive summary. The results for other subpopulations were reported in the resubmission but not incorporated into the overall financial implications of PICO Set 1.

Table 25 Net financial implications of FSL to the NDSS (PICO Set 1 – Subpopulation 1)

	PICO Set 1 – Subpopulation 1					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	57,925	58,504	59,089	59,680	60,277	60,879
Uptake %	**Redacted %**	**Redacted %**	**Redacted %**	**Redacted %**	**Redacted %**	**Redacted %**
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]	**Redacted**[3]	**Redacted**[3]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted** [4]	**$Redacted** [5]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [7]
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]
Net cost of FSL	**$Redacted** [4]	**$Redacted** [5]	**$Redacted** [5]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]
Change in SMBG use						
Less cost offsets (reduced glucose strips)	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [8]	**$Redacted** [4]	**$Redacted** [4]
Total net cost	**$Redacted** [4]	**$Redacted** [9]	**$Redacted** [9]	**$Redacted** [5]	**$Redacted** [5]	**$Redacted** [5]

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] 10,000 to < 20,000
[2] 30,000 to < 40,000
[3] 40,000 to < 50,000
[4] $10 million to < $20 million
[5] $40 million to < $50 million
[6] $50 million to < $60 million
[7] $60 million to < $70 million
[8] $0 to < $10 million
[9] $30 million to < $40 million

Table 26 Net financial implications of FSL to the NDSS (PICO Set 1 – Subpopulation 2)

	PICO Set 1 – Subpopulation 2					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	151,189	152,701	154,228	155,771	157,328	158,902
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[3]	**Redacted**[3]	**Redacted**[3]	**Redacted**[3]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted** 4	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted** 6	**$Redacted** 7	**$Redacted** 7	**$Redacted** 7	**$Redacted** 7	**$Redacted** 7
Net cost of FSL	**$Redacted** 8	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5
Change in SMBG use						
Less cost offsets (reduced glucose strips)	**$Redacted** 6	**$Redacted** 9	**$Redacted** 9	**$Redacted** 9	**$Redacted** 9	**$Redacted** 9
Total net cost	**$Redacted** 10	**$Redacted** 11	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5	**$Redacted** 5

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] 30,000 to < 40,000
[2] 90,000 to < 100,000
[3] 100,000 to < 200,000
[4] $50 million to < $60 million
[5] $100 million to < $200 million
[6] $0 to < $10 million
[7] $10 million to < $20 million
[8] $40 million to < $50 million
[9] $20 million to < $30 million
[10] $30 million to < $40 million
[11] $90 million to < $100 million

PICO Set 2

In the resubmission, the ADAR estimated there would be 39,107 women with GDM (with or without insulin) in Australia in 2026. This was verified from the NDSS snapshot data on 19 January 2026. In the resubmission, the applicant used the same 1% annual growth rate used in PICO Set 1 for future projections. However, in the PSD of the original ADAR, ESC noted that 'the assumed growth in GDM patient numbers in PICO Set 2 was inconsistent with declining fertility rates and could only be reasonable if the increase in the incidence of GDM is greater than this decrease in fertility'. This issue has not been addressed or discussed in the resubmission.

Based on the results presented in the resubmission, the financial implications of PICO Set 2 to the NDSS resulting from the proposed listing of FSL are summarised in Table 27.

It should be noted that according to the new Australian guidelines, earlier testing and extended CGM use in high-risk pregnancies (change from 11–15 weeks to around 28 weeks) may increase the number of FSL sensors, while a reduced GDM prevalence under updated diagnostic threshold may decrease the FSL utilisation.

Table 27 Net financial implications of FSL to the NDSS (PICO Set 2)

	PICO Set 2					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	39,107	39,498	39,893	40,292	40,695	41,102
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]	**Redacted**[3]	**Redacted**[3]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[5]	**$Redacted**[5]
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]
Net cost of FSL	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]
Change in SMBG use						
Less cost offsets (reduced glucose strips)	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]
Total net cost	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]	**$Redacted**[4]

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] 10,000 to < 20,000
[2] 20,000 to < 30,000
[3] 30,000 to < 40,000
[4] $0 to < $10 million
[5] $10 million to < $20 million

PICO Set 3

The ADAR assumed that the number of 'other' diabetes patients was informed by NDSS snapshot data in 2026. This number for 'other' diabetes (8,867) was verified. However, the estimate of 7.8% for those under 21 years old appears inconsistent with the age distribution in the financial Excel file or the relevant NDSS snapshot data provided by the applicant.

