Access to insulin pumps and their associated costs in Australia



JDRF Australia's recommendation for the Insulin Pump Program (IPP)

JDRF Australia recommend an expansion of the IPP, encompassing both the eligibility criteria and number of funded insulin pumps available on the Program. This is needed to respond to increasing demand and current oversubscription of the Program, but also to provide a pathway for adults to access interoperable systems, such as hybrid closed loop, to better manage their T1D.

Ideally JDRF would like to see the program offer:

- Expanded choice so that the applicant and the HCP can decide what technology would work best for the individual, and
- Expansion of program eligibility and size so that people with T1D over 21 who are unable to afford private health insurance would be eligible for the program. This would mean a program expansion to those on low-income health care cards.

The Prosthesis List and Private Health Insurance

Pricing for insulin pumps in Australia is determined by the Private Health Insurance (Prostheses) Rules, which is a legislative instrument made under the Private Health Insurance Act 2007. Pricing for insulin pumps vary but most are around \$8000.

By law, private health insurers are required to pay a benefit for a product if:

- The product is on the Prostheses List
- The patient receives the product as part of hospital treatment or hospital substitute treatment
- The patient has appropriate health insurance to cover for the treatment.

For those who can afford private health insurance, this pathway provides access to an insulin pump. Hospital cover is required for this avenue, which 45% of the Australian population currently have. Individuals may also choose to purchase an insulin pump directly from a manufacturer, if this option is feasible for them.





The Insulin Pump Program

About the Program

The exception to accessing an insulin pump via private health insurance is through the Government-funded Insulin Pump Program (IPP). This is a small program administered by JDRF Australia, designed to provide insulin pumps to children and young adults who could not otherwise afford to access life-changing devices.

The Program aims to distribute up to 394 insulin pumps annually to eligible participants under 21, who live with T1D and meet specific medical and financial eligibility. The average family income of recipients is around \$51,600.

Changes to the IPP

From 1 July – 24 October 2023, the IPP was on hold at the direction of the Department of Health (DOH), awaiting the outcome of negotiations between the DOH and device manufacturers about which insulinspumps were offered as part of the IPP. Subsequent to this, the DOH entered into a contract with a single tenderer, Ypsomed.

The selection of a single supplier was a surprise to JDRF Australia, who had recommended to the DOH that choice remain top of mind for any decisions made, and was a surprise to healthcare professionals (HCPs) and the T1D community. Following this decision, there was a period of intense engagement with HCPs and the community to understand what the changes to the Program would mean to applicants and recipients.

The DOH indicated that while the evaluation panel recognised the value of having a choice of products, ultimately a single supplier was chosen on the basis that this would result in additional people being able to benefit from the program with more pumps supplied.

Importance of device choice

Diabetes technology is developing rapidly, and more insulin pumps and continuous glucose monitors (CGMs) are available to the T1D community now than ever before. Access to a broader choice of insulin pump options via the IPP is vital to ensure applicants can access the full benefits of diabetes management technologies, particularly when used in tandem with CGM products. Currently, wider access to different pump options is only available to those with private health insurance.

Diabetes management is different for each individual and a choice to be able to access diabetes technologies and systems that suit their individual clinical needs and lifestyles, is essential. Broader product choice needs to be available on the IPP to ensure that individuals have access to new and updated technologies that suit their needs, regardless of their income.

Gaps in technology access

A technology access gap exists for the T1D community. While CGM is now subsided for all those with T1D, insulin pumps are still out of reach for adults over 21 who cannot afford private health insurance, disproportionately impacting people with a disability and many Aboriginal and Torres Strait Islander people. This means for them, there is no pathway to access an insulin pump.

References

1. APRA, Quarterly private health insurance statistics, June 2023, available online.



RESEARCH EXPLAINER

The stages of type 1 diabetes and why they're important

Through decades of research, we know that type 1 diabetes (T1D) starts well before symptoms develop and diagnosis typically occurs. We can use this knowledge to prevent people from developing serious illness at the point of diagnosis, improve their long-term health, and investigate therapies which, in future, could stop T1D in its tracks.



