

PROPOSAL FOR A PILOT SCHEME TO PROVIDE AFFORDABLE ACCESS TO CONTINUOUS GLUCOSE MONITORING FOR AUSTRALIANS WITH TYPE 1 DIABETES

Recommendations

- That affordable access for people with type 1 diabetes to potentially lifesaving continuous glucose monitoring (CGM) technology be provided through a new Australian Government pilot access scheme for CGM to commence from 1 July 2016.
- That the initial investment (year one) be \$1.65 million growing to \$10.28 million in year four, and this funding will provide for grants of up to \$4000 to 4000 people to subsidise the full or partial cost of CGM.
- That the access scheme be implemented as a pilot with clear measures of activity, uptake, and patient impact.
- That the pilot access scheme initially prioritise individuals with the highest clinical risk and with the greatest clinical need including:
 - People with type 1 diabetes who experience serious hypoglycaemia and who also experience impaired hypoglycaemia awareness;
 - Young children with type 1 diabetes under 10; and
 - Women with type 1 diabetes during pregnancy.
- That the delivery of the pilot access scheme be integrated into the National Diabetes Services Scheme (NDSS) for efficient administration, monitoring and reporting, and as most CGM products are consumable items consistent with other diabetes self management products provided through the NDSS

Overview

Australia is lagging behind many developed countries in providing affordable access for people with type 1 diabetes to new, proven technologies such as CGM that can significantly improve the management of type 1 diabetes. This technology can potentially save and change lives for people and families affected by type 1 diabetes. Australians with type 1 diabetes with the greatest clinical risk or need should be supported with affordable access to Continuous Glucose Monitoring (CGM).

For people with type 1 diabetes, keeping blood glucose levels within a normal range is difficult to achieve and can place an enormous burden on the individual and their families. Traditionally, this has involved a constant regimen of finger prick tests to monitor blood glucose levels and avoid severe consequences including severe hypoglycaemia (low blood glucose) and hyperglycaemia (high blood glucose).

Some people with type 1 diabetes have particular difficulties with severe hypoglycaemia (very low blood glucose defined as needing the assistance of another person for recovery). Some people with type 1 diabetes lack (or have impaired) awareness of the warning signs of impending hypoglycaemia, known as “hypo unawareness”. Some people (and families) experience significant fear of hypos with high levels of distress and anxiety. Hypoglycaemia is responsible for approximately 5-8 per cent of deaths in people with type 1 diabetes, some of which are sudden, unexpected and unexplained deaths during sleep (known as “dead in bed” syndrome). This syndrome is not limited to children or young people and sudden, unexplained death can occur in people with type 1 diabetes in their 20's, 30's and later in life.

While sudden death during sleep is extremely tragic, it is not the only important risk to consider. Some people with type 1 diabetes also experience serious hyperglycemia (very high blood glucose). If left untreated, this can result in diabetic ketoacidosis (DKA), a serious condition which may lead to diabetic

coma and can be fatal. Many of the consequences of type 1 diabetes can require costly hospitalisation and are potentially life threatening.

More recent evidence shows that both hypoglycaemia and hyperglycaemia can adversely affect brain development in young children.

Women with type 1 diabetes get pregnant and have children and both the mother and baby in utero can be seriously at risk of hypoglycaemia and hyperglycaemia which can worsen during pregnancy.

Technologies such as CGM can cost-effectively assist in managing blood glucose levels and pre-empt occurrences of severe hypoglycaemia and DKA.

CGM sensors are placed under the skin to measure and record blood glucose levels. The sensors link to a transmitter that sends signals to a hand-held receiver (such as a mobile phone) or an insulin pump. CGM offers the major advantage of not only providing more glucose levels to enable the patient to adjust his or her treatment, but also allowing the assessment of trends in glucose levels up or down helping the patient to avoid serious hyperglycaemia and hypoglycaemia. The ability of others to remotely monitor glucose levels provides a level of safety and re-assurance for parents to monitor children and for people who live alone.

