

News Release

Contact: press@diabetes.org

The American Diabetes Association Announces Statement on Compounded Incretin Products

ARLINGTON, VA. (Dec. 2, 2024) – Today, the American Diabetes Association® (ADA) released a guidance statement on the use of compounded GLP-1 RA (glucagon-like peptide-1 receptor agonist) and dual GIP/GLP-1 RA (glucose-dependent insulinotropic polypeptide and GLP-1 RA) medication classes. The statement recommends against using non-Food & Drug Administration (FDA)-approved compounded GLP-1 and dual GIP/GLP-1 RA products due to uncertainty about their content, safety, quality, and effectiveness.

GLP-1 RA and dual GIP and GLP-1 RA medication classes are recommended by the ADA's *Standards of Care in Diabetes* for use in people with type 2 diabetes. Over the past few years, the FDA has approved several of these pharmacotherapies for weight management. The increasing utilization of these pharmacotherapies has contributed to intermittent shortages, thus prompting multiple entities to produce and market compounded formulations of these medications directly to consumers.

Compounded medications are customized formulations produced to meet individualized clinical needs. While compounded medications play a critical role in our health care system, several concerns have emerged regarding the widespread availability of non-FDA-approved versions of these medication classes. The ADA's statement seeks to provide guidance for health care professionals and people with diabetes and/or obesity to consider when FDA-approved medications are unavailable, including resources and advice for those still considering the use of a compounded GLP-1 RA or dual GIP/GLP-1 RA products.

"These medications are critical not just for diabetes and weight management, but also for mitigation of cardiovascular and kidney disease risks in high-risk individuals," said Dr. Joshua J. Neumiller, the ADA's president-elect, health care & education and the statement's lead author. "We urge health care professionals to consider this guidance statement due to concerns around the safety, quality, and effectiveness of compounded versions of these products."

"It is important to consider this guidance as use of incretin-based therapies continues to expand. As demand continues to increase, it is possible that intermittent shortages may occur. We encourage health care professionals and people living with diabetes and obesity to consider this guidance in conjunction with clinical judgment and individual preferences when making informed care decisions," said Dr. Nuha ElSayed, the ADA's senior vice president, health care improvement and the manuscript's senior author.

The statement is published online ahead of print in *Diabetes Care*® and is freely accessible.

2451 Crystal Drive Suite 900 Arlington, VA 22202 1-800-DIABETES (342-2383)



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About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to end diabetes and helping people thrive. For 84 years, the ADA has driven discovery and research to prevent, manage, treat, and ultimately cure diabetes. There are 136 million Americans living with diabetes or prediabetes. Through advocacy, program development, and education, we're fighting for them all. To learn more or to get involved, visit us at <u>diabetes.org</u> or call 1-800-DIABETES (800-342-2383). Join the fight with us on Facebook (<u>American Diabetes Association</u>), Spanish Facebook (<u>Asociación Americana de la Diabetes</u>), LinkedIn (<u>American Diabetes Association</u>), and Instagram (<u>@AmDiabetesAssn</u>).