



Medtronic

Federal Budget Submission 2015-2016

Continuous Glucose Monitoring Sensor: the need to invest in type 1 diabetes



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Executive Summary

The Federal Government recognises **diabetes** as a National Health Priority Area because it significantly contributes to the burden of illness within Australia. Contributing to this burden is type 1 diabetes - a degenerative autoimmune disease currently without prevention or cure. Affecting up to 130,000 Australians, half of whom are diagnosed before 18 years of age, type 1 diabetes is one of the most common serious diseases in children.

A serious acute complication of type 1 diabetes is severe hypoglycaemia (low blood glucose levels needing third party assistance to treat) which, at the very least, is disabling and, at worst, can be fatal. In affected individuals, severe hypoglycaemia and its consequences (e.g. seizure, coma) can occur anywhere and anytime without warning.

Indeed, a particular devastating outcome in (typically) young people, for which severe hypoglycaemia is implicated, is sudden unexpected overnight death called "Dead-in-Bed" syndrome. It is estimated this may needlessly claim the lives of at least 10 Australians with type 1 diabetes each year.

Robust Australian research shows that CGM (glucose) sensors can potentially protect vulnerable patients from hypoglycaemia related serious adverse outcomes such as seizures and coma.

Accordingly, this submission requests the Federal Government, as a stakeholder already committed to diabetes research and developing a new National Diabetes Strategy, consider these recommendations:

Recommendation 1:

Commit to subsidising CGM (glucose) sensors on the National Diabetes Services Scheme (NDSS) in 2015-2016 for high risk children and adults with type 1 diabetes and impaired awareness of the warning symptoms of severe hypoglycaemia, yet can be protected by sensors from seizure, coma and potential death.

High Risk Patients: Compared to those with normal hypoglycaemia awareness, individuals with impaired hypoglycaemia awareness have a **sixfold** higher incidence of severe hypoglycaemia, among whom some can experience multiple episodes each year. Recurrent hypoglycaemia or prior severe hypoglycaemia also predisposes individuals to more severe hypoglycaemia episodes, placing vulnerable people at further risk.

Clinical Evidence: The abovementioned Australian research showed that hypo unaware children and adults using CGM sensors with an automated insulin suspension pump (which requires the sensor to detect low glucose levels in order to stop insulin delivery) were protected from severe hypoglycaemia events, i.e. no seizures, comas or deaths.

Cost-effectiveness: Based on this research, the cost-effectiveness of CGM sensors used with the automated insulin suspension pump was demonstrated within the Australian healthcare setting. This cost-effectiveness analysis was subsequently published in 2014 in *Value in Health*, which is a leading international health economic journal.

Cost: A severe hypoglycaemic event that results in hospitalisation is a greater cost to the Australian healthcare system than the annual cost of CGM sensors to protect an individual with type 1 diabetes from this serious outcome. The cost to treat an individual for type 1 diabetes-related complications is also considerably higher than the incremental annual cost of CGM sensors per patient, assuming real world use as in the Australian study.

Submission to the Department of Health (DOH): Both the Australian clinical research and cost-effectiveness analysis formed the basis of a submission to the DOH in February 2013, requesting listing of the CGM sensor on the NDSS. The DOH review is expected to be completed in Quarter 2 of 2015. *However, in the absence of a process for listing new technologies on the NDSS, this matter is expected to go before the Health Minister for consideration.*

NDSS Suitability: The CGM sensor is a disposable item worn for up to six days and then replaced. This is why the NDSS is an appropriate mechanism for funding the CGM sensor, along with other diabetes consumable products.

Eligible NDSS Patients: NDSS funding of the CGM sensor is proposed for a well-defined limited group of children, adolescents and adults with type 1 diabetes who are using an automated insulin suspension pump, yet remain at high risk of severe recurrent hypoglycaemia events such as seizures, comas and possible death due to impaired hypoglycaemia awareness. These patients are also described as being "hypo unaware". The proposed NDSS listing would give these individuals equitable and affordable access to the CGM sensor - which they currently do not have - to self-manage their risk of severe hypoglycaemia.

NDSS Investment: Robust NDSS budget estimates in the DOH submission propose **\$4.4M** in 2015-16 to **\$8.4M** in 2019-20 for **1,537** to **2,934** eligible people, respectively, using the CGM sensor. This modest investment will help to protect these high risk patients from the catastrophic outcomes of severe hypoglycaemia due to their hypo unaware state. With the yearly cost of CGM sensors less than half the cost of a hospitalisation for seizure or coma, this investment represents both Government and taxpayer value for money.