Based on the results presented in the resubmission, the financial implications of PICO Set 3 to the NDSS resulting from the proposed listing of FSL are summarised in Table 28.

Table 28 Net financial implications of FSL to the NDSS (PICO Set 3)

	PICO Set 3					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	8,174	8,256	8,338	8,422	8,506	8,591
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]
Net cost of FSL	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]
Change in SMBG use						
Less cost offsets (reduced glucose strips)	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]
Total net cost	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]	**$Redacted**[3]

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] 500 to < 5,000
[2] 5,000 to < 10,000
[3] $0 to < $10 million

Overall

Based on the results presented in the resubmission, the overall financial implications to the NDSS resulting from the proposed listing of FSL are summarised in Table 29. This table reflects the applicant's preferred funding populations: PICO Set 1 T2D patients using insulin (subpopulations 1 and 2), as well as PICO Sets 2 and 3. The overall net financial impact to the NDSS for subsiding FSL was estimated to be $50 million to < $60 million in Year 1, increasing to $100 million to < $200 million by Year 6 (Table 29).

Table 29 Net financial implications of FSL to the NDSS (PICO Set 1 [Subpopulation 1 & 2] and PICO Set 2 and 3)

	PICO Set 1 [Subpopulation 1 & 2], PICO Set 2 and PICO Set 3					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	256,395	258,959	261,548	264,164	266,806	269,474
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[2]	**Redacted**[2]	**Redacted**[3]	**Redacted**[3]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted**[4]	**$Redacted**[5]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted**[7]	**$Redacted**[8]	**$Redacted**[8]	**$Redacted**[8]	**$Redacted**[9]	**$Redacted**[9]
Net cost of FSL	**$Redacted**[4]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[6]
Change in SMBG use						
Less cost offsets (reduced glucose strips)	**$Redacted**[8]	**$Redacted**[10]	**$Redacted**[10]	**$Redacted**[11]	**$Redacted**[11]	**$Redacted**[11]
Total net cost	**$Redacted**[12]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] 60,000 to < 70,000
[2] 100,000 to < 200,000
[3] 200,000 to < 300,000
[4] $70 million to < $80 million
[5] $100 million to < $200 million
[6] $200 million to < $300 million
[7] $0 to < $10 million
[8] $10 million to < $20 million
[9] $20 million to < $30 million
[10] $30 million to < $40 million
[11] $40 million to < $40 million
[12] $50 million to < $60 million

Scenario analysis

Scenario analysis: number of T2D patients requiring insulin

In the original ADAR, the applicant presented 2 scenario analyses to account for uncertainty in the number of T2D patients requiring insulin and the uptake of FSL. In the resubmission, however, no scenario analysis was conducted for the number of T2D patients requiring insulin. The applicant stated that there was no uncertainty in this estimate, as it was based on DUSC data.

It is acknowledged that the DUSC data provided by the department is more accurate and reliable than Prospection data. However, uncertainties remain regarding the use of this source and the subsequent calculations, despite the selection of a more appropriate data source.

- The DUSC data do not directly inform the number of T2D patients requiring insulin, as they capture the overall number of patients using insulin, rather than limited to patients with T2D.
- The future projections were based on historical data from 2020 to 2025, relying on an average growth rate over a period that included the COVID-19 outbreak (2020–2025). This may not adequately capture the underlying growing trend of prevalence and could introduce considerable uncertainty.
- It is not appropriate to directly subtract absolute numbers derived from 2 different datasets. Using proportions/percentages may result in a more consistent and reasonable comparison.

Scenario analysis: FSL uptake rate

Based on the results presented in the resubmission, the financial implications to the NDSS resulting from a 10% increase in the uptake rates are summarised in Table 30. The resultant overall net financial impact to the NDSS was higher, increasing from $80 million to < $90 million in Year 1 to $200 million to < $300 million by Year 6 (Table 30).

