

May 16, 2024

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No.FDA-2024-N-1718 for “Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

To Whom it May Concern:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide comments for the Endocrinologic and Metabolic Drugs Advisory Committee’s (Committee) consideration of NNC0148–0287 Injection (insulin icodec). As an organization that represents individuals living with diabetes and their advocates, we are pleased to offer our perspective on the value of additional therapeutic options for diabetes, the potential benefits of once-weekly insulin dosing for reducing patient burden and improving adherence, the value of including continuous glucose monitor-derived (CGM) time in range (TIR) metrics in the labels of antidiabetic medications, and the importance of ensuring that innovations in diabetes treatment are available and accessible to all individuals living with diabetes.

More than 38 million Americans like me are impacted by diabetes,¹ a chronic condition that requires proactive daily management of glucose levels to help prevent and reduce the serious and life-threatening complications of the disease. The diaTribe Foundation maintains a long-standing commitment to engaging in the federal legislative and regulatory processes to help secure policies and programs that improve the lives of individuals living with diabetes. To that end, the voices of people with diabetes must be heard when discussing treatments that directly affect them, and we appreciate the Committee providing this opportunity.

The diaTribe Foundation

The mission of The diaTribe Foundation is to help people with diabetes and prediabetes and to advocate for action. Our goal is to ensure that people have the resources and education needed to thrive with diabetes. The diaTribe Foundation is dedicated to bringing people with diabetes to the conversation on regulatory issues, connecting the field and the diabetes community, and changing the narrative around diabetes. Through our publication, *Learn*, which reaches more than six million people each year, we offer deep insights into the patient experience and closely cover the latest research, treatments, and initiatives in diabetes.

In addition, because everyone with diabetes deserves to have the tools, therapies, and technologies to live their best life, we established *The Time in Range Coalition* (TIRC), a multi-stakeholder group of foundations, non-profit organizations, researchers, people with diabetes, clinicians, and industry with the goal of establishing time in range (TIR) as an essential part of diabetes care and making TIR accessible to all people with diabetes and their care teams. Using TIR in daily diabetes management can positively change lives^{2,3}—we are spearheading the work to make that a reality for everyone with diabetes.

The diaTribe Foundation also aims to reduce the impact of diabetes on society and improve the lives of people with diabetes by fostering an understanding of the disease and eliminating misplaced blame through the work of our program, *dStigmatize*.

Value of Additional Therapeutic Options

As a person living with diabetes for over a quarter of a century, the innovations I have been able to incorporate into my own diabetes management have dramatically improved my quality of life. Some of those innovations have been therapeutic and others have included technology. The options that have made the most significant impact for me have included both insulin and continuous glucose monitoring; these two breakthroughs have been game changers for many people living with type 1 diabetes. Yet, while many individuals living with diabetes have benefited from therapeutic advances in recent years, disease management remains a significant challenge for too many. Though not every medical advance is appropriate for every person living with diabetes, continued innovation in safe and effective therapeutic options is critical to allowing patients and their care providers to personalize their treatment to meet their individual needs. Life with diabetes can be unpredictable. There are 42 factors that affect glucose levels⁴—innovations, like once-weekly insulin, give people with diabetes the tools to have more therapeutic flexibility in their daily lives.

Reducing Patient Burden and Improving Adherence

If found safe and effective, a once-weekly-dosed insulin has the potential to reduce the existing burden of disease management and improve insulin adherence. Reduction of diabetes burden is connected to lower risk of diabetes distress⁵—a serious issue that can negatively impact a person’s quality of life and health outcomes.^{6–10} Innovation in new treatments has the potential to change how people see their life-long illness. For many people with diabetes, injection site reactions,¹¹ fear of needles/injections,^{12–15} and the inconvenience and difficulty of insulin administration^{16,17} affect adherence to a prescribed dosing schedule. Less frequent injections could minimize these barriers.