Estimates for the first five years of listing are:

| | Year 1 2015-16 | Year 2 2016-17 | Year 3 2017-18 | Year 4 2018-19 | Year 5 2019-20 |
|------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Patient number | 1537 | 2052 | 2500 | 2787 | 2934 |
| NDSS Investment | \$4.40M | \$5.87M | \$7.15M | \$7.97M | \$8.39M |

Potential Cost Savings: Listing CGM sensors for high risk patients may deliver potential healthcare budget savings, which means this technology could potentially deliver even greater value to the Government and taxpayer.

Recommendation 2:

Understand and accept the importance of access to CGM sensors as part of Real-Time Continuous Glucose Monitoring (RT-CGM) that is a clinically proven advance on finger prick tests for glucose control, as well as a technology used with insulin pump therapy which, collectively, are the basic building blocks for current and future diabetes therapies including the “closed loop” artificial pancreas system.

Good glucose control to effectively manage diabetes is achieved with RT-CGM, which measures glucose levels continuously via a CGM sensor connected to a wireless transmitter that the patient wears. The CGM sensor communicates glucose readings via the transmitter every five minutes for up to six days to an insulin pump or separate monitor device, which displays the glucose level results.

The use of RT-CGM with an insulin pump that can automatically suspends insulin delivery before glucose levels reach a pre-set low threshold, collectively, currently represents the closest available therapy to an artificial pancreas. *The insulin pump capability to suspend insulin, however, is only enabled with the CGM (glucose) sensor.* This system, which requires the CGM (glucose) sensor to operate, is currently the best available option to avoid or reduce diabetes-related seizures, comas and potential death, as well as longer term serious and costly complications.

It is critical that the CGM sensor is subsidised, otherwise current and future technologies representing even further advances toward an artificial pancreas will remain out of reach for Australians with type 1 diabetes, while the healthcare system continues to bear the cost burden of serious diabetes-related complications.

Recommendation 3:

Commit to funding subsidised access to the CGM sensor from 2015-16 for a special high risk population with type 1 diabetes who were studied in critical research conducted in Australia and for which the end result should be that these patients now benefit from this technology that has proven to deliver improved health outcomes.

Patients with impaired hypoglycaemia awareness have waited several years for CGM sensors to be listed on the NDSS – a wait that began well before Medtronic lodged a submission with the Department of Health two years ago. Given that CGM sensors are clinically proven to help protect against diabetes related seizures and comas when used with an automated insulin suspension pump, the undue delay to listing CGM sensors on the NDSS is an inequitable situation that needs resolution. If not, these individuals will continue to face serious and life threatening hypoglycaemic events, which may incur healthcare expenditure well in excess of the annual cost of CGM sensors.

The value of CGM sensors as a technology that can help prevent hypoglycaemia related seizures and coma and thus avoid the potentially high healthcare costs of these events, is a direct result of Australian research. It is therefore appropriate that real world improved health outcomes are now delivered from this investment whereby high risk patients with impaired hypoglycaemia awareness can receive the benefits of CGM sensor research. Otherwise, such research will be in vain if patients cannot access CGM sensor technology proven to help protect them against the devastating consequences of severe hypoglycaemia.

The CGM sensor research conducted in Australia, without consequent patient access to this technology, remains just that, i.e. research from which Australians with type 1 diabetes cannot benefit because they have no access. With this important research complete, a longstanding cost-effectiveness submission lodged with the Department of Health and subsequently published in a leading international health economic journal, the next important step should be real world delivery of improved health outcomes among Australians who can minimise their high risk of serious hypoglycaemia related seizures, coma and potential death with access to the CGM sensor. Now is the time for the Australian Government, which as a stakeholder in diabetes is also investing in further sensor augmented pump research currently underway, to act in bringing CGM sensor technology access to these high risk individuals.

Introduction

Diabetes is recognised as a National Health Priority Area by the Federal Government, because it significantly contributes to the burden of illness within Australia.¹ Such is the growing diabetes burden that a new national diabetes strategy is being developed under the Coalition Government, for which a purposely appointed national Diabetes Strategy Advisory Group is due to report to the Federal Health Minister in April 2015.²

The Government has also committed \$35 over five years towards advancing research into effective treatments and an eventual cure for type 1 diabetes³. This is a degenerative autoimmune disease that currently cannot be prevented or cured, yet affects up to 130,000 people in Australia, half of whom are diagnosed before their 18th birthday.⁴

Indeed, around one in every 700 Australian children has type 1 diabetes, making it one of the most common serious diseases amongst children.⁴

In keeping with the Government's commitment to a national diabetes strategy and research is the need to invest in subsidised access to proven treatments that can minimise or prevent the serious complications of type 1 diabetes, which can be devastating. Otherwise, research efforts will be in vain if Australians living with type 1 diabetes cannot benefit from accessing the resultant technologies shown to substantially improve their health outcomes and reduce the high burden of this disease.

