Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1786 – FreeStyle Libre 2 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: **31 July 2025**

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

1. Purpose of application

An application requesting National Diabetes Services Scheme (NDSS) funding of the FreeStyle Libre 2 (FSL2) continuous glucose monitoring (CGM) system for people with type 2 diabetes (T2D) requiring treatment with insulin (PICO Set 1), pregnant women with gestational diabetes (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.

PICO Set 3 was subsequently expanded (following a meeting including the department and the applicant) to include all people aged ≥21 years with other conditions similar to type 1 diabetes (T1D) requiring insulin. The applicant also expanded the PICO to include the FSL2 Plus, planned for launch at the end of March 2025.

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 continuous glucose monitoring (CGM) system for people with insulin dependent type 2 diabetes (T2D), gestational diabetes and people aged over 21 years with type 3c diabetes.

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. The trials were relatively small, short term, and did not report end-organ outcomes. The reduction in HbA1c was lower than the level considered a meaningful improvement by the Pharmaceutical Benefits Advisory Committee and regulatory agencies. However, MSAC considered that CGM had other benefits for patients and T2D management. This includes empowering patients to manage their T2D and manage blood sugar levels during times of acute illness. MSAC considered CGM could improve quality of life and this was reflected in strong consumer support for public funding. MSAC considered that the proposed population was large with variable clinical needs and anticipated benefits from CGM. MSAC considered the economic evaluation lacked face validity and could not be used to reliably establish cost-effectiveness. MSAC considered that the proposed T2D population was heterogeneous and considered that CGM may be more clinically effective and cost-effective for some of the subpopulations, including patients who use both long acting and short acting insulin, people using insulin with higher levels of glycated haemoglobin (e.g. > 8%) as well as Aboriginal and Torres Strait Islander people. MSAC

considered that it may be beneficial to identify the subgroups of patients with T2DM most likely to receive the greatest clinical benefit from CGM. MSAC also noted that CGM may be used intermittently to establish better glycaemic control rather than continuously. MSAC considered that there was clinical need in the gestational diabetes and type 3c populations, but noted that evidence was limited. MSAC considered that there was substantial uncertainty around estimated utilisation. MSAC considered 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 CGM and are more likely to benefit from CGM, as well as presenting evidence around two different patterns of usage, and any more recent clinical evidence of effectiveness. MSAC further advised that a resubmission should present a revised economic evaluation focussed 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.

Consumer summary
This is an application from Abbott Australasia Pty Ltd requesting public funding under the National Diabetes Services Scheme (NDSS) for the FreeStyle Libre 2 (FSL2) and FSL2 Plus continuous glucose monitoring (CGM) system for people with type 2 diabetes (T2D) requiring treatment with insulin, pregnant women with gestational diabetes, and all people aged ≥21 years with other conditions similar to type 1 diabetes requiring insulin, including type 3c diabetes. Diabetes is a condition that can cause high blood sugar, which is when sugar (glucose) builds up in the bloodstream. The most common types of diabetes are called type 1 and type 2. People can also develop diabetes during pregnancy, known as gestational diabetes. 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. Gestational diabetes can cause problems not only for the mother, but also the baby. The amount of sugar in a person's bloodstream is usually controlled by a hormone called insulin. Insulin is like a key, which unlocks cells and allows sugar to move from the bloodstream into the cells. 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 might need to use insulin, and their blood sugar level will help them work out how much insulin they need. If their blood sugar levels are too low, they might need to eat more food to raise their blood sugar level and not use insulin. 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). This is a small device that sits on the skin (usually worn on the back of the upper arm), with a sensor that 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 could be for example over the past 24 hours, or longer time periods (e.g. over past 90 days), which helps people understand the effects of their behaviour (for example, what they eat, or how much they exercise) on their

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blood sugar levels. CGM can also reduce the burden on carers, provide information to doctors about treatment, and enable remote monitoring, which may improve access to care. One such CGM device is called FreeStyle Libre 2 (FSL2). FSL2 is already funded under Australia's National Diabetes Service Scheme (NDSS) for people with type 1 diabetes. This application is requesting funding for FSL2 be broadened to include people with type 2 diabetes who use insulin, as well as people who develop diabetes while they are pregnant, and people with some similar conditions. An application was also considered by MSAC for another type of CGM device (Application 1785). MSAC acknowledged the large amount of public consultation input received for this application and appreciated the effort that people had gone to in sharing their experiences. MSAC noted that a major theme in the feedback was the importance of supporting self-management through patient education and empowerment. MSAC considered that CGM systems with similar features and functionality were likely similarly safe and effective regardless of the brand of device. MSAC considered using CGM systems to be as safe as finger pricking for SMBG. MSAC noted the application claimed CGM was more effective than SMBG for monitoring blood glucose levels, and that this claim was based on monitoring using CGM resulting in more of a reduction in long-term average blood glucose levels using a measure called glycated haemoglobin, also known as HbA1c, than SMBG. On average, CGM resulted in a reduction in HbA1c that was around 0.3% more than SMBG, which the application stated was clinically meaningful. However, MSAC noted that a difference in reduction in HbA1c of 0.5% has previously been accepted as the smallest difference needed to show better clinical outcomes by international committees that evaluate medicines and medical services and by diabetes organisations. The follow-up time in the studies was also relatively short (1 year or less), so MSAC considered that the long-term benefits of CGM were not shown in these studies. MSAC noted that there is a large group of people with type 2 diabetes, with a wide range of different backgrounds and clinical needs, and therefore that it was not likely the effects of CGM would be the same for everyone with type 2 diabetes. MSAC also noted that sometimes CGM is used intermittently rather than continuously, to achieve better glucose control, and then check that control has been obtained. MSAC also noted that the estimated financial impact to the NDSS of funding CGM for everyone with type 2 diabetes was very large, which MSAC considered may not be reasonable for a technology that has not been demonstrated to have significant clinical benefit. MSAC also identified some problems with the economic modelling used to assess the costs and benefits to the health system of funding this technology, which meant that its cost effectiveness was uncertain. However, MSAC considered that CGM could be particularly beneficial for some groups of people with type 2 diabetes and at certain times. Such groups could include First Nations people, who may particularly benefit from this intervention and for whom finger prick testing may not be culturally appropriate; people who have a disability that increases the burden of finger prick testing on carers or on themselves; and people with baseline HbA1c levels over 8%. MSAC also considered that it may be most beneficial and cost-effective to fund CGM for shorter periods rather than continuously. More evidence is needed to determine whether CGM is especially useful in these circumstances. For people with gestational diabetes and other conditions similar to type 1 diabetes, MSAC noted that evidence was limited because these types of diabetes are less common. However, MSAC felt that these were small, but important, subgroups who would most likely benefit from CGM.

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MSAC advised that, if CGM is funded for any of the identified populations in the future, the funding arrangements should match those in place for type 1 diabetes, to ensure that public funding of CGM is equitable. **MSAC's advice to the Commonwealth Minister for Health, Disability and Ageing** MSAC deferred its decision on public funding for this application, with a mind to support a resubmission if the applicant addresses the issues raised by MSAC. MSAC requested that more work is done to clearly identify the subgroups of people with type 2 diabetes who would gain the most benefit from CGM, and to fix problems with the economic model to ensure its results are reliable.

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

MSAC noted that this application was from Abbott Australasia Pty Ltd requesting National Diabetes Services Scheme (NDSS) funding of the FreeStyle Libre 2 (FSL2) and FSL2 Plus continuous glucose monitoring (CGM) system for people with type 2 diabetes (T2D) requiring treatment with insulin (PICO set 1), pregnant women with gestational diabetes (PICO set 2), and all people aged ≥21 years with other conditions similar to type 1 diabetes (T1D) requiring insulin, including type 3c diabetes (T3cD) (PICO set 3). MSAC noted that the proposed NDSS eligibility criteria for FLS2 for PICO set 2 (pregnant women with gestational diabetes) did not specify that this population needed to be using insulin.

MSAC noted the recommendations from the Royal Australian College of General Practitioners (RACGP) regarding when blood glucose levels (BGLs) should be actively checked. BGL checking is usually conducted using self-monitoring of blood glucose (SMBG) via finger prick testing. MSAC noted that the number of times per day a patient needs to check their BGL varies widely and depends on the context. MSAC noted that people on long-acting once daily insulin generally need to check their blood glucose only once a day (in the morning), except for during times of illness, dosage adjustment or if they are on other medications that cause hypoglycaemia (such as sulfonylureas which is now rarely used). People on both short- and long-acting insulin may need to check their blood glucose more often.

CGM systems are designed to replace SMBG. MSAC noted that the FSL2 CGM system uses a sensor to measure glucose concentrations in interstitial fluid, then reports the measurements in real time via a Bluetooth-enabled display device. The system issues alerts for readings indicative of hypo- and hyperglycaemia to aid timely blood glucose management. Patients using FSL2 or FSL2 Plus only require finger prick testing if the system fails to give a reading or if a reading is inconsistent with their symptoms.

MSAC noted the history of funding under the NDSS for people with type 1 diabetes mellitus (T1D) in Australia. Funding was initially made available to people with T1D aged under 21 in April 2017, with access further expanded in 2019 and in 2022. For some groups, there is a co-payment (equivalent to around $35.90 per month). MSAC noted that NDSS funding is not currently available for CGM for people with T2D.

MSAC noted that the NDSS currently funds CGM products from 3 manufacturers, 2 of which have submitted applications for consideration at the July 2025 meeting. MSAC Application 1785 seeks funding for the Dexcom ONE+ CGM system.

MSAC noted the similarities and differences between this application and Application 1785. Both applications requested funding for CGM systems in patients with T2D who use insulin, and specific subpopulations of these patients. The subpopulations in this application are people using intensive insulin therapy (IIT; defined as multiple daily insulin injections or continuous subcutaneous insulin infusion) users and people using non-IIT. In application 1785, the subpopulations are also IIT and non-IIT users, although the definition of IIT differs (treatment with basal insulin and rapid-acting insulin). Application 1785 was restricted to people with T2D and did not include the additional populations defined in PICO sets 2 and 3 of this application. The primary outcome in both applications was change in glycated haemoglobin (HbA1c).

MSAC recalled its previous review of CGM products provided via the NDSS for people with T1D in 2021 (MSAC Review 1663). MSAC recalled it considered further work was required to define the patient populations that would benefit most from CGM, noting that available guidelines recommend CGM for all people with T1D treated with multiple daily insulin injections. MSAC recalled the review concluded that based on the available evidence, CGM is likely no different to SMBG in terms of HbA1c change and safety for most patients. MSAC recalled the review's conclusion that the economic model failed to provide a reliable basis for estimating the cost-effectiveness of CGM compared to SMBG and failed to adequately capture the range of clinical and quality of life (QoL) benefits that CGM devices could potentially offer. The review recommended that the primary outcomes modelled should also include avoidance of hypoglycaemic events, time in optimal glycaemic range and QoL measures. In the review, MSAC further noted the lack of evidence available to suggest a significant difference in clinical outcomes between CGM devices and considered the revised economic model should be device agnostic.

The applicant was granted a hearing at the MSAC meeting. The applicant's clinical expert noted that a reduction in HbA1c of 0.3% as shown in the data supporting the application may appear modest, but claimed that any reduction in HbA1c is clinically meaningful as it reduces the risk of microvascular complications over time. They also noted that many patients prefer CGM to SMBG using a finger-prick sample, and the usage rate of the CGM device is high, including in patients in remote First Nations communities. The expert noted that several CGM devices are available, but that there is currently inequity in accessing CGM in Australia, because it is subsidised for T1D via the NDSS but not for T2D or other types of diabetes, which means that people with T2D can only access the technology if they can afford the associated costs. The applicant's representative stated the value of CGM is in improving glycaemic control and reducing the incidence of hyperglycaemic and hypoglycaemic episodes. The applicant's representative emphasised patient preference for CGM over SMBG. MSAC noted that PICO set 1 (people with T2D who require insulin) is a broad group and queried whether there may be differential impacts in different subpopulations; however, the applicant's clinical expert noted there were HbA1c reductions across the board in this group.

MSAC noted the large number of consultation inputs received for this application, with a total of 2,270 inputs from consumers, health professionals and organisations. MSAC acknowledged the effort that people had gone to in sharing their experiences. MSAC noted that consultation inputs from patients who have experience with CGM indicate a clear patient preference for CGM in place of SMBG, which can lead to increased compliance and device use. Inputs noted the reduced risk of hypoglycaemic episodes with CGM, leading to peace of mind, and particular benefits for people with disability and their carers. MSAC also noted the high importance of patient education and empowerment of patients using CGM, which can support behaviour change and improved self-management. Consultation inputs identified CGM as particularly beneficial for First Nations people, where SMBG can be seen as culturally unacceptable and can be associated with shame.

MSAC noted that people with T2D are a very heterogeneous population. Ideal HbA1c targets will vary among individuals based on their age, risk factors, comorbidities, life goals and other personal contextual factors.

MSAC noted that the comparator in each of the 3 PICO sets was SMBG using a finger-prick capillary blood sample, glucose test strips and a glucose meter, and considered this to be appropriate.

MSAC noted that the evidence base presented in the applicant-developed assessment report (ADAR), which comprised 3 randomised controlled trials (RCTs) and 2 cohort studies for PICO set 1, and 5 observational studies each for PICO sets 2 and 3. MSAC noted that the evidence presented was from older versions of the FreeStyle Libre device, which MSAC did not consider to be of concern, noting that version updates would be unlikely to impact overall functionality and clinical benefit. MSAC considered that the studies for all PICO sets involved small patient numbers (considering the size of the population with diabetes) and short timeframes. MSAC further noted that the trials did not report end organ outcomes. MSAC noted that there were no Australian studies included in the evidence for PICO set 1 and all the patients in the included studies were adult patients. MSAC considered that the evidence for PICO sets 2 and 3 was low quality with high risk of bias, but acknowledged that RCTs would be difficult to conduct in these groups.

MSAC noted that the clinical claim was non-inferior safety and superior effectiveness compared with SMBG. MSAC considered that the evidence base was weak, although adverse events and safety issues were minor. MSAC agreed with ESC that the claim of noninferior safety was not well supported directly by the evidence, but was, on balance, appropriate.

MSAC noted that comparative effectiveness for PICO set 1 was primarily based on changes in HbA1c. MSAC noted that the difference in reduction of HbA1c between CGM and SMBG associated with FSL was 0.29% based on a meta-analysis of comparative studies. In the ADAR, a 0.3% reduction was selected as the MCID for change in HbA1c, and therefore the demonstrated change was argued to demonstrate superior effectiveness. MSAC agreed with ESC's observation that this threshold is lower than the MCID of 0.5% for superiority that has previously been used by the Pharmaceutical Benefits Advisory Committee (PBAC). The International Diabetes Federation[1], England's National Institute for Health and Care Excellence[2,3], the Australian Diabetes Society[4] and the Royal Australian College of General Practitioners[5] have also nominated 0.5% as the MCID for HbA1c.The European Medicines Agency[6] guidance supports the use of a 0.3% HbA1c to establish non-inferiority. MSAC noted the applicant's pre-MSAC response and the expert opinion provided in the applicant's hearing, which restated that any reduction in HbA1c has beneficial outcomes. MSAC noted that the pre-MSAC response also argued that the clinical evidence presented does not show a singular change in HBA1c of 0.3% but rather a range

[1] International Diabetes Federation. Recommendations for managing type 2 diabetes in primary care, 2017. www.idf.org/managing-type2-diabetes

[2] National Institute for Health and Care Excellence (NICE). Type 2 diabetes in adults: management (NICE guideline). [NG28]. London: NICE; 2015.

[3] National Institute for Health and Care Excellence (NICE) Surveillance of diabetes (type 1 and type 2) in children and young people: diagnosis and management [NG18]. London: NICE; 2022.

[4] https://treatment.diabetessociety.com.au/plan/

[5] The Royal Australian College of General Practitioners. Management of type 2 diabetes: a handbook for general practice. East Melbourne, Vic: RACGP, 2020.

[6] European Medicines Agency (2023). Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus. CPMP/EWP/1080/00 Rev.2. https://www.ema.europa.eu/en/clinical-investigation-medicinal-products-treatment-or-prevention-diabetes-mellitus-scientific-guideline

of 0.3-0.73% if single-arm studies based on real world evidence (RWE) are included. However, MSAC considered the meta-analysis to be the most appropriate evidence given the high risk of bias associated with the single-arm studies. MSAC agreed with ESC that stronger evidence would be needed to accept a MCID of 0.3% for a superiority claim. MSAC noted ESC advice that Appendix 12 of the MSAC Guidelines outlines an approach to establishing an alternative MCID (p 296) using a meta-regression of randomised trials (in this case of any intervention in T2D) comparing the observed treatment effect on the proposed surrogate measure (in this case HbA1c within the first 12 months) with the observed treatment effect on the target patient-relevant clinical outcome (in this case any one or more of the modelled diabetes complications over subsequent years).

MSAC considered that if the claim of superior effectiveness could not be established based on HbA1c change alone, other data would be required, including quality of life (QoL). MSAC noted that patient-related outcomes reported in the ADAR evidence base were indicative of benefits but were variable among the studies listed. MSAC considered that CGM has other benefits for patients and T2D management. This includes empowering patient to manage their T2D and manage blood sugar levels during times of acute illness as well as avoid hypoglycaemia, particularly nocturnal. MSAC considered CGM could improve quality of life and this was reflected in strong consumer support for public funding.

MSAC agreed with ESC that evidence to support the clinical claim of superior effectiveness for PICO sets 2 and 3 was very limited. However, MSAC considered that these were small but important subgroups for which there was potential for improved clinical outcomes using CGM.

MSAC noted the differing approaches to economic evaluation used for each PICO set. PICO set 1 used a cost-utility analysis (CUA), PICO set 2 used a cost-consequence analysis (CCA), and there were insufficient data for economic modelling for PICO set 3.

MSAC noted that the pre-MSAC response had only partially addressed the concerns raised by ESC about the economic model used for the CUA. MSAC considered that the pre-MSAC response did clarify that the RECODe risk equations were validated to capture incremental effects across interventions as part of an external validation study. However, the pre-MSAC response did not address the concern that the equations were not up to date. 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.

MSAC noted that the pre-MSAC response had reported that if the only benefit assigned to CGM was due to a utility improvement from avoiding finger-pricking, this would yield an ICER of $35,000 to < $45,000 per quality-adjusted life year (QALY). The pre-MSAC response suggested that this showed CGM was cost effective even if HbA1C reductions were ignored. However, the 0.03 disutility applied to finger-pricking was from Matza et al. (2017) which had not been included in the ADAR clinical evidence base and which had derived this value from differences in utilities elicited from members of the general public for sensor-based glucose monitoring and SMBG. MSAC questioned the applicability of the population in Matza et al (2017), which comprised 209 participants from the UK general population, to the proposed Australian population of people living with diabetes, and the inferential method used to obtain the difference between the derived utilities for sensor-based glucose monitoring and conventional glucose monitoring to estimate the 0.03 disutility. However, MSAC accepted that SMBG is associated with some level of disutility, as many patients avoid finger-pricking. MSAC also considered that the level of disutility would vary depending on the person's individual circumstances; that is, it would be context dependent, rather than associated with particular demographic groups.