The use of CGM can result in better clinical outcomes, in terms of improved HbA1c (average blood glucose over the past 8-12 weeks) and reduced exposure to hypoglycaemia.¹²³⁴⁵ This can reduce health costs both in the immediate term, in terms of fewer hospital visits, and in the longer term by slowing and reducing the risk, progression and impact of major diabetes complications including blindness, limb amputation and kidney failure.

Diabetes Australia, JDRF Australia, the Australian Diabetes Educators Association (ADEA), the Australian Diabetes Society (ADS), and the Australian Paediatric Endocrine Group (APEG) are working together to increase access to CGM technology. We believe Australians with type 1 diabetes with the greatest clinical risk or need should be supported with affordable access to CGM to improve their health and quality of life, prevent and avoid the consequences of severe hypoglycaemia, and deliver savings to the Australian health system.

There are currently around 120,000 Australians living with type 1 diabetes. While CGM is neither necessary nor appropriate for all people with type 1 diabetes, there are high clinical risk and needs individuals who would benefit significantly from, and should be initially prioritised with, access to CGM. With the assistance of Australia's leading scientific, clinical, and diabetes health professional groups, the ADS, ADEA, and APEG, these have been identified as:

- people with type 1 diabetes with severe hypoglycaemia who also have impaired hypoglycaemic awareness due to poorer health outcomes and quality of life;
- children with type 1 diabetes under 10 years of age due to the general lack of hypoglycaemic awareness and the impact of hypoglycaemia on brain maturation, as well as the burden of fear that the risk of hypoglycaemia poses for parents; and
- women with type 1 diabetes during pregnancy due to the impact that hypoglycaemia can have on the unborn child.

¹ The *National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes for Children, Adolescents and Adults*, developed by the Australian Paediatric Endocrine Group and the Australian Diabetes Society, conclude that evidence favours the effectiveness of CGM, particularly in people with poorly controlled diabetes. The Guidelines also conclude CGM devices are potentially valuable in preventing severe hypoglycaemia.

² Ly T et al. A cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycaemic unaware patients with type 1 diabetes. *Value in Health* 2014;17:561 - 69. This study showed that in a randomised trial that hypoglycaemic unaware type 1 diabetes patients experienced episodes of severe hypoglycaemia (requiring assistance when using insulin pumps alone but NONE when these were augmented with CGM and LGS was activated).

³ Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. *British Medical Journal* 2011; 343: d3805.

⁴ Liebl AL, Henrichs HR, Heinemann L et al; Continuous Glucose Monitoring: Evidence and Consensus Statement for Clinical Use, *Journal of Diabetes Science and Technology* 7: 500-519, 2013.

⁵ Floyd B, Chandra P, Hall S, Comparative Analysis of the efficacy of Continuous Glucose Monitoring and Self-Monitoring of Blood Glucose in T1DM. *Journal of Diabetes Science and Technology*: 6,2012.

There are 10,000 people or approximately 8.5% of people with type 1 diabetes who fall into these high risk categories and would benefit greatly from CGM.⁶ (See detail in Section 5)

However, CGM may not be sought or be suitable for all these people. International experience suggests about 40% in this group will seek or actually utilise CGM (See Section 4). Some people will only require the technology for intermittent use or for use over short periods of time.

CGM technologies have been approved by the Therapeutic Goods Administration and available for sale in Australia for 15 years. Uptake and use is very low due to cost. There are currently no Government, private health subsidies or affordable access schemes available for CGM sensors which are consumable items.

The annual cost of CGM is approximately \$4,000 per person (See Section 2), making this vital technology too expensive for most people and families with type 1 diabetes. Australians are missing out on the life saving and life changing benefits of this technology and the Australian health system is missing out on the potential savings.

We seek a commitment \$1.65 million in the first year, growing on a planned and managed basis to \$10.28 million in year four to support affordable access to CGM for a small, high risk/high need cohort of patients with type 1 diabetes, as identified above. We estimate this investment could save the Australian health system between \$19.58 million to \$40.3 million in year one rising to between \$76.05 million and \$160.23 million in year four.