TYPE 1 DIABETES STARTS BEFORE YOU HAVE ANY SYMPTOMS

T1D is an autoimmune condition where the immune system mistakenly attacks the beta cells in the pancreas. These cells are responsible for producing insulin, a hormone essential for regulating blood sugar levels. The immune attack results in the gradual loss of beta cells or impacts their function so people with established T1D can no longer produce their own insulin. This means that people with T1D need to inject insulin to control their blood sugar levels for life.

We previously thought that T1D starts shortly before (or when) people show signs of the <u>4T symptoms</u>: thirst, toilet (frequent urination), thinness and tiredness.

But decades of research have discovered that there are several detectable changes in people before these symptoms develop.

These changes can occur months or even years before diagnosis typically occurs.

These so called 'pre-symptomatic stages' are Stage 1 and Stage 2 T1D. Stage 3 T1D is when diagnosis traditionally occurs after people start showing the 4T symptoms of T1D (Fgure 1).

While people in Stage 1 and Stage 2 don't officially have T1D, being in these stages increases the chance of developing T1D down the track. Clinicians and researchers can take advantage of this information to help those people who are at risk.

THE STAGES OF T1D DEVELOPMENT

Researchers think that some people are genetically susceptible to T1D. In those people, the condition starts when something in the environment triggers the immune attack on the insulin-producing beta cells in the pancreas.

Researchers – including those involved in the Environmental Determinants of Islet Autoimmunity (ENDIA) study here in Australia – are working hard to unveil what these environmental triggers may be. For example, there's strong evidence that a family of viruses called enteroviruses are associated with T1D development, and part of the ENDIA study is looking to further identify these. Learn more about ENDIA in Case Study 2 in our impact report.

So how do researchers know if someone is in the early stages of T1D? When there's an immune attack against pancreatic beta cells, the body produces proteins called autoantibodies. These autoantibodies can be detected in blood.

There are several T1D autoantibodies we know of (see below). While they can appear in any order, their number and persistence can predict if someone will go on to develop the condition. For example, people who have two or more persistent autoantibodies have a 70% chance of developing T1D in the next 10 years, and nearly 100% chance of developing T1D in their lifetime. This means that nearly all people with two or more autoantibodies will go on to develop T1D in the future.



TID AUTOANTOBODIES

Somone in all stages of T1D may have the following autoantibodies in their blood

- **GAD-65**: glutamic acid decarboxylase 65 autoantibody
- IA-2A: insulinoma-associated protein 2 autoantibody
- **ZnT8**: zinc transporter 8 autoantibody
- IAA: insulin autoantibodies
- ICA: islet cell autoantibodies

Research has shown that T1D progresses through the following stages:

No T1D: There is a 'normal' level of beta cells in the pancreas, and they produce enough insulin to maintain normal blood sugar levels. The person does not need inject insulin to live.

Triggering events: In people who are genetically susceptible to the condition, environmental factors (such as viral infections) trigger the body's own immune system to attack beta cells. Autoantibodies are produced, and these can be detected in blood through a blood test.

Stage 1: Two or more autoantibodies are detected in the blood, but the person still has normal blood sugar levels. The immune attack results in healthy beta cells being destroyed and beta cell mass falling. There are no obvious symptoms at this time.

Stage 2: Two or more autoantibodies are detected in the blood. The person's blood sugar levels become harder to control, with abnormal changes. Beta cell loss continues.

Stage 3: The person exhibits the 4T symptoms of T1D as a result of high blood sugar levels. This is the stage where traditional diagnosis occurs. By this stage, the immune attack has resulted in a significant loss of beta cell mass and function, and not enough insulin is produced to maintain blood sugar levels in a normal range. The person usually starts insulin treatment. Two or more autoantibodies are still detected in the blood

Stage 4: The person has longstanding T1D after living with the condition for numerous years and is insulin dependent. <u>Long-term health</u> <u>complications</u> are common. Two or more autoantibodies may or may not be detected in the blood.