Table 30 Net financial implications of FSL to the NDSS (Scenario analysis: FSL uptake rate)

	PICO Set 1 (Subpopulation 1 & 2), PICO Set 2 and PICO Set 3					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	256,395	258,959	261,548	264,164	266,806	269,474
Uptake %	**Redacted**%	**Redacted**%	**Redacted**%	**Redacted**%	**Redacted**%	**Redacted**%
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[2]	**Redacted**[3]	**Redacted**[3]	**Redacted**[3]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	$**Redacted**[4]	$**Redacted**[5]	$**Redacted**[5]	$**Redacted**[5]	$**Redacted**[5]	$**Redacted**[5]
Less cost offset (patient contributions, applies to 30% [or 27%] of population who are general patients, the remaining with concession pay $0 contribution)	$**Redacted**[6]	$**Redacted**[7]	$**Redacted**[8]	$**Redacted**[8]	$**Redacted**[8]	$**Redacted**[8]
Net cost of FSL	$**Redacted**[4]	$**Redacted**[4]	$**Redacted**[5]	$**Redacted**[5]	$**Redacted**[5]	$**Redacted**[5]
Change in SMBG use						
Less cost offsets (reduced glucose strips)	$**Redacted**[7]	$**Redacted**[9]	$**Redacted**[10]	$**Redacted**[10]	$**Redacted**[10]	$**Redacted**[10]
Total net cost	$**Redacted**[11]	$**Redacted**[4]	$**Redacted**[4]	$**Redacted**[4]	$**Redacted**[5]	$**Redacted**[5]

FSL = FreeStyle Libre Continuous Glucose Monitoring; SMBG = self-monitoring of blood glucose
Notes: All currencies represent AUD.

The redacted values correspond to the following ranges:
[1] 90,000 to < 100,000
[2] 100,000 to < 200,000
[3] 200,000 to < 300,000
[4] $100 million to < $200 million
[5] $200 million to < $300 million
[6] $0 to < $10 million
[7] $10 million to < $20 million
[8] $20 million to < $30 million
[9] $30 million to < $40 million
[10] $40 million to < $50 million
[11] $80 million to < $90 million

15. Other relevant information

ESC considered that it would be informative for MSAC to consider a respecified multivariate RECODe base case with the following elements

- Halving of finger-prick disutility
- Halving of SHE costs and disutilities
- Halving of diabetes complication costs and disutilities

An estimate of this respecified base case 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 applicant is invited to comment.

Table 31 Estimated respecified RECODe base case for applicant comment

	1. Incremental cost ($)	2. Incremental QALY
A. Base case (RECODE)	**Redacted**	0.431
B. 50% finger-prick disutility[1]	**Redacted**	0.278
C. Contribution of 50% finger-prick disutility to base case (A-B)	**Redacted**	0.153
D. Exclude all diabetes complication costs[1]	**Redacted**	n.a.
E. Diabetes complication contribution to base case incremental cost (A-D)	**Redacted**	n.a.
F. SHE contribution to base case[2]	**Redacted**	0.002
G. Incremental QALYs prior to decrements[3]	**Redacted**	0.102
H. Diabetes complication contribution to base case QALY (A2-2*C2-F2-G2)	**Redacted**	0.021

Abbreviations: QALY= Quality Adjusted Life Years; SHE=severe hypoglycaemic events

1. Table 3-17 of ADAR
2. Table 3-12 of ADAR
3. Table 3-15 of ADAR

Incremental cost = A1-(0.5*E1)-(0.5*F1)=$**Redacted**

Incremental QALY= A2-C2-(0.5*F2)-(0.5*H2)=0.2665

Revised ICER (approximation) = **$25,000 to < $35,000 per QALY**

The pre-MSAC response reported that re-running the RECODe base case model with these specifications resulted in an ICER of $25,000 to < $35,000/QALY.

16. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- The resubmission ADAR did not present evidence for each of the subpopulations of interest requested by MSAC in its consideration of the previous ADAR. Nonetheless, ESC considered that the evidence presented on effectiveness in the broader population 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.

Economic issues:

- ESC remained concerned about (i) whether the disutility associated with finger-prick testing and the relatively large QALY gains from avoiding finger-prick testing was overestimated, (ii) the size of severe hypoglycaemic events (SHE) cost offsets in the modelling, 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 that halves the diabetes complications costs and disutilities, halves the finger-prick disutility, and halves the SHE costs and disutilities.