This proposal is based on sound clinical and cost effectiveness evidence, and is a realistic and fiscally responsible approach that will be warmly and strongly supported by people living with type 1 diabetes and their families and provides an excellent return on investment.

⁶ Data sourced from the National Diabetes Services Scheme, the Australian Bureau of Statistics, and The Diabetes MILES Study.

1. Context and Timing

- Improved access to technology is recognised as a key action area in the Government's recently released Australian National Diabetes Strategy 2016-2022. The Strategy identifies the need to 'improve affordable access to medicines and devices' as a key action to reduce the occurrence of diabetes-related complications and improve quality of life among people with diabetes.
- A new National Diabetes Services Scheme (NDSS) agreement with Diabetes Australia will begin from 1 July 2016, presenting an opportunity to introduce CGM access as a new initiative in the new NDSS Agreement and integrate this with access to insulin pumps and associated consumables under a revised and more integrated approach to access to diabetes self monitoring and management consumables and technologies through the NDSS.
- There is an extremely strong and growing community appetite for a policy response in this area.

2. Cost of CGM

CGM has been approved and marketed to Australian consumers for a number of years, with several products available to Australian consumers. The technology can be utilised as stand-alone units or in conjunction with an insulin pump.

CGM technology consists of three parts: the receiver, transmitter and sensors.

The receiver (generally an insulin pump or a mobile phone) displays blood glucose levels; the transmitter is affixed to the sensor to transmit glucose level readings to the receiver; and the sensor measures glucose levels just underneath the skin.

The average, annual cost of CGM, incorporating both the transmitter (hardware) and sensors (consumable) is estimated at around \$4,000 per annum. This annual cost includes an allowance for the costs of sensors (replaced every six to seven days depending on the model) and transmitters (replaced every 6-12 months).

3. How does access in Australia compare to other countries?

In Australia, there is no public or private support for CGM access.

A number of countries provide affordable access programs for CGM for type 1 diabetes. Some examples of these are below:

Israel	Children; women with type 1 diabetes planning for and during pregnancy; people who are hypo-unaware
Netherlands	Children; women planning for and during pregnancy; whose diabetes is difficult to manage
Slovenia	Children; women planning for and during pregnancy; people experiencing severe hypoglycaemia or who are hypo-unaware
Sweden	Children; people who experience severe hypoglycaemia; people whose diabetes is difficult to manage
Switzerland	People suffering from severe hypoglycaemia; people whose diabetes is difficult to manage
USA	Broad coverage by insurance schemes, includes people who experience severe hypoglycaemia, who are hypo-unaware. Some payers focus on adults, others include adults and children

4. What has been the experience with rates of uptake in other countries?

CGM is not necessary and not recommended for all people with type 1 diabetes. Many people with well established self management regimens who maintain stable blood glucose levels may not need this technology and may not want to adopt the technology.

International experience has demonstrated that uptake of CGM is not rapid, even when affordable access programs are introduced. People cite a number of reasons for not using CGM including discomfort, functionality and its influence on a person's lifestyle, as well as individual choice – some people simply don't want the technology.⁷ A study found that, accounting for those who don't want CGM or don't keep using it, less than 25 per cent of those eligible under an access program used CGM continuously or intermittently.⁸

Based on the above evidence and experience in other countries, we anticipate that - at most - 40 per cent of eligible people with type 1 diabetes will access CGM through the proposed access scheme. We believe this is a conservatively high estimate.

Even amongst children with type 1 diabetes, the uptake of CGM is not expected to be higher. Experience internationally has shown that the uptake of CGM for this cohort, even if funded, is less than 50 per cent. The landmark JDRF CGM trial demonstrated 30 per cent compliance in adolescence and 50 per cent in younger children despite the patients being in a specific trial with all the supports and encouragement available⁹. In Perth, fewer than 1 in 5 young families currently offered funded CGM (for the short term) take up the offer. While parents may be concerned about overnight hypoglycaemia, they manage this in different ways.