Multiple studies have shown that both health care providers and patients are often reluctant to initiate insulin therapy for reasons that include fear of needles and of pain and the complexity of insulin dosing.^{14,15,18–21} These factors contribute to therapeutic inertia—the slowing of therapy initiation or dosage increases—which leads to suboptimal glycemic management.^{15,19}

Once-weekly insulin dosing may have particular benefits for specific populations, such as individuals in long-term care facilities and frail individuals who need assistance with dosing,¹⁸ where simplification of therapeutic regimen is recommended.²² Further, the need to regularly test and inject insulin can be extremely disruptive and interfere with an individual’s work, school, or caregiving schedule. Unfortunately, many Americans do not have employment arrangements that allow them the flexibility to test their blood glucose and dose insulin in a manner that meets their healthcare needs. Many of these individuals are those who are hourly wage workers, who may not have health insurance and/or a regular source of care, further contributing to poor health outcomes. As such, we believe that once-weekly insulin dosing—if accessible—has the potential to improve health equity and reduce health disparities.

As a person living with diabetes, I can affirm the aforementioned fear of needles is real and disruptive to life. When I was first diagnosed with type 1 diabetes and I took my first insulin injection, I passed out in the doctor's office. This continued to happen for the first week and I had to be monitored and observed at every injection for several months—like a toddler. But I was a 21-year-old college student. I was faced with requiring multiple daily insulin injections to stay alive, but also the concern of what might happen if I passed out while piercing my flesh with a piece of sharp metal. I hope this fear is not taken lightly—because it is a reality for the 8.4 million Americans who rely on insulin every day to survive.²³

I began petitioning for my first insulin pump when the doctors advised I needed to increase my injections to 4–6 shots a day. Back then, I would have gladly welcomed the option of a once-weekly insulin. Today, as a diabetes advocate, I see how unique diabetes looks for members of the community and how different treatment options are needed to effectively meet the needs of individuals living with this disease. No matter how someone's diabetes is managed, innovation is imperative to our well-being. Diabetes is not a one-size-fits-all condition.

Time in Range in Drug Labeling

Reflecting its importance to quality of life and health outcomes for individuals living with diabetes, a central goal of The diaTribe Foundation and its work through the TIRC has been for CGM-derived TIR data to be used in regulatory decision-making, specifically for TIR to serve as an endpoint to support diabetes drug approvals, as a complement to HbA1c (A1c), and for TIR data to be incorporated into the product prescribing information to support the clinician's treatment decision. TIR provides healthcare professionals and people with diabetes the opportunity for immediate intervention to improve their disease management by providing real-time, detailed information on day-to-day glycemic patterns not delineated by A1c alone. CGM use by people with type 1 diabetes exceeds 50 percent in the United States.^{24,25} Each time my diabetes requires a change in therapy, I am grateful my CGM provides safety alerts, as well as the TIR data needed to guide adjustments that minimize future hyper- and hypoglycemic events.

Ensuring that individuals with diabetes have access to the kind of actionable information about drug therapies that CGM data provides can help improve glycemic control and prevent or mitigate the impact of the serious and life-threatening complications of this disease. We welcomed²⁶ FDA's indication in its May 2023 draft guidance²⁷ of its willingness to include CGM-based metrics in Section 14 of the drug label and would urge FDA to maximize the incorporation of this data in the drug label for insulin icodec, if approved, to the full extent supported by the data submitted by the sponsor.

Access to Innovative Therapies

The diaTribe Foundation is committed to ensuring that people with diabetes can access the therapies they need and to eliminating cost-prohibitive barriers to life-sustaining medication. We appreciate the importance of adequate investment incentives, but also recognize that patients cannot benefit from innovations that are inaccessible because they are financially out of reach. A 2021 study found that 1 in 6 or 1.3 million Americans rationed insulin due to its high cost, with rationing most common among those without health insurance coverage, individuals under the age of 65 not eligible for Medicare, and Black insulin users.²⁸ Insulin is a life-saving drug—access to it should not be determined by a person's race, socioeconomic status, or vocation. In the United States in 2024, a diabetes diagnosis should not

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have to be a death sentence. While not an issue within the remit of this Committee, we urge all stakeholders to join us in working to ensure that all individuals with diabetes have access to the life-saving therapies they need and deserve.

Thank you again for the opportunity to provide comment to the Committee. We respectfully request that you consider these perspectives as you conduct your review.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Heverly". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Julie Heverly
Senior Director, Time in Range Coalition
The diaTribe Foundation

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