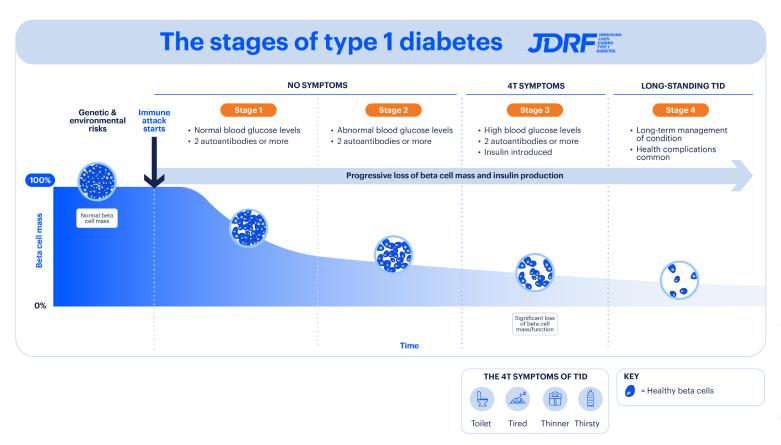


Figure 1: There are several stages of T1D development, which progress over time. In those who are genetically susceptible, environmental triggers start the body's immune attack on insulin-producing beta cells. Stages 1 and 2 occur before symptoms are noticed, and before the person knows they're at risk of developing T1D. At these stages, we can detect two or more autoantibodies in the blood. This is when T1D screening can occur. Stage 3 is the time of traditional diagnosis and is the symptomatic period when the 4T symptoms of T1D occur (thirst, tiredness, thinness and toilet [increased urination]). Stage 4 is long-standing or established T1D. Each stage is associated with decreasing beta cell mass or function as these cells are incorrectly destroyed by the immune system. This results in less insulin being produced. Two or more autoantibodies can be detected in the blood from as early as Stage 1 T1D, and blood sugar levels become more difficult to control as the condition progresses.

WHY ARE THE PRE-SYMPTOMATIC STAGES IMPORTANT?

We now have the technology to easily detect if someone is in Stage 1 or 2 of T1D.

This is done with a simple blood test that detects the presence of autoantibodies.

Knowing whether someone is in the presymptomatic stages of T1D is beneficial for several reasons outlined below.

Screening for T1D risk

By detecting autoantibodies in the blood, we can determine the chance of someone going on to develop T1D. If this chance is high, the person can be monitored by health services and reduce the shock of diagnosis.

Importantly, we know that screening, combined with health follow-ups and education, can significantly reduce the rate of developing a dangerous condition called <u>diabetic ketoacidosis (DKA)</u> when diagnosed. In fact, it has been shown that T1D screening and health follow-up reduces rates of DKA at diagnosis by 90 per cent.

DKA occurs when low levels of insulin and high blood sugar levels result in acidic ketones in the blood. Left untreated, DKA can be fatal. DKA at diagnosis is also associated with worse long-term health effects, so preventing it from happening is important.

Screening can also allow people at high risk of developing T1D to enter clinical trials looking to delay the progression to Stage 3 T1D.

New therapies for T1D

There are currently a lot of research projects that are looking at drugs called 'disease modifying therapies'. Researchers aim to use these drugs to halt T1D progression or prevent it in the first place. Many of these focus on preventing people from moving from Stage 2 to Stage 3 T1D, essentially stopping T1D in its tracks.

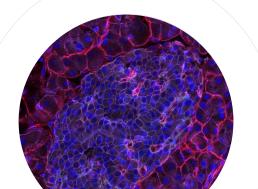
Identifying people in these presymptomatic stages is essential if they'd like to access clinical trials testing these therapies or use these therapies in the future as they become available.

