

# Ypsomed – 2022-23 Pre-Budget Submission

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## 1.1 Summary of Recommendation

<b>Issue</b>	<p>Continuous Glucose Monitoring (CGM) is only subsidised through the CGM Initiative as part of the National Diabetes Services Scheme (NDSS) for those under the age of 21, pregnant women, concession card holders and Aboriginal or Torres Strait Islanders.</p> <p>This results in suboptimal health and economic outcomes as a cohort of Australians are excluded from using an Automated Insulin Delivery (AID) system, comprising an insulin pump + CGM + insulin dosing algorithm.</p>
<b>Solution</b>	<p>Expand the subsidy under the NDSS so all Australians currently using an insulin pump can access CGM through the NDSS.</p>
<b>Health benefits</b>	<p>AID systems have demonstrated improved HbA1c levels, more time-in-optimal blood glucose range, and less hypoglycaemia, compared to alternative treatment strategies. Patient quality of life is improved.</p>
<b>Economic benefits</b>	<p>Use of an AID system, compared with multiple daily injections and capillary glucose testing, resulted in an incremental cost-effectiveness ratio of \$37,767 per quality-adjusted life year (QALY) gained, which is below the traditionally cited willingness to pay a threshold of \$50,000 per QALY gained in the Australian setting.</p>
<b>Investment required</b>	<p>The annual cost to Government of providing CGM to insulin pump users not currently eligible via the NDSS is estimated to be \$224M over the 5-year forward period (\$31M in Year 1 to \$59M in Year 5).</p>

## 1.2 Introduction

Australia has a world-class health system, which at its core is guided by the principle that access to fundamental health care is not dictated by an individual's financial situation.

This Pre-Budget Submission proposes a solution to further build on this strong system and improve access to life-changing Continuous Glucose Monitoring (CGM) for patients with Type 1 Diabetes (T1D).

Accurate and accessible glucose monitoring is key to effective diabetes management. CGM is a means of measuring glucose levels continuously to gain insight into patterns and trends in glucose levels throughout the day and night.

Diabetes technologies have transformed management options in T1D. The most notable innovations include the commercialisation of insulin pumps, advancements in glucose monitoring (CGM) and the capacity for these technologies to interact via insulin dosing algorithms.

When an insulin pump, CGM and algorithm are combined as an Automated Insulin Dosing (AID) system, the technologies have demonstrated:

- enhanced flexibility in insulin delivery<sup>1</sup>
- improved glucose control (AIDs have demonstrated the greatest time in range [TIR], HbA1c reduction and composite ranking for A1c and severe hypoglycaemia, compared to alternative technologies)<sup>2,3</sup>
- an opportunity to enhance quality of life (QoL)<sup>2</sup>
- to be a cost-effective solution, compared with the standard of care of multiple daily injections (MDI) and capillary glucose testing (SMBG)<sup>4</sup>

This submission urges the Australian Government to expand access to CGM to all Australians on insulin pump therapy.

### 1.3 Issue

Diabetes is the fastest growing chronic condition in Australia and one of the biggest challenges confronting Australia's health system. Approximately 1.39 million Australians have diabetes, with Type 1 Diabetes (T1D) accounting for ~9 per cent of all diabetes and increasing.<sup>5</sup>

The annual economic cost of T1D in Australia has recently been estimated as \$2.9bn, with 19% of the total cost incurred by the government.<sup>6</sup> The excess cost of diabetes to individuals and Government is substantial and greater in those with complications, such as blindness, amputations, heart disease and kidney disease.

There is consensus amongst clinicians, in Australia and globally, that the best practice approach to managing T1D is by using an insulin pump + CGM + insulin dosing algorithm in combination, so called AID systems – this is the game-changing solution required to optimise health and economic outcomes for patients and the broader health care system. It is also the best pathway to limiting the serious complications and comorbidities discussed above.

As outlined in the American Association of Clinical Endocrinology Clinical Practice Guideline:

*“AID systems are strongly recommended for all persons with T1D, since their use has been shown to increase TIR, especially in the overnight period, without causing an increased risk of hypoglycaemia. Given the improvement in TIR and reduction in hyperglycaemia with AID, this method of insulin delivery is preferred above other modalities....”<sup>7</sup>*

A recent review by a Melbourne-based research team compared the relative efficacy of available technologies for the management of T1D (Pease 2020).<sup>8</sup> Twelve technologies were compared via the results of 52 studies. They concluded that AID systems appeared best for HbA1c reduction, without increased risk of severe hypoglycaemia, and possibly improving quality of life.

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<sup>1</sup> Snaith & Walker. *Technologies in the management of type 1 diabetes*. MJA 2021. 2415 (5):202-205.

<sup>2</sup> Pease A et al. *The Efficacy of Technology in T1D: A Systematic Review, Network Meta-analysis and Narrative Synthesis*. Diabetes Technology and Therapeutics 2020;22(5):411-421.