MSAC noted that the CCA for PICO set 2 concluded that CGM would be cost saving compared to SMBG for gestational diabetes. MSAC noted that this did not include consideration of hyper- or hypoglycaemia and that all cost-effectiveness came from reduction in macrosomia of the infants of people with gestational diabetes. MSAC considered this a crude measure but acknowledged that people with gestational diabetes is an important group and that considering the health of affected infants was critical. MSAC noted the financial and budgetary impacts.

MSAC noted uncertainty in the size of the eligible patient population – this application estimated the eligible population for PICO set 1 (intensive insulin users) to be 33,361 patients. MSAC noted the differences in estimates between this application and Application 1785 which need to be resolved (although noting the differences were partly based on different definitions of the IIT population). MSAC also considered that uptake had likely been underestimated, with the ADAR proposing uptake of REDACTED% in year 1 and rising to REDACTED% in year 6 for PICO set 1. MSAC noted that even accepting these estimates at face value, the overall budget impact was high due to the large size of the eligible patient population in PICO set 1 and the lifelong time horizon of device use.

MSAC considered the evidence presented in this application, and that of application 1786, and considered that there was likely no difference between the FSL and Dexcom devices in terms of clinical effectiveness. On balance, MSAC agreed with ESC that there is likely to be some degree of class effect with this technology when CGM systems have similar features and functionality but that further consideration should be given as to whether devices with specific features should be considered equivalent.

Given that the outcomes for the Dexcom ONE+ and FSL CGM systems were judged to be comparable, MSAC considered that price is the main difference between the 2 applications. MSAC agreed with ESC that either a price premium or price competition approach would be appropriate. REDACTED.

MSAC noted the current equity issues with funding, in that T1D patients can currently access CGM through the NDSS, with some patients making a co-payment. MSAC advised that any funding for CGM for T2D patients should match the funding model for T1D patients.

MSAC noted that most patients with T2D are managed in a general practitioner (GP) setting, but GPs are not currently included in the set of health professionals who can certify eligibility for CGM products through the NDSS. MSAC considered that the insufficient numbers of endocrinologists and diabetes educators (who are currently able to certify eligibility for CGM products) would create bottlenecks if CGM devices are funded for people with T2D. MSAC considered that allowing GPs to approve CGM for both T1D and T2D (if funded), with guidance, would be appropriate. MSAC noted that consumer feedback also supports an extended role for GPs. MSAC noted that the RACGP does not support mandating GPs to complete additional education before they are able to sign CGM application forms. MSAC considered that changes to the NDSS IT system may also be needed to ensure access to CGM products is limited to those who are in cohorts that have newly received access.

Overall, MSAC considered the PICO set 1 population proposed in this application is very broad and heterogeneous and that the evidence presented is not sufficient to fully support a claim of superior clinical effectiveness. The reduction in HbA1c reported from the evidence base was lower than the level considered to be a meaningful improvement by the PBAC and regulatory agencies. The economic model presented for PICO set 1 included outdated risk equations and generated implausible results.

MSAC considered that CGM may be more clinically effective and cost-effective for some of subpopulations and this should be further considered. MSAC therefore deferred its advice on

public funding of the FSL2 and FSL2 Plus CGM system until these issues are adequately addressed.

MSAC considered that certain subpopulations are likely to have greater clinical need, derive more clinical benefit and/or show greater QoL improvements if they use a CGM device, although further evidence that is more up-to-date and specific to these groups is required.

MSAC therefore considered that a resubmission may wish to consider the clinical evidence for these and other subpopulations with T2D to evaluate whether CGM would be better targeted to these subpopulations. These subpopulations could include

- people using insulin with higher baseline levels of glycated haemoglobin (e.g. > 8% and >9%)
- First Nations people (e.g. with baseline HbA1c >7%)
- people who use both long acting and short acting insulin
- people with disability (including mental health issues and neurodivergence) for which checking BGLs creates a high burden on the individual and/or carer.

For example, MSAC noted that finger prick testing does not constitute culturally respectful care in many First Nations communities due to the shame and stigma surrounding this testing method. Additionally, First Nations people typically have worse diabetes outcomes, and therefore may derive more benefit from CGM. MSAC noted that CGM systems may be especially useful for First Nations community members, and considered that funding access to the technology will be beneficial in closing the gap. MSAC also noted that based on consultation inputs, CGM may also have increased utility in the case of people living with conditions such as depression, attention-deficit/hyperactivity disorder (ADHD) and neuropathy, and that these people may not have been captured in the clinical trials. MSAC also noted anecdotal evidence that CGM systems may be useful on a temporary basis for people on long-acting insulin in periods of illness or when hypoglycaemic events are suspected.

MSAC considered the following groups with T2D may benefit from short-term or intermittent CGM, although as for the more targeted subpopulations, 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 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.

MSAC advised that, if the applicant maintains a claim of clinical superiority, a resubmission would need to demonstrate superior effectiveness based on the MCID threshold of 0.5% (unless an alternative threshold could be justified as per the section of the MSAC Guidelines previously cited).

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.

MSAC advised that a resubmission should present a revised economic evaluation focussed on the populations with a higher clinical need and addresses the issues in the model. MSAC also considered revised estimates of utilisation would be required to more accurately estimate the size of the subpopulations. MSAC advised that the resubmission would need to be considered by ESC in addition to MSAC.

MSAC also deferred its advice on public funding for PICO sets 2 and 3. While acknowledging the uncertainties in the data for these populations, MSAC noted that the populations are small and have a high clinical need, and that robust data are unlikely to be generated to strengthen the evidence base. MSAC noted that access to CGM for people with the conditions defined in PICO set 3 is already funded for those under 21 years of age, while access to CGM for PICO set 2 will only be for months rather than years.

MSAC advised that if CGM for any of the identified populations is supported in future, co-payment arrangements for these populations should align with existing co-payments for people with type 1 diabetes, to ensure equity of access. MSAC considered that, based on the evidence presented, different CGM systems with similar features were likely to be equivalent and did not yield differences in magnitude or type of benefit. MSAC therefore considered it appropriate to fund different brands of CGM systems with comparable functionality in a device agnostic manner, but noted that further consideration should be given as to whether devices with specific features should be considered equivalent.

4. Background

The Medical Services Advisory Committee (MSAC) has not previously considered CGM systems for people with T2D requiring insulin, pregnant women with GDM, or people aged ≥21 years with conditions similar to type 1 diabetes which require insulin (e.g. T3cD). In addition to the application discussed in this commentary, an MSAC application for the Dexcom ONE+ CGM system for people with T2D requiring insulin is currently under consideration (MSAC Application 1785).

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

5. Prerequisites to implementation of any funding advice

The FSL2 is listed as a medical device on the Australian Register of Therapeutic Goods (ARTG) under a single item for an invasive interstitial-fluid glucose monitoring system. Table 1 provides details of the Therapeutic Goods Administration status from the ARTG for the invasive interstitial-fluid glucose monitoring system. No prerequisites for FSL2 were stated by the applicant. As noted, the applicant expanded the PICO to include the FSL2 Plus. As of 1 April 2025, the FSL2 Plus is subsidised through the NDSS for all people with T1D and for some people under the age of 21 with rare conditions similar to T1D. The assessment group assumed that FSL2 Plus will be covered by the same ARTG item. FSL2 and FSL2 Plus will henceforth be referred to as 'FSL products'.

Table 1 FreeStyle Libre 2 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.

Abbreviations
ARTG = Australian Register of Therapeutic Goods, **GMDN** = Global Medical Device Nomenclature.
Source
ARTG Public Summary documents. Verified by assessment group on 10 March 2025.

6. Proposal for public funding

The applicant-developed assessment report (ADAR) for FSL2 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).

The applicant proposed that the technology is publicly funded through the NDSS (i.e. no Medicare Benefits Schedule listing required). The proposed populations for NDSS funding of FSL2 products are narrower than the indication in the ARTG listing. Currently, subsidised CGM products are only available through the NDSS for people with T1D and some people <21 years with other rare conditions similar to T1D. The FSL2 sensor is currently available through the NDSS for these populations. At the time of writing, the FSL2 (available via the NDSS) has no connectivity to insulin pumps. However, the FSL2 Plus (pump connectivity provided) is subsidised through the NDSS for all people with T1D and some people under the age of 21 with rare conditions similar to T1D.

Expanding subsidised access to real-time CGM (RT-CGM) technology aligns with recent recommendations from the 2024 Parliamentary Inquiry into Diabetes in Australia,[7] which advocates equitable access to advanced diabetes technologies for all individuals requiring insulin: *'The Committee recommends that subsidised access to Continuous Glucose Monitors (CGMs) be further expanded. In the first instance, all access limitations in relation to patients with Type 1 diabetes should be removed. Furthermore, individuals with insulin-dependent Type 3c diabetes and patients with gestational diabetes should be made eligible for subsidised CGMs and for those with Type 2 diabetes requiring regular insulin. The Committee recommends prioritising the removal of age limitations on access to subsidised access for Type 1 diabetes patients'* (Recommendation 15, Diabetes Inquiry).

FSL CGM products are sensor-based, factory-calibrated monitoring systems with two key components: a disposable 14-day (FSL2) or 15-day (FSL2 Plus) sensor and a reader (either a smartphone application or a physical reader). The products are designed to continuously measure glucose levels in the interstitial fluid and provide glucose trends, variability and patterns across a 24-hour period.

[7] Diabetes Inquiry. 2024. [Online]. Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Inquiry_into_Diabetes/Report [Accessed 23 April 2025]

Key features of FSL2 and FSL2 Plus include:

- A discrete sensor inserted into the subcutaneous tissue at the back of the upper arm providing 1,440 minute-by-minute glucose readings every day.
- An inbuilt transmitter that transmits glucose data continuously to the application or scanned by the reader over 14 or 15 days (the applicant stated that a 1-second scan of the sensor yields an 8-hour glucose profile and the overall glucose trend).
- Additional alarms that can warn of upcoming episodes of high or low glucose levels.
- Two mobile medical applications: FreeStyle LibreLink to read glucose levels and LibreLinkUp to enable authorised caregivers to remotely receive alarms and glucose data. Application data are automatically uploaded to LibreView, allowing users and healthcare professionals to see the full glycaemic picture, including the ambulatory glucose profile showing a person's hypo- and hyperglycaemic trends. These applications allow patients to access their data.

The FSL2 system has some limitations regarding use. Currently, it is incompatible with automated insulin dosing systems, including closed-loop and insulin-suspend systems. When launched (estimated date end of March 2025), the FSL2 Plus can be used with the Omnipod 5 insulin pump. The sensor must be removed before magnetic resonance imaging, computed tomography and some airport body scanning systems. It is necessary to apply a new sensor and allow it to proceed through the 1-hour warm-up period before CGM readings are available for use. Taking ascorbic acid (vitamin C) supplements above therapeutic recommended dosages (>500 mg per day for FSL2 and 1000 mg per day for FSL2 Plus) while wearing the FSL2 sensor may falsely raise sensor glucose readings. Furthermore, the LibreView website is only compatible with certain computer operating systems and internet browsers, and LibreLinkUp is only compatible with certain mobile devices and operating systems.

The ADAR reported that, compared with the FSL2, the FSL2 Plus has an extended wear duration from 14 to 15 days, an accuracy improvement from 9.2% to 8.2% mean absolute relative difference[8], partnership with both the Omnipod 5 system and NovoPen 6[9], and expanded use from 4 years of age to 2 years of age.

The ADAR noted that patients in the existing and proposed treatment pathways will be managed in very similar ways, with FSL2 replacing self-monitoring of blood glucose (SMBG) in the proposed clinical management algorithm. The NDSS currently allows prescription of FSL2 in T1D by certified diabetes educators, nurse practitioners, physicians and paediatricians, but not by general practitioners or practice nurses. The FSL2 system is intended for use at home or in a residential aged care facility (i.e. a non-clinical setting) with assistance from a carer or parent if necessary.

Currently, FSL products are self-funded for populations in PICO Set 1, 2 and 3. For T1D, FSL2 is subsidised through the NDSS; it is 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

[8] The mean absolute relative difference measures average difference between the FSL measurement and the reference measurement at normal to high glucose levels. It is a measure of accuracy, indicating how close the sensor readings are to actual blood glucose levels.

[9] The Omnipod 5 system is a tubeless, hybrid closed-loop insulin delivery system that integrates with the FSL2 Plus sensor. The NovoPen 6 is a smart insulin pen that automatically records insulin dosing information for each injection.

>21 years without a concession card (copayment of $16.20 per FSL2 sensor as of 1 January 2025).

The population eligible to access FSL products proposed in the ADAR is: “people with T2D requiring insulin or women with GDM or people with other types of diabetes including T3cD or conditions similar to T1D that are over the age of 21”.

The ADAR estimated that an average of 26.07 FSL2 sensors and 24.35 FSL2 Plus sensors would be required per year if 100% of the population was fully adherent/compliant. This was rounded down to assume 24 sensors per year (2 per month). This indirectly assumed adherence/compliance of 92% for FSL and 99% for FSL 2 Plus. The applicant used anecdotal evidence and comparisons to self-reported medication studies to state that 100% adherence/compliance was unrealistic, and the overall cost estimate was conservative.

The annual cost for FSL (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 $REDACTED for NDSS distribution) and 24 sensors per year. With the evidence available, 2 sensors per month appears to be an appropriate estimate.

The ADAR noted that ‘this MSAC application does not constitute any form of price offer to the Commonwealth Government by Abbott.’

7. Population

Three PICO sets were defined for the FSL products: one for people with T2D requiring insulin (PICO Set 1; Table 2), one for people with diabetes mellitus (PICO Set 2; Table 3), and one for people with other conditions similar to type 1 diabetes requiring insulin, including T3cD (PICO Set 3; Table 4). PICO Set 1 (T2D) also includes a dedicated subpopulation for people requiring intensive insulin therapy (IIT), defined as requiring ‘multiple daily insulin injections or continuous subcutaneous insulin infusion who are recommended to carry out frequent monitoring of their blood glucose.’

The PICO sets presented in the ADAR were relatively closely aligned with those in the ratified PICO confirmation. [10] However, several outcomes were not included where data were unavailable. Outcomes listed in the ratified PICO that were not included in this ADAR include psychological health, monitoring (CGM or SMBG) failure rate, self-efficacy and any outcomes related to change in management. As noted previously, the applicant also added the newer FSL2 Plus version of the CGM system to the PICO, which was not included in the ratified PICO.

In all 3 PICO sets, FSL CGM products are intended to displace (replace) SMBG in the monitoring of glucose levels. However, people using FSL may still need to perform SMBG in certain scenarios (e.g. where their diabetes symptoms do not match the FSL readings). This level of detail is acknowledged in the clinical management guidelines for PICO Set 2 (GDM) and Set 3 (other conditions similar to T1D requiring insulin) but is absent from PICO Set 1 (T2D requiring insulin).

[10] MSAC Application 1786: PICO Confirmation. 2024. [Online]. Available at: https://www.msac.gov.au/sites/default/files/2025-02/1786_final_ratified_pico_-_redacted_0.pdf [Accessed 23 April 2025]

Table 2 PICO Set 1 criteria for assessing FSL products for improving glycaemic outcomes in 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 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?

Abbreviations
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; **TIR** = time in range; **TBR** = time below range, **TAR** = time above 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 3 PICO Set 2 criteria for assessing FSL products for improving glycaemic outcomes in people 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?

Abbreviations
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; **TIR** = time in range; **TBR** = time below range, **TAR** = time above 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 3 criteria for assessing FSL products for improving glycaemic outcomes in people with other conditions similar to T1D requiring insulin including 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 o HbA1c o TIR, TBR, TAR ~~o number of hypoglycaemic/hyperglycaemic excursions~~ o 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)?

Abbreviations

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, **TIR** = time in range; **TBR** = time below range, **TAR** = time above 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 phrasing of the nominated comparator in each PICO varied slightly. The comparator listed in ADAR PICO Set 1 was phrased as 'SMBG with glucose monitoring test strips', whereas the comparator listed in the ratified PICO Set 1 was phrased as 'SMBG test using a finger prick blood sample'. The comparator listed for PICO Set 2 and Set 3 is more detailed: 'SMBG using a finger prick capillary blood sample, glucose test strips and a glucose meter.' It is unclear why the comparator wording varied between PICO sets; however, it is likely that this is due to an error during the drafting process and not due to actual differences in comparators. Generally, SMBG is a suitable comparator for all PICOs because it is the standard of care for blood glucose testing across the proposed populations and no other CGM systems are currently subsidised through the NDSS for these populations (although Dexcom ONE+ is currently being assessed through ADAR 1785).

Australian Diabetes Clinical Quality Registry data from 2023 indicated that 84.1% of people with T2D perform regular blood glucose monitoring, with 78.7% of these using finger prick blood samples.[11] The frequency of SMBG is individualised. However, the ADAR noted that once a patient is prescribed insulin (regardless of diabetes type), they are advised to check blood glucose levels using SMBG at least before breakfast, before lunch/dinner, 2 hours after a meal, before bed and before driving/exercising: a minimum of 4 times per day.[12] The ADAR stated that a recent survey of Australia's leading diabetes health professionals reported that Australian patients currently use SMBG testing on average 2.2 times per day and up to 10 times per day (although no reference for this was provided). The 2025 American Diabetes Association guidelines[13] state that 'many individuals' on IIT require SMBG testing 6 to 10 times per day.

The assessment group noted that 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 be sufficient to carry out SMBG only 5 times per day. 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 information was not included in the ADAR.

[11] Australian Diabetes Clinical Quality Registry. Annual Report 2024. [Online]. Available at: https://www.monash.edu/__data/assets/pdf_file/0016/3920002/adcqr-2024-annual-report.pdf

[12] National Diabetes Services Scheme. 2021. Fact sheet: Blood glucose monitoring. [Online]. Available at: https://www.ndss.com.au/wp-content/uploads/fact-sheets/fact-sheet-blood-glucose-monitoring.pdf

[13] American Diabetes Association Professional Practice Committee. 5. Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes: Standards of Care in Diabetes-2025. Diabetes Care. 2025 Jan 1;48(Supplement_1):S86-S127. doi: 10.2337/dc25-S005. Erratum in: Diabetes Care. 2025 Jan 23:dc25er04a. doi: 10.2337/dc25-er04a. PMID: 39651983; PMCID: PMC11635047.