One such serious acute complication of type 1 diabetes is severe hypoglycaemia (low blood glucose levels needing third party assistance to treat) which, at the very least, is disabling and, at worst, can be fatal.

This submission outlines the urgent need for the Federal Government to subsidise Continuous Glucose Monitoring (CGM) sensors on the National Diabetes Services Scheme (NDSS) for a specific patient group with type 1 diabetes who is at particular high risk of seizure, coma and potential death as a result of severe hypoglycaemia. In these individuals, severe hypoglycaemia and its serious acute consequences (e.g. seizure, coma) can occur anywhere, anytime and without warning. Yet the clinical evidence shows CGM sensors can potentially protect these vulnerable patients.

Real-Time Continuous Glucose Monitoring (RT-CGM) is a clinically proven technology shown to prevent severe hypoglycaemia events such as seizure and coma in high risk patients who are "hypoglycaemia unaware" when used with an insulin pump that can automatically suspend insulin delivery to avoid these dire outcomes.^{5,6}

Recommendations for Patient Access to Continuous Glucose Monitoring (CGM) Sensors

Recommendation 1:

Commit to subsidising CGM (glucose) sensors on the NDSS in 2015-2016 for high risk children and adults with type 1 diabetes who have impaired awareness of the warning symptoms of severe hypoglycaemia, yet can be protected by these sensors from the catastrophic consequences of seizure, coma and potential death.

1. Recognise the high burden of hypoglycaemia and its impact on Australians living with type 1 diabetes.

Good glucose (sugar) control in diabetes is critical because poor control can lead to serious and costly longer-term diabetes-related complications such as blindness, kidney failure, amputations, heart disease and strokes.

A major contributor to poor glucose control is hypoglycaemia (low blood glucose level), which has been called "*the single greatest barrier to achieving and maintaining good glycaemic control in patients with diabetes.*"⁷ It causes significant morbidity ranging from various physical symptoms (e.g. palpitations, neurological impairments such as seizure, coma) to adverse psychological outcomes (e.g. cognitive deficiencies, mood disturbance).

As a much feared complication of diabetes, hypoglycaemia is also responsible for up to 10% of deaths in people with type 1 diabetes.^{8,9,10} A particular devastating complication of type 1 diabetes is (typically) young people, for which

¹ <http://www.aihw.gov.au/national-health-priority-areas/> [Accessed 30 January 2015]

² [http://www.health.gov.au/internet/ministers/publishing.nsf/Content/9171394579AAD408CA257C350081D467/\\$File/PD020.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/9171394579AAD408CA257C350081D467/$File/PD020.pdf) [Accessed January 2015]

³ <http://www.arc.gov.au/ncgp/sri/diabetes.htm> [Accessed 30 January 2015]

⁴ Garvan Institute. Diabetes – Type 1 <http://www.garvan.org.au/research/diseases-we-research/diabetes-type-1> [Accessed 30 January 2015]

⁵ Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. JAMA 2013; 310(12):1240-1247

⁶ Bergenstal RM et al. Threshold-based insulin-pump interruption for reduction of Hypoglycaemia. N Engl J Med 2013; 369(3):224-32

⁷ Pickup JC. Insulin-pump therapy for type 1 diabetes mellitus. N Engl J Med 2012;366(17):1616-24

⁸ Cryer PE. Severe hypoglycaemia predicts mortality in diabetes. Diabetes Care 2012;35:1814-1816

⁹ Skriverhaug T et al. Long-term mortality in a nationwide cohort of childhood-onset type 1 diabetic patients in Norway. Diabetologia (2006) 49: 298–305

¹⁰ Gehlert R et al. Revisiting hypoglycemia in diabetes. Osteopathic Family Physician 2014;1:19-25

severe hypoglycaemia is implicated, is sudden unexpected death occurring overnight called “Dead-in-Bed” syndrome.¹¹

Dead-in-bed syndrome needlessly accounts for up to 5-10% of deaths in individuals with type 1 diabetes under 40 years of age and is currently estimated to claim the lives of at least 10 Australians each year.¹¹

2. Recognise the need for Australians with type 1 diabetes and consequent impaired hypoglycaemia awareness, who are at high risk of severe hypoglycaemia events, to have subsidised access to CGM sensors for use with an insulin pump that has automated insulin suspension capability.

People with type 1 diabetes who are at high risk of suffering severe recurrent hypoglycaemia events (e.g. seizure, coma, potential death) are those with impaired awareness of the warning symptoms of hypoglycaemia. They are often described as being “hypo unaware”.

