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Baricitinib Information for People with Newly Diagnosed Type 1 Diabetes

Research Results: In December 2023, investigators from the Australasian Type 1 Diabetes Immunotherapy Collaborative (ATIC) published results of the BANDIT (Baricitinib in new onset type 1 diabetes) clinical trial involving 91 people, aged 10 to 30 years, who were within 100 days of type 1 diabetes diagnosis. These people also had a level of ongoing insulin production. Sixty participants received one year of baricitinib treatment via a daily tablet and 31 received matching placebo/dummy tablets. The study showed that treatment for one year with baricitinib preserved remaining beta cells without major safety concerns. Those people taking baricitinib also had improved glucose levels and decreased insulin requirements, but most still required some injected insulin and continued to monitor glucose after one year of treatment.

What is Baricitinib? Baricitinib is a medication, known as an immunotherapy, that is currently approved for use in the treatment of rheumatoid arthritis and alopecia areata. It works by interacting with the immune system to slow the progression of certain conditions. In type 1 diabetes, baricitinib works to preserve remaining insulin producing beta cells by stopping/slowing the damage to the beta cells by the immune system.

How to Access Baricitinib for Type 1 Diabetes Treatment: As Baricitinib is not currently approved in Australia for the treatment of type 1 diabetes, it cannot be prescribed by your doctor in the same way as medicines that are approved. There are two current ways that baricitinib could be accessed in Australia:

- Clinical Trials: The most straightforward step is to make inquiries about the availability
 of clinical trials currently underway and participate in these. Your doctor may be able to
 provide information on current clinical trials or you could refer to the ATIC website for
 more information.
- 2. Off-Label Use: It is also possible to discuss taking baricitinib "off-label" with your doctor as it is currently available in Australia for other diseases. The decision to take baricitinib is best made by you (together with family/carers where applicable) and your doctor. ATIC researchers/clinicians are available for guidance if required. There is a separate guidance document on the use of baricitinib in type 1 diabetes for doctors.

Cost Considerations: An important consideration is cost. Baricitinib prescribed for "off-label" purposes will cost significantly more than a standard pharmacy script. This cost may mean that this treatment is not affordable for you. If this is the case, participation in a clinical trial may be a preferable option.







Things to Consider Regarding Undergoing Treatment with Baricitinib:

- Prior to treatment, your doctor will need to perform blood tests to confirm your type 1
 diabetes diagnosis and to ensure that you still have some remaining insulin producing
 cells, and ensure that you do not have any conditions that mean taking baricitinib may
 be harmful.
- It is important to be up to date with recommended vaccinations before commencing treatment.
- Be aware that the BANDIT study showed that consistently taking the daily medication was needed to achieve and maintain beneficial effects.
- After every 6 months of treatment with baricitinib, your doctor will need to perform blood tests to ensure that the baricitinib is having an effect and that your insulin producing cells are being maintained, assess insulin use, blood glucose levels and HbA1C, and discuss ongoing treatment and alternatives.
- It is likely that treatment will need to continue to sustain any benefits observed. There is no data on treatment effect beyond one year's duration.