5. Advantages of CGM and who should receive access to it

As outlined earlier, the key advantages of CGM are that it:

- provides additional glucose levels and, importantly, allows patients to assess trends in glucose (up or down and rate of change). This in turn improves self management and results in better glucose control and reduced hypoglycaemia. This is important in all patients but especially pregnancy and childhood when control is difficult. This applies to both injection and pump therapy.
- provides safety for people at particular risk of hypoglycaemia through a number of mechanisms including better ability to predict low glucose, alarms for impending low glucose, and remote monitoring by caregivers if connected to an appropriate insulin pump by insulin suspension.

CGM can deliver the greatest quality of life improvements and the greatest cost-savings if it is effectively targeted at the people who need it most. Under the proposed pilot scheme, we recommend targeting a clearly-defined and identifiable subset of people with type 1 diabetes with high clinical risk/need as an initial priority:

- **Children with type 1 diabetes under 10 for whom hypoglycaemia can have a major adverse effect on the developing brain;**^{10,11} Type 1 diabetes is more difficult to control during childhood with a risk of both poor metabolic control and hypoglycaemia, both of which may affect brain development and cognition. Studies have shown the benefits of CGM in childhood with improvements in glycemic control and hypoglycaemia rates.
- **Women with pre-existing type 1 diabetes during pregnancy;** Diabetes may be unstable at this time, however for the wellbeing of the foetus and mother, glucose control needs to be

⁷ Wong, J., Foster, N., Maahs, D., Raghinaru, D., Bergenstal, R., Ahmann, A., Peters, A., Bode, B., Aleppo, G., Hirsch, I., Kleis, L., Chase, H., DuBose, S., Miller, K., Beck, R. and Adi, S. (2014). Real-Time Continuous Glucose Monitoring Among Participants in the T1D Exchange Clinic Registry. *Diabetes Care*, 37(10), pp.2702-2709.

⁸ Ramchandani, N., Arya, S., Ten, S. and Bhandari, S. (2011). Real-Life Utilization of Real-Time Continuous Glucose Monitoring: The Complete Picture. *Journal of Diabetes Science and Technology*, 5(4), pp.860-870.

⁹ Tamborlane WV, Beck RW, Bode BW et al; Juvenile Diabetes Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *NEJM* 2008; 359:1464-1476.

¹⁰Duvanel, C., Fawer, C., Cotting, J., Hohlfeld, P. and Matthieu, J. (1999). Long-term effects of neonatal hypoglycemia on brain growth and psychomotor development in small-for-gestational-age preterm infants. *The Journal of Pediatrics*, 134(4), pp.492-498.

¹¹ Rankins, D., Wellard, R., Cameron, F., McDonnell, C. and Northam, E. (2005). The Impact of Acute Hypoglycemia on Neuropsychological and Neurometabolite Profiles in Children with Type 1 Diabetes. *Diabetes Care*, 28(11), pp.2771-2773.

excellent with minimal hypoglycaemia. The *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults* state: “Elevated blood glucose levels are toxic to the developing foetus.” This can result in an increased rate of pregnancy complications and a heightened risk of harm to the baby including cardiac and neural tube defects, and malformations of the renal and urinary tract, gastrointestinal and skeletal systems.¹²¹³¹⁴ CGM is considered extremely beneficial for women with type 1 diabetes during pregnancy.

- **People with type 1 diabetes who experience severe hypoglycaemia and who also experience hypoglycaemia unawareness;** Approximately 25 per cent of people with type 1 diabetes suffer impaired hypoglycaemia awareness, placing them at increased risk of severe hypoglycaemia. However, impaired awareness is a spectrum and for most, the impairment is not severe. Recent research has identified approximately 8.5 per cent of people with type 1 diabetes experience impaired awareness of hypoglycaemia and a severe hypoglycaemic event in a six month period.¹⁵ People who experience severe hypoglycaemia have a greater fear of hypoglycaemia and diabetes-related distress, poorer emotional well-being, and lower diabetes-specific positive wellbeing.¹⁶

High risk/ high needs cohort	Age target	Cohort	Estimated number of people
• People with type 1 diabetes with severe hypoglycaemia who also suffer from impaired hypoglycaemic awareness	10 - 59 years old**	8.5 per cent	6171 people 2,468 people*
• Women with type 1 diabetes during pregnancy		0.3 per cent of pregnancies	934 people 374 people*
• Young children with type 1 diabetes under 10		100%	3,054 people 1,222 people*
Total			4064

* These figures are modelled on a 40 per cent take up rate

**The cost modelling excludes people living with type 1 diabetes aged over 60 (41,769 people). This cohort are less likely to adopt this new technology as they have established methods of managing their diabetes.