While the average person with type 1 diabetes experiences one severe hypoglycaemia episode per year, people with impaired hypoglycaemia awareness or hypo unaware have, on average, 2.8 episodes per year, among whom some can experience multiple episodes each year.^{11,12}

Compared to those with normal hypoglycaemia awareness, people with impaired hypoglycaemia awareness have a **sixfold** higher incidence of severe hypoglycaemia.¹² Recurrent hypoglycaemia or prior severe hypoglycaemia also predisposes individuals to more severe hypoglycaemia episodes, placing vulnerable people at further risk.^{11,12}

3. Recognise the clinical effectiveness and cost-effectiveness of CGM sensors that can potentially protect patients against severe hypoglycaemia events such as seizures and comas when used with an insulin pump that has automated insulin suspension capability.

Two recent landmark clinical studies found that severe hypoglycaemia episodes in type 1 diabetes are prevented when CGM sensors are used with an insulin pump that can automatically suspend insulin delivery to avoid or minimise hypoglycaemia episodes such as seizure and coma before glucose levels go too low.^{13,14}

Importantly, one of these studies is an Australian trial by Ly et al 2013, which showed hypo unaware children and adults using CGM sensors with an automated insulin suspension pump were protected from severe hypoglycaemia events. In these high risk patients there were no seizures, comas or deaths.¹³

Based on this clinical study, the cost-effectiveness of the CGM sensor used in combination with the automated insulin suspension pump was demonstrated within the Australian healthcare setting.¹⁵ The cost-effectiveness analysis was subsequently published in *Value in Health* - a leading international health economic journal that is also the official publication of The International Society for Pharmacoeconomics and Outcomes Research.¹⁵ The full cost-effectiveness article is available at: [http://www.valueinhealthjournal.com/article/S1098-3015\(14\)01885-3/pdf](http://www.valueinhealthjournal.com/article/S1098-3015(14)01885-3/pdf)

There is an urgent need for hypo unaware patients using an insulin pump that can automatically suspend and resume insulin delivery to have subsidised access to CGM sensors for maintaining glucose levels within an acceptable range. These sensors are needed for the automated insulin suspension pump to be fully operational in preventing low glucose levels and so help protect this high risk patient group from the acute catastrophic consequences of severe hypoglycaemia including seizures, coma and potential death.

4. Recognise that the annual cost of CGM sensors per patient is less than the cost of hospitalisation for a severe hypoglycaemic event, as well as the additional costs of diabetes-related complications.

A severe hypoglycaemic event that results in hospitalisation is a greater cost to the Australian healthcare system than the annual cost of CGM sensors to protect an individual with type 1 diabetes from this serious outcome.

¹¹ Jenkins A & O’Neal. Dead-in-bed syndrome and severe nocturnal hypoglycemia in type 1 diabetes and potential preventative options. *Infusystems Asia* 2013 8(2):13-17

¹² Gold AE et al. Frequency of severe hypoglycaemia in patients with type 1 diabetes with impaired awareness of hypoglycaemia. *Diabetes Care* 1994;17(7):697-703.

¹³ Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. *JAMA* 2013; 310(12):1240-1247

¹⁴ Bergenstal RM et al. Threshold-based insulin-pump interruption for reduction of Hypoglycaemia. *N Engl J Med* 2013; 369(3):224-32

¹⁵ Ly T et al. A Cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycemic unaware patients with type 1 diabetes. *Value in Health* 2014;17:561– 6 9

While the total population cost of severe hypoglycaemia in type 1 diabetes has not been quantified in Australia, it is known that the consequences and treatment of severe hypoglycaemia impose significant strain on the health care system and society by way of direct medical costs and indirect lost productivity costs.¹⁶ For example, the annual cost of acutely treating hypoglycaemia episodes with hospitalisation and ambulance in 2008 in the UK - which has a comparable healthcare system to that in Australia - was estimated at £15 million.¹⁶ In today's money terms, this translates to \$35.5M Australian dollars (assuming historical annual inflation rates and exchange rate £1 = 1.96) for severe hypoglycaemia events requiring hospitalisation and ambulance services.^{17,18}

The comparisons in Table 1 show that the incremental annual cost of glucose sensors per patient, assuming real world use as in the Australian study¹⁹ is considerably lower than the additional yearly healthcare cost to hospitalise a patient for one hypoglycaemic event²⁰ or to treat the individual for type 1 diabetes-related complications.²¹