<sup>3</sup> Pease A et al. *Time in Range for Multiple Technologies in Type 1 Diabetes: A Systematic Review and Network Meta-analysis*. Diabetes Care 2020; 43: 1967-1975.

<sup>4</sup> Pease A et al. *Cost-Effectiveness Analysis of a Hybrid Closed-Loop System Versus Multiple Daily Injections and Capillary Glucose Testing for Adults with Type 1 Diabetes*. Diabetes Technology and Therapeutics 2020;22(11):812-821.

<sup>5</sup> NDSS Snapshot data. <https://www.ndss.com.au/about-the-ndss/diabetes-facts-and-figures/diabetes-data-snapshots/>, accessed 21 Sept 2021.

<sup>6</sup> JDRF/Accenture. *Economic Cost of Type 1 Diabetes in Australia*. April 2021. <https://jdrf.org.au/100years/the-cost-of-t1d/>

<sup>7</sup> AACE clinical practice guideline: April 2021

<sup>8</sup> Pease A et al. *The Efficacy of Technology in T1D: A Systematic Review, Network Meta-analysis and Narrative Synthesis*. Diabetes Technology and Therapeutics 2020;22(5):411-421. DOI: 10.1089/dia.2019.0417

However, there is a cohort of Australians currently using insulin pump therapy without CGMs due to cost. We estimate that the cohort with access to insulin pump therapy, but without CGMs, through the NDSS was approximately 7,600 patients in 2021.

Currently, CGMs are subsidised through the NDSS for those under the age of 21, pregnant women, concession card holders and Aboriginal or Torres Strait Islanders”.

For those not covered by the NDSS, the cost is approximately \$4,000 per annum<sup>9</sup> and the cheapest CGM product on the market is not compatible with insulin pumps.

Deficiencies in the current system have been highlighted through the consensus statement of the Australian Diabetes Society, the Australian Diabetes Educators Association, the Australasian Diabetes in Pregnancy Society, and the Australasian Paediatric Endocrine Group Working Group in its comments on the current NDSS arrangements:

*“While the CGM Initiative greatly assists some groups, it does not facilitate equitable access to interstitial glucose sensors, as most adults do not have concessional status. Furthermore, the CGM Initiative will negatively affect young people who do not retain concessional status once they reach 21 years of age and thus lose access to a vital self-management tool.”<sup>10</sup>*

This feature of ‘ageing out’ is of particular concern, and presents undesirable restrictions on those of limited means.

## 1.4 Solution

To respond to this inequity, this submission proposes that the Australian Government invest approximately \$224M over the 5-year forward period through the NDSS to ensure all Australians on insulin pump therapy can access CGM.

This investment will deliver significant savings to government and improve the care of patients with T1D.

Importantly, it will also represent a strengthening of our world-class health system, which will benefit all Australians.

### 1.4.1 Benefits

We know that T1D and its complications can lead to significant costs to patients and their families, the health system and ultimately, the Australian taxpayer. Improving access to CGMs for insulin pump users will deliver health and economic benefits to Australians resulting in savings to Government and ultimately, a stronger health system.

According to JDRF and Accenture’s report, *Economic Cost of Type 1 Diabetes in Australia*, access to CGMs and pump technologies can minimise the risk of complications and emergencies, reducing average lifetime costs by 14 per cent and yielding a benefit cost ratio of 1.5.<sup>11</sup>

#### 1.4.1.1 Health benefits

A recent network meta-analysis by Pease et al (2020)<sup>12</sup> reported that integrated insulin pump and CGM systems with low-glucose suspend or hybrid closed-loop algorithms reduced HbA1c levels by 0.96% (predictive interval [95% PrI] 0.04-1.89) and 0.87% (95% PrI 0.12-1.63), compared to MDI with either flash glucose monitoring or capillary glucose testing, respectively.

In addition, integrated systems had the best ranking for A1c reduction utilising the surface under the cumulative ranking curve (SUCRA=96.4). While treatment effects were nonsignificant for many technology comparisons regarding severe

<sup>9</sup> JDRF/Accenture. Economic Cost of Type 1 Diabetes in Australia. April 2021. <https://jdrf.org.au/100years/the-cost-of-t1d/>

<sup>10</sup> Pease A, Andrikopoulos S, Abraham MB, Craig ME, Fenton B, Overland J, Price S, Simmons D, and Ross GP on behalf of the ADS, ADEA, APEG, and ADIPS Working Group 2021. Utilisation, access, and recommendations regarding technologies for people living with type 1 diabetes: A consensus statement of the Australian Diabetes Society (ADS), the Australian Diabetes Educators Society (ADEA), the Australasian Paediatric Endocrine Group (APEG), and the Australasian Diabetes in Pregnancy Society (ADIPS) Working Group. Australia. Available from: <https://diabetessociety.com.au/position-statements.asp>.

