Diabetes Alliance submission to the Health Technology Assessments Policy and Methods Review

Background

The Australian Diabetes Alliance, which includes Diabetes Australia, the Australian Diabetes Educators Association, the Australian Diabetes Society, JDRF Australia, the Australasian Diabetes in Pregnancy Society, and the Australian and New Zealand Society for Paediatric Endocrinology and Diabetes, has provided a submission to the Health Technology Assessment (HTA) Policy and Methods Review.

The Health Technology Assessments process refers to all bodies the Federal Government uses to fund and subsidise health technologies and medicines. This includes the Therapeutic Goods Administration, the Pharmaceutical Benefits Scheme, the Medicare Benefits Scheme, the National Immunisation Program, and the Life Saving Drugs Program.

Looking to the future

The Alliance believes Australians living with diabetes generally have appropriate access to diabetes technology and medicines but there are areas for improvement, particularly with regards to both the time it takes for people to be able to access new medicines and technologies, and how equitable that access is.

These challenges are being amplified by the technology-driven healthcare revolution currently underway. Research breakthroughs are leading to new therapies, medicines, and technologies at a faster pace than at any time in human history. This is particularly true of diabetes medicines and technology. The pace of change is placing a heavier burden on Australia's regulatory systems than previously seen. It is critical our approvals and reimbursement framework is flexible enough to keep pace with these changes.

This is essential to ensure both the Australian health system and people living with diabetes can experience the considerable benefits from access to the technologies, including reduced incidence of diabetes-related complications.

What is working well

People living with all types of diabetes can access a wide range of products to help them manage their condition. Many of these products are available without charge or heavily subsidised via the National Diabetes Services Scheme (NDSS). They include insulin pens, needles and syringes, consumable products for insulin pumps and continuous glucose monitoring (CGM) systems, and blood glucose and ketone urine testing strips.

A major recent advancement has been the expansion of access to CGM and Flash Monitoring subsidies to include all people living with type 1 diabetes. This is already improving diabetes self-management, reducing preventable hospitalisations resulting from diabetes-related complications, and significantly improving the mental and emotional health of some people. Academic studies have shown it is a cost-effective health intervention.

Additionally, the thoroughness of the evidence-based assessment and review process gives people living with diabetes and their health professionals confidence in the efficacy and safety of medicines and technologies.

Other positive examples of the HTA's policies and methods include the addition to the NDSS of the Medtronic 780G insulin pump, the Dexcom G6 CGM system, and the Omnipod DASH patch pump.

The availability of all these technologies increases the choices for people living with diabetes. Best practice diabetes care is individualised, and different technologies can support people's diabetes management in different ways. This is why choice and equitable access in diabetes technology and medicines is central to our position.

Areas for improvement

The main areas in which the Diabetes Alliance would like to see improvement include:

- greater flexibility to allow prompt assessments of evolving technologies that don't fit current criteria;
- faster access to technology and medicines that have already been approved in reputable international markets such as the European Union and the United States;
- increased access to technology, including insulin pumps as well as CGM and Flash Monitoring, for people living with type 2 diabetes using insulin; and
- considering the patient's needs, including mental health benefits, during the assessment of new technology.

More flexible assessment processes

In Australia, there is an emerging theme among new technologies which are available internationally: they do not fit neatly into existing categories for assessment. Examples include interoperative or combined insulin pump and CGM systems, smart insulin pens and bionic pancreases. These technologies will deliver improved physical and health outcomes for the people living with diabetes who choose to use them.

A key area of advancement is interoperability. In diabetes, this refers to an insulin pump that can respond to data from a CGM to adjust insulin dosages based on algorithms that determine the correct amount of insulin required to regulate a person's blood glucose levels. This type of system is often called a hybrid closed loop system. This is the gold standard of care for people living with type 1 diabetes, both in terms of physical and mental health outcomes.

The current HTA policy and methods are not suitable for considering hybrid systems that incorporate technology currently assessed in different categories. Any changes to the HTA policy and methods should ensure they are nimble enough to accommodate technologies that fall outside rigid categories. This is particularly important given the rapid speed of technological developments.

The bionic pancreas is another technology similar to interoperable insulin pumps and CGM systems. The FDA has recently approved the iLet ACE insulin pump and the iLet dosing decision software for people living with type 1 diabetes. The dosing system uses an adaptive closed-loop algorithm to calculate insulin needs. The two devices, along with an FDA-approved CGM, will comprise the iLet bionic pancreas. It uses an algorithm that determines and commands insulin delivery.

There is currently no pathway for approval or reimbursement of this technology in Australia, despite it being one of the most transformative technologies since the discovery of insulin.

Another example is the Omnipod Dash system which was first approved by the FDA in 2005, has only recently become available via the NDSS to people living with diabetes in Australia because it does not conform to simple categories. Rather than a traditional pump based around hardware (the pump) and consumables (tubes and wires), the Omnipod is both the pump and the consumables. It is a disposable insulin pump designed to be worn for three days. Its approval was delayed as it did not fit into the current approval categories.

Other new and emerging technology that may encounter challenges with Australia's existing approvals and reimbursement methods include new smart insulin pens that are connected to glucose monitoring devices and calculate insulin dosage based on inputted carb ratios and other data. They are currently available in some countries. Implantable glucose sensors, sensors for additional analytes, more rapid-acting insulins, longer-lasting glucose sensors and insulin delivery infusion sets, as well as alternative technologies for glucose sensing, continue to be investigated.