Financial issues:

- Higher uptake rates were applied in the resubmission to estimate the number of eligible patients (IIT users: **redacted-redacted**%; non-IIT users: **redacted-redacted**% from year 1 to year 6), compared with the original ADAR. Although this is approach is consistent with MSAC's previous comments, the derivation of these specific rates was unclear. The biases are uncertain and their impact on the base case is unclear. The robustness of the process used to derive the assumed market growth rates is unknown.

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 Abbott Australasia Pty Ltd requested National Diabetes Services Scheme (NDSS) funding for the FreeStyle Libre 2 continuous glucose monitoring (CGM) system for people with insulin-dependent type 2 diabetes (T2D; PICO set 1), gestational diabetes (PICO set 2) and people aged over 21 years with conditions similar to T1D requiring insulin, including type 3c diabetes (PICO set 3).

MSAC previously considered this application at its July 2025 meeting but deferred its advice at that time (see the public summary document for Application 1786 from July 2025). MSAC advised that a resubmission should focus on the subpopulations who have a greater clinical need for CGM and are more likely to benefit from CGM, as well as presenting evidence around 2 different patterns of usage (continuous and intermittent), and any more recent clinical evidence of effectiveness. MSAC further advised that a resubmission should present a revised

economic evaluation focused on the populations with a higher clinical need and addressing the issues in the model. MSAC 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 1786, MSAC also considered Application 1785 for NDSS funding of the Dexcom ONE+ 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 1785.

ESC noted and welcomed public consultation on this application from 7911 individuals and 31 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, 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 other 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. The applicant-developed assessment report (ADAR) proposed revising the MCID to ≥0.35%, citing a recent meta-regression analysis of 44 randomised controlled trials (RCTs; Diallo 2025) that examined the association between HbA1c reduction and clinical outcomes, including major adverse cardiovascular event (MACE) and all-cause mortality. However, ESC noted that the cited study does not define an MCID and the resubmission did not adequately explain why this evidence justifies a lower MCID (using the approach set out by Appendix 12 of the MSAC Guidelines). In particular, ESC noted that the evidence presented from Diallo lacked data on prediction bands which would be needed to demonstrate any surrogate threshold effect for HbA1c reduction and therefore to assess whether a 0.35% reduction would reliably translate into patient-relevant benefits. However, ESC noted that, compared to the model in the previous submission, the revised model used RCT-based HbA1c treatment effects. Further, in the evidence presented for this application, ESC noted a consistency in the direction of effects on HBA1c favouring CGM over SMBG, and that the broader evidence suggested CGM may be associated with patient relevant benefits.

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 ADAR partially addressed this request in the resubmission by including studies on clinical effectiveness in the intensive insulin therapy (IIT) and non-IIT populations, as well as people with baseline HbA1c of ≥8.5% and ≥9.5%, gestational diabetes, and some data on those with diabetes similar to T1D. The ADAR stated that other populations (pregnancy; Aboriginal and Torres Strait Islander people; existing heart, stroke and vascular disease or chronic kidney disease; previous cardiovascular or cerebrovascular event or on dialysis/kidney transplant) could not be evaluated due to the lack of relevant evidence in these groups. 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 also noted that the applicant had argued that pregnant women at increased risk of diabetes did not necessarily need to be using insulin to justify access. ESC considered that, where this may also include pregnant women with T2D (not only GDM), it results in some tension between this population framing and the focus on insulin-treated populations for the other T2D populations.

ESC noted that many subgroups who are likely to benefit involve small numbers of patients (such as people with type 3 diabetes, 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 treatment 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 requested that the included clinical studies be limited to RCTs only. ESC noted that the applicant had addressed this in the resubmission but did not include a comparison of baseline characteristics between the included studies. ESC also noted that the assessment group had determined the quality of the included evidence for many outcomes to be very low, although the applicant disagreed with the assessment group's appraisal of the quality of the evidence in its pre-ESC response. ESC considered that during its evaluation the commentary had appeared to apply a higher standard to non-randomised studies, compared to RCTs, and that the assessment group should re-evaluate the risk of bias in the included studies to ensure that evidentiary standards are applied consistently across the application before MSAC's consideration. ESC noted that, in its pre-ESC response, the applicant defended the use of change in HbA1c of 0.3% as a clinically important threshold, acknowledged possible data errors in reporting of the evidence as identified by the Commentary but argued that they were immaterial, and contended that the Commentary's reassessment of GRADE was overly harsh. ESC considered that these responses addressed some presentational concerns but did not remove the underlying uncertainty about the evidentiary and economic basis for a broad listing.