<sup>11</sup> <https://jdrf.org.au/costly-chronic-and-complicated-new-report-sheds-light-on-challenges-of-life-with-type-1-diabetes/>

<sup>12</sup> Pease A et al. *The Efficacy of Technology in T1D: A Systematic Review, Network Meta-analysis and Narrative Synthesis*. Diabetes Technology and Therapeutics 2020;22(5):411-421.

hypoglycaemia and QoL, simultaneous evaluation of outcomes in cluster analyses as well as narrative synthesis appeared to favour integrated insulin pump and continuous glucose monitors.

Further, closed-loop systems led to greater percent time in range than any other management strategy, and mean percent time in range was 17.85 (95% predictive interval 7.56–28.14) longer than with usual care of multiple daily injections with capillary glucose testing.<sup>13</sup>

#### 1.4.1.2 Economic benefits

A recently conducted cost-effectiveness analysis comparing an AID to MDI and SMBG among adults with T1D over a lifetime horizon, from the perspective of the Australian health care system, demonstrated that the cost of funding these devices would be offset by the projected long-term reductions in complications.<sup>14</sup>

The analysis by Pease et al (2020) resulted in an incremental cost-effectiveness ratio of \$37,767 per QALY gained. This is below the traditionally cited willingness to pay a threshold of \$50,000 per QALY gained in the Australian setting. Sensitivity analyses that varied baseline glycaemic control, treatment effects, technology costs, age, discount rates, and time horizon indicated the results to be robust.

#### 1.4.1.3 Savings to Government

As outlined in the *Australian National Diabetes Strategy 2021 – 2030*, diabetes can result in a range of health complications, including heart disease, stroke, eye disease, kidney disease, nerve damage, foot problems and gum disease. Diabetes is also associated with significant mental health challenges, including mental distress, anxiety and depression.

These complications lead to significant costs. As found in JDRF/Accenture's report:

*"In 2020, T1D cost \$2.9 billion through healthcare costs, reduced wellbeing, lower employment and additional care. This equates to \$51 billion over the life of individuals who currently have T1D.*

*"The majority of this cost is driven by complications. The average annual cost of T1D for individuals with no complications is around \$9,000. This annual cost increases to around \$32,000 should the individual develop a severe T1D-related complication – such as blindness or chronic kidney disease.*

*"Given current complication prevalence, the average annual cost of T1D is \$22,000 per person."<sup>15</sup>*

This same report also calculated the net economic benefits of expanding access to CGM devices and insulin pumps, finding:

*"Expanding access to young Australians between the age of 20-30, who are just entering the workforce and typically unable to afford private insurance, could achieve a net economic benefit of \$312 million."*

In addition, the report found:

*"Providing more Australians with access to this effective treatment could deliver a significant benefit that outweighs the cost. Providing CGM and pump access costs ~\$120,000 for each individual over their lifetime but can save \$174,000 in lifetime costs due to reduced complications and their significant impact on lives. This results in a net saving of \$54,000, or a benefit-cost ratio of 1.5."*

#### 1.4.1.4 Health equity

Finally, expanding access to CGM via the NDSS will address health inequity for patients who do not currently fulfil the eligibility criteria for the CGM Initiative, including young adults who lose access to CGM after they reach 21 years of age.

<sup>13</sup> Pease A et al. *Time in Range for Multiple Technologies in Type 1 Diabetes: A Systematic Review and Network Meta-analysis*. *Diabetes Care* 2020; 43: 1967-1975.

<sup>14</sup> Pease A et al. *Cost-Effectiveness Analysis of a Hybrid Closed-Loop System Versus Multiple Daily Injections and Capillary Glucose Testing for Adults with Type 1 Diabetes*. *Diabetes Technology and Therapeutics* 2020;22(11):812-821.

<sup>15</sup> JDRF/Accenture. *Economic Cost of Type 1 Diabetes in Australia*. April 2021. <https://jdrf.org.au/100years/the-cost-of-t1d/>

It has been estimated that access to CGMs and insulin pumps can help individuals reduce their risk of developing complications, saving \$54,000 per person.<sup>16</sup>

The benefits of AID have been recognised by the Australian Diabetes Society, the Australian Diabetes Educators Association, the Australasian Diabetes in Pregnancy Society, and the Australasian Paediatric Endocrine Group Working Group, which has concluded:

*“... that all people with type 1 diabetes should have equitable access to the most effective management systems, including technology, where clinically appropriate, regardless of age, concessional status or level of private health insurance cover.”*

## 1.5 Case Study

*David Burren, T1D patient*

After 39 years of having T1D, David Burren knows how difficult it is to manage the condition safely and enjoy a decent quality of life without access to CGM.