6. Assessment of eligibility

Assessment for eligibility against these criteria should be a clinical determination by a medical specialist (endocrinologist, obstetrician, physician) practicing at an accredited multidisciplinary diabetes centre involved in insulin pump therapy commencement and/or specialist diabetes management.

Under the pilot scheme, the number of people accessing CGM would be capped each year. The spectrum for people with type 1 diabetes with severe hypoglycaemia who also suffer from impaired hypoglycaemic awareness can be broad. Specialist assessment will be particularly important for this cohort. Individuals with such a level of impairment will already be managed in a dedicated diabetes centre. A defined approach using established measures (Clarke Questionnaire and rates of hypoglycaemic seizure or coma) that is subject to audit should be used. Education should be the first line of management before CGM is recommended.

¹² Craig ME, Twigg SM, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group. National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults, Australian Government Department of Health and Ageing, Canberra 2011.

¹³ Ylinen, K., Aula, P., Stenman, U., Kesaniemi-Kuokkanen, T. and Teramo, K. (1984). Risk of minor and major fetal malformations in diabetics with high haemoglobin A1c values in early pregnancy. *BMJ*, 289(6441), pp.345-346.

¹⁴ Miodovnik, M., Mimouni, F., Dignan, P., Berk, M., Ballard, J., Siddiqi, T., Khoury, J. and Tsang, R. (1988). Major malformations in Infants of IDDM Women: Vasculopathy and Early First-Trimester Poor Glycemic Control. *Diabetes Care*, 11(9), pp.713-718.

¹⁵ Hendrieckx, C., Halliday, J., Bowden, J., Colman, P., Cohen, N., Jenkins, A. and Speight, J. (2014). Severe hypoglycaemia and its association with psychological well-being in Australian adults with type 1 diabetes attending specialist tertiary clinics. *Diabetes Research and Clinical Practice*, 103(3), pp.430-436.

¹⁶ Hendrieckx, C. et al.

Establishing this credentialing and authorisation process would be a simple and inexpensive process which could be easily integrated into the existing NDSS systems, database and administration to enable efficient, effective and integrated assurance of eligibility, monitoring and oversight of the program.

7. Cost savings

The cost savings that accrue from improved access to CGM fall into two categories:

- Short term savings relating to reduced hospital and healthcare costs as a result of fewer incidences of severe hypoglycaemia;
- Long-term savings from reduced rates of macro- and microvascular complications.

Research suggests the cost of a severe hypoglycaemic event, including healthcare and productivity costs, is around \$18,257 for all people and \$14,944 for people aged 12 years and older.¹⁷ Around 20 per cent of people with type 1 diabetes experience at least one severe hypoglycaemic event in a six-month period.¹⁸

Diabetes complications substantially increase the cost of providing healthcare to a person with diabetes. Evidence shows the cost of providing healthcare to a person with diabetes and macrovascular and microvascular complications rises by \$11,287 per annum compared to a person with diabetes and no complications.¹⁹

Extensive evidence suggests CGM can contribute to better blood glucose management²⁰ which substantially decreases an individual's likelihood of developing complications.

Providing access to CGM may substantially reduce the number of subsidised blood glucose testing strips used. Based on a per-unit cost of \$0.385 cents for people with Health Care and Pensioner Cards and \$0.24 cents for all others and a reduction of five testing strips per person per day, this could save between approximately \$438 and \$702 per person per annum.

Excluding long-term savings based on reduced rates of complications, we believe the program could deliver savings of between \$19.58 million and \$40.3 million in the first year rising to between \$76.03 million and \$160.23 million in year four. These savings are based on the prevention of 2.6 severe hypoglycaemic events at the top end and 1.3 severe hypoglycaemic events at the low end.²¹

An annual investment of \$4,000 per person in CGM would generate healthcare and productivity savings that would offset the initial investment.