Table 1: Comparison of CGM Sensor and Annual Healthcare Costs Per Patient With Type 1 Diabetes

| Healthcare Item | Annual Cost / Patient |
|---|-----------------------|
| CGM sensor reimbursed @\$75 per sensor (each sensor used for 6 days) | \$2,746 |
| Hospitalisation for one severe hypoglycaemic event (e.g. seizure, coma) ²⁰ | \$5,684 |
| Additional cost of microvascular complications (e.g. retinopathy, kidney damage or failure, nerve damage) @ \$6,310 versus no complications @ \$2,644 ²¹ | \$3,666 |
| Additional cost of macro-vascular complications (e.g. coronary heart disease, stroke, peripheral vascular disease) @ \$11,363 versus no complications @ \$2,644 ²¹ | \$8,719 |
| Additional cost of both macro-vascular and microvascular complications @ \$13,931 versus no complications @ \$2,644 ²¹ | \$11,287 |

5. Commit to listing CGM sensors on the NDSS in fiscal year 2015-16 for a specific well-defined patient group with type 1 diabetes and impaired hypoglycaemia awareness who are at high risk of severe hypoglycaemic events. These patients require timely access to the CGM sensor that enables the function of an insulin pump with automated insulin suspension to help protect them against severe hypoglycaemia and its dire consequences including seizure, coma and potential death.

The Department of Health is currently reviewing a submission by Medtronic lodged February 2013, which requests that CGM sensors be listed on the NDSS. The sensor is a disposable item worn for up to six days and then replaced, which is why the NDSS is considered an appropriate mechanism for funding this device, along with other diabetes consumable products. *In the absence of a process for listing new technologies on the NDSS, this matter is expected to go before the Health Minister for consideration.*

The request is for a well-defined limited population of children, adolescents and adults with type 1 diabetes who are using an automated insulin suspension pump, yet remain at high risk of experiencing severe recurrent hypoglycaemia events such as seizures, comas and possible death due to their impaired hypoglycaemia awareness.

The proposed NDSS investment is **well under \$10 million per year in each of the first five years** of listing for these high risk patients. Robust NDSS budget estimates in the submission from **\$4.4M** in 2015-16 to **\$8.4M** in 2019-20 are based on **1,537** to **2,934** eligible people, respectively, using the CGM sensor. This modest investment will help to protect these high risk patients from catastrophic outcomes. With the yearly cost of CGM sensors less than half the cost of a hospitalisation for seizure or coma, this investment represents both Government and taxpayer value for money.

Table 2: NDSS Budget Implications of Listing the CGM Sensor

| | Year 1 2015-16 | Year 2 2016-17 | Year 3 2017-18 | Year 4 2018-19 | Year 5 2019-20 |
|------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Patient number | 1537 | 2052 | 2500 | 2787 | 2934 |
| NDSS Investment | \$4.40M | \$5.87M | \$7.15M | \$7.97M | \$8.39M |

¹⁶ Kedia N. Treatment of severe diabetic hypoglycemia with glucagon: an underutilized therapeutic approach. Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy 2011;4:337-346.

¹⁷ <http://www.rateinflation.com/inflation-rate/australia-historical-inflation-rate> [Accessed 3 February 2015]

¹⁸ <http://www.oanda.com/currency/live-exchange-rates/GBPAUD/> [Accessed 3 February 2015]

¹⁹ Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. JAMA 2013; 310(12):1240-1247

²⁰ Round 14 cost weight Public sector national estimates (2009-2010)

²¹ Colagiuri S, Brnabic A, Gomez M, Fitzgerald B, Buckley A, Colagiuri R. DiabCo\$t Australia Type 1: Assessing the burden of Type 1 Diabetes in Australia. Diabetes Australia, Canberra. November, 2009.

Furthermore, there are potential healthcare budget savings by listing CGM sensors on the NDSS for these patients, which means this technology can deliver even greater value to the Government and taxpayer.

The table below shows the financial implications to the Government, net of cost savings elsewhere in the healthcare budget, for different scenarios that vary the assumptions regarding likelihood of seizure or coma without the combined CGM sensor / automated insulin suspension pump, as well as the treatment costs, i.e. extent of healthcare professional services and hospitalisation.

These scenarios all assume zero severe hypoglycaemia events, i.e. no seizures or coma, for patients using the combined CGM sensor / automated insulin suspension pump based on evidence from the Australian clinical study.²² This is compared in each scenario with the probability of severe hypoglycaemia events for high risk patients receiving pump therapy **without** CGM sensor protection, which ranges from at least an 8.61% based on the Australian study to 100% if all patients experience a severe hypoglycaemia event (seizure, coma) resulting in hospitalisation.