9. Summary of public consultation input

Consultation input was welcomed from:

1786 – FreeStyle Libre 2 continuous glucose monitoring system for people with insulin dependent type 2 diabetes, gestational diabetes and type 3c diabetes (Abbott Australasia Pty Ltd)	No. of Inputs Received
Organisations (23)	
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.	9
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.	14
Health Professionals (66)	
I am a health professional or health academic working in the area.	66
Consumers (2,181)	
I have the health condition that this health service or technology is for.	677
I have the health condition that this health service or technology is for and have experience with the proposed health service or technology.	1370
I am a parent, partner or another person caring for someone from the above two groups.	98
I am an interested individual who does not fall into any of the above categories.	36
Grand Total	**2270**

The organisations that submitted input were:

- Australia and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZPED)
- Australian Diabetes Society (2)
- Medtronic Australasia (2)
- Primary Care Diabetes Society of Australia
- Pharmaceutical Society of Australia
- Royal Australian College of General Practice (RACGP)
- NeuroEndocrine Cancer Australia
- Rumbalara Aboriginal Cooperative (2)
- Western Sydney Diabetes (2)
- Pancare Foundation
- Mito Foundation
- Australian Centre for Accelerating Diabetes Innovations
- Diabetes Victoria
- Roche Diagnostics Australia
- Diabetes Alliance
- Rare Cancers Australia
- Diabetes WA
- CF Together
- Spanish Speaking Diabetes and Heart Association of Australia

Level of support for public funding

There was strong support for public funding, with >96 per cent of consumers and >90 per cent of health professionals answering 'support' to the question 'Do you support public funding for the health service or technology, as it is proposed to be delivered.' Of those who answered, 'do not support' or 'unsure', many indicated support for continuous glucose monitoring (CGM) elsewhere in their comments but raised concerns about the population or implementation (see below).

Some consumers who had experience with CGM described it as life changing. Health professionals described CGM as revolutionising diabetes care.

Medtronic Australasia were of the view that MSAC should take a device-agnostic approach to evaluating CGMs, with specific devices considered through the NDSS. They asserted that if MSAC establishes the precedent of evaluation by device type for CGM, this will result in multiple brand-specific assessments for the same therapy, increasing MSAC costs and workload. Roche Diagnostics Australia also urged MSAC to clarify as part of its advice to the Minister whether MSAC assessment of other CGM will be required to enable inclusion on the NDSS and if so, under what circumstances.

Comments on PICO

- Respondents agreed with the comparator and outcomes but raised concerns regarding the proposed population.
- Numerous respondents indicated they would like to see the proposed populations expanded to other groups. This included all diabetics on insulin, regardless of the type of diabetes, and groups with non-insulin dependent diabetes who are at high risk of poor health outcomes. Suggestions included:
    - first nations peoples. For example, the Rumbalara Aboriginal Cooperative - Health and Wellbeing Clinic reported improvements in diabetes management during a community trial of CGM. It noted that Aboriginal and Torres Strait Islander communities are at a disproportionate risk of developing cardiovascular and renal diseases if diabetes management is not optimised. In their view, subsidised access to CGM is without a doubt the key to preventing cardiovascular and renal diseases.
    - people with disabilities, including intellectual disability, dementia, vision impairment and dexterity issues which may make finger prick monitoring difficult
    - T2DM on medications that increase risk of hypoglycaemia
    - older Australians with diabetes living in residential aged care facilities or alone (who are at increased risk of hospitalisation)
    - people undergoing cancer treatment who have comorbid diabetes and are at high risk of morbidity and mortality. NeuroEndocrine Cancer Australia (NECA) was highly supportive of subsidised access to CGM for individuals with insulin-dependent type 3c diabetes but emphasised that there are individuals within the neuroendocrine cancer population who are not insulin dependent but would greatly benefit from access to CGM. CF Together also advocated for subsidised access to CGM for people with cystic fibrosis and diabetes, regardless of insulin status.
    - adolescents. ANZPED notes that youth-onset type 2 diabetes particularly affects marginalised and socioeconomically vulnerable youth. It has been described as a “severe aggressive phenotype” with more rapid development of complications and reduced treatment response. They argue that use of CGM in this population would help to optimise blood glucose levels, so as to improve their diabetes outcomes and reduce their very high risk of long-term diabetes complications. It would also reduce health system costs in managing complications.
    - other high risk populations, such as homeless people and those living in rural/remote areas who may have limited access to health care services.

- Western Sydney Diabetes recommended an intermittent use model—for example, providing up to 25% annual coverage (equivalent to one sensor every quarter) for patients not on insulin but at high risk or with suboptimal glycaemic control.

Perceived Advantages

- Consumers outlined a range of benefits of CGM, including:
    - Real-time data, providing enhanced awareness of the impact of different foods and exercise on blood glucose levels. Respondents indicated that this allowed them to better manage their diabetes. They reported improved HbA1C results.
    - Reduced finger pricking, which was described as painful/uncomfortable. Some respondents reported scarring from multiple finger pricks, which interfered with some activities.
    - Improved quality of life. Respondents indicated that CGM helped them make informed dietary choices and manage their condition more effectively, leading to fewer health issues and hospital visits.
    - Data sharing with healthcare providers, including remotely, resulting in better management and with family members, providing peace of mind.
    - Increased confidence in their ability to monitor glucose levels and reduced anxiety related to potential hypoglycaemic episodes.
- Health care professionals emphasised the potential for improved patient outcomes through more accurate diagnostics and personalized treatment plans, efficiency gains in healthcare delivery, cost savings by minimizing unnecessary tests and procedures, and the importance of staying ahead in medical advancements to provide the best care possible. All had experience with CGM and reported positive results for patients using CGM, including lower HbA1C results and more 'time in range'.

Perceived Disadvantages

- Despite the numerous perceived benefits, many consumers said they stopped using CGM as they could not afford the monthly cost. Some felt the cost was unreasonably high.
- In addition to cost, other disadvantages mentioned by some respondents included:
    - Concerns about sensor accuracy and reliability
    - Skin irritation caused by the sensor adhesive
    - Accessibility, particularly for some demographic groups. For example, people in rural or remote areas with poor internet connections, and those who are not tech-savvy, cannot afford a smart phone, or have limited access to healthcare services.
    - Burnout from constant monitoring
    - Not suitable for wearers without appropriate technology (e.g., phone receivers)
    - Training requirements for wearers.

Support for Implementation and Issues

- Most health care professionals indicated they would like to see the measure implemented in their practice/area.
- Many respondents highlighted the need for support from diabetes educators and dietitians when using CGM devices. Respondents noted that these professionals are essential for

understanding how to interpret glucose data and make informed lifestyle choices. Several health practitioners and organisations (e.g., the Diabetes Alliance, Diabetes WA) noted the need to increase the number of visits to diabetes educators that attract a rebate per year, noting that the five visits funded under a chronic diseases plan are inadequate, especially if the patient also needs to access other services, such as podiatry.

- Access to GPs and endocrinologists for diabetes management was also seen as important. Respondents indicated that CGM devices should be integrated with professional guidance to maximise benefits and improve overall health outcomes.
- One respondent noted that their public clinics were 'slammed' when CGM was subsidised for T1DM. Staff were overwhelmed with the demand and had to work overtime to cope. They recommended that if the technology is extended to other populations, it be rolled out in stages and consideration should be given to the number of health professionals required for successful implementation. Others, such as Diabetes Victoria, also noted the importance of ensuring that workforce issues are considered as part of implementation.
- The Primary Care Diabetes Society of Australia, noted that access to subsidised CGM requires certification by an endocrinologist/physician and diabetes educators, which is problematic for people living in low socio-economic areas; living in rural and remote Australia; or with significant mental, cognitive, and/or physical disabilities. They recommended that certification be broadened to include GPs, practice nurses, Aboriginal health workers, dietitians, and pharmacists.
- Other respondents also considered the current limited certification requirements as a barrier to access, with a number arguing that GPs should be able to prescribe CGM. The RACGP argued that GPs are a central part of the care team for diabetes, and often the most accessible, and that, as such, GPs should be allowed to provide access to CGM without endocrinologist approval. Removing patients from the GP setting they argue, could impact healthcare economics, patient satisfaction and accessibility, particularly in regional and rural areas with more limited access to endocrinologists and CDEs.

10. Characteristics of the evidence base

The evidence base provided by the ADAR comprised studies demonstrating the direct effects of FSL usage on HBA1c and other glycaemic outcomes. This differs from the linked-evidence approach originally proposed in the PICO, which would have required additional evidence, e.g. on change in patient management.

However, in the ratified PICO, PASC considered that if adequate direct from test to intermediate health outcome evidence was available to support the assessment (where the intermediate health outcome was HbA1c levels) a full linked evidence approach may not be necessary. However, PASC further advised that this would require sufficient evidence linking HbA1c levels (i.e. glycaemic outcomes) to more direct and long-term health outcomes. Although evidence linking glycaemic outcomes to more direct health outcomes is not discussed in the clinical section of the ADAR, the economics section of the ADAR contains a brief discussion of RECODe risk equations on complications of T2D (used in the economic model to correlate HbA1C levels to risk of T2D complications and validated from clinical studies), including some discussion of why it was appropriate to apply to the Australian population.

It should be noted that the intervention reported in all studies is FSL, not FSL2 or FSL2 Plus (the proposed interventions). No concordance studies between FSL/FSL2/FSL2 were reported in the ADAR.

Table 5 Included studies for PICO Set 1 (T2D)

Study ID	Ajjan 2023	Bosi 2022	Haak 2017	Nathanson 2025	Yaron 2019
Number of study participants	36 (FSL) 34 (SMBG)	109 (FSL) 213 (SMBG)	149 (FSL) 75 (SMBG)	Insulin users: 2,876 (MDI) 2,292 (basal) controls: 33,584 (MDI matched) 43,424 (basal matched)	53 (FSL) 48 (SMBG)
Study design	Open-label RCT	Prospective observational cohort study	Open-label RCT	Retrospective cohort with matched controls	Open-label RCT
Risk of bias (ROBINS-1) derived by applicant	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Risk of bias (Cochrane ROB2 for RCTs, ROBINS-I for cohort studies) derived by assessment group	Low risk of bias	Moderate risk of bias	Low risk of bias	Low risk of bias	Moderate risk of bias
Population	Adult UK T2D patients with recent onset MI. Includes an insulin-using subpopulation.	Adult Italian T2D patients using basal-bolus insulin	Adult European T2D patients using insulin (bolus, basal-bolus, CSII)	Adult Swedish patients using insulin (basal or MDI)	Adult Israeli T2D patients using insulin (aged 30 to 80 years).
Intervention	FSL	FSL	FSL	FSL	FSL
Comparator	SMBG	SMBG	SMBG	SMBG	SMBG
Key outcome(s)					
HbA1c mean change from baseline, %	-	√	√	√	√
Hypoglycaemic time / events	√	-	√	√	√
Hyperglycaemic time / events	√	-	√		
Glycaemic variability	-	-	√		
Treatment satisfaction (DTSQ)	-	-	√	-	√
Insulin dose/frequency	√	√	√		√
Oral antidiabetic use	√	-			-
SMBG use	-	-	√		-
Hospital admissions	-	√	-	√	-
Adverse events	√	√	√	-	-
Longest endpoint/follow-up timepoint	3 months	3 to 6 months	6 months	24 months	10 weeks

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring; **CSII** = continuous subcutaneous insulin infusion, **DTSQ** = Diabetes Treatment Satisfaction Questionnaire, **HbA1c** = glycated haemoglobin; **MDI** = multiple daily injections, **MI** = Myocardial Infarction, **SMBG** = self-monitoring of blood glucose; **T2D** = type 2 diabetes; **RCT**= randomised controlled trial.

Methodological considerations

Details of the search process for all 3 PICOS were not clearly reported and do not reflect what would be regarded as a reasonable quality search. During the commentary process, the assessment group noted several reasons for this, including a limited selection of search resources, inadequate reporting of search methods, search terms not including subject headings, use of inappropriate search terms for study design limitations, and no rationale for the language restriction.

The reporting of the systematic review methods was also inadequate. A list of studies excluded at full text (along with reason for exclusion) was not provided in Appendix C of the ADAR. Furthermore, it was unclear how data extraction was undertaken and by whom. Best practice for systematic reviews requires that data extraction forms and procedures be established a priori, regardless of the reviewers' expectations of what the final evidence base will include.

Although comparative evidence from 3 trials and 2 cohort studies was available for PICO Set 1, the applicant's review included a large number of single-arm studies. Several of the single-arm studies were published as abstracts or letters to the editor, with no details about their methods. These types of publications do not undergo the same scrutiny as published full-text papers and are at a higher risk of bias. Given the availability of higher-quality comparative data, the assessment group considered the inclusion of single-arm evidence inappropriate for this ADAR.

Risk of bias – randomised controlled trials

The risk of bias assessment for randomised controlled trials (RCTs) was incorrectly carried out using the Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I) tool, which is designed for the assessment of non-randomised studies. During the commentary process, the assessment group re-conducted the risk-of-bias assessments for the RCTs using the correct Cochrane ROB2 tool. For PICO Set 1, the assessment group identified 2 trials as having a low risk of bias and 1 trial as having a moderate risk of bias (the ADAR assessed all 3 as having a low risk of bias). For PICO Set 2, the assessment group identified 1 trial as having a moderate risk of bias and 1 trial as having serious risk of bias (the ADAR assessed both as having a low risk of bias).

Risk of bias – cohort studies

To conduct risk-of-bias assessments for the cohort studies, the ADAR correctly used the ROBINS-I tool. However, the individual and overall judgements on the ROBINS-I tool were applied incorrectly. For PICO Set 1, one cohort study (Bosi 2022) was described by the ADAR as prospective, while the other (Nathanson 2025) was described as retrospective. Both studies used existing registry or hospital data and, therefore, should have been reported as retrospective. During the commentary process, the assessment group re-conducted the ROBINS-I risk of bias assessment, with one cohort study identified as having a low risk of bias and the other as having a moderate risk of bias (the ADAR had assessed both of these as having a low risk of bias). The assessment group did not re-assess cohort studies for PICO Set 2.

Risk of bias – case-series studies

To conduct risk-of-bias assessments for the case-series studies, the ADAR correctly used the ROBINS-I tool. However, the individual and overall judgements on the ROBINS-I tool were applied incorrectly. During the commentary process, the assessment group re-conducted the ROBINS-I risk of bias assessment for 3 randomly selected case-series studies for PICO Set 1. None of the risk-of-bias assessments conducted by the assessment group matched the conclusions made in the ADAR. In all cases, the ADAR under-estimated the risk of bias. In 2 cases, it was unclear if any decisions were reached because the studies were reported as abstracts only, with no information

about the study methods. The assessment group did not continue to re-assess cohort studies for PICO Set 2 or PICO Set 3.

GRADE

Grading of Recommendations Assessment, Development and Evaluations (GRADE) is a tool used to summarise different aspects of bias and show the overall effect of a body of evidence. The GRADE assessments were incorrectly applied, causing an overestimation of evidence quality, overestimation of the treatment-effect magnitude, and underestimation of the uncertainty. Specifically, the ADAR applied the inconsistency, indirectness and publication bias incorrectly, and imprecision was not addressed.

11. Comparative safety

PICO Set 1

Five studies reported adverse events (AEs). The consistency of reporting was very low. From the evidence presented, some AEs are associated with FLS, including sensor insertion/site reactions such as insertion site bruising, oedema and pain. It is unclear whether this is significantly different from the AEs associated with SMBG because only one trial compared AEs and event rates were low (4% FSL vs 0% SMBG).

In PICO Set 1, the claim for non-inferior safety is unclear due to a lack of data. There are very few studies reporting AE data and, for those that do, the number of patients experiencing these events is very small.

PICO Set 2

One case series study reported AE data. There were no severe or unanticipated AEs. Local, mild AEs were reported in 8 FSL patients (33%) (n=7 pruritus, n=2 erythema, n=1 pain), none of which resulted in withdrawal. As only one case-series study reported safety data for the GDM population, the claim of non-inferior safety is not met for PICO Set 2.

PICO Set 3

No safety outcomes were reported. Therefore, the claim for non-inferior safety in this PICO is not met.

12. Comparative effectiveness

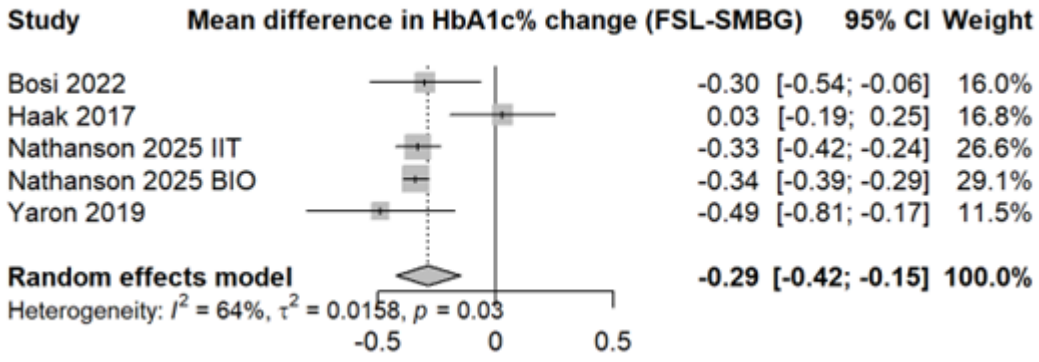
PICO Set 1

Change in HbA1c from baseline

The difference in mean change in HbA1c from baseline is the primary outcome needed to demonstrate glycaemia-lowering efficacy for new diabetes treatments. In the ADAR, the main results for this outcome were based on a meta-analysis conducted by the applicant, which reports the mean difference in HbA1c for studies comparing FSL to SMBG (Figure 1). Although the meta-analysis included data for comparative studies, the weight given to the cohort studies (Bosi 2022, Nathanson 2025) totalled more than 70%. The ADAR claimed that the meta-analysis results met the proposed minimum clinically meaningful difference (MCID) of 0.3% to 0.5%. However, the meta-analysis identified an HbA1c reduction of 0.29%—falling below the 0.3% threshold proposed by the applicant. Moreover, the applicant did not justify using a 0.3% change in HbA1c as the MCID, when 0.5% is the internationally accepted threshold (International

Diabetes Federation,[14] National Institute for Health and Care Excellence (NICE) guidelines for diabetes management in adults[15] and in children and young people,[16] the Australian Diabetes Society,[17] and the Royal Australasian College of General Practitioners[18]). Excluding the cohort studies in a sensitivity analysis results in a smaller HbA1c reduction, further challenging the applicant's claim that FSL products meet the accepted MCID for this outcome.

