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By Email (*comments.pdab@maryland.gov*)

Maryland Prescription Drug Affordability Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Drugs Referred to the Stakeholder Council

Dear Council and Staff:

Eli Lilly and Company (Lilly") is the manufacturer of Trulicity® and submits these written comments to the Maryland Prescription Drug Affordability Stakeholder Council (the "Council") in response to Trulicity's inclusion on the "Drugs for Referral to the Stakeholder Council" listing from the Maryland Prescription Drug Affordability Board (the "Board"). Lilly urges the Council recommend that the Board not select Trulicity for a cost review under COMAR regulation 14.01.04.

Affordability for Maryland patients

Trulicity is affordable. Patients in Maryland paid an average of $2 to $39 per month for their therapy, which equates to only 0.2% to 4% of the list price[1]. This affordability stems from exceptional access provided by payers within the state, as well as affordability programs provided by Lilly: 80% to 90% access across formularies and segments (including healthcare marketplace, Medicaid and Medicare)[2]. Lilly continues to advocate for patient choice, with most patients having the ability to choose the incretin therapy that is appropriate for them with the help of their healthcare provider. This choice has maintained healthy competition in the broader incretin therapy market. We feel Trulicity is both competitively priced based on the clinical value it provides and the class in which it competes.

[1] Based on information licensed from IQVIA: IQVIA™, Real-World Evidence Claims Data for the period March 2023 - Feb 2024 reflecting estimates of real-world activity. All rights reserved. Accessed on April 23, 2024.
[2] Ibid.

Therapeutic Alternatives

As part of the Cost Review Study Process, "Trulicity Proposed Therapeutic Alternatives" was published by the Board. Lilly believes a number of drugs contained on this listing are not valid alternatives for therapy with Trulicity. Semaglutide (Ozempic), liraglutide (Victoza), exenatide (Byetta), lixisenatide (Adlyxin), exenatide-extended release (Bydureon), semaglutide (Rybelsus), tirzepatide (Mounjaro) are valid alternatives that should remain on the listing. All other products, which are not glucose-dependent insulinotropic polypeptide (GIP) receptor or glucagon-like peptide-1 (GLP-1) receptor agonist products, should be removed prior to any further comparisons in products potentially subject to a cost review.

Unintended consequence to patient access and cost

Lilly encourages the Council and the Board to be thoughtful about the process to assess cost challenges to Maryland patients and to balance the likely consequence of limiting access to patients as a result of instituting an Upper Payment Limit ("UPL"). In addition, UPLs are unlikely to impact the patient out-of-pocket experience at the pharmacy counter, which is the ultimate goal of the creation of the Board and its regulations.

Value of Trulicity® to patients[3]

Trulicity is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular (CV) events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors. Trulicity is the only GLP-1 RA that provides this combination of benefits: powerful A1C reduction across 4 doses, proven CV benefit in both primary and secondary prevention patients, simply delivered.[4] In fact, in AWARD-11, Trulicity provided sustained A1C reduction at 1 year of <7%.[5] Trulicity acts like the natural human hormone, GLP-1, helping the body do what it's supposed to do naturally:

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[3] See full Prescribing Information for Trulicity at https://uspl.lilly.com/trulicity/trulicity.html#pi
[4] Treating Adults with Type 2 Diabetes | HCP | Trulicity (dulaglutide)
[5] Clinical Trials: Lowering A1C, Weight Change & CV Data | HCP | Trulicity (dulaglutide)

reduces hepatic glucose production by decreasing glucagon secretion, slows gastric emptying and releasing glucose-dependent insulin. Reductions in fasting and postprandial serum glucose were observed as quickly as 48 hours after the first dose of Trulicity.[6]

We appreciate that the Council and the Board share our commitment to prescription drug affordability, and we are proud to lead the industry in making our products affordable. We are proud of the impact that our efforts have had on making Trulicity affordable for Maryland patients and believe the Council's review will demonstrate the meaningful impact Trulicity have had for patients with type 2 diabetes.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

[6] How Trulicity Works, MOA & FPG and PPG Reductions | HCP | Trulicity (dulaglutide)