Table 3: Net Healthcare Budget Implications of Listing the CGM Sensor on the NDSS

| | Year 1 2015-16 | Year 2 2016-17 | Year 3 2017-18 | Year 4 2018-19 | Year 5 2019-20 |
|---|-------------------|-------------------|-------------------|-------------------|-------------------|
| Patient number | 1537 | 2052 | 2500 | 2787 | 2934 |
| NDSS Investment | \$4.40M | \$5.87M | \$7.15M | \$7.97M | \$8.39M |
| Net financial implications - scenarios | | | | | |
| Base case: 8.61% probability of seizure /coma events without CGM sensors); 23.1% treated by a HCP of which 28% are hospitalized | \$4.23M | \$5.65M | \$6.89M | \$7.68M | \$8.08M |
| Vary treatment costs only: 8.61% probability of seizure /coma events without CGM sensors; all events treated by a healthcare professional (HCP) and hospitalized | \$3.05M | \$4.07M | \$4.96M | \$5.53M | \$5.82M |
| 32.05% seizure/coma probability without CGM sensors and all events treated by a HCP & hospitalized (≈ cost neutral) | \$53 | \$70 | \$86 | \$96 | \$101 |
| 50% seizure/coma probability without CGM sensors; 76.9% treated by a HCP of which 100% are hospitalized (cost saving) | (\$344k) | (\$460K) | (\$560K) | (\$625K) | (\$657K) |
| 100% seizure/coma probability without CGM sensors and all events treated by a HCP and hospitalized (cost saving) | (\$3.77M) | (\$5.04M) | (\$6.13M) | (\$6.84M) | (\$7.20M) |

The base case scenario that conservatively assumes an 8.61% probability of seizures or coma translates to net Government costs of **\$4.23M** in 2015-16 to **\$8.08M** in 2019-20 due to MBS and PBS cost savings from treating fewer of these severe hypoglycaemic events.

However, the base case scenario does not factor in various health complications likely to result from inadequately controlled low and high glucose levels nor that individuals with impaired hypoglycaemia awareness have, on average, approximately three severe hypoglycaemic events per year²³, which may all require hospitalisation.

Indeed, for hypo unaware individuals at high risk of severe hypoglycaemic events or who have experienced seizures, coma or other serious consequences requiring admission to hospital one or more times per year, the more realistic scenario is cost neutrality or healthcare system savings. Indeed, if only a 32% probability of seizure or coma requiring hospitalisation is assumed in these high risk patients, the CGM sensor is at least cost neutral to the healthcare system, while delivering the major benefit of protection against seizures and coma.

*Note: There are two types of insulin pump with automated insulin suspension, which are available on the Protheses List and accessible to patients who have appropriate private health insurance. There is also an automated insulin suspension pump available on the Government Insulin Pump Program. This Budget submission makes no explicit requests or inferences in relation to any of these insulin pumps. **The only request in this submission is that the Government commits to the timely listing of CGM sensors on the NDSS from 2015-16.***

²² Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. JAMA 2013; 310(12):1240-1247

²³ Gold AE et al. Frequency of severe hypoglycaemia in patients with type 1 diabetes with impaired awareness of hypoglycaemia. Diabetes Care 1994;17(7):697-703.

6. Commit to subsidising the CGM sensor within expected NDSS budgets for years 2015-16 to 2019-20 so high risk patients in need of this technology can have timely, reliable and affordable access.

While the Australian Government has a responsibility to ensure the ongoing sustainability and strength of healthcare schemes such as the NDSS and is operating within a fiscal climate with budget challenges, it is important to recognise that the proposed investment for CGM sensors represents a modest allocation of funds within the annual NDSS budget for a high risk patient subgroup in need of access to the CGM sensor.

Also important is that strict patient eligibility criteria for the CGM sensor have been proposed in the submission to the Department of Health, in line with the Australian clinical study inclusion criteria. This helps to provide fiscal certainty for the proposed investment from current and future NDSS budgets with minimal opportunity for 'leakage'. The proposed patient criteria are yet to be finalised with the Department of Health pending completion of their review.

Via the NDSS, the Australian Government aims to ensure that people with diabetes have timely, reliable and affordable access to products and services enabling them to effectively self-manage their condition. The CGM sensor is consistent with this tenet whereby the patient uses the sensor for self-managing real time continuous glucose monitoring in combination with insulin pump therapy. This combined system giving patients advanced warnings and alerts to glucose values outside of acceptable range, thus enabling the patient to take timely action to prevent hypoglycaemia episodes.

The proposed NDSS listing would give hypo unaware individuals equitable and affordable access to the CGM sensor - which they currently do not have - to self-manage their risk of severe hypoglycaemia. Subsidising CGM sensors on the NDSS is critical so these individuals can use the automated insulin suspension pump (which is already accessible to them) to fully benefit from its capabilities in providing optimum glucose control and, in particular, self-protect against severe hypoglycaemia and its dire consequences.