Figure 1. Meta-analysis of incremental change from baseline in HbA1c (%) for FSL vs SMBG in the comparative studies



Abbreviations
BIO = **Basal insulin only, FSL** = FreeStyle Libre Continuous Glucose Monitoring; **CI** = confidence interval, **IIT** = Intensive insulin therapy (includes all non-basal regimens), **SMBG** = self-monitoring of blood glucose.

During the commentary process, the assessment group suggested that statements surrounding the main evidence should be re-written as follows:

- 'Two RCTs reported change in HbA1c. One showed no significant difference between FSL and SBGM (0.03% (SE 0.11) p=0.82). Although the second trial showed a statistically significant difference, it fell short of a clinically meaningful change at the 0.5% threshold (0.49% (SE 0.16) p<0.0001).'
- 'Two cohort studies reported change in HbA1c. Both reported statistically significant differences but did not show clinically meaningful change at a 0.5% threshold.'

The applicant also conducted a meta-analysis on each arm of the comparative studies, creating a pooled analysis of the FSL arms only (−0.50% change in HbA1c) and of the SMBG arms only (−0.20% change in HbA1c). This was inappropriate because the values were taken from comparative studies with the intention that they are paired. The data for HbA1c change from baseline was then used in the SMBG-arm of the economic model. There was significant heterogeneity (I^2=87%) that was not addressed.

[14] International Diabetes Federation. Recommendations For Managing Type 2 Diabetes In Primary Care, 2017. www.idf.org/managing-type2-diabetes

[15] National Institute for Health and Care Excellence (NICE) . Type 2 diabetes in adults: management Clinical Guideline. [NG28]. London: NICE; 2015.

[16] National Institute for Health and Care Excellence (NICE) Surveillance of diabetes (type 1 and type 2) in children and young people: diagnosis and management [NG18]. London: NICE; 2022

[17] https://treatment.diabetessociety.com.au/plan/

[18] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic: RACGP, 2020.

The ADAR also combined data from the FSL arms of the comparative studies with an additional 15 single-arm studies (19 studies total). This process substantially increased the change in HbA1c from baseline from 0.29% to 0.73%. Significant heterogeneity (I^2=95%) was not addressed, and this was subsequently used in the economic model. The change in HbA1c data that was used for the model was inappropriately derived from the available studies, and the inclusion of lower-quality evidence has inflated the change from baseline for FSL by a notable margin.

Other glycaemic outcomes

Time in hypoglycaemia was measured at <3.9 mmol, <3.1 mmol and <2.5 mmol concentrations, as well as at night- and daytime. At each of these measurements, time in hypoglycaemia was found to be statistically significantly reduced in the FSL group compared with the SMBG group. However, this was the equivalent of 13–28 minutes per day, which the Commentary considered may not be clinically significant. There were no statistically significant differences in time in range (TIR) or time in hyperglycaemia.

Glucose variability was reported by one trial. Thirteen measures were used to measure glucose variability and, of these, 5 reported significant differences in favour of FSL. The remaining 8 measures showed no statistically significant differences between groups.

Treatment satisfaction

Two trials reported treatment satisfaction (Haak 2017 and Yaron 2019). Haak 2017 reported that the Diabetes Treatment Satisfaction Questionnaire (DTSQ) total score showed significant improvement in the FSL group compared with the SMBG group. However, there were no significant differences in how patients scored the perceived frequency of hyperglycaemia (p=0.61) or perceived frequency of hypoglycaemia (p=0.23). The same trial reported outcomes for the Diabetes Quality of Life Instrument, which reports a score comprised of 4 subcomponents. The results for the total score showed no differences between FSL and SMBG (p=0.39). Three of the 4 subcomponents (social worry, p=0.31; diabetes worry, p=0.32; impact of treatment, p=0.68) showed no differences between groups. One subcomponent (satisfaction with treatment) showed a significant improvement in the FSL group (p=0.026). This trial also reported results for the Diabetes Distress Scale, which were omitted in the ADAR. There were no significant differences between groups for total score or any of the 4 subscores (emotional burden, physician distress, regimen distress, interpersonal distress).

The second trial (Yaron 2019) reported no significant differences between groups using the DTSQ.

Change in management

No change in insulin or any other oral diabetic medication was reported in one RCT (Haak 2017) and one cohort study (Bosi 2022). The ADAR omitted data on the frequency of SMBG use reported in 2 trials.

Hospitalisation

Two cohort studies reported this outcome. One study (Bosi 2022) reported that the numbers of emergency department visits, hospital admissions and paramedic callouts were low in each group, with no emergency department visits or hospital admissions for hypoglycaemia reported for either group. A second study (Nathanson 2025) reported that among intensive insulin users, the risk of admissions for severe hypoglycaemia, stroke, non-fatal myocardial infarction or hospitalisation for any reason was statistically significantly lower in the FSL group. Among basal

insulin users, the risk of heart failure or hospitalisation for any reason was statistically significantly lower among FSL patients.

Clinical claim

The applicant claimed that FSL products have superior effectiveness compared with SMBG, as measured by a 0.3–0.5% reduction in change in HbA1c. However, this effectiveness claim is not supported based on the evidence presented: the reduction in HbA1c is only 0.29%.

If MSAC does not accept a 0.3% change in HbA1c as the MCID, then neither a claim of superiority (change in HbA1c of 0.5%) or non-inferiority (change in HbA1c of 0.3%) has met internationally accepted MCID thresholds.

PICO Set 2

The populations reported in the studies for PICO Set 2 appeared to be consistent with the PICO 2 population.

Effectiveness for person with GDM

One RCT (Majewska 2023) reported that there were no differences between FSL and SMBG in mean fasting glycaemia during the first month of the study (p=0.437). Mean postprandial glycaemia during the first month was reported to be significantly lower in the SMBG group (p=0.011). TIR data were collected only in the FSL group, so no comparative data were available for this outcome.

A second RCT (Zhang 2021) reported that the incidence of hypoglycaemic events (blood glucose <3.9 mmol/L) was significantly lower with FSL (5.45% vs 21.82% in control SMBG group, p=0.012). The same trial reported that use of FSL was associated with significantly greater improvements in the management of GDM compared with SMBG, with reported improvements in the regularity of blood glucose monitoring, diet control, weight monitoring, appropriate exercise, regular obstetric checks and adherence with monitoring (all p<0.05 for FSL vs SMBG). Adherence to blood glucose monitoring was higher in the FSL group compared with SMBG (95% vs 75%, p=0.004) after the first 2 weeks. However, these results should be interpreted cautiously because the assessment group identified this trial as having a serious risk of bias and outcomes were reported over a 2-week study period only.

Effectiveness for baby of person with GDM

One RCT (Majewska 2023) reported that the incidence of macrosomia[19] was significantly lower in FSL patients compared with SMBG patients. No significant differences in birthweight, large for gestational age,[20] small for gestational age or neonatal hypoglycaemia were reported. One cohort study (Bastobbe 2023) reported several perinatal outcomes and noted no significant benefits for FSL patients. Mean HbA1c was significantly lower in mothers assigned to SMBG compared with FSL at delivery. A second cohort study (Won 2025) reported no significant differences in perinatal outcomes between FSL and SMBG.

Treatment satisfaction

Two cohort studies reported treatment satisfaction. One study of 25 patients (Won 2025) (reporting DTSQ total score) showed significant improvement in the FSL group compared with the SMBG group; however, there were no significant differences in how patients scored the perceived

[19] Note that fetal macrosomia was defined as ≥4000g and the number of babies with macrosomia was 2 in the FSL group.

[20] Note that 'large for gestational age' was defined as birthweight >90th percentile.

frequency of hyperglycaemia (p=0.170) or hypoglycaemia (p=0.09). There was no comparative analysis of DTSQ change in the second cohort study or 18 patients (Bastobbe 2023). A third study of 24 patients reported data for useability and reported that patients strongly agreed that applying the FSL sensor was less painful than SMBG (83%).

Clinical claim

There are insufficient data available to support the clinical claim of superior effectiveness in this population.

PICO Set 3

Change in HbA1c

Three single-arm studies reported mean change from baseline in HbA1c:

- One prospective case-series study of 30 cystic fibrosis-related diabetes patients reported a mean change from baseline in HbA1c of −0.6% (p=0.006).
- One retrospective case-series study of 78 cystic fibrosis-related diabetes patients reported a median change in HbA1c from 58.5 mmol to 55 mmol, which was found to be statistically significant (p=0.014).
- One prospective case-series study of 12 cystic fibrosis-related patients reported a median change in HbA1c of −0.6 (calculated by the applicant, not the study author), which was not statistically significant (p=0.05).

Glycaemic variability

One single-arm study (Lee 2022) reported that 21 patients with T3cD using insulin were not at increased risk of glycaemic variability compared to patients with T1D or T2D when using FSL.

Time in range

One retrospective case-series study in 78 cystic fibrosis-related diabetes patients (Shimmin 2020) reported no difference in TIR between baseline and follow up when FSL was used.

Clinical claim

There are insufficient data available to support the clinical claim of superior effectiveness in this population.

13. Economic evaluation

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

The cost-effectiveness analysis (CEA) compared the FSL2 or FSL2 Plus CGM 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) microsimulation model,[21] developed in Microsoft Excel. The model structure is presented in Figure 2, obtained from the ADAR. The model used Monte Carlo simulation methods

[21] Szafranski, K et al. (2024). The Determination of Diabetes Utilities, Costs, and Effects Model: A Cost-Utility Tool Using Patient-Level Microsimulation to Evaluate Sensor-Based Glucose Monitoring Systems in Type 1 and Type 2 Diabetes: Comparative Validation. *Value Health* 27(4):500-507. doi: 10.1016/j.jval.2024.01.010.

to simulate 50,000 unique adults living with T2D and being treated with insulin. The properties of a microsimulation model allowed for each individual to experience a unique journey through the model. This means that the heterogeneity of T2D was appropriately captured and quantified.

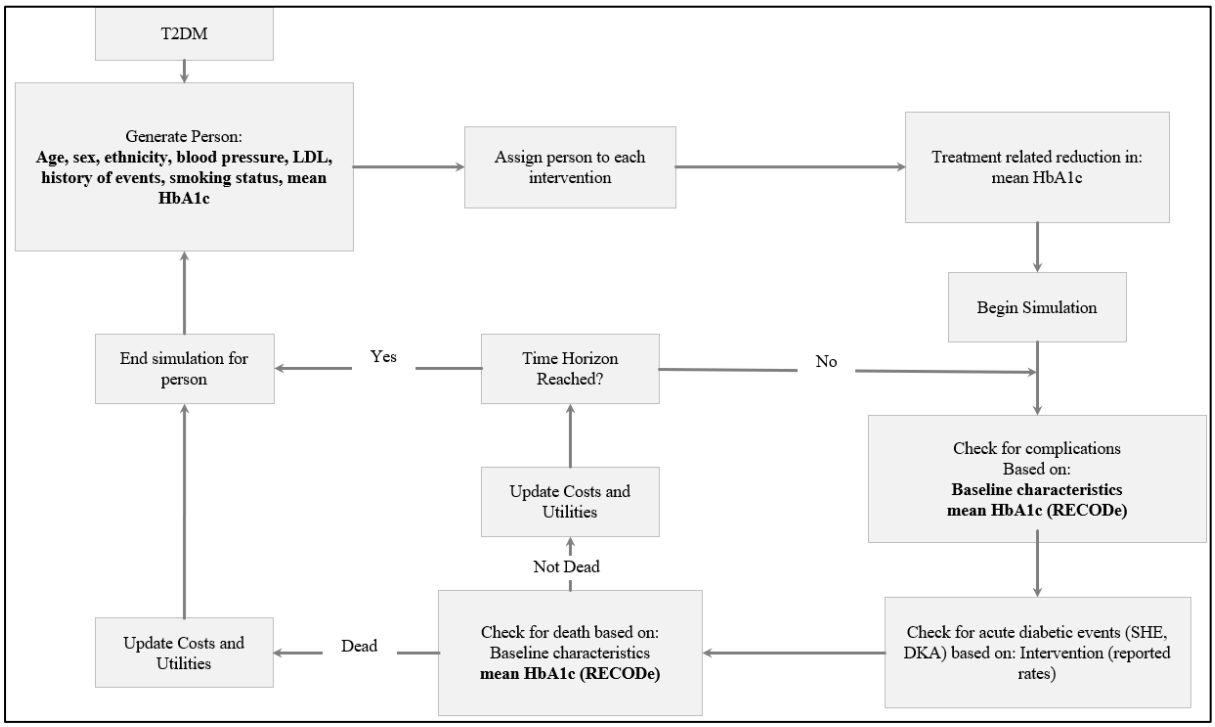
Upon model entry, an individual was assigned to either the FSL CGM arm or the SMBG arm. It was assumed that, depending on the arm, each individual experienced an immediate, one-time reduction in HbA1c. In each model cycle (length of 1 year), an individual's clinical characteristics and complication history data were fed into the published Risk Equations for Complications of Type 2 Diabetes (RECODe), which were developed and validated using data from the Action to Control Cardiovascular Risk in Diabetes study (ACCORD), and validated for microvascular events and cardiovascular events using data from the Diabetes Prevention Program Outcomes Study (DPPOS) and Action for Health in Diabetes (Look AHEAD), respectively.[22] The risk equations estimate the per-cycle (annual) probability of a diabetes-related complication (micro- or macrovascular) or death occurring. HBA1c is a covariable in the RECODe risk equations, thus it impacts these probabilities (i.e. lowering HbA1c will reduce the probability of a complication). However, the model assumes that an individual can only experience costs and complications associated with T2D after 1 year of treatment, which is not reflective of clinical practice.

Acute diabetic events (ADE) are not a covariable or an outcome in the RECODe equations. Therefore, it was assumed ADEs were independent from complications. The per-cycle probability of an ADE was informed by results from the RELIEF study, which assessed the rates of hospitalisation for acute diabetes complications in France for a year before and after use of the FSL began.

Monte Carlo methods were employed to determine whether a complication or death occurred in each cycle. Each complication experienced by the individual incurred a cost and impacted health-related quality of life (HRQoL). The lifeline costs and benefits of ADEs, diabetes-related complications, treatment and monitoring were captured over the lifetime of the simulated population. A first-order analysis was conducted for the base case. An Australian healthcare system perspective was taken. Table 6 provides a summary of the economic evaluation and an overview of the model parameters.

[22] Basu, S et al. (2017). Development and validation of Risk Equations for Complications Of type 2 Diabetes (RECODe) using individual participant data from randomised trials. *Lancet Diabetes Endocrinol* 5(10):788-798. doi: 10.1016/S2213-8587(17)30221-8.

Figure 2 DEDUCE model schematic



Abbreviations:
DEDUCE= Determination of Diabetes Utilities, Costs and Effects model; DKA= diabetic ketoacidosis; HbA1c= glycated haemoglobin; LDL= low-density lipoprotein; RECoDe= Risk Equations for Complications Of type 2 Diabetes; SHE= severe hypoglycaemic event; T2DM = type 2 diabetes mellitus

Table 6 Summary of the economic evaluation

	Scope of Decision Problem
Economic analysis	CEA
Population	Patients with T2D requiring 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	Lifetime (modelled as 50 years)
Computational method	Patient-level microsimulation
Generation of the base case	Modelled approach that 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	The complications within DEDUCE for T2D are based on the RECODe risk engine regardless of maintenance therapy. Both macrovascular (i.e. myocardial infarction, stroke, congestive heart failure) and microvascular (renal failure, blindness) complications are included. Note that amputation, which is a consequence of a chronic condition associated with T2D, has not been included in the model, despite having one of the largest utility decrements reported. Multiple covariates act as predictor variables for complications; HbA1c levels are covariates across all complications.
Discount rate	5% for both costs and outcomes
Software	Excel

Abbreviations
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.

Population

PICO Set 1 outlines the population as those with T2D requiring insulin. FSL CGM products are indicated for children (with adult supervision) and adults. Specifically, FSL2 is indicated for children aged 4 to 17 years, and FSL2 Plus is indicated for children aged 2 to 13 years. The PICO outlines 2 sub-populations of interest: people receiving basal insulin or premixed insulin only; and people requiring IIT (i.e. those who require multiple daily insulin injections or continuous subcutaneous insulin infusion who are recommended to perform frequent monitoring of their blood glucose). It is unlikely that children are captured in the model because the average age in

the model is 64.5 years (SD:13.1), and the ADAR did not present any clinical or economic evidence for children or adolescents.

Baseline characteristics

The ANDA dataset was a key source of baseline characteristics. ANDA reports age and mean HbA1c by diabetes type and insulin use. Where data were unavailable for insulin users, the ADAR assumed baseline characteristics would align with those of the 'all diabetes' population, consisting of 30.6% people with T1D and <70% people using insulin. The urine albumin:creatinine ratio was sourced from a US, T2D population reported in the ACCORD study (Basu 2017), in which 35% of the population was insulin users.

The 'all diabetes' population in ANDA and the data in ACCORD do not align with the population in PICO Set 1. The applicant did not seek clinical opinion to determine whether these populations were comparable with each other and the population in PICO Set 1, nor did the ADAR discuss the impact of using data from 3 different populations to simulate the population. The population of interest, as per PICO Set 1, is people with T2D requiring insulin. Only 2 of the 15 baseline characteristics are representative of this population (age and HbA1c level). 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.

The commentary considered that use of data representative of the population in PICO Set 1 would be more appropriate. It is important to note that use of a population representative of PICO Set 1 will not adequately reduce uncertainty in the model estimates, given that there are other assumptions and inputs that are more critical areas on uncertainty.

Baseline characteristics were used to simulate a unique individual using Monte Carlo methods. In addition, 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 (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. Baseline characteristics were assumed to be sustained throughout the individual's lifetime. The ADAR assumed age changed once every 10 years.

RECODe risk equations

The RECODe risk equations (2017) were built using data from the ACCORD study (n=9635; 2001–09; median follow-up = 4.7 years), which recruited patients from 77 clinical sites in the United States and Canada. The risk equations were validated using two large diabetes studies: the Diabetes Prevention Program Outcomes Study (DPPOS, n=1018; 1996–2001) and Action for Health in Diabetes (Look AHEAD, n=4760; 2001–12, used to validate cardiovascular events only).

There are numerous risk equations developed to model diabetes across a variety of settings. The ADAR claimed that RECODe risk equations were appropriate (compared with the others) because they were 'more recent'. Details on commonly used risk equations (United Kingdom Prospective Diabetes [UKPDA] and Building, Relating, Assessing and Validating Outcomes [BRAVO]) are presented below:

- UKPDS-82 (2013) was built using data from the UKPDS trial (n=5,102; 1977–1997) and the 10-year post-trial follow-up of 4,031 survivors. Median follow-up was 17.6 years leading to 89,760 person-years of data. UKPDS risk equations have recently been updated to UKPDS-90 (2021) with 24 years follow-up and up to 65,252 person-years of data.