Now, the 54-year-old, who has been using Automated Insulin Delivery with CGM since 2017, knows well the difference this technology makes to living a healthy life.

“Before CGM, I had HbA1c results up into the 7-8% range, and trying to keep it down was a lot of work,” David said.

“The constant injections and blood testing before I could access Automated Insulin Delivery technology, was a significant day-to-day, moment-to-moment burden, and really contributed to sense of anxiety and lack of control.

“Switching to a pump system in 2010 made injections less intrusive, but didn’t really fix the issue of intermittent testing.

“Thankfully, I had the means to pay for CGM in 2016 and found out what was actually going on. It was eye-opening.

“It wasn’t cheap, but it let me see what I needed to do, and it gave me far greater control over my condition and my life.

“Having access to a system of Automated Insulin Delivery, with CGM, fixed the little things that I forget to do. It gave me peace of mind and living became easier.

“Most importantly, it improved my health outcomes. Since 2018 my HbA1c has been in the ‘non-diabetic’ reference range (at or below 5.6%) and my medical team seem continually amazed.

“I’m confident my health is now in the best place it could be, and diabetes does not feel like something that’s going to shorten my life.”

Fortunately for David, he is one the lucky few Australians who can afford to pay for such treatment, but he knows it is out of reach for too many.

“Access to CGM is not cheap. I’m not eligible for any current NDSS CGM subsidy, and health insurance doesn’t give any help either,” he said.

“But my story highlights the benefits of having access to Automated Insulin Delivery, which depends on CGM, and more Australians should have that opportunity.”

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<sup>16</sup> JDRF/Accenture. Economic Cost of Type 1 Diabetes in Australia. April 2021. <https://jdrf.org.au/100years/the-cost-of-t1d/>

## 1.6 Implementation and Costing

As aforementioned, an analysis conducted by Accenture to assess the economic cost of T1D in Australia estimated that providing CGM and pump access costs ~\$120,000 for each individual over their lifetime but can save \$174,000 in lifetime costs due to reduced complications and their significant impact on lives.<sup>17</sup> This results in a net saving of \$54,000, or a benefit-cost ratio of 1.5.

**Table 1** presents modelling conducted for this submission which demonstrates that the annual cost to government of expanding CGM access as proposed would be approximately \$224M over the 5-year forward period (\$31M in Year 1 to \$59M in Year 5).<sup>18</sup>

**Table 1 Estimated cost to Government of expanding CGM access to insulin pump users**

	2021	2022	2023	2024	2025	2026		5-year totals
Number Adults with T1DM	112492	114742	117037	119377	121765	124200		
<b>Current pump users eligible for CGM</b>	<b>7601</b>	<b>7838</b>	<b>8495</b>	<b>9174</b>	<b>9878</b>	<b>10605</b>		
Uptake of CGM	-	100%	100%	100%	100%	100%		
Annual CGM cost per patient	-	\$4,000	\$4,000	\$4,000	\$4,000	\$4,000		
<b>Annual cost to Government (Millions)</b>	<b>-</b>	<b>\$31.4</b>	<b>\$34.0</b>	<b>\$36.7</b>	<b>\$39.5</b>	<b>\$42.4</b>		<b>\$184.0</b>
Annual consumables cost	-	\$2,500	\$2,500	\$2,500	\$2,500	\$2,500		
Additional pump users	-	0	1538	3129	4777	6481		
<b>Additional consumable cost (Millions)</b>	<b>-</b>	<b>\$0</b>	<b>\$3.8</b>	<b>\$7.8</b>	<b>\$11.9</b>	<b>\$16.2</b>		<b>\$39.8</b>
<b>Total cost (Millions)</b>	<b>-</b>	<b>\$31.4</b>	<b>\$37.8</b>	<b>\$44.5</b>	<b>\$51.4</b>	<b>\$58.6</b>		<b>\$223.7</b>

Source: Data on File, Ypsomed Australia

## 1.7 About Ypsomed Australia

Ypsomed Australia was founded in 2016 and is based on Sydney. Approximately, 500 Australian patients use Ypsomed insulin pumps.

We are a wholly owned subsidiary of the Ypsomed Group, headquartered in Switzerland, is a developer and manufacturer of injection and infusion systems for self-medication. The company has more than 30 years' experience in the use of insulin pumps for the control of diabetes.

Our primary focus is serving people with diabetes with mylife Diabetescare's excellent range of products and services.

We have extensive experience with insulin pumps. Our philosophy is to embrace innovation to make our pumps work together with other technologies to ensure optimal outcomes for patients.

## 1.8 Contact

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<sup>17</sup> JDRF/Accenture. Economic Cost of Type 1 Diabetes in Australia. April 2021. <https://jdrf.org.au/100years/the-cost-of-t1d/>

<sup>18</sup> This includes the costs associated with increased insulin pump penetration