ESC also noted an additional RCT (FreeDM2 trial, published since the applicant's literature search) that showed an adjusted mean difference in HbA1c between the CGM group and the SMBG group of −0.5%. The applicant's pre-ESC response included additional data for the subgroup of people with baseline HbA1c ≥9.5% – when meta-analysed with the MOBILE study population already reported (ADAR Table 2-16), the subgroup results show a statistically significant change in HbA1c of −0.9% (95% CI −1.34, −0.47).

The applicant stated that limited evidence is available on intermittent use of CGM and that the main benefit of CGM was for behavioural change and ongoing patient management. The applicant noted literature demonstrates that intermittent CGM may improve glycaemic control and patient management, but the available evidence is insufficient to inform robust economic modelling. Data were provided from an observational study[10] of CGM over 12 months that suggest a possible benefit of intermittent use of CGM compared with no CGM, although ESC noted this study likely had significant residual confounding issues. It was suggested that qualitative evidence or expert opinion may be useful to further explore the benefits of intermittent CGM use.

ESC noted the evidence for gestational diabetes mellitus (GDM). The evidence base comprised five open-label randomised controlled trials. The commentary judged all trials to have some concerns of bias, primarily reflecting their open-label design, except Elkind-Hirsch 2026[11], which was judged at high risk of bias. The pooled outcomes did not demonstrate consistent superiority across clinically relevant endpoints.

ESC noted that the evidence for type 3c diabetes and other similar forms of diabetes remained sparse. The sole study, Lund-Jacobsen 2025, included 40 people using continuous glucose monitoring and 30 using self-monitoring of blood glucose after total pancreatectomy and was judged by the commentary to be at serious risk of bias because of multiple exclusions related to

[10] Hirsch et al., Continuous glucose monitoring frequency and glycemic control in people with type 2 diabetes, JAMA Network Open 2025;8:e2539278.

[11] Elkind-Hirsch K, Armatta M, Griffen C, Welsh JB, Veillon E, Guedry S, Ballard J, Crawford MA, Monroy A, Singh H, Cappon G. Continuous glucose monitoring in early gestational diabetes improves maternal and neonatal outcomes-The Steady Sugar trial. Diabetes Obes Metab. 2026 Jan;28(1):691-700.

death and missing continuous glucose monitoring data. ESC considered that although the evidence was weak, there was reasonable clinical plausibility of benefit in this subpopulation.

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. ESC noted the Australian Diabetes Society's statement on the need for minimum quality standards for CGMs and agreed that a robust quality assurance system should be in place. However, ESC also noted that each sensor is only worn for up to 2 weeks before being replaced, which may help to minimise any potential safety risk 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.

In the economic analysis, ESC noted that the applicant had addressed or partially addressed several issues raised by MSAC, including focusing on patients with greater clinical need, addressing some model features that implausibly favoured CGM, updating the previously validated North American cardiovascular risk equations with more recent Western Australian (Fremantle) equations in a separate model, improving the model traces, removing or revising poorly supported hospitalisation cost offsets, allowing disutilities for myocardial infarction and congestive heart failure to extend beyond the year of onset, providing more extensive second-order probabilistic sensitivity analyses, removing the anomalies of a poorer ICER/QALY with a shorter time horizon and implausibly large incremental life-year gains against incremental QALY gains, and partly addressing concerns about baseline utility and assumed standard errors in the probabilistic sensitivity analyses.

ESC noted, however, that several concerns remained unresolved or inadequately addressed. There was still limited evidence or analysis for the proposed short-term-use subgroups and for some long-term-use subgroups; uncertainty remained regarding whether, and to what extent, HbA1c changes translate into patient-relevant outcomes such as diabetic complications, notwithstanding the applicant's separate REFLECT model extrapolating from a Swedish retrospective cohort study; and the possibility of a lag between biomarker improvement and downstream health outcomes remained insufficiently justified, although the pre-ESC response noted that reductions in some events emerged in year 1 of the Swedish observational study. ESC also noted that assumptions of perfect adherence and lifelong CGM use remained unsupported; the assumption of constant incremental HbA1c benefit over the model lifetime had not been tested; and the conversion of 10-year risks to annual risks retained the concern that complications may be brought forward in the model.