- BRAVO (2018) risk equations were also built using the ACCORD trial, with median follow-up of 3.7 years and 39,043 person-years of data. These include severe hypoglycaemia as a covariable.

Despite a 2017 publication date, the RECODe risk equations used data from 2001 to 2009. Therefore, the follow-up period in the 2 trials intersect. The commentary considered that more evidence was needed to substantiate the ADAR's claim that RECODe reflects more recent treatment practices. Other risk equations have been published since RECODe, including BRAVO and an updated version of UKPDS-OM2 (UKPDS-90). These were not discussed in the ADAR.

The commentary noted that 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, additional uncertainty exists as to whether the model predictions are appropriate for an Australian population.

The pre-MSAC response outlined that the RECODe equations were sufficiently validated to capture incremental effects across interventions as part of the external validation in the DEDUCE model that simulated two large trials, EMPA-REG and CANVAS (Szafranski K et al. 2024) . Assessment of model accuracy in each respective trial included predicting the complication incidence rates and hazard ratios between the intervention and control arms attributed to the reduction in HbA1c.

The following clinical characteristics were fed into the RECODe risk equations in each model cycle: age, sex, race (i.e. Black, Hispanic or White), SBP, history of cardiovascular disease (CVD), treatment type (blood pressure medication, statins, OADs, anti-coagulants), HbA1c, total cholesterol, high-density lipoprotein (HDL) cholesterol, serum creatinine and albumin:creatinine ratio.

The applicant assumed that the coefficient in the RECODe equations for those who were Aboriginal/Torres Strait Islander (9.7%) was equivalent to the coefficient of the Black population. Given that racial differences in T2D are driven by social disparities (e.g. level of remoteness and socioeconomic disadvantage), this assumption seems appropriate.

It was assumed that these clinical characteristics (listed above) did not change from baseline. Age and HbA1c were the exceptions. It was assumed that age increased in 10-year increments. For example, a person may enter the model aged 50, the age would remain 50 in cycles 1 to 10, then increase to 60 in cycles 11 to 20 and so on. Each person experienced an immediate, treatment-related HbA1c reduction in the first cycle, as described in Figure 2.

The RECODe risk equations used the above data to output a 10-year risk score of the following diabetes-related complications: renal failure, blindness, myocardial infarction, stroke, congestive heart failure, atherosclerotic cardiovascular disease, cardiovascular death and all-cause mortality. The ADAR converted the resultant 1-year risk score into a per-cycle (annual) probability of each complication. It was assumed that the probability was uniformly distributed across the 10 years (referring to the example above, it was assumed renal failure was equally likely at age 60 as at age 69).

Monte Carlo methods were used to determine whether a person experienced each complication in each cycle. To align with clinical practice, chronic complications (e.g. blindness) could only occur once in an individual's lifetime. A person could experience several of the same type of acute complications in a lifetime (e.g. stroke); however, only one of the same type of complication could occur in each 1-year cycle. Several different complications could occur in each 1-year cycle (e.g. blindness, renal failure and stroke).

History of CVD is a covariable of the RECODe risk equations. Figure 2 shows that, following a CVD event in the model time horizon, the individual's clinical history should update, impacting the resultant risk score estimates from the RECODe risk equations. However, this is not what occurred in the model. It was assumed that a CVD event (e.g. a myocardial infarction or stroke) occurring within the model time horizon had no impact on an individual's future risk of complications or death. The commentary considered that this assumption was clinically unrealistic. The pre-MSAC response noted that the model did not simulate the potentiating effects of future CVD events among individuals with prior CVD events due to limited published evidence to capture this effect in the analysis, capturing this effect would improve ICERs in favour of FSL.

Amputation, which is associated with T2D, has not been included in the model, despite having one of the largest utility decrements reported. This is a common complication in other diabetes models. The UKPDS-OM2 and BRAVO risk equations both include this.

Treatment effect

Reduction in HbA1c

The change from baseline HbA1c with FSL (reported as −0.73%) was informed by a meta-analysis of comparative and single-arm evidence. The commentary noted that this approach was inappropriate given the availability of comparative evidence. Moreover, the change from baseline HbA1c with SMBG (reported as −0.20%) was informed from comparative data only. The ADAR did not discuss whether the two were comparable.

NICE developed an economic model for continuous glucose monitoring in adults with T2D (NG28)[23]. The NG28 model assumed a one-off decrease in HbA1c for CGMs and SMBG. The ADAR's approach aligns with an existing approach in NICE guidance; however, there was no significant, clinical evidence to justify the use of −0.20%. The ADAR did not justify this approach, nor did it explore a scenario with the absolute difference in HbA1c of FSL and SMBG (−0.29%).

It was assumed that there was an immediate one-time absolute reduction in HbA1c for both arms (FSL and SMBG). This aligns with the one-off decrease assumed in the NG28 model. After the initial reduction, HBA1c was assumed to remain constant in each arm for the remainder of the time horizon. 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)[24]. 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.

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[25]. 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

[23] NICE. 2022. Type 2 diabetes in adults: management. Available at: https://www.nice.org.uk/guidance/ng28/evidence/economic-model-report-pdf-11013295213

[24] Daly, MJ et al. (2022). A Review of Economic Models Submitted to NICE's Technology Appraisal Programme, for Treatments of T1DM & T2DM. *Front Pharmacol* 13:887298. doi: 10.3389/fphar.2022.887298.

[25] Liu, L et al. (2022). Associations of the baseline level and change in glycosylated hemoglobin A1c with incident hypertension in non-diabetic individuals: a 3-year cohort study. *Diabetol Metab Syndr* 14(1):54. doi: 10.1186/s13098-022-00827-8.

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.

The ADAR did not provide any evidence to support the claim that the treatment effect was constant over time.

Base case scenario: Comparative clinical trial and RWE meta-analysis

In the base case scenario, the immediate one-time absolute change in baseline HbA1c for FSL was inputted as 0.73% (95% CI −0.88%, −0.59%). However, this was informed by a meta-analysis combining comparative and single-arm data. The assessment group noted that this approach was inappropriate, given the availability of substantial comparative data. The base case should have used data from comparative evidence only, which was reported as −0.29% compared to SMBG.

The ADAR reported a change from baseline HbA1c of −0.2% (−0.35, −0.05%) for SMBG, occurring at 3–6 months.

Scenario 1: Comparative clinical trial meta-analysis

The immediate one-time absolute change in HbA1c for both the FSL and SMBG was informed by comparative evidence. The ADAR reported a change from baseline HbA1c of −0.50% (95% CI: −0.69%, −0.31%) for FSL. As per the base case scenario, the ADAR assumed a change of −0.2% (−0.35, −0.05%) for SMBG.

Exploratory second-order probabilistic sensitivity analysis scenario: Comparative clinical trial and real-world evidence meta-analysis (FSL only)

The immediate one-time absolute change in baseline HbA1c for FSL was reported as −0.73% (95% CI −0.88%, −0.59%), which was informed by the meta-analysis of comparative and single-arm evidence. As discussed previously, the commentary considered that this approach is inappropriate. The ADAR assumed no change in HbA1c for the SMBG arm.

Additional scenario analyses

The following scenarios were performed assuming a change of −0.2% (−0.35, −0.05%) for SMBG (as per the base case):

- T2D patients using intensive insulin. FSL: −0.66 (−0.81, −0.51) (baseline mean HbA1c = 8.24%).
- All T2D insulin patients with HbA1c ≥8%. FSL: −0.78 (−0.94, −0.63) (baseline mean HbA1c = 9.38%).
- All T2D insulin patients with HbA1c ≥8.7%. FSL: −0.93 (−1.12, −0.75) (baseline mean HbA1c = 9.60%).

Reduction in acute diabetic events

The ADAR used data from the 12-month RELIEF study to inform the rates of acute diabetic events (ADE) requiring hospitalisation in each arm. This study identified 40,846 people with T2D in the French national claims database who initiated FSL. People were either receiving IIT (88%) or single basal insulin injection (7.5%) and non-insulin regimens (4.5%). 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.

The ADAR highlighted that hyperosmolar hyperglycaemic state (HHS) events were more common in T2D than were DKA events. However, these events were not captured in the RELIEF study. Thus, it was assumed that the rates of HHS in people with T2D were equivalent to the rates of DKA in T2D. The ADAR did not provide any clinical evidence for this assumption.

The number of non-severe hypoglycaemia events (NSHE) was informed by a meta-analysis that reported that 52% of people receiving insulin experienced an average of 23.31 mild or moderate hypoglycaemia events per year (Edridge et al. 2015). The ADAR assumed people in the model in the SMBG arm experienced 23.31 SHE per year, and relative risk was applied to this to derive the number of NSHE experienced by the FSL arm (16.50 events per year). The model was not adjusted to account for the 48% of people not experiencing NSHE. NHSE events were not associated with a cost of HRQoL impact; therefore the input is inconsequential to the overall cost and HRQoL results.

HRQoL inputs

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.

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.

The utility decrement applied for frequent finger pricks was 0.03, based on a UK-based study by Matza et al. (2017). The assessment group noted that the value of 0.03 is the difference between the derived utilities for sensor-based glucose monitoring and conventional glucose monitoring. The utility decrement for frequent finger pricks and a utility related to a fear of hypoglycaemia are applied only in the first cycle of SMBG.

Cost inputs

SMBG costs

The ADAR assumed that the cost of test strips is $**REDACTED** for 100 strips. This is the cost of FreeStyle Optium Blood Glucose Test Strips, which the ADAR claimed to be the most dispensed brand. This cost incorporated the payer contribution and the user co-payment in accordance with MSAC guidelines (17.3). Therefore, this cost is appropriate.

An RCT of 26 European centres and 75 intensive-insulin users on SMBG was used to inform the average number of test strips used per person in the SMBG arm (3.8 strips per day) (Haak et al. [2017]). This was assumed to be equivalent for non-intensive and intensive insulin users. This contradicts the recommendations presented in Section 8. However, while the UK has similar recommendations to Australia, recommendations in France (8 sites in Haak et al. [2017]) and Germany (10 sites in Haak et al. [2017]) state that intensive insulin users require at least 4

strips per day, compared with 2 strips per day recommended for non-intensive insulin users.[26,27] Therefore, the number of strips required may be underestimated in both the SMBG and the FSL CGM arm.

The ADAR estimated that if each person used 3.8 strips per day, 1,387 test strips would be required per year. This would generate an annual cost of $REDACTED per year.

The ADAR presented a one-way sensitivity analysis. The applicant did not explore the impact that the number of strips used per day had on the cost of FSL-CGM or SMBG. However, the analysis illustrated that the model results were extremely sensitive to changes in SMBG costs. Increasing the number of strips would increase the cost for both arms (albeit SMBG costs will still be higher in the intervention arm than the comparator arm); however, the results presented suggest that a change in the costs will not change the overall conclusion.

FSL costs

The ADAR estimated that an average of 26.07 FSL sensors and 24.35 FSL2 Plus sensors would be required per year if 100% of the population was fully adherent/compliant. The annual cost for FSL was calculated based on a monthly sensor cost of $REDACTED (for 2 sensors, based on $REDACTED per sensor plus the standard $REDACTED for NDSS distribution) and 24 sensors per year. This indirectly assumed adherence/compliance of 92% for FSL and 99% for FSL 2 Plus. The applicant used anecdotal evidence and comparisons to self-reported medication studies to state that 100% adherence/compliance was a conservatively high estimate, and was likely unrealistic. The ADAR did not discuss whether excess sensors were expected to be used because of failure or removal (e.g. at airports), and did not explore any scenarios around the adherence/compliance or the number of sensors. With the evidence available, 2 sensors per month appears to be an appropriate estimate. The one-way sensitivity analysis showed that changing the cost of FSL was the key driver of cost-effectiveness. Increasing the cost of FSL would increase the ICER.

It was also anticipated that people in the FSL arm would require 109.5 blood glucose test strips per year (0.3 per day), costing an additional $REDACTED per year. The total annual cost for FSL was reported as $REDACTED.

Complication costs

Complication costs were sourced from published literature (Dinh et al. 2022). This study reported the costs of major complications in people with and without diabetes in Tasmania. Costs were reported in the year 2020 and were inflated to 2024 costs using data provided by the Australian Bureau of Statistics[28]. Costs for chronic complications for the first and subsequent years were extracted.

[26] Haute Autorité de Santé. Self-monitoring of blood glucose in type 2 diabetes: limited use for a target population. April 2011. LEAFLET ON GOOD PRACTICE IN HEALTHCARE TECHNOLOGY USE. PDF available at: https://www.has-sante.fr/upload/docs/application/pdf/2011-12/good_practice_-_self-monitoring_blood_glucose_type_2_diabetes.pdf. Downloadable from: www.has-sante.fr

[27] German Diabetes Association: Clinical Practice Guidelines. Glucose Measurement and Control in Patients with Type 1 or Type 2 Diabetes. 2022. Available at: https://www.ddg.info/fileadmin/user_upload/05_Behandlung/01_Leitlinien/Englische_Leitlinien/Glucose_Measurement_and_Control.pdf

[28] Australian Bureau of Statistics. 2025. Consumer Price Index, Australia. [Online]. Available at: https://www.abs.gov.au/statistics/economy/price-indexes-and-inflation/consumer-price-index-australia/latest-release

As noted, individuals in the model cannot experience more than two of the same complication within one cycle (e.g. 2 strokes). However, individuals in the model can experience different types of complications within one cycle (e.g. stroke and myocardial infarction).

There was no evidence that suggests complication costs differ between arms, therefore the ADAR used the same costs for both arms. This approach was appropriate.

While the RECODe risk equations predict end-stage renal disease (i.e. stage 5 chronic kidney disease [CKD]), the cost assumed for end-stage renal disease ($29,582) is more reflective of CKD stage 4 (based upon estimates from Chen et al. 2024). Chen et al. (2024) found that overall annual per-person cost for CKD stage 5 was $67,117. However, costs of renal disease were in the top 10 key drivers of cost-effectiveness. The ADAR did not discuss the validity of these costs.

The model assumed an annual event cost of severe hypoglycaemia of $29,532 and DKA (HHS) of $28,403. The commentary noted that this is significantly larger than the median cost of DKA and hypoglycaemia estimated by Rasekaba et al. (2012) even after taking account of the study being more than 10 years old. The ADAR did not discuss whether this was plausible even though the incremental cost of HHS events had the largest impact on total costs compared with other complications (incremental costs of −$**REDACTED**) (see Table 9). The pre-ESC response noted however that Rasekaba 2012 was based on just 357 subjects with diabetes, compared to Dinh 2022 which utilised actual hospital records on 45,378 Tasmanians.

Mortality

Several mortality methods were included in the model. The probability of all-cause mortality (ACM) was informed by estimates from risk equations including age and sex covariables. The applicant applied age- and sex-adjusted Australian life tables to the ACM probabilities. This approach ensured that survival in the diabetic population did not exceed that of the general population.

Monte Carlo methods are applied to the probability of ACM and the probability of death due of ADEs to determine whether a death event occurs. After a death, no other outcomes can be accrued. Cardiovascular death and atherosclerotic cardiovascular disease (ASCVD) are programmed into the model (events occur based on Monte Carlo methods) and included in the results plots, but they have no impact on the overall cost, HRQoL or mortality outcomes.

Results

The first-order analysis (Table 7) was run over the lifetime (maximum 50 years) of 50,000 unique individuals. The ADAR did not state whether the outcomes converged. Total and incremental life years, QALYs and costs were presented for both steps 1 and 2. The second-order probabilistic sensitivity analysis was presented as an additional step.

Table 7 Results of first-order economic analysis

Parameter	FSL	SMBG	Increment
Step 1: Scenario (treatment effect informed by comparative trials only)			
Cost	**$Redacted**	**$Redacted**	**$Redacted**
LY	10.92	10.78	0.14
QALY	7.657	7.362	0.295
Incremental cost per LY gained			**$Redacted[1] per LY gained**
Incremental cost per QALY gained			**$Redacted[2] per QALY gained**
Step 2: First-order base case analysis (treatment effect informed by comparative trials and real-world evidence)			
Cost	**$Redacted**	**$Redacted**	**$Redacted**
LY	11.000	10.779	0.221
QALY	7.723	7.362	0.362
Incremental cost per LY gained			**$Redacted[3] per LY gained**
Incremental cost per QALY gained			**$Redacted[3] per QALY gained**

Abbreviations
FSL = FreeStyle Libre continuous glucose monitoring products, **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] $35,000 to < $45,000
[2] $15,000 to < $25,000
[3] $5,000 to < $ 15,000

The first step used monitoring approach-specific outcomes from the pooled single arms of the five comparative studies (−0.5 and −0.2 for FSL and SMBG, respectively) to inform the initial HbA1c improvement. This resulted in an ICER of $15,000 to < $25,000 per QALY gained.

The second step used monitoring approach-specific outcomes from the pooled evidence from comparative and single-arm studies (−0.73 and −0.2 for FSL and SMBG, respectively) to inform the initial HbA1c improvement, resulting in an ICER of $5,000 to < $15,000 per QALY gained, which was presented as the base case.

The second-order probabilistic analysis was run over 1,000 lifetimes of 5,000 unique individuals (Table 8.) The ADAR did not discuss whether outcomes converged. The population was reduced because of computing time; however, the impact on the overall ICER was not discussed. 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.

The QALYs and life years are lower, and the costs are higher, in the second-order probabilistic analysis compared with the first-order analysis. This suggests that more events are predicted in the second-order analysis. The ICER was $15,000 to < $25,000 per QALY gained, which is almost double that of the first-order analysis. The pre-MSAC response reported that a second order probabilistic analysis using only comparative results produced an ICER of $15,000 to < $25,000 per QALY gained.

The commentary considered that the first-order outcomes are, therefore, a poor fit for the second-order outcomes. However, the drivers for this were not explained. The applicant made some atypical decisions when choosing which variables to change in the second-order analysis. Time horizon, discount rates and population size were varied. The commentary noted that this is not usually undertaken, given that these are parameters subject to uncertainty. The commentary considered that the ADAR did not present credible intervals around the probabilistic outcomes to

quantify uncertainty. It was stated that 100% of second-order probabilistic iterations were cost-effective at a threshold of $50,000 per QALY gained. It is important to note that cost-effectiveness thresholds are not used by MSAC.