8. Annual Cost of Pilot Program

Affordable access to CGM technology should also give consideration to an individual's capacity to pay and socio-economic circumstances. We propose a maximum level of subsidy of up to \$4000 for Health Care Card and Pension Card holders to cover the cost of transmitters and the cost of consumables (sensors).

For non- Health Care Card holders, we propose a partial subsidy of \$3000.

¹⁷ Ly, Trang T., Alan J.m. Brnabic, Andrew Eggleston, Athena Kolivos, Margaret E. McBride, Rudolf Schrover, and Timothy W. Jones. "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*: 561-69. Print.

¹⁸ Hendrieckx, C. et al.

¹⁹ Colagiuri S, Brnabic A, Gomez M, Fitzgerald B, Buckley A, Colaguir R. DiabCo\$t Australi Type 1: Assessing the burden of Type 1 Diabetes in Australia. Diabetes Australia, Canberra, November, 2009.

²⁰ Langendam M(1), Lujiff YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus (Review) *Cochrane Database of Systematic Reviews* 2012.

²¹ Leiter, L.A. et al. Assessment of the impact of fear of hypoglycemic episodes on glycemic and hypoglycaemia management. *Canadian Journal of Diabetes* 29, 186-192 (2005).

Recipients may not need to access the full subsidy as some CGM manufacturers may offer products at a discounted rate. Some individuals will only use CGM a for short periods and have a lower level of annual subsidy

Private Health Insurers (PHIs) currently support insulin pump access for members and we expect PHIs will consider supporting CGM transmitters for their members.

The table below outlines the proposed government investment of \$1.65 million to support access for 1000 individuals rising to \$10.28 million to support access for 4064 individuals (40 per cent uptake within the eligible market) in year four.

	Year 1	Year 2	Year 3	Year 4
Year	2015-16	2016-17	2017-18	2018-19
Unit costings				
Cost of CGM (sensors) p/a	\$3,000	\$3,000	\$3,000	\$3,000
Cost of CGM (transmitter) p/a	\$1,000	\$1,000	\$1,000	\$1,000
Total cost per unit	\$4,000	\$4,000	\$4,000	\$4,000
Uptake modelling				
Fully subsidised (Health Care Card holders)	310	627	943	1260
Partly subsidised (Non-Health Care Card holders)	690	1394	2099	2804
Total CGM uptake	1,000	2021	3042	4064
Total Costs				
Fully subsidised (Health Care Card holders @ \$4,000 p/)	\$1,240,000	\$2,506,040	\$3,772,080	\$5,039,360
Partly subsidised (Non-Health Care Card Holders @ \$3,000 p/a)	\$2,070,000	\$4,183,470	\$6,296,940	\$8,412,480
Cost at end of year	\$3,310,000	\$6,689,510	\$10,069,020	\$13,451,840
Actual annual cost (assuming even spread of uptake)	\$1,655,000	\$4,172,255	\$7,120,638	\$10,286,239

This table assumes approximately 30 per cent of Australians with type 1 diabetes under 60 years hold Health Care or Pensioner Cards.

9. Delivery mechanism

The National Diabetes Services Scheme is the appropriate program delivery mechanism as:

- CGM sensors are consumable products for diabetes management and the NDSS is the intended sole access scheme for such products for the Australian Government;
- there is optimal integration of the access program with insulin pump consumables access (common for many); and
- this maximises operational efficiency of the program through existing Government program infrastructure and administration.

Administration costs can be included and integrated as part of the new NDSS agreement which will minimise costs and maximise efficiency and integration of Government funding.

10. Management and monitoring the initiative

This new access initiative can be easily and efficiently implemented and monitored/reported through the NDSS administered by Diabetes Australia. There should be annual reporting with clear measures regarding activity, uptake, and patient impact. De-identified health information could be utilised to improve strategies for supporting people with type 1 diabetes investment.

Further information:

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