Medicare Data: Significant Reductions in Amputations, Emergency Visits, and Hospital Readmissions Associated with Advanced Treatment Using Skin Substitute Products for Lower Extremity Diabetic Ulcers (LEDUs)

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New study shows advanced treatment (AT) for management of LEDUs among Medicare beneficiaries is associated with significant reductions in major and minor amputation, emergency department (ED) use, and hospital readmissions vs. LEDUs managed without AT (NAT)

MARIETTA, Ga., Aug. 17, 2021 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, today announced publication of its peer-reviewed study in the *Journal of Wound Care* (JWC), addressing the observed impact of Advanced Treatment (AT) using all high-cost skin substitute products in lower extremity diabetic ulcers (LEDUs) based on data from the Medicare Limited Dataset (October 1, 2015 through October 2, 2018). The study assessed outcome in patients receiving AT with all high-cost skin substitute products, as designated by the Centers for Medicare and Medicaid Services (CMS), for LEDUs versus No Advanced Treatment (NAT), and found that AT use could lead to a 42% reduction in major and minor amputations and all related costs, compared to NAT. Further, the study highlights preferable outcomes when AT follows parameters for use (FPFU), underscoring the importance of early treatment with regular intervals and well-defined treatment guidelines.

"The data derived from this study are important for a number of reasons," noted Dr. David G. Armstrong, Professor of Surgery and Director of the Southwestern Academic Limb Salvage Alliance (SALSA) at the Keck School of Medicine of the University of Southern California. "Most notably, it is the first, to our knowledge, to broadly evaluate the parameters for use and associated observed impact of these advanced treatments in the wound care space. The substantial reduction, not only in amputation, but also in hospital readmission rates and visits to the emergency room suggests that our patients may be able to live more hospital-free and activity-rich days when we focus on getting to wound closure."

In 2018, an estimated three million Americans suffered from diabetic foot ulcers (DFUs) – a type of LEDU. Among patients with DFUs, more than half will develop an infection. Up to 20% of infected DFUs require major or minor amputations.

"Understanding the health outcome and financial implications of different courses of treatment is essential to improving patient health and reducing cost burden to providers, patients, families, payors, and the healthcare system overall," said Dr. William Tettelbach, a lead author of the study and MIMEDX Principal Medical Officer, Medical Affairs. "These data demonstrate the significant beneficial impact of AT with all high-cost skin substitute products for difficult-to-heal LEDUs, and the additional benefit of treating quickly and regularly with AT."

In addition to the physical and emotional impact on patients and caregivers, DFUs create significant economic burden, accounting for up to $4.5 billion in Medicare spending – and up to $18.7 billion when the cost of infection management is included. In 2014, Medicare spending for the treatment of DFUs was an estimated $6.2–18.7 billion. The annual payor burden of DFU treatment ranged from $9.1–13.2 billion, in large part due to increased hospitalizations, home healthcare, emergency department visits, and outpatient or physician office visits.

Reducing major and minor amputations has a long-term effect on ongoing health costs, evidenced by 2010 estimates of $60,000 per patient amputation, with care costs in the year following an amputation of $44,200. The longer a DFU remains open, the greater the risk for infection, osteomyelitis, and amputation. In patients with diabetes, 85% of lower-extremity amputations are preceded by a non-healing DFU and the study's findings indicate that 42% of these amputations may be preventable.

The immediate physical and economic toll on people with diabetic lower extremity complications, including amputations, have been correlated to an increased five-year mortality rate. While these costs were not examined in this study, their inclusion could extend the economic and quality of life benefits gained by using AT.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "As a company dedicated to advancing scientific and health economic research that informs and improves patient care and outcomes, we see these analyses as providing crucial validation that advanced treatment can reduce the suffering and expenses caused by chronic LEDUs. Future research must build upon these findings and inform better treatment guidelines and reimbursement policies, so that together, we raise the standard of care for patients with LEDUs."

About MIMEDX

MIMEDX is an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental biologics, we have both a base business, focused on addressing the needs of patients with acute and chronic non-healing wounds, and a promising late-stage pipeline targeted at decreasing pain and improving function for patients with degenerative musculoskeletal conditions. We derive our products from human placental tissues and process these tissues using our proprietary methods, including the PURION® process. We employ Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce our allografts. MIMEDX has supplied over two million allografts, through both direct and consignment shipments. For additional information, please visit www.mimedx.com.

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