There are uncertainties associated with the assumptions that inform the risk equations, most notably, that baseline characteristics did not change over time. This was not explored in the sensitivity analysis. The ADAR conducted a one-way sensitivity analysis, varying some uncertain inputs ±20% of the mean. The ADAR did not use published literature (e.g. 95% confidence intervals) to explore upper and lower values, despite this literature being available. No reasoning for this was provided. As per the second-order analysis, the ADAR reduced the population size to 5,000 individuals. It was not discussed whether outcomes converged with 5,000 individuals. The base case ICER increased from $5,000 to < $15,000 to $5,000 to < $15,000 in the one-way sensitivity analysis. The top 10 drivers of cost-effectiveness (as determined by the one-way sensitivity analysis) were obtained from the ADAR (Figure 3).

Key first-order scenario analyses are summarised in Table 10. These explore uncertainties including time horizon, cost categories reimbursed by the Australian healthcare system and—most notably—the absolute reduction in HbA1c from baseline.

The mean baseline characteristics were not varied in the second-order probabilistic sensitivity analysis (PSA). The commentary noted that this is a common point of contention among economic modellers. Some argue that the uncertainty is already captured in the first-order PSA, as in this analysis. However, the first-order PSA only captures uncertainty in the populations; the second-order PSA captures the uncertainty in the measures.

Table 8 Results of second-order probabilistic analysis

Parameter	FSL	SMBG	Increment
Second-order probabilistic analysis (treatment effect informed by comparative trials and real-world evidence)			
Cost	$**Redacted**	$**Redacted**	$**Redacted**
LY	10.975	10.772	0.203
QALY	7.690	7.349	0.340
Incremental cost per LY gained			$**Redacted**[1] **per LY gained**
Incremental cost per QALY gained			$**Redacted**[2] **per QALY gained**

Abbreviations
FSL = FreeStyle Libre continuous glucose monitoring products, **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] $25,000 to < $35,000
[2] $15,000 to < $25,000

Table 9 Key drivers of the model

Description	Method/Value	Impact
One-time absolute HbA1c reduction	The one-time, absolute HbA1c reduction for FSL was explored in the one-way sensitivity analysis (Figure 3) and varied ±20% of the mean (−0.73). The one-time, absolute HbA1c reduction caused by FSL on the baseline HbA1c was explored using different sources • meta-analysis of comparative trials informed the FSL treatment effect (−0.5%) for T2D patients. • T2D patients using intensive insulin informed the FSL treatment effect (−0.88%). • All T2D insulin patients with HbA1c ≥8% informed the FSL treatment effect (−0.78%). • All T2D insulin patients with HbA1c ≥8.7% informed the FSL treatment effect (−0.93%). • No additional benefit from SMBG scenario analysis: ''Funding FSL vs not'' A meta-analysis of all trials informed the FSL treatment effect (−0.73%). The SMBG treatment effect was assumed to be 0.	High value for FSL: Favours FSL Low value for FSL: Favours SMBG FLS was not cost saving for any of the scenarios presented above. The ADAR did not provide any threshold analysis to present the treatment effect required to be cost-effective or cost-saving.
Treatment acquisition costs	Costs of FSL and SMBG were explored in the one-way sensitivity analysis (Figure 3) and varied ±20% of the mean.	Figure 3 shows that the treatment acquisition cost for FSL and SMBG were both among the top 3 drivers of cost-effectiveness. A lower cost of FSL favoured FSL. Reducing the cost of FSL by 20% did not change the conclusion (i.e. cost-effective but not cost saving) A higher cost of FSL favoured SMBG. However, FSL remained cost-effective at a threshold of $50,000 per QALY gained when the annual cost was increased by 20%. Low cost of SMBG favours SMBG and high cost of SMBG favours FSL.
Utilities	The baseline utility was explored in the one-way sensitivity analysis (Figure 3) and was varied ±20% of the mean.	The baseline utility was among the top 10 drivers of cost-effectiveness (Figure 3) • High, favours FSL (i.e. more value if someone is living event-free) • Low, favours SMBG (i.e. more value if someone is living event-free) The company did not describe whether the high value of 0.922 was plausible in the population. The population enters the model at age 65.
Diabetes-related complication costs	Costs of diabetes-related complications were explored in the one-way sensitivity analysis (Figure 3) and was varied ±20% of the mean.	Increasing the cost of chronic complications (renal failure, blindness, stroke, MI) by 20% favours FSL. This is because more value was attributed to the reduction in complications caused by FSL,

Description	Method/Value	Impact
	The applicant also explored the outcomes when these costs were not included in the model in the scenario analysis.	particularly in chronic complications with long-term cost. Decreasing the cost of chronic complications by 20% favours SMBG, as there was less value associated with avoiding complications. The applicant did not discuss whether the costs (based on a Tasmanian study) were representative of the costs observed in mainland Australia or whether the remoteness of Tasmania impacts costs. These chronic costs were in the top 10 drivers of cost-effectiveness (Figure 3) When all diabetes-related complication costs were removed, the ICER increased to $$25,000 to < $35,000 per QALY gained.
HHS events	The ADAR shows that a reduction in HHS events reduced overall costs by −$0 to < $5,000. This complication had the largest impact on costs overall. Parameters associated with HHS events were varied in the analysis.	The one-way sensitivity analysis (Figure 3) showed that the 'DKA deaths' input (i.e. deaths due to HHS) was in the top 10 key drivers of cost-effectiveness. A low probability of death favours FSL. A high probability of death favours SMBG. This is likely driven by the terminal care cost, which increases the HHS cost ($28,403) by $6,858 for each death event. The probability of HHS events was informed by the probability of DKA events. However, the applicant claimed that HHS events are expected to be more common than DKA events. Therefore, the impact of this parameter may be underestimated.

Abbreviations
AE = adverse events, **DKA** = diabetic ketoacidosis, **FSL** = FreeStyle Libre Continuous Glucose Monitoring, **HHS** = hyperosmolar hyperglycaemic state, **HbA1c** = glycated haemoglobin, **MI** =myocardial infarction, **QoL** = quality of life, **SMBG** = self-monitoring of blood glucose, **QALY** = quality-adjusted life year, **T2D** = type 2 diabetes.

Figure 3. One-way sensitivity analyses, tornado diagram from the ADAR

[Figure redacted]

Abbreviations
DKA = diabetic ketoacidosis, **ICER** = incremental cost-effectiveness ratio, **SMBG** = self-monitoring of blood glucose.

Table 10 First-order scenario analyses

Analyses	Incremental cost	Incremental QALY	ICER
Base case	**$Redacted**	**0.362**	**$Redacted**[1]
All FSL studies baseline HbA1c (8.16%)	**$Redacted**	0.359	**$Redacted**[1]
Exclude all diabetes-related complication costs	**$Redacted**	0.362	**$Redacted**[2]
Exclude HHS and SHE diabetes-related complication costs only	**$Redacted**	0.362	**$Redacted**[3]
Shorter horizon (25 years)	**$Redacted**	0.327	**$Redacted**[1]
One-time absolute HbA1c reduction (refer to Table 9, key drivers of the model, row 1 for the reduction assumed)			
T2D patients using intensive insulin	**$Redacted**	0.337	**$Redacted**[1]
All T2D insulin patients with HbA1c ≥8%	**$Redacted**	0.374	**$Redacted**[1]
All T2D insulin patients with HbA1c ≥8.7%	**$Redacted**	0.422	**$Redacted**[4]
No additional benefit from SMBG scenario analysis: "Funding FSL vs not"	**$Redacted**	**0.289**	**$Redacted**[4]
Discounting			
Cost discount: 0% Utility discount: 0%	**$Redacted**	0.712	**$Redacted**[1]
Cost discount: 3.5% Utility discount: 3.5%	**$Redacted**	0.430	**$Redacted**[1]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **HbA1c** = glycated haemoglobin, **HHS** = hyperglycaemic hyperosmolar syndrome, **ICER** = incremental cost-effectiveness ratio, **QALY** = quality-adjusted life year, **QoL** = quality of life, **SHE** = severe hypoglycaemic events, **T2D** = type 2 diabetes.
Note
All results involved 50,000 microsimulations.
All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] $5,000 to < $15,000
[2] $25,000 to < $35,000
[3] $15,000 to < $25,000
[4] $0 to < $5,000

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 11.

Table 11 Summary of the economic evaluation

Component	Description	MSAC Guidelines Reference
Perspective	Australian publicly funded healthcare system	TG 17.3
Population	Women with GDM	TG 19
Prior testing	Diagnosis of GDM in weeks 24 to 28	TG 19
Comparator	SMBG	TG 17.2
Type(s) of analysis	Cost-consequence analysis	TG 17.5
Outcomes	Cost of glucose monitoring Cost of foetal macrosomia	TG 21
Time horizon	12 weeks (scenario with 16 weeks)	TG 18.2
Computational method	Simple cost calculator	TG 18.3
Generation of the base case	Modelled • applicant estimated the total cost of glucose monitoring for FSL and SMBG by estimating resource use • incidence (%) of foetal macrosomia obtained from the RCT by Majewska et al. (2023) and a cost-estimate applied to this	TG 17.6
Cycle length	Time of treatment	TG 18.3
Discount rate	0%	TG 17.4
Software	Microsoft Excel	TG 18.3

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **GDM** = gestational diabetes, **RCT** = randomised controlled trial, **SMBG** = self-monitoring of blood glucose.

Parameters

Glucose monitoring

For FSL, it was assumed that people would require 2 sensors per month (assumed to be 4 weeks). The per-month cost of $REDACTED aligned with the CEA for people with T2D on insulin.

Cost for SMBG was $REDACTED for a pack of 100 strips, which aligned with the CEA for insulin-using people with T2D. This cost incorporated the payer contribution and the user co-payment (i.e. took account of the full cost of the technology) in accordance with MSAC guidelines (17.3), and was therefore appropriate.

The ADAR estimated that people with GDM would require 25.2 strips for FSL and 319.2 strips for SMBG, per gestation period (12 weeks). The ADAR assumed no wastage, thus the payer paid for each SMBG strip, rather than a cost per pack. This assumption was not justified. Given the co-payment associated with SMBG strips, it is likely that a patient would acquire a pack of 100 rather than the healthcare professional handing each patient 25.2 and 319.2 strips at treatment initiation.

Foetal macrosomia

Independent Hospital Pricing Authority 2024/2025 data were used to estimate the cost of foetal macrosomia. Appropriate AR-DRG codes (P68B and P68D) were used as surrogate AR-DRG codes for foetal macrosomia. The cost was estimated at $5,128 per neonate.

Incidence of foetal macrosomia was 4.08% for the FSL arm and 20.00% for the SMBG arm, informed by the RCT by Majewska et al. (2023). The odds ratio was 5.62 (95% CI 1.16 to 27.22).

This RCT had relatively small populations, with 49 people participating in the FSL arm and 50 people in the SMBG arm. The ADAR did not explore any scenarios around these.

Results

FSL was cost-saving in women with GDM (Table 12). The ADAR explored 2 different time horizons, finding that FSL was cost-saving for the plausible range of FSL use of 12–16 weeks.

The applicant acknowledged the uncertainty around the foetal macrosomia, therefore a break-even analysis was performed. The ADAR found that FSL was cost-saving for all costs of foetal macrosomia >$**REDACTED** per neonate. The ADAR did not explore other uncertainty parameters.

Table 12 Results of cost-consequence analysis

Step	FSL	SMBG	Increment
Base case: Cost of GDM over a 12-week time horizon			
Cost of glucose monitoring	**$Redacted**	**$Redacted**	**$Redacted**
Cost of foetal macrosomia	$209	$1,026	−$816
Total cost	**$Redacted**	**$Redacted**	**$Redacted**
Scenario: Cost of GDM over a 16-week time horizon			
Cost of glucose monitoring	**$Redacted**	**$Redacted**	**$Redacted**
Cost of foetal macrosomia	$209	$1,026	−$816
Total cost	**$Redacted**	**$Redacted**	**$Redacted**

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **GDM** = gestational diabetes, **SMBG** = self-monitoring of blood glucose.
Notes
All currencies represent AUD.

Conclusion

Given the uncertainty around the inputs associated with foetal macrosomia (e.g. the odds ratio for the incidence was 5.62 (95% CI 1.16 to 27.22) and that the cost was an estimate, the potential overall impact on decision uncertainty is very high.

Other diabetes (PICO Set 3)

The ADAR did not present any clinical or economic evidence for FSL in populations with conditions similar to type 1 diabetes which require insulin. However, in the ratified PICO, PASC acknowledged that there would likely be insufficient information available to model the potential health outcomes specifically for patients in PICO Set 3.

14. Financial/budgetary impacts

The financial analysis took an epidemiological approach to estimate the anticipated 6-year financial implications of FSL2 to the federal NDSS budget in the 3 PICO populations:

- People with T2D requiring insulin.
- People with GDM.
- People with conditions similar to type 1 diabetes which require insulin.

The applicant chose not to include potential additional savings associated with FSL to other funding sources. Costs related to reduction in event costs are largely borne by state health

budgets. Cost and uptake data focused on FSL2 and did not consider FSL2 Plus. The applicant did not state whether FSL2 Plus would replace FSL2 or be used concurrently.

Across all 3 populations, it was estimated that:

- Sensors were costed as per Section 13 ($**REDACTED** per FSL sensor plus $**REDACTED** for distribution plus 0.3 SMBG test strips per day at $**REDACTED** per 100 test strips).
- People on SMBG would require 3.8 daily tests, with SMBG at $**REDACTED** per 100 test strips.
- The weighted average patient's co-payment would be $**REDACTED** (as derived by the applicant) and the remainder ($**REDACTED**) was assumed to be NDSS contributions.
- Users would require an average of 24 sensors annually (accounting for additional sensors required because of lack of compliance). The applicant claimed that FSL 2+ can be worn for longer than FSL, therefore 24 is a conservative estimate.

The ADAR assumed that SMBG resource use would be equivalent across all 3 populations, but provided no evidence to support this.

PICO Set 1

The ADAR compared population data of insulin-using people with T2D from the NDSS (2024) (315,432 Australians with T2D required insulin therapy as of 30 June 2024) with Prospection data (2022) (201,080 people with T2D who had an insulin script dispensed over a 12-month period on the PBS in 2022). Given that the Prospection (2022) data identified people who were dispensed insulin, the ADAR claimed it was likely the most accurate data source; during the commentary process, the assessment group were unable to ascertain the validity of the Prospection (2022) data because it was not included in the applicant's reference pack. Of these 201,080 people, 32,380 were intensive insulin users (presence of a pump) and the remainder (168,070) was assumed to be non-intensive insulin users. The ADAR used estimates from ANDA to validate the percentage of intensive insulin users. Uptake was estimated using real-world data from FSL introduction in France and Sweden. Uptake is estimated to be higher in people using intensive insulin than those using non-intensive insulin.

The ADAR assumed population growth to be 1% per annum. No source was provided for this. The 2025 population (those entering the financial analysis) was sized at 33,361 for intensive insulin users and 173,812 for non-intensive insulin users.

Financial implications to the NDSS resulting from the proposed listing of FSL for intensive and non-intensive insulin users are summarised together in Table 13, and separately in Table 14 and Table 15, respectively.

Table 13 Net financial implication of FSL to NDSS (PICO Set 1)

	PICO Set 1					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	207,173	209,245	211,337	213,450	215,585	217,741
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[3]	**Redacted**[4]	**Redacted**[5]	**Redacted**[6]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	$**Redacted**[7]	$**Redacted**[8]	$**Redacted**[9]	$**Redacted**[10]	$**Redacted**[11]	$**Redacted**[11]
less cost offset (patient contributions, applies to 30% (or 27%) of population who are general patients, the remaining with concession pay $0 contribution)	$**Redacted**[12]	$**Redacted**[12]	$**Redacted**[12]	$**Redacted**[12]	$**Redacted**[12]	$**Redacted**[12]
Net cost of FSL	$**Redacted**[7]	$**Redacted**[8]	$**Redacted**[9]	$**Redacted**[14]	$**Redacted**[10]	$**Redacted**[11]
Change in SMBG use						
less cost offsets (reduced glucose strips costing $19.10 per pack)	$**Redacted**[12]	$**Redacted**[13]	$**Redacted**[13]	$**Redacted**[13]	$**Redacted**[13]	$**Redacted**[13]
Total net cost	$**Redacted**[15]	$**Redacted**[16]	$**Redacted**[8]	$**Redacted**[17]	$**Redacted**[9]	$**Redacted**[14]

The redacted values correspond to the following ranges:
[1] 20,000 to < 30,000
[2] 40,000 to < 50,000
[3] 50,000 to < 60 000
[4] 60,000 to < 70,000
[5] 70,000 to < 80,000
[6] 80,000 to < 90,000
[7] $30 million to < $40 million
[8] $50 million to < $60 million
[9] $70 million to < $80 million
[10] $90 million to < $100 million
[11] $100 million to < $200 million
[12] $0 to < $10 million
[13] $10 million to < $20 million
[14] $80 million to < $90 million
[15] $20 million to < $30 million
[16] $40 million to < $50 million
[17] $60 million to < $70 million

Table 14 Net financial implication of FSL to NDSS (intensive insulin users)

	PICO Set 1 – T2D intensive insulin users					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	33,361	33,695	34,032	34,372	34,716	35,063
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]	**$Redacted** [3]	**$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** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]
Net cost of FSL	**$Redacted** [6]	**$Redacted** [4]	**$Redacted** [5]	**$Redacted** [5]	**$Redacted** [5]	**$Redacted** [5]
Change in SMBG use						
less cost offsets (reduced glucose strips costing $19.10 per pack)	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]	**$Redacted** [6]
Total net cost	**$Redacted** [6]	**$Redacted** [4]	**$Redacted** [4]	**$Redacted** [4]	**$Redacted** [5]	**$Redacted** [5]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **SMBG** = self-monitoring of blood glucose, **T2D** = type 2 diabetes.
Notes
All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] 5,000 to < 10,000
[2] 10,000 to < 20,000
[3] 20,000 to < 30 000
[4] $10 million to < $20 million
[5] $20 million to < $30 million
[6] $0 to < $10 million

Table 15 Net financial implication of FSL to NDSS (non-intensive insulin users)

	PICO Set 1 – T2D non-intensive insulin users					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
FSL use						
Patients	173,812	175,550	177,305	179,078	180,869	182,678
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[3]	**Redacted**[4]	**Redacted**[5]	**Redacted**[5]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted**[6]	**$Redacted**[7]	**$Redacted**[8]	**$Redacted**[9]	**$Redacted**[10]	**$Redacted**[11]
less cost offset (patient contributions, applies to 30% (or 27%) of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[12]
Net cost of FSL	**$Redacted**[6]	**$Redacted**[13]	**$Redacted**[7]	**$Redacted**[9]	**$Redacted**[9]	**$Redacted**[10]
Change in SMBG use						
less cost offsets (reduced glucose strips costing $19.10 per pack)	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[12]	**$Redacted**[14]	**$Redacted**[14]	**$Redacted**[14]
Total net cost	**$Redacted**[14]	**$Redacted**[13]	**$Redacted**[7]	**$Redacted**[7]	**$Redacted**[8]	**$Redacted**[9]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **SMBG** = self-monitoring of blood glucose, **T2D** = type 2 diabetes.
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] 40,000 to < 50,000
[5] 50,000 to < 60,000
[6] $20 million to < $30 million
[7] $40 million to < $50 million
[8] $50 million to < $60 million
[9] $60 million to < $70 million
[10] $70 million to < $80 million
[11] $80 million to < $90 million
[12] $0 to < $10 million
[13] $30 million to < $40 million
[14] $10 million to < $20 million

PICO Set 2

The ADAR used NDSS snapshot data to determine that the population of women with GDM was 45,290 (as of June 2024). This was determined to be more accurate than other sources, for example, the Australian Institute of Health and Welfare (AIHW)[29]. It was assumed that uptake in people with GDM was equivalent to uptake in intensive insulin users (calculated using French and Swedish real-world data). The financial implications to the NDSS resulting from the proposed

[29] Australian Institute of Health and Welfare. 2024. Diabetes: Australian facts. [Online]. Available at: https://www.aihw.gov.au/reports/diabetes/diabetes/contents/how-common-is-diabetes/gestational-diabetes

listing of FSL in people with GDM are summarised in Table 16. The ADAR did not take into account social disparities in the prevalence of diabetes or the pregnancy rate in Australia when calculating the population in the financial analysis for GDM (for instance, Aboriginal and/or Torres Strait Islander people were 2.9 times as likely to be living with T2D as were non-Indigenous adults).