One such disease modifying therapy, called <u>Teplizumab</u>, <u>has already been</u> <u>approved in the US</u> to prevent progression from Stage 2 to 3 T1D in those aged eight years and older. Many other drugs are at <u>the clinical trial stage</u>, <u>and rapid progress is being made</u> to identify which ones can prevent symptomatic T1D from taking hold.

Other drugs, like <u>baricitinib</u>, might one day be used to stop the progression of T1D in those newly diagnosed. In the future, these may be able to halt the progression from Stage 3 to 4. Research is ongoing.

Causes of T1D and prevention

By studying people who develop presymptomatic T1D, we may be able to identify which environmental events are associated with the start of T1D. In this way, we'll be able to further understand the causes of T1D and, in turn, develop preventive strategies for genetically susceptible people. These might one day include things like vaccines and nutritional interventions.



JDRF LEADS THE WAY IN RESEARCH THAT FOCUSES ON T1D STAGES

JDRF is committed to a world without T1D. That's why we fund research which will ultimately prevent people from reaching clinical T1D (Stage 3 T1D).

Specifically, JDRF Australia is funding the following research projects under our T1D Clinical Research Network (T1DCRN):

Screening for T1D: The Australian Type 1 Diabetes National Screening Pilot aims to identify the best T1D screening method for Australia by screening 9,000 children and infants for the presence of autoantibodies. This will indicate if they're in the early stages of T1D and then connect their family to a healthcare team. While we know that T1D can run in families, nine out of 10 people diagnosed with it have no family history of the condition. This is why a screening of the general population is important. We also fund Type1Screen, which screens for autoantibodies in the family members of people with T1D.

New therapies to slow T1D progression:

JDRF heavily invests in clinical trials which test disease modifying therapies, drugs to slow down T1D progression across the different stages. We've established the <u>Australasian Type 1</u>
<u>Diabetes Immunotherapy Collaborative</u> (ATIC), which allows the testing of

disease modifying therapies that target the immune system attack seen in T1D. For example, JDRF funding led to breakthrough results showing that baricitinib can delay the progression of T1D in those newly diagnosed. Other clinical trials are planned for the future.

To learn more about how you can participate in clinical trials and studies, see our clinical trials page.

FOR FURTHER READING

- Type1 Diabetes TrialNet: <u>T1D Facts |</u> <u>TRIALNET Type 1 Diabetes TrialNet</u>
- Staging Presymptomatic Type 1
 Diabetes: <u>A Scientific Statement of JDRF</u>, the Endocrine Society, and the American Diabetes Association.
- T1Detect: <u>Learn About Type 1 Diabetes</u> Risk Screening
- Disease-Modifying Therapies in Type
 1 Diabetes: <u>A Look into the Future of</u>
 Diabetes Practice.
- Stages of Type 1 Diabetes and Mechanism of Action of Teplizumab.

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Routine screening could have a real benefit for families by diagnosing children early, connecting families to care and reducing the risk of DKA. Importantly it would also allow us to identify those in the very early, presymptomatic stages of type 1 diabetes and offer them therapies as they become available. This means we can essentially stop type 1 diabetes before it really gets started.

Dr Kristine Bell, Principal Investigator of the JDRF-funded Australian Type 1 Diabetes National Screening Pilot













RESEARCH EXPLAINER

A cure for type 1 diabetes: where are we at?

We have entered a new phase of type 1 diabetes (T1D) research. But which are the therapy front runners in the search for a T1D cure?



T1D is an autoimmune condition where the immune system mistakenly attacks the beta cells in the pancreas. These cells are responsible for producing insulin, a hormone essential for regulating blood sugar levels.

The immune attack results in the gradual loss of beta cells or impacts their function so people with established T1D can no longer produce their own insulin. This means that people with T1D need to inject insulin to control their blood sugar levels for life.