Faster access through greater weighting of international approval

Australia is a relatively small, secondary market for many companies. This means they delay introducing technology here until it has been launched in larger markets such as the US and Europe. Therefore, Australia's assessment and approval process generally trails assessments conducted by the Food and Drug Administration (FDA - US), the European Medicines Agency (EMA – EU), and the Medicines and Healthcare products Regulatory Agency (MHRA – UK).

There is an opportunity to provide greater weighting to international approvals by respected international agencies. This would streamline the process for introduction into Australia, especially if international approvals could be leveraged for faster access in Australia for updated or advanced models of already approved technology.

Increased and more equitable access

Insulin pumps are a clear example where the current health technology and assessment policies and methods are not providing all people living with diabetes equitable access to the equipment and technology updates that will help them.

There are currently two pathways to accessing subsidised insulin pumps in Australia. The first is the Federal Government's Insulin Pump Program, administered by JDRF Australia, for eligible people aged up to 21. Funding is limited and restricts the number of children and young people aged under 21 years who can access subsidised insulin pens under this scheme to 230 people. There are around 16,000 Australians living with type 1 diabetes in this age group, which means only around 1.4% of children and young people can access insulin pumps via this pathway.

The other route to subsidised insulin pumps is through private health insurance. Firstly, pumps must be included on the Prostheses List which sets out the minimum requirements for private health insurance coverage of certain medical devices including insulin pumps. The eligibility requirements of the List are not flexible enough to respond to novel and emerging technologies.

Secondly, insulin pumps are only required to be offered only under "gold" or premium plans. Insulin pumps are essential therapy for many people living with type 1 diabetes. The pumps should be available on "basic" plans. The impact of this inequity will become more acute as closed loop systems and other more advanced technologies become available. It significantly restricts the number of people who can access the technology.

Around 80% of all pumps in Australia are provided to people with private health insurance. Australians without private insurance do not have affordable access to insulin pumps. Due to cost and poor access, only 14,990 Australians with type 1 diabetes, or 12 percent of people living with type 1, have access to insulin pump therapy. This compares poorly to the US which has twice the level of access, estimated at 25%.

People who cannot afford private health insurance or unsubsidised treatments and technology are being placed at higher risk of diabetes-related complications, and poorer mental and emotional health outcomes because of this unfair funding model.

There is also an urgent need to provide people living with type 2 diabetes using multiple daily injections of insulin subsidised access to insulin pumps.

CGM is another area of diabetes technology that has lacked equitable reimbursement mechanisms. When the technology was introduced to Australia there was no pathway to access subsidised CGM. Instead, access was achieved through successful advocacy by the diabetes sector across multiple election cycles.

Consequently, subsidised access to CGM is currently restricted to people living with type 1 diabetes, despite an emerging body of evidence showing improved physical and mental health outcomes among people living with type 2 diabetes who use multiple daily injections of insulin to manage the condition.

It is important that future decisions regarding subsidies to support access to diabetes technology should be more closely aligned to a person's diabetes management requirements and risk of complications than a particular 'type'. For instance, a person living with type 2 diabetes using multiple daily injections of insulin has basically the same needs for diabetes medical and technology.

Diabetes Australia is currently advocating for the expansion of access to CGM and Flash Monitoring technology to people living with type 2 diabetes.

Finally, new technology subsidies need to be supported by clear reimbursement mechanisms (such as an MBS item number). The introduction of CGM subsidies saw a large increase in the number of people living with diabetes requiring education and support to commence using this technology. However, there were no education reimbursement arrangements in place despite education being essential to realising the full benefits of the technology.

Looking beyond clinical criteria in assessments

For people living with diabetes, the best care is one that reflects an individual's personal preferences for managing the condition. Everyone is different, and people who are managing a 24/7 lifelong chronic condition have preferences for how they do this that should be respected.

This includes being able to choose the technology and medicines that best suit their preferences and biological needs, including during childhood and pregnancy. Therefore, while there may be three or four options available in a particular technology class, a new alternative may have slightly different features that could be of great benefit to a person living with diabetes.

In some cases, the clinical outcomes may be very similar, but the product may confer a psychosocial or lifestyle benefit that significantly improves a person's quality of life.

The mental and emotional impacts of diabetes are serious and can include often severe, widespread diabetes-related complications. Up to 50 per cent of people living with diabetes experience mental health challenges annually. This can include general mental health conditions as well as diabetes-specific challenges including diabetes burnout, diabetes-related anxiety, fear of hypoglycaemia and depression.

Diabetes technology can play a substantial role in alleviating some of the mental health challenges associated with living with diabetes. It can help reduce the fear and anxiety related to unpredictable blood glucose levels, give people greater freedom, and reduce worry about diabetes-related complications. This is why the Diabetes Alliance believes assessment of diabetes technology and medicines should consider the quality of life and mental and emotional health benefits of new therapies. This could include Patient Reported Outcomes, international experiential reviews, quality of life measures, and other data to ensure the HTA process remains person-centred.

Additionally, it must be noted that the clinical criteria used to assess diabetes technology is evolving. An HbA1c check, which measures an individual's average blood glucose levels, has long been the gold standard. In some cases, a healthy HbA1c result incorporates large fluctuations in blood glucose levels but because those fluctuations are tallied into an average number, the result can disguise potentially dangerous highs and lows. Time in Range (TIR) is fast emerging as a more accurate indicator of improved long-term outcomes. TIR measures the percentage of time a person's blood glucose levels are in a target range over the course of a day. The more time spent in range, the lower the risk of diabetes-related complications. As improvements in clinical criteria evolve, our assessment and approval systems need to be flexible enough to incorporate them.