ESC further noted unresolved concerns regarding the applicability of overseas risk equations, overseas baseline characteristics and UK correlation matrices to the Australian setting; the absence of validation of the risk equations for non-cardiovascular diabetes complications; the handling of severe hypoglycaemic event costs and disutilities; the likely overestimation of the finger-prick testing disutility; uncertainty around GDM prevalence under revised diagnostic guidelines; and the use of non-significant neonatal intensive care unit (NICU) admission and caesarean delivery differences as cost offsets in the GDM cost-consequences analysis. The direction and size of these impacts on the results of the economic evaluations were not clear.

For PICO set 1, the economic evaluation presented 3 cost-utility analyses calculated as patient-level microsimulations:

- Model 1 – REFLECT-based model: complication risks were derived from those observed in the REFLECT retrospective cohort study (reported in Nathanson 2025). This model incorporates relative risks and the baseline rates from Nathanson (2025), which reports observed patient outcomes from use of CGM rather than via surrogate outcomes (that is, HbA1c levels) linked to final patient outcomes.
- Model 2 – RECODe- (HbA1c) based model: similar to that presented in the original ADAR, with additional features including annual risk adjustments and dynamically updated risk factors.
- Model 3 – RECODe-Fremantle– (HbA1c) based model: incorporates the Fremantle cardiovascular disease risk equations (Davis 2020) in place of those from North America.

The time horizon of the models was reduced to 30 years from 50 years in the previous submission. Six subpopulation analyses were also presented, achieved by changing various baseline characteristics and net reductions in HbA1c.

Under Model 1, CGM was dominant for all subpopulations. Under Models 2 and 3 the ICER (for all type 2 diabetes populations) was $15,000 to < $25,000 and $15,000 to < $25,000 per quality-adjusted life-years (QALYs), respectively. In general, under Models 2 and 3, populations with higher baseline HbA1c appeared to have more favourable incremental cost-effectiveness ratios (ICERs), which may reflect greater absolute reductions in diabetes-related complications and healthcare utilisation. ESC noted that a re-estimate of the ICER which ignored any changes in hospitalisation and complications costs and which focused only on the benefit of avoiding finger-prick disutility resulted in ICERs of $25,000 to <$35,000, $35,000 to <$45,000 and $25,000 to <$45,000 per QALY for Models 1, 2 and 3, respectively.

Overall, ESC considered that the changes to the economic model for PICO set 1 provided a weak basis to address MSAC's proposed subpopulations, and residual structural and parameter uncertainties remained. The applicant stated in its pre-ESC response that presenting multiple models helps to show consistency of conclusions; however, ESC considered that each model must be assessed on its own merits, and consistency does not necessarily indicate accuracy.

ESC noted that the incremental QALYs in the model were driven by incremental quality-of-life gains, not incremental life-years, and there was no obvious correlation across results between incremental costs, life-years and QALYs.

ESC remained concerned that the disutility associated with finger-prick testing and the relatively large QALY gains from avoiding finger-prick testing were overestimated. ESC advised that using the general population to derive these utilities, rather than people with diabetes, likely overestimated 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 noted that the scenario analyses remained limited and that the reported one-way "deterministic scenario analyses" varying parameters by an arbitrary plus or minus 10% did not provide useful insight. ESC suggested that a respecified multivariate RECODe base case, including halving the diabetes complications costs and disutilities, halving the finger-prick disutility, and halving severe hypoglycaemic event costs and disutilities would be beneficial for MSAC's consideration. ESC considered that this respecified base case 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, (ii) the size of severe hypoglycaemic events cost offsets in the modelling, and (iii) the existence and extent of the translation of HbA1c levels to diabetic complications. ESC noted that an approximation of these ICERs generated indirectly by relying on results from previously reported sensitivity analyses indicated that this respecified multivariate base case generated an ICER of $25,000 to <$35,000 per QALY.[12]

For PICO set 2, the model was a cost-consequences analysis that changed the source of claimed cost offsets from the previous submission (included cost offsets from reduced NICU admissions and caesarean births, and removed those associated with macrosomia). The base case results indicated that CGM would be cost saving. However, ESC noted that these cost offsets were based on outcomes (in NICU admissions and caesarean births) for which the risk difference estimates were not statistically significant in the supporting meta-analyses of RCTs (see Table 14).

