

## MEDIA RELEASE

### **TRULICITY® (dulaglutide) in combination with insulin is now available on the PBS for Australians with type 2 diabetes**

**1 March 2021, Sydney** – Eli Lilly Australia is pleased to announce that dulaglutide (TRULICITY®) is now reimbursed under the Pharmaceutical Benefits Scheme (PBS) for concomitant use with insulin for patients with type 2 diabetes (T2D). This is in addition to the existing reimbursement criteria for dulaglutide as dual therapy with metformin or triple therapy with metformin and sulphonylurea.

In Australia, diabetes affects the health of at least 1.5 million people<sup>1</sup>. Type 2 Diabetes, a progressive condition where the body becomes resistant to the normal effects of insulin and/or gradually loses the capacity to produce enough insulin, accounts for 85-90 per cent of all cases<sup>1</sup>.

One of the key goals of pharmacological management of patients with T2D is to maintain glycaemic control to a target HbA1c range of around 7 percent for most patients, alongside lifestyle modifications, such as diet and exercise<sup>3</sup>. While international consensus statements recommend the use of GLP-1 RA medication class prior to insulin for the majority of patients with T2D<sup>3,4</sup>, the progressive nature of the disease means that patients may eventually require the combination of these two foundational injectable therapies.

Professor Richard Maclsaac, Director, Department of Endocrinology & Diabetes, St Vincent's Hospital, Melbourne, and Professorial Fellow, University of Melbourne commented,

*“Despite their best efforts, many patients struggle to achieve adequate glycaemic control. While in Australia we have had an approved indication for some time covering the combined use of Trulicity and insulin, the fact that this was not reimbursed under the PBS has meant that this treatment option has been under-utilised by clinicians, often due to the cost for their patients”*

*“Adding a GLP-1 to insulin for patients with Type 2 Diabetes should achieve better control of their blood glucose levels and they may even experience a decrease in body weight. The data also suggests that some patients will be able to reduce the required insulin dose or come off insulin all together due to the insulin sparing effect of a GLP-1RA such as Trulicity, which is given as once a week injection from a pre-filled pen. This PBS listing of Trulicity® in combination with insulin is welcome news,”* he added.

The TRULICITY® reimbursement update is based on the AWARD-9 clinical trial, a Phase 3b, randomised double-blind, placebo-controlled, 28-week study that evaluated the efficacy and safety of once-weekly TRULICITY® 1.5mg in combination with titrated insulin glargine, with or without metformin<sup>5</sup>.

TRULICITY® is available as a ready-to use, single-use pre-filled pen (autoinjector) with an integrated, hidden needle. No dose titration is required<sup>7</sup>.

Ben Basil, General Manager Eli Lilly Australia & New Zealand, added, *“Lilly introduced the world’s first commercially available insulin product for the treatment of diabetes, then a fatal disease with no effective treatment options. A hundred years on, we are even more determined and the PBS listing of Trulicity in combination with insulin demonstrates Lilly’s ongoing commitment to making life better for people living with type 2 diabetes.”*

## TRULICITY® (dulaglutide) MINIMUM PRODUCT INFORMATION

**INDICATIONS** – TRULICITY is indicated for adult patients with Type 2 diabetes as 1) an adjunct to diet and exercise to improve glycaemic control; and 2) as an adjunct to standard of care therapy to reduce the risk of major adverse cardiovascular events in those with either established cardiovascular disease or multiple risk factors for cardiovascular disease. **CONTRAINDICATIONS** – Hypersensitivity to dulaglutide or any of the excipients. **PRECAUTIONS** – should not be used in patients with Type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis; severe gastrointestinal disease – not recommended; acute pancreatitis – discontinue treatment if suspected; hypoglycaemia – combining treatment with sulfonylurea or insulin may increase risk; congestive heart failure – limited therapeutic experience; carcinogenicity – caused statistically significant dose-related increases in the incidence of thyroid C-cell tumours in rats, however, the human relevance of these findings is unknown. Use in Pregnancy Category B3. **ADVERSE EFFECTS** Clinical Trials Experience – Very Common (≥10%) gastrointestinal disorders (nausea, vomiting and diarrhoea), hypoglycaemia (in combination with insulin non-/secretagogues and/or insulin); Common (≥1 and <10%) abdominal pain, decreased appetite, dyspepsia, fatigue, hypoglycaemia (as monotherapy), immunogenicity. **DOSAGE AND ADMINISTRATION** – Dosage: Adults (≥ 18 years): 1.5 mg once weekly, at any time of day, independently of meals. Elderly Patients (≥65 years): dose adjustment not required. Children and adolescents (<18 years): safety and effectiveness have not been established. Renal Impairment: no dose adjustment is required in mild, moderate or severe renal impairment; not recommended in end-stage renal disease. Hepatic Impairment: no dose adjustment required. Administration: subcutaneous injection in the abdomen, thigh or upper arm. Should not be administered intravenously or intramuscularly. Single-use in one patient only. Discard the pen once the injection is completed. Please review full PI before prescribing. Full PI is available on request from Eli Lilly. Eli Lilly Australia Pty Ltd, 112 Wharf Road, West Ryde NSW 2114. Phone 1800 454 559. Based on PI approved 14 July 2020.

TRULICITY® (dulaglutide) Consumer Medicine Information-  
<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-CMI-01316-1&d=202102251016933>

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### About Lilly

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteering. Since its founding, Lilly has pioneered major breakthroughs like insulin and the polio vaccine and has worked to make sure these discoveries reach the people around the world who need them most. For more information, visit: [www.lilly.com.au](http://www.lilly.com.au)

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PP-DG-AU-0552. Date of preparation: 26 February 2021

## References

1. Pharmaceutical Benefits Scheme (PBS). Available at: [www.pbs.gov.au](http://www.pbs.gov.au). Last accessed 1 March 2021.
2. Diabetes Australia, 2015. Type 2 Diabetes. Available at: <https://www.diabetesaustralia.com.au/type-2-diabetes> [Accessed February 2021].
3. Davies MJ et. al. Diabetes Care 2018; 41:2669–701.
4. Buse JB et. al., Diabetologia 2020; 63, 221–228.
5. Pozzilli et. al., Diabetes Obes Metab. 2017;19:1024–1031.
6. AIHW 2016. Incidence of insulin-treated diabetes in Australia. 2016
7. Trulicity (dulaglutide) Consumer Medicine Information. July 2020 [Available at: [tga.gov.au](http://tga.gov.au)]