



## Policy Change Allows Approval For Medicare Patients Living With Diabetes To Use Both Afrezza® And Continuous Glucose Monitoring Devices Beginning July 18

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- Restriction of choosing between the two diabetes tools lifted for Medicare patients

WESTLAKE VILLAGE, Calif., June 28, 2021 /PRNewswire/ -- **MannKind Corporation (Nasdaq: MNKD)** appreciates the recent efforts of the Centers for Medicare and Medicaid Services (CMS) in conjunction with the Medicare Administration Contractors (MACs) to implement a policy change to the Local Coverage Determination (LCD) L33822, allowing the approval to Medicare patients living with diabetes to select both Afrezza® and Continuous Glucose Monitors (CGMs). Effective July 18, the criteria change lifts the restriction on patients of having to choose between the two diabetes tools.



"Prior to this change, Medicare denials were occurring for patients using CGMs and inhaled insulin as an alternative to injected mealtime insulin," explained Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "MannKind is committed to providing convenience for patients, and believes that patients should have the choice to use any of today's tools to help manage their diabetes."

MannKind requested that the Durable Medical Equipment (DME) MACs reconsider the existing language in the LCD: Glucose Monitors (L33822) to include use of inhaled insulin. Previously, the criteria defined patients as taking insulin either with multiple daily injections or an insulin pump. The amended definition now includes a patient that takes insulin with inhalation as an alternative.

"This is a win-win for Medicare patients and providers that serve those patients," said Stella Ilyayeva, MD, FACE, an Endocrinology, Diabetes and Metabolism specialist. "In 2020, almost 2/3 of T1D Afrezza patients were utilizing a CGM concomitantly. I anticipate this change will open up more doors for the population of Afrezza users."

### **About Afrezza®**

Available by prescription, Afrezza® (insulin human) Inhalation Powder is an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza consists of a dry powder formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and passes quickly into the bloodstream (in less than one minute). This rapid absorption allows Afrezza to begin reducing blood sugar levels within minutes of administration. Afrezza is available in 4-unit, 8-unit and 12-unit single-dose cartridges of insulin

powder that can be used, as prescribed by a health care professional, in combination with other diabetes medications to achieve target blood sugar levels. For Afrezza doses exceeding 12 units, patients may use a combination of existing cartridge strengths. For more information about Afrezza, please visit [afrezza.com](http://afrezza.com).


### **About MannKind Corporation**

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only inhaled ultra-rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. Afrezza is also available by prescription in Brazil, where it is commercialized by the Company's partner, Biommm SA. MannKind was established in 1991, and is headquartered in Westlake Village, Calif., with a manufacturing and R&D facility based in Danbury, Conn. The Company also employs field sales and medical representatives across the U.S. Please visit [mannkindcorp.com](http://mannkindcorp.com) to learn more.

### **Forward-looking Statements**

Statements in this report that are not statements of historical fact are forward-looking statements. Words such as "plans," "anticipates," "expects," "intend," "will," "targeted," "potential" and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding: providing convenience to patients and opening more doors for Afrezza users. These forward-looking statements are based upon MannKind's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: risks that Afrezza may not become widely accepted by physicians, patients, third-party payers and the healthcare community, and risks that third-party payers may not cover Afrezza. These and other risks are detailed in MannKind's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in MannKind's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 12, 2021. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

AFREZZA is a registered trademark of MannKind Corporation.

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CONTACTS: Christie Iacangelo, MannKind Corporate Communications, (818) 292-3500, [media@mannkindcorp.com](mailto:media@mannkindcorp.com); Rose Alinaya, Investor Relations, (818) 661-5000, [ir@mannkindcorp.com](mailto:ir@mannkindcorp.com)