Without subsidised access to the sensor which is a critical component that signals to the automated insulin suspension pump to stop insulin delivery *before* glucose levels go too low, these high risk hypo unaware individuals are highly unlikely to be able to protect themselves against seizures, comas and potential death. These severe hypoglycaemia related events can occur anywhere and anytime, especially at night during sleep when individuals are not awake to take action against low glucose levels.

Patients with impaired hypoglycaemia awareness have waited several years for CGM sensors to be listed on the NDSS – a wait that began well before the Medtronic submission was lodged with the Department of Health. Given this technology is clinically proven to help protect against diabetes related seizures and comas when used with an automated insulin suspension pump, the undue delay to listing the CGM sensor is an inequitable situation that needs resolution. If not, these individuals will continue to face serious and life threatening hypoglycaemia related events, which may incur considerable healthcare expenditure well in excess of the annual cost of CGM sensors.

7. Commit to placing Australian patients with type 1 diabetes on a par with patients in other countries who have subsidised access to CGM sensors.

Multiple countries around the world including European countries such as the UK, Switzerland, The Netherlands, France, Italy, as well as Japan and the US, among others are subsidizing CGM sensors according to varying clinical eligibility criteria.^{24,25} *Australia lags behind Westernised countries in providing public and private subsidised access to continuous glucose monitoring.* For example, the UK National Health Service - the most comparable to Australia's healthcare system - publicly funds around 85% of CGM use.²⁴

²⁴ Heinemann L et al. Reimbursement for Continuous Glucose Monitoring: A European View. Journal of Diabetes Science and Technology 2012;6(6):1498-1502

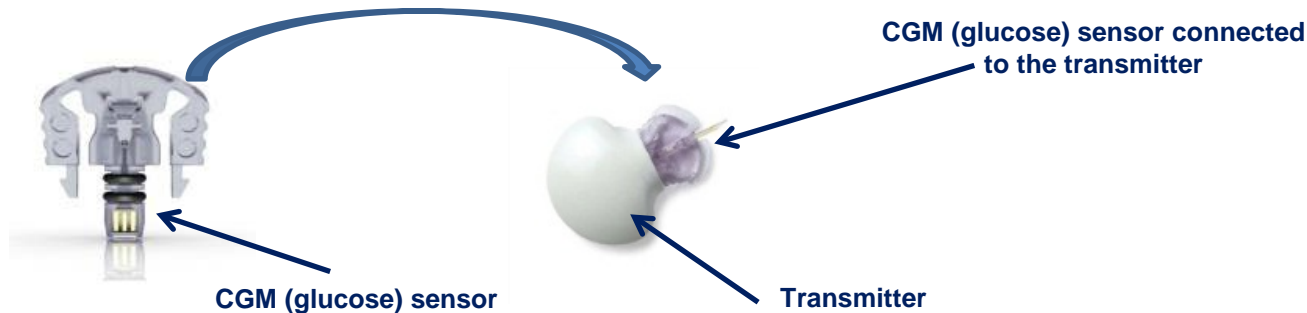
²⁵ Data on file

Recommendation 2:

Understand and accept the importance of access to CGM sensors as part of RT-CGM that is a clinically proven advance on finger prick tests for glucose control, as well as a technology used in combination with insulin pump therapy, which collectively are the basic building blocks for current and future diabetes therapies including the “closed loop” artificial pancreas system.

Good glucose control to effectively manage diabetes is achieved with Real-Time Continuous Glucose Monitoring (RT-CGM), which measures glucose levels continuously via a sensor connected to a wireless transmitter that the patient wears. The CGM glucose sensor and transmitter components are shown in **Figure 1**.

Figure 1: CGM (Glucose) Sensor and Transmitter



The CGM (glucose) sensor is a critical component of RT-CGM for people with diabetes. The disposable sensor communicates glucose readings every five minutes for up to 6 days via the transmitter to an insulin pump or separate monitor device, which displays the glucose level results.

As an advance on finger prick testing, RT-CGM is the only test method that measures and shows fluctuating glucose levels continuously throughout the day, every day, enabling analysis of glucose patterns in real time. This predictability allows patients to take timely action to avoid high and low glucose levels not identified by other methods and so avoid serious adverse outcomes.

When RT-CGM is combined with an insulin pump that predicts low glucose levels in advance based on glucose sensor readings, the pump will automatically stop insulin delivery and then resume insulin release when glucose levels recover. This integrated system is shown in **Figure 2** overleaf.