Table 16 Net financial implications of FSL to NDSS (GDM)

	PICO Set 2 – GDM					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FSL use						
Patients	45,290	45,743	46,200	46,662	47,129	47,600
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted** [1]	**Redacted** [1]	**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** [4]
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 costing $19.10 per pack)	**$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]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **GDM** = gestational diabetes, **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] $0 to < $10 million
[4] $10 million to < $20 million

PICO Set 3

There was a paucity of data to inform the population size, therefore the most accurate source was determined to be NDSS snapshot data. The ADAR used a population of 8,009 who were registered with the NDSS as 'other diabetes' requiring insulin (as of June 2024). It was assumed that uptake in people with other diabetes was equivalent to uptake in intensive insulin users (calculated using French and Swedish real-world data). As for T2D people requiring insulin, the ADAR assumed 24 sensors would be required annually. The financial implications to the NDSS resulting from the proposed listing of FSL in people with 'other' diabetes are summarised in Table 17.

Across all 3 PICO sets and all insulin users, the ADAR assumed equivalent use of SMBG per user. No evidence was provided to support this.

Table 17 Net financial implications of FSL to NDSS ('other' diabetes)

	PICO Set 3 – other diabetes					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FSL use						
Patients	7,362	7,436	7,510	7,585	7,661	7,738
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted** [1]	**Redacted** [1]	**Redacted** [1]	**Redacted** [1]	**Redacted** [1]	**Redacted** [1]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]
less cost offset (patient contributions, applies to 30% (or 27%) of population who are general patients, the remaining with concession pay $0 contribution)	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]
Net cost of FSL	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]
Change in SMBG use						
less cost offsets (reduced glucose strips costing $19.10 per pack)	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]
Total net cost	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]	**$Redacted** [2]

Abbreviations
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] $0 to < $10 million

Scenario analysis

The ADAR presented 2 scenario analyses accounting for uncertainty in the number of T2D patients requiring insulin and the uptake of FSL.

T2D requiring insulin

The number of T2D patients requiring insulin was assumed to align with the number of patients from the 30 June 2024 NDSS snapshot (315,432). The applicant assumed that 16% of NDSS-registered T2D insulin users required an intensive-insulin regimen (proportional to the findings from the Prospection analysis). This scenario included 50,469 intensive insulin users and 264,962 non-intensive users. As per the base case, growth rate was assumed to be 1% per year.

The financial implications to the NDSS resulting from the proposed listing of FSL in people with T2D using insulin (scenario 1) are summarised in Table 18.

Table 18 Net financial implications of FSL to NDSS (T2D with insulin, scenario 1)

	PICO Set 1					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FSL use						
Patients	371,238	374,950	378,699	382,486	386,311	390,174
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**[8]	**$Redacted**[8]	**$Redacted**[9]	**$Redacted**[9]	**$Redacted**[9]	**$Redacted**[9]
Net cost of FSL	**$Redacted**[4]	**$Redacted**[10]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]
Change in SMBG use						
less cost offsets (reduced glucose strips)	**$Redacted**[9]	**$Redacted**[9]	**$Redacted**[6]	**$Redacted**[6]	**$Redacted**[11]	**$Redacted**[11]
Total net cost	**$Redacted**[7]	**$Redacted**[12]	**$Redacted**[10]	**$Redacted**[5]	**$Redacted**[5]	**$Redacted**[5]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **SMBG** = self-monitoring of blood glucose, **T2D** = type 2 diabetes.
Notes
All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] 40,000 to < 50,000
[2] 80,000 to < 90,000
[3] 100,000 to < 200 000
[4] $50 million to < $60 million
[5] $100 million to < $200 million
[6] $20 million to < $30 million
[7] $40 million to < $50 million
[8] $0 to < $10 million
[9] $10 million to < $20 million
[10] $90 million to < $100 million
[11] $30 million to < $40 million
[12] $70 million to < $80 million

Uptake of FSL

The financial implications to the NDSS resulting from a higher market uptake rate (scenario 2) are summarised in Table 19.

Table 19 Net financial implications of FSL to NDSS (FSL uptake rate, scenario 2)

	PICO Set 1					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FSL use						
Patients	259,825	262,423	265,048	267,698	270,375	273,079
Uptake %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %	**Redacted** %
Number of patients taking up FSL	**Redacted**[1]	**Redacted**[2]	**Redacted**[3]	**Redacted**[4]	**Redacted**[4]	**Redacted**[4]
Number of FSL 2 sensors (1 sensor/pack)	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**	**Redacted**
Total cost of FSL	$**Redacted**[5]	$**Redacted**[6]	$**Redacted**[7]	$**Redacted**[7]	$**Redacted**[7]	$**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**[9]	$**Redacted**[9]	$**Redacted**[9]
Net cost of FSL	$**Redacted**[5]	$**Redacted**[10]	$**Redacted**[11]	$**Redacted**[7]	$**Redacted**[7]	$**Redacted**[7]
Change in SMBG use						
less cost offsets (reduced glucose strips)	$**Redacted**[8]	$**Redacted**[9]	$**Redacted**[9]	$**Redacted**[12]	$**Redacted**[12]	$**Redacted**[12]
Total net cost	$**Redacted**[13]	$**Redacted**[14]	$**Redacted**[10]	$**Redacted**[11]	$**Redacted**[7]	$**Redacted**[7]

Abbreviations
FSL = FreeStyle Libre Continuous Glucose Monitoring, **SMBG** = self-monitoring of blood glucose, **T2D** = type 2 diabetes.
Notes
All currencies represent AUD.
The redacted values correspond to the following ranges:
[1] 40,000 to < 50,000
[2] 70,000 to < 80,000
[3] 90,000 to < 100,000
[4] 100,000 to < 200 000
[5] $40 million to < $50 million
[6] $80 million to < $90 million
[7] $100 million to < $200 million
[8] $0 to < $10 million
[9] $10 million to < $20 million
[10] $70 million to < $80 million
[11] $90 million to < $100 million
[12] $20 million to < $30 million
[13] $30 million to < $40 million
[14] $60 million to $70 million

15. Other relevant information

Post-ESC analysis - economics

Post-ESC the assessment group was requested to provide its opinion summarising its views on the transparency of the economic model used in this ADAR with reference to TG 18.3 of the MSAC Guidelines. The assessment group's views are provided below.

The Applicant used the Determination of Diabetes Utilities, Costs, and Effects (DEDUCE) microsimulation model. To justify this approach, the Applicant described how the history of complications impacts individuals' future complications and prognosis. The Applicant stated that "need for a model memory necessitates and explains the choice of a microsimulation model design" (Section 3.2.5 in the ADAR). The justification and approach are appropriate. The applicant did not explore other possible model structures.

The Applicant used the RECODe algorithm (or risk equations) to predict the occurrence of complications. Risk equations are the 'engine' of the model. The Applicant also described the alternate UKPDS-82 risk equation used for modelling type 2 diabetes that were identified in the literature review. The applicant justified the use of RECODe risk equations by stating that they were "newer" and the ACCORD study from which they were derived was "more reflective of recent treatment practices" than UKPDS-82, which were derived from the UKPDS study. This justification is not sufficient given that the follow-up period in the two trials intersect. The Applicant did not discuss the applicability of other risk equations published after RECODe (namely, UKPDS-90 and BRAVO). The applicant did not discuss whether RECODe was more appropriate for the Australian population, and whether RECODe had been validated against this population.

The DEDUCE model was developed in Excel and a copy was available to the Evaluators. The Evaluators' scope of work did not include a comprehensive model quality check; however, the model was functional. The Applicant ran the model with 50,000 individuals in the first-order analysis. The applicant did not state whether the results converged. The model run time was less than 30 minutes. The Evaluator was able to replicate the results when the model was run.

16. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- The ADAR proposed a minimal clinically important difference (MCID) for change in glycated haemoglobin (HbA1c) at 0.3%. This is lower than the threshold of 0.5% previously used by the PBAC (for example, semaglutide Public Summary Document [PSD], March 2021 PBAC meeting). An MCID of 0.5% is also accepted by NICE (England). The ADAR did not establish that a HbA1c reduction of 0.3% is clinically significant. If 0.5% remains accepted as the MCID for HbA1c in type 2 diabetes (T2D), the claim of superior clinical effectiveness based on the change in HbA1c cannot be accepted. If a claim of superior clinical effectiveness based on HbA1c change cannot be established, an alternative may be for the applicant to establish a claim of non-inferior effectiveness. The applicant may also wish to consider establishing a claim of superior effectiveness if there is substantial evidence of improvement in other patient-relevant outcomes, such as quality of life (QoL). While QoL improvements for patients using continuous glucose monitoring (CGM) would be expected because of the reduced need for finger prick testing, this was not supported by QoL outcomes reported in the studies presented in the application.
- **REDACTED.** Therefore, device-agnostic funding for these products would likely be appropriate as the devices likely have a class effect.
- Insufficient data are available to support the clinical claim of superior effectiveness for PICO sets 2 and 3. However, ESC noted that PICO sets 2 and 3 were small but important subgroups for which there was potential for good clinical outcomes from using CGM.

Economic issues:

- The diabetes complication events were generated using RECODe equations, but it was unclear whether the RECODe equations have been validated in terms of disease progression only or also in terms of incremental effects across interventions. The applicant should demonstrate that the model has been sufficiently validated to estimate increments in effect on the patient-relevant health states following any HbA1c improvement to assess the effect of the expected lag of onset of effect and less than full epidemiological prediction.

- The clinical evidence for effectiveness used for the economic evaluation did not meet the studies' prespecified MCIDs of 0.35% and 0.5%, which means it is unclear whether there was any treatment effect on HbA1c.
- For transparency, the applicant should provide the results of the second-order probabilistic analysis for scenario 1 in the T2D model without varying the discount rate or time horizon from the first-order economic evaluation. These should include tabulated results for the CGM arm, the SMBG arm and the increment; the aggregate discount costs, life years and QALYs; and the discounted cost per life year and cost per QALY (increment only).

Financial issues:

- There was a difference in device cost per year presented between the FSL2 ($**REDACTED**) and the Dexcom ONE ($**REDACTED**) for likely similar clinical outcomes. ESC advised that, if a device-agnostic listing is approved, MSAC could consider a cost-minimisation approach for CGM products accessed via the NDSS, accounting for the different durations of sensor performance, such as direct price competition or the introduction of a price premium for more expensive options.

Other relevant information:

- 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).
- 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 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.

ESC discussion

ESC noted that this application from Abbott Australasia was originally to request National Diabetes Services Scheme (NDSS) funding of the FreeStyle Libre 2 (FSL2) continuous glucose monitoring (CGM) system for:

- people with type 2 diabetes mellitus (T2D) requiring treatment with insulin (PICO set 1)
- pregnant women with gestational diabetes mellitus (GDM) (PICO set 2)
- people with type 3c diabetes (T3cD) requiring treatment with insulin (PICO set 3).

ESC noted that, following a meeting including the department and the applicant, PICO set 3 had been expanded to include people aged 21 years and over who have conditions similar to type 1 diabetes mellitus (T1D) and require insulin.

ESC noted the history of subsidised CGM monitoring in Australia. CGM technology has received public funding since 2017, when the NDSS provided full subsidies for T1D patients under the age of 21 years. In March 2019, access was expanded to include:

- T1D patients aged 21 years and over with concession status and a specified set of clinical needs
- T1D patients who are pregnant, actively planning pregnancy or immediately post-pregnancy
- patients aged under 21 years who have conditions similar to T1D and require insulin.

In 2022, the NDSS expanded funding of CGM technology to all patients with T1D (with an equivalent monthly co-payment currently of around $35.90 for people aged 21 years and over who do not have concessional status).

MSAC conducted a review of CGM products provided via the NDSS for people with T1D in 2021 (see MSAC Review 1663). After considering the available evidence, the review concluded that there is most likely no difference between CGM and self-monitoring of blood glucose (SMBG) in terms of safety and effectiveness. However, the review noted that clinically relevant outcomes and clinical needs vary according to the patient and recommended that the clinical and quality of life (QoL) benefits of CGM be further explored.

ESC noted that there are currently 3 manufacturers of CGM products on the NDSS, 2 of which are currently under consideration by MSAC. Application 1785 seeks funding for the Dexcom ONE CGM system for people with T2D requiring insulin.

This application (1786) requests public funding for FSL2 for:

- people with T2D requiring insulin
- women with GDM
- people over the age of 21 with other conditions similar to T1D requiring insulin, including Type 3c diabetes.

ESC noted that the proposed NDSS eligibility criteria for FSL2 did not specify poor glycaemic control (represented by HbA1c above a certain threshold), unlike the proposed eligibility criteria for application 1785. ESC considered that the eligibility criteria for patients with T2D requiring insulin could be defined without a need to define intensity of insulin usage among different sub-populations but queried whether the proposed eligibility criteria for FSL2 should also specify a HbA1c threshold (like application 1785).

ESC noted that GPs are not authorised to certify eligibility to access CGM products through the NDSS. Endocrinologists, certified diabetes educators and other health professionals specialising in diabetes can determine whether patients meet the eligibility criteria for CGM on the NDSS. However, ESC considered it appropriate that general practitioners (GPs) be authorised to certify eligibility to access CGM products through the NDSS. ESC noted that most patients with T2D are diagnosed and managed by a GP who regularly monitors their HbA1c. ESC considered that there was no capacity for all patients to see an endocrinologist or diabetes educator (currently authorised to certify eligibility) and that this was a significant issue for equity, especially in rural areas where patients may have less access to non-GP health professionals. ESC also considered the ability for GPs to certify eligibility would be especially important for GDM patients. ESC discussed whether a pharmacist could authorise eligibility; however, ESC considered that it was unclear how they could do this without requesting data from a GP or how they would manage FSL2 use and outcomes going forward.

ESC considered the public consultation feedback received for this application alongside the feedback received for MSAC Application 1785. ESC noted that a large number of submissions in this feedback had been received and that the feedback came from a variety of sources, including professional organisations, peak bodies, medical device companies, individual healthcare providers, and Aboriginal health and community service providers.

The feedback focused on the potential benefits of CGM products, highlighting the capacity for real-time monitoring to reduce hypoglycaemic events, especially at night. This capability reduces the fear of hypoglycaemic events and provides peace of mind to patients and their carers, especially when a patient is older, has cognitive disability or is living alone. The feedback also noted that the real-time feedback afforded by CGM helps people understand the impact of their lifestyle on blood glucose levels (BGLs) in real time, which in turn builds confidence and self-efficacy, facilitates more informed and timely decision-making, and helps people feel more engaged in their own treatment.

Additional potential benefits highlighted through public consultation included the potential for reduced comorbidities and complications; reduced anxiety about insulin dosing and fluctuations in BGL, especially for people with needle aversion; reduced need for painful finger prick testing. CGM allows more discreet monitoring which reduces stigma, fear and shame, especially for Aboriginal and Torres Strait Islander patients. The feedback also mentioned the capacity for remote monitoring by carers (which may be especially useful for patients in aged or supported care), higher confidence for carers, reduced emotional and logistical load on carers, enhanced opportunities for patient education, and (where relevant) improved support for the involvement of families in informed and collaborative care decisions. Some of the feedback highlighted the potential for CGM to improve equity and access to care, especially for people with physical disability or those in rural and remote areas. ESC considered that formal evidence was needed for some of the potential benefits proposed by the public consultation feedback.

Several submissions in the feedback flagged a need for workforce skill-building opportunities to ensure the technology is used effectively. Support was expressed for the inclusion of GPs in the list of health professionals authorised to certify eligibility to access CGM products through the NDSS. There were also suggestions that subsidised access to CGM products could be expanded to include their short-term use in newly diagnosed T2D patients for the purpose of education and prevention of progression. ESC noted that there was currently no evidence related to short-term use.

ESC noted the separate clinical management algorithms for the 3 PICO sets. In the proposed clinical management algorithm for PICO set 1, ESC noted that there was no mention of the need for SMBG if a person's symptoms did not match their CGM results. ESC considered that patients using CGM would still need access to SMBG in this situation. In the proposed clinical management algorithm for PICO set 2, ESC noted that the prescribed duration of use should be from week 24-28 until delivery for patients with GDM, unless they have been diagnosed earlier.

ESC noted that the comparator in each of the 3 PICO sets was SMBG using a finger-prick capillary blood sample, glucose test strips and a glucose meter, and considered this appropriate.

ESC noted the clinical claim of non-inferior safety compared with SMBG for all PICO sets. ESC considered that there was a low level of evidence for this claim and that the evidence was uncertain. For PICO set 1, ESC noted that 5 studies reported adverse events (AEs), but that the consistency of reporting was very low – only one study reported AEs for SMBG and the event rates were low. ESC noted that AEs associated with the FSL included sensor insertion and site reactions such as insertion site bruising, oedema and pain. For PICO set 2, ESC noted that only one case series study reported AEs and that no severe or unanticipated AEs were reported. Local, mild AEs were reported for 8 FSL patients (33% of patients), none of which resulted in withdrawal. Pruritus was reported for 7 patients, erythema for 2 patients and pain for one patient. For PICO set 3, ESC noted that no safety outcomes were reported. ESC considered that the clinical claim of non-inferior safety for all 3 PICO sets was not evidence-based but was, on balance, acceptable.