No economic analysis was presented for PICO set 3.

ESC noted that, in the revised financial analysis, patients using pre-mixed insulin were moved into the IIT subpopulation, resulting in more patients with T2D getting larger diabetes strip cost offsets and thus possibly underestimating the financial implications of CGM. 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.

For PICO set 1, the net financial impact to the NDSS for subsidising FSL for IIT users increases from $30 million to <$40 million in year 1 to $100 million to <$200 million in year 6. For non-IIT users, the net impact increases from $10 million to <$20 million in year 1 to $40 million to < $50 million in year 6. Across all 3 PICO sets, the overall net financial impact to the NDSS for subsiding FSL was estimated to be $50 million to <$60 million in year 1, increasing to $100 million to < $200 million by year 6.

ESC noted that higher uptake rates were applied in the resubmission to estimate the number of eligible patients (IIT users: **redacted**-**redacted**%; non-IIT users: **redacted**-**redacted**% from year 1 to year 6), compared with the original ADAR. Although this is consistent with MSAC's previous comments, the derivation of these rates was unclear and could not be verified. ESC also noted the comparison with application 1785, including that FreeStyle Libre had a **redacted** annual cost of $**redacted** compared with $**redacted** for Dexcom, but that the broader 1786 population still led to **redacted** total net costs over time.

ESC noted that the commentary presented a sensitivity analysis to assess the impacts of a 10% increase in uptake rates[13] and reported this resulted in a 16% increase in net financial costs.

ESC noted that implementation issues if CGM funding were to be supported for the identified subpopulations were the same as those raised for application 1785 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 clinician appointments. ESC considered whether a staged approach might include 4 CGM

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

[13] From **redacted**% and **redacted**% and **redacted**% in years 1 to 6, respectively.

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

Abbott welcomes MSAC's recommendation to remove the age restriction for government-funded CGM access for Australians living with type 3c diabetes and other types of diabetes that are similar to type 1, an important step towards addressing unmet need and supporting more equitable access for this population.

Abbott is encouraged by MSAC's recognition of the substantial unmet need among several priority groups for future consideration. Together with the nearly 8,000 submissions received through public consultation, this reinforces the importance of continuing efforts to expand access to CGM technology. Strong clinical evidence supports the use of CGM, with funded access already established in many countries.

We acknowledge that MSAC has deferred its advice for the second time on NDSS subsidisation of the FreeStyle Libre CGM system for other priority populations, including people living with insulin-treated type 2 diabetes. The 2024 Parliamentary Inquiry into Diabetes recommended expanding subsidised CGM access to type 2 diabetes requiring regular insulin, gestational diabetes, and insulin-dependent type 3c diabetes.

Abbott remains committed to working with MSAC, the Australian Government, and the diabetes community to improve equitable access to CGM technology.

18. Further information on MSAC

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

Attachment A - Organisations providing consultation input to MSAC application 1786

1. The Canberra Hospital, Canberra Health Services
2. The Wright Advice Nutrition and Diabetes Management
3. Gold Coast University Hospital
4. Mater Health Townsville
5. Northern Health
6. Western Sydney Diabetes
7. Manning Support Services
8. Albury Wodonga Health
9. Derby Aboriginal Health Service
10. HK Medical
11. Cootamundra Family Medical Centre
12. Australia and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZSPED)
13. Cystic Fibrosis Australia
14. Sugar Sisters
15. Adult Cystic Fibrosis Centre, The Prince Charles Hospital
16. Royal Brisbane and Women's Hospital
17. Queensland Diabetes Clinical Network (QDCN) (2 inputs)
18. Northern Territory Diabetes Network
19. Royal Adelaide Hospital Cystic Fibrosis Service
20. Pankind, Pancreatic Cancer Australia
21. CF Together
22. Diabetes Victoria
23. Rare Cancers Australia
24. Launceston General Hospital – John Morris Diabetes Centre
25. Diabetes Health Network, Department of Health, Western Australia
26. Australian Diabetes Society
27. Ord Valley Aboriginal Health Service
28. NSW Health
29. Diabetes Australia
30. Australasian Diabetes in Pregnancy Society