The sensor augmented pump therapy system with automated insulin suspension has consistently demonstrated health outcome benefits in numerous robust clinical studies,^{26,27,28,29,30,31,32} as well as shown to be cost-effective in the Australian healthcare setting.³³

The combined use of RT-CGM with an insulin pump that can automatically suspend insulin delivery before glucose levels reach a pre-set low threshold provides an integrated diabetes management system, which represents the closest available therapy to an artificial pancreas. *However, the insulin pump capability to suspend insulin is only enabled with the CGM (glucose) sensor.*

The CGM sensor, transmitter and automated insulin suspension pump available in Australia, used collectively as one integrated system to avoid hypoglycaemia, are the basic building blocks of a future “closed loop” artificial pancreas that would mimic the human pancreas. This system, which requires the CGM (glucose) sensor to operate, is currently the best available option to avoid or reduce diabetes-related seizures, comas and potential death, as well as longer term serious and costly complications. It is critical that the CGM sensor is subsidised, otherwise current and future technologies representing even further advances toward an artificial pancreas will remain out of reach for Australians with type 1 diabetes, while the healthcare system continues to bear the cost burden of disease complications.

²⁶ Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. *JAMA* 2013; 310(12):1240-1247

²⁷ Bergenstal RM et al. Threshold-based insulin-pump interruption for reduction of Hypoglycaemia. *N Engl J Med* 2013; 369(3):224-32

²⁸ Choudhary P et al. Insulin pump therapy with automated insulin suspension in response to hypoglycemia: reduction in nocturnal hypoglycemia in those at greatest risk. *Diabetes Care* 2011 Sep;34(9):2023-5

²⁹ Ly T et al. Analysis of glucose responses to automated insulin suspension with sensor-augmented pump therapy. *Diabetes Care* 2012;35:1462-5

³⁰ Danne T et al. Prevention of hypoglycemia by using low glucose suspend function in sensor-augmented pump therapy. *Diabetes Technology and Therapeutics* 2011;13(11):1129-34

³¹ Agrawal P et al. Usage and effectiveness of the low glucose suspend feature of the Medtronic Paradigm Veo insulin pump. *Journal of Diabetes Science and Technology* 2011;5(5):1137-41

³² Garg S et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. *Diabetes Technology and Therapeutics* 2012;14(3):1-5

³³ Ly T et al. A Cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycemic unaware patients with type 1 diabetes. *Value in Health* 2014;17(2014)561 – 6 9

Recommendation 3:

Commit to funding subsidised access to the CGM sensor from 2015-16 for a special high risk population with type 1 diabetes, who were studied in critical research conducted in Australia and for which the end result should be that these patients now benefit from this technology that has proven to deliver improved health outcomes.

It is noteworthy that the Australian Government, as a stakeholder in diabetes, is investing in other Australian research currently underway, which involves use of CGM sensors with an automated insulin suspension pump that has hypoglycaemia predictive capabilities. The sensors will enable the pump to predict when hypoglycaemia is going to occur and thus stop insulin delivery early enough to prevent it from happening.

This additional research builds on the outcomes of the Australian study by Ly et al 2013, which showed the prevention of diabetes-related seizures and comas from severe hypoglycaemia when the CGM sensor is combined with an automated insulin suspension pump.³⁴

It is therefore appropriate that high risk patients with impaired hypoglycaemia awareness now receive the benefits of CGM sensor research completed by Ly and colleagues, in order to avoid the serious consequences of severe hypoglycaemia. Otherwise, such research will be in vain if patients cannot access the technologies proven to deliver superior health outcome benefits.

Importantly, the completed research was the main clinical and economic basis of the CGM sensor submission by Medtronic to the Department of Health, a key component of which was the demonstration of cost-effectiveness of the sensor. In turn, this cost-effectiveness analysis was subsequently published Ly et al 2014³⁵ in a leading international health economic journal, *Value in Health*.

CGM sensor research conducted in Australia without consequent patient access to this technology remains just that – research from which Australians with type 1 diabetes cannot benefit because they have no access. With a landmark Australian study completed, a longstanding cost-effectiveness submission lodged with the Department of Health and subsequently published in a leading international health economic journal, the appropriate conclusion and next step should be the delivery of improved health outcomes among Australians who can minimise their high risk of serious hypoglycaemia related seizures, coma and potential death with timely and affordable access to the CGM sensor. Now is the time for the Australian Government as a key stakeholder in diabetes, which is also investing in further Australian research underway involving CGM sensors and a more advanced insulin pump with hypoglycaemia predictive capabilities, to take action in bringing CGM sensor technology access to these at risk individuals.

³⁴ Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: A randomised Clinical Trial. *JAMA* 2013; 310(12):1240-1247

³⁵ Ly T et al. A Cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycemic unaware patients with type 1 diabetes. *Value in Health* 2014;17(2014)561 – 69

Figure 2: CGM (Glucose) Sensor Used in Combination With An Automated Insulin Suspension Pump To Predict Low Glucose Levels



Insulin Pump With Glucose Reading



CGM Transmitter & Glucose Sensor



How the Pump & Glucose Sensor is worn