ESC queried whether there could be safety issues if a CGM system gave an inaccurate reading, which could lead to a patient taking a higher than required dose of insulin and experiencing hypoglycaemia, but noted that the Therapeutic Goods Administration would have considered this issue when approving the device. ESC noted that CGM systems measure glucose levels in the interstitial fluid, rather than blood glucose levels (BGL) as measured by SMBG. Therefore there can be a delay between changes in BGL and changes in glucose levels in the interstitial fluid as measured by CGM systems, which may raise safety issues. However, ESC noted that it is recommended that patients use SMBG if their symptoms do not match their CGM results.

ESC noted the clinical claim of superior effectiveness compared with SMBG. For PICO set 1, ESC noted that there were 5 comparative studies including 2 randomised controlled trials (RCTs) and that the evidence base was mainly small, open studies with varied timeframes. ESC noted that there were no Australian studies and that all the studies were in adult patients. ESC noted that the result of the meta-analysis of the incremental change from baseline in HbA1c for the FSL compared with SMBG including all 5 comparative studies was −0.29%. ESC noted that the weighting given to the 3 cohort studies in this meta-analysis was approximately 70%. Two cohort studies demonstrated a reduction in hospitalisations due to glycaemic-related events.

ESC noted that the applicant had proposed a minimum clinically important difference (MCID) of 0.3% as the threshold for clinical effectiveness which was not technically met by the meta-analysis result (i.e. without rounding up). This threshold is lower than the MCID of 0.5% that has previously been accepted by the Pharmaceutical Benefits Advisory Committee (PBAC), including to assess clinical effectiveness in HbA1c changes in T2D (refer to the PBAC PSD for semaglutide). The International Diabetes Federation, England's National Institute for Health and Care Excellence, the Australian Diabetes Society and the Royal Australian College of General Practitioners have also nominated 0.5% as the MCID for HbA1c. The European Medicines Agency[30] guidance supports the use of a 0.3% HbA1c to establish non-inferiority.

ESC considered that PBAC has set a long standing precedent for 0.5% as the MCID for HbA1c and to the ADAR did not provide a basis to accept a smaller MCID. ESC considered this would lead to a conclusion of non-superiority of FSL compared to SMBG in clinical effectiveness based on the primary outcome of change in HbA1C. ESC acknowledged that there was some evidence of a linear epidemiological relationship between HbA1C and various diabetes-related complications from the UK Prospective Diabetes Study (UKPDS) but this study was conducted more than 25 years ago.

ESC noted the argument for acceptance of a MCID of 0.3% for CGM products in the applicant's pre-ESC response. The pre-ESC response noted that the Ratified PICO confirmation stated that "…the minimum clinically important difference (MCID) for change in HbA1c for T2D reported in the published literature ranges from 0.3% to 0.5%" The pre-ESC response also cited the European Medical Agency (EMA), which stated that "even apparently small reductions in HbA1c have been shown to be clinically relevant in terms of risk reduction of diabetic complications", with both the FDA and EMA recommending a HbA1c change non-inferiority margin of 0.3% based on the level of clinical benefit linked to reduced long term complications.

ESC advised that substantive evidence should be provided in support of any change to the 0.5% MCID that was accepted by the PBAC. ESC noted that HbA1c is a surrogate outcome for diabetes-related health outcomes. ESC referred to Appendix 12 of the MSAC Guidelines, which describes (p 296) an approach to establishing a surrogate threshold effect using a meta-regression of randomised trials (in this case of any intervention in T2D) comparing the observed treatment effect on the proposed surrogate measure (in this case HbA1c within the first 12 months) with the observed treatment effect on the target patient-relevant clinical outcome (in this case any one or more of the modelled diabetes complications over subsequent years).

ESC considered that if a claim of superior clinical effectiveness cannot be established based on mean change in HbA1c, an alternative, consistent with MSAC suggestions in MSAC Review 1663, may be to establish a claim of superior effectiveness accompanied by substantial evidence of improvement on other patient-relevant outcomes, such as quality of life (QoL). However, ESC noted that the ADAR did not provide such evidence. ESC acknowledged that gathering such

[30] European Medicines Agency (2023). Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus. CPMP/EWP/1080/00 Rev.2. https://www.ema.europa.eu/en/clinical-investigation-medicinal-products-treatment-or-prevention-diabetes-mellitus-scientific-guideline

evidence is difficult, given that it is not possible to conduct blinded studies comparing SMBG and CGM. ESC suggested that alternative measures of effectiveness, such as the percentage of patients achieving a target HbA1c level of less than 7%, could also be considered.

For PICO set 2, ESC noted that there were 5 studies in the evidence base, which it considered provided a low level of evidence. ESC noted that there were 2 RCTs that reported effectiveness for people with GDM. The RCT by Majewska et al. (2023) reported no difference between patients using the FSL and SMBG in mean fasting glycaemia during the first month of the study. The RCT by Zhang et al. (2021) reported that maternal hypoglycaemic events were significantly lower in the FSL group compared with the SMBG group, and that FSL use was associated with significantly greater improvements in the subjective management of GDM, but ESC noted that there was a high risk of bias associated with the study. ESC noted that there were 3 studies that reported effectiveness outcomes for the newborns of people with GDM. Majewska et al. (2023) reported that the secondary outcome of incidence of macrosomia was significantly lower in patients using the FSL, although ESC noted that no significant difference was reported in the primary outcome (glycaemic control). The non-randomised study by Bastobbe et al. (2023) reported no significant benefits for patients using the FSL and that mean HbA1c was significantly lower in patients using SMBG compared with patients using the FSL, however ESC considered HbA1c is a less reliable measurement of glycaemic control in pregnancy due to physiological changes in pregnancy. The non-randomised study by Won et al. (2025) reported no significant differences in perinatal outcomes between patients using FSL and patients using SMBG. ESC considered that there were insufficient data available to support the clinical claim of superior effectiveness for PICO set 2. However, ESC noted that PICO set 2 was a small but important subgroup for which there was potential for good clinical outcomes from using short term CGM.

For PICO set 3, ESC noted that there were 5 studies in the evidence base, 2 of which were retrospective cohort studies and 3 of which were prospective cohort studies. ESC considered that this provided a low level of evidence. Rahman et al. (2020) reported a change in HbA1c from baseline of −0.6% among patients with cystic fibrosis–related diabetes. Shimmin et al. (2020) reported a median change in HbA1c from 58.5 mmol to 55 mmol among patients with cystic fibrosis–related diabetes. Hagan et al. (2020) reported a median change in HbA1c of −0.6% among patients with cystic fibrosis–related diabetes, which was not statistically significant. Lee et al. (2022) reported that patients with T3cD were not at increased risk of glycaemic variability compared with patients with T1D or T2D when using the FSL. Shimmin et al. (2020) reported no difference in time in range between baseline and follow-up in a study of patients with cystic fibrosis–related diabetes. ESC considered that there were insufficient data available to support the clinical claim of superior effectiveness for PICO set 3. However, ESC noted that PICO set 3 was a small but important subgroup for which there was potential for good clinical outcomes from using CGM.

ESC noted the evidence on patient-related outcomes. For PICO set 1, the RCT by Haak et al. (2017) reported a significant improvement in the Diabetes Treatment Satisfaction Questionnaire score in patients using the FSL. There was no change in patients' perceived frequency of hypoglycaemia or hyperglycaemia. For PICO set 2, the non-randomised study by Won et al. (2025) reported a significant improvement in Diabetes Treatment Satisfaction Questionnaire scores in patients using the FSL. There was no significant difference in patients' perceived frequency of hypoglycaemia or hyperglycaemia. In another study, 83% of patients agreed that applying the FSL sensor was less painful than SMBG. ESC considered that there were limited data available but that the evidence was indicative of potential for improved clinical outcomes. ESC also considered that the patient-related outcomes may be underestimated because the application was based on an older version of the device (FSL) which does not include alarms for high and low BGL, unlike the FSL2.

REDACTED. ESC considered that a device-agnostic NDSS listing may be appropriate.

ESC noted that a cost-utility analysis was used for the economic evaluation for PICO set 1, which it considered appropriate. ESC also considered that the comparator, outcomes, costs, perspective, time horizon, computational method, cycle length and discount rate used were appropriate. However, ESC had concerns with a range of issues relating to the generation of the base case, the assumed health states and the transition probabilities used.

Step 1 of the model used the difference in HbA1c reduction (0.3%) reported across the two RCTs and provided an incremental cost-effectiveness ratio (ICER) of $15,000 to < $25,000 per quality adjusted life year (QALY). Step 2 used a greater difference in HbA1c reduction (0.53%) reported across all five comparative studies as the first-order base case analysis and provided an ICER/QALY of $50,000 to < $15,000. Step 3 used the HbA1c reduction from step 2 as the second-order probabilistic analysis and provided an ICER/QALY of $15,000 to < $25,000. ESC noted that the ICER/QALY for CGM over SMBG was under $15,000 to < $25,000 in all the scenarios reported in all three steps while no sensitivity analyses generated an ICER/QALY of $25,000 to < $35,000 or greater. However, ESC noted a fully editable model did not appear to be provided, and considering that this raised issues for model transparency, asked that this be clarified. 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.

ESC again noted that the applicant had selected an MCID of 0.3% as the threshold for clinical effectiveness. ESC noted that neither of the RCTs by Haak et al. (2017) and Yaron et al. (2019) met their prespecified MCIDs (of 0.35% and 0.5%, respectively). ESC reiterated that this meant it was unclear whether there was any treatment effect on HbA1c.

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.

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 type 2 Diabetes (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. ESC also noted that the equations were based on datasets from the United States and Canada, and that its applicability to Australian populations was not clearly established. 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.

ESC noted that all risk variables in the model are constant over time, except age (which changes every 10 years) and HbA1c (which is reduced to a greater extent at baseline for CGM). 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 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.

ESC noted other issues with the economic modelling, including that the model included a large cost offset generated by reduced hospitalisations for hypoglycaemic episodes or diabetic ketoacidosis. ESC noted that these events were generated from a separate before-and-after study from France, which it considered is of unclear applicability to Australia. Also, ESC noted that the baseline utility across both arms was derived from all T2D patients rather than only T2D patients requiring insulin and was not based on Australian findings on patient utility. ESC also noted that only two of the baseline characteristic variables were from people with T2D requiring insulin and that most of the remaining variables were from people with T2D regardless of insulin use.

With regard to the time horizon, ESC considered it implausible that a more favourable ICER would be generated over the shorter time horizon of 25 years ($5,000 to < $15,000 per QALY) than the longer 50 years base case ($5,000 to < $15,000 per QALY). ESC also considered that the estimated life years gained seemed large compared with the estimated QALYs gained and queried whether the reason for this might have been due to the adjustment to avoid double-counting cardiovascular deaths.

ESC noted that the following assumptions in the model for PICO set 1 led to minor uncertainties. However, ESC noted that these assumptions had conservative implications (i.e. were biased against CGM), and therefore considered that the associated uncertainties were ultimately not of significant concern:

- A 1-year disutility duration was assumed for chronic diabetic complications.
- The model assumed patients in the comparator arm used less than recommended number of blood glucose monitoring strips per day, resulting in a reduced estimated cost offset.
- The assumed cost of renal complications was likely underestimated which also resulted in a reduced cost offset.
- The model's nine diabetic complication health states omitted amputation, which resulted in reduced utility gains and reduced cost offsets.

ESC accepted the explanation in the applicant's pre-ESC response that the attenuation of effect on HbA1c relates to SMBG, not CGM.

For PICO set 2, ESC noted that a cost-consequence analysis was presented, which claimed a net cost saving. ESC noted that this was based on a reduction in macrosomia from the RCT by Majewska et al. (2023), which ESC considered to be uncertain because this secondary outcome result was not consistent with the negative primary (glycaemic) outcome result. ESC also noted that the result was based on costing each macrosomia event at $5,128 per neonate admitted, with $REDACTED being the breakeven cost. The ADAR did not explore any scenarios around these estimates despite the confidence interval around the odds ratio being very large.

For PICO set 3, ESC considered that no economic evaluation could be reasonably provided.

ESC considered the approach taken to calculating the financial implications to be reasonable.

ESC noted that the CGM uptake/substitution rates for all PICO set estimates relied on assumptions with supporting evidence from similar markets. For all PICO set estimates, the unit cost of a pack of blood glucose test strips seems appropriate because the cost to the NDSS appropriately excluded patient copayments for the applicable percentage of the patient population and therefore the estimated SMBG cost offsets were also appropriate.

ESC noted that the prevalence estimates of patients with T2D using insulin (201,080 in 2022 from a 10% sample of PBS data) used in PICO set 1 were consistent with the department's advice that PBS data was more accurate than NDSS data, as the latter covers all people that have T2D that may have used insulin at some point and will therefore tend to overestimate this figure.

ESC noted that the model for PICO set 1 assumed substantial adherence with use of the FSL2 as well as lifelong use of the device. ESC considered that uptake of, and compliance in using, the FSL2 in older patients may be uncertain, as they may experience more difficulties attaching and using CGM systems. ESC also considered that lifelong use may be an unrealistic assumption in the real world.

ESC noted that CGM products are currently free for most patients with T1D through the NDSS and that expanding access to the larger T2D population is estimated to increase the NDSS budget by between $20 million to < $30 million in year 1 and $80 million to < $90 million in year 6.

ESC considered 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. ESC also noted that, for PICO set 2, use of the device would be for months, not years, which would limit its overall financial impact. ESC also noted that new Australian guidelines for diagnosis of GDM were being developed and that these may change the financial impact. Post-ESC, ESC noted the updated guidelines had been published[31] and are due to be implemented on 1 July 2025. These guidelines set a higher threshold for diagnosis, which is likely to reduce the prevalence of diagnosed GDM and therefore the financial impact of funding access to CGM products for this population. However, the guidelines also recommend that women at higher risk of GDM are tested earlier in pregnancy, specifically recommending testing at 10-14 weeks, which may increase the duration of CGM use (and subsequently increase costs).

ESC noted that the prevalence estimates for patients aged 21 years and over with conditions similar to T1D requiring insulin were uncertain, but considered that the prevalence was unlikely to be large.

ESC noted that current NDSS listings do not differentiate between CGM products. REDACTED. Based on this, ESC considered that a device-agnostic descriptor for CGM products would likely be appropriate as the devices likely have a class effect. ESC also noted the substantial difference in device cost per year for the FSL2 ($REDACTED) and the Dexcom ONE ($REDACTED) for the assumed same outcome.

ESC noted that the populations in PICO sets 2 and 3 are small and it is unlikely that scientifically robust datasets will be developed for these two populations. Moreover, access to CGM for people with the conditions defined in PICO set 3 is already funded for those under 21 years of age while access to CGM for PICO set 2 will only be for months not years. Based on these considerations, ESC advised that MSAC may wish to assess the case for funded CGM for these populations separately from the larger PICO set 1, and that MSAC may consider a lower level of evidence sufficient for these two smaller PICO sets.

ESC noted equity of access issues related to CGM. In particular ESC noted that while CGM is fully funded for concessional status patients with T1D, an equivalent monthly co-payment of $35.90 currently applies for people aged 21 years and over who do not have concessional status. ESC

[31] Sweeting A, *et al.* (2025). Australasian Diabetes in Pregnancy Society (ADIPS) 2025 consensus recommendations for the screening, diagnosis and classification of gestational diabetes. *Med J Aust*. doi: 10.5694/mja2.52696.

noted that the T2D population is much larger than the T1D population and that funding CGM for the T2D population will have a considerable impact on budgets. ESC noted that CGM could also be considered for short-term use in newly diagnosed T2D patients for education and prevention of progression.

ESC suggested that if MSAC supports any aspect of the requested funding, MSAC may also wish to consider advising on 3 broader aspects of government policy regarding NDSS funding:

- MSAC could consider recommending that a co-payment be applicable for CGM funding for non-Aboriginal and Torres Strait Islander and non-concessional beneficiaries aged 21 years or over. This is because ESC considered that applying a full subsidy of CGM for T2D patients would 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). ESC considered that while applying the T1D CGM co-payment may marginally reduce the rate and extent of expected uptake and the associated costs, it would give the subpopulations with greatest need access to the full subsidy. Similarly, MSAC should also be aware that the request to fully subsidise CGM in GDM is consistent with the existing full subsidy of patients with T1D in the context of pregnancy.
- MSAC could recommend adoption of a device-agnostic cost-minimisation approach across suitable TGA-approved CGM systems. This approach could potentially also be extended to flash glucose monitors (FGMs). If MSAC is not satisfied that a particular CGM (and/or FGM) would provide superior health outcomes over any other CGM (and/or FGM), at least two cost-minimisation approaches could be considered to improve cost-effectiveness, noting that the upfront costs of changing between these options are relatively small (compared to T1D, in which there are clearer links for some patients using insulin pumps). The approach should also account for the different durations of sensor performance. One possible approach is straight price competition, where options which are more expensive than the cheapest option(s) are not NDSS-subsidised. An alternative approach would be similar to the PBS Therapeutic Group Premium Policy, in which the subsidy is only provided up to the cost of the cheapest option so patients pay the premium associated with the more expensive option, so there is more patient choice for more NDSS-subsidised options.
- MSAC could consider whether the proposed restriction on allowing GPs to authorise requests for the NDSS subsidy should be retained given that similar restrictions on GP authorisation do not apply to blood glucose test strips. Although PASC advised that this is not a matter for MSAC, MSAC may wish to consider whether retaining a tighter group of approved authorisers might inappropriately restrict access for the larger T2D population, reducing the rate and extent of expected uptake and the resulting financial implications. However, the equity issues raised above regarding access to authorised health professionals should be taken into account if this option is considered with expected large impact on rural and remote patients.

ESC requested that the applicant provide the following additional information to support its contention that the economic model has been sufficiently validated:

- 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. 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.
- 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).
- 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 and modelled discounted QALYs (graphed, accrued).
    - Modelled discounted cost/QALY (increment only, graphed, accrued).
- 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).

ESC also requested that further information be extracted from the studies identified in the ADAR on (i) the longevity of the treatment effect (on HbA1c levels) related to CGM use and (ii) 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).

17. Applicant comments on MSAC's Public Summary Document

Abbott is committed to working with MSAC to expand access to FreeStyle Libre (FSL) for Australians with type 2 diabetes using insulin, building on the proven benefits already seen in the funded access for type 1 diabetes. Recommendation 15 of the 2023 Parliamentary Inquiry into Diabetes identified insulin-using subpopulations as priority groups for FSL access, and this recommendation, recognised by the PICO Advisory Subcommittee (PASC), needs to be considered pragmatically by MSAC. Access for people with insulin-requiring T2D is already established in many countries.

18. Further information on MSAC

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