THE SEARCH FOR A T1D CURE: DISEASE-MODIFYING THERAPIES

A 'cure' for T1D may be achieved through different means.

It could be achieved through regenerating the beta cells lost to the immune attack or by replacing them with healthy cells from an outside source. A cure could also be achieved by preventing people at risk of T1D from developing the condition in the first place. Another angle is to ensure that any healthy beta cells that remain shortly after diagnosis are able to continue producing insulin, essentially preserving their function.

All of these avenues could theoretically be achieved through the use of drugs called disease-modifying therapies (DMTs).

Disease-modifying therapies are drugs which can alter the course of T1D. DMTs aim to slow down or halt T1D progression, prevent its development, or reverse it entirely.

DMTs can work on different stages of T1D, from those yet to be diagnosed to those who already have the condition (see JDRF's publication: *The stages of type 1 diabetes and why they're important*).

Of all therapy avenues, DMTs are the most advanced in terms of the development pipeline and will likely reach the hands of the T1D community the fastest. Many of these therapies have been re-purposed from other autoimmune conditions such as rheumatoid arthritis where they have been used to dampen the immune system and achieve remission.

TEPLIZUMAB: THE FIRST DMT AVAILABLE FOR TID

Decades of research investment including from JDRF have led to an explosion in DMT research and significant advances in this area.

We are now entering a new era where DMTs are becoming part of the therapeutic arsenal against T1D.

Notably, in 2022 **teplizumab** (Tzield ®) was approved by the FDA to delay the progression of the condition from its early stages (Stage 2) to clinical diagnosis (Stage 3) in those over 8 years of age.

Teplizumab is delivered by a daily infusion (into the vein) for approximately two weeks, and is able to delay T1D clinical diagnosis by around two to three years.

Teplizumab was specifically developed for T1D and represents the first therapy to significantly change the course of the condition since insulin was developed over 100 years ago.



While teplizumab is currently only approved and available in the US, its regulatory approval is being considered in other regions such as the UK (Medicines & Healthcare products Regulatory Agency) and Europe (European Medicines Agency).

In Australia, JDRF Australia is engaged in ongoing conversations with Tzield ® makers — Sanofi Australia and Sanofi International — about the pathways required for Australian regulatory approval through the Therapeutics Goods Administration.

OTHER DMTS ON THE HORIZON

Other DMTs are in the development pipeline with <u>many at the advanced</u> <u>clinical trial stage</u>. One example is **baricitinib** which, in a world-first, JDRF-funded Australian study called BANDIT, researchers showed that it was <u>able to suppress the progression of T1D</u> in those newly diagnosed.

Other DMTs currently being tested include:

1. Verapamil

Isoptin ™, Ispotin SR ™, Anpec ™, Anpec SR ™, Cardilox SR ™, Veracaps SR ™

A cheap, oral drug normally used for blood pressure with a good safety profile. A <u>JDRF-funded clinical trial</u> showed that it can slow down T1D progression in children and teens newly diagnosed with the condition.

2. Golimumab

Simponi IV ™, Simponi ™, Simponi Smartject ™

An injectable drug normally used in other autoimmune conditions like rheumatoid arthritis. Golimumab has been shown to result in increased insulin production and less insulin use in young people recently diagnosed with T1D.

3. Anti-thymocyte globulin (ATG)

Atgam ®, Thymoglobulin ®

An injectable drug normally used to prevent organ rejection after transplantation. A JDRF-funded pilot study showed that it allowed those newly diagnosed with T1D to produce more insulin. A small, proof of concept study showed ATG may also be able to delay progression from Stage 2 to Stage 3 T1D in some cases.

More information on <u>current DMTs in the</u> pipeline can be found here.

WHERE NEXT FOR DMTS?

The next stage of research is to determine whether combining these therapies can drive a better therapeutic effect. The idea is that because these therapies work in different ways to delay T1D, combining them may enhance their therapeutic effect.

JDRF research is currently planned for 2024 to test these combination therapies in T1D.









