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Advancing foot and ankle medicine and surgery

Diabetes Mellitus Interagency Coordinating Committee Meeting
Oral Comments of Dr. Paul Kesselman
Provided on Behalf of the American Podiatric Medical Association
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My name is Dr. Paul Kesselman and I am speaking on behalf of the American Podiatric Medical Association (APMA), the national organization representing the vast majority of the nation's doctors of podiatric medicine, also known as podiatric physicians and surgeons, or podiatrists, I would like to thank you for the opportunity to provide comments on the potential impact of Digital Health Technology to Type 2 Diabetes Management.

The financial expenditure for diabetes makes up a significant part of the Medicare budget and was estimated to exceed $250B in 2018. Twenty-five percent of those expenses ($80B) is attributed to the diagnosis and treatment of diabetic foot pathology and has repeatedly been estimated to be equivalent to the costs for treating the top four cancers.[1]

Podiatric physicians are at the forefront of an epidemic of diabetic foot ulcers (DFU) and the myriad of subsequent pathologies and complications that result. This includes infections, hospitalizations, and skin grafting. Unfortunately, this often results in amputations with an associated 5-year mortality of 50%.[2] The impact on the US budget, loss of work hours, family caregiver and taxpayer costs cannot be overestimated. Any emerging technologies capable of alleviating this financial burden should be welcomed and incentivized.

Prior to the Public Health Emergency (PHE) created by COVID-19, telemedicine and telehealth digital platforms were rarely used. Despite the formal end of the PHE, both patients and providers have embraced these technologies. Most patients would agree that these digital platforms have increased access to their providers. Thus, these platforms should be encouraged, expanded, and continue to be paid at the non-facility office rate. This is because many providers only perform telemedicine or telehealth services in their office or home offices, with similar overhead as if they were in the physical presence of the patient.

Over the last few years several new digital products have been brought to the market which have the potential to diagnose or treat diabetic foot pathologies. By diagnosing and initiating treatment at earlier stages of development there can be a significant reduction in morbidity and mortality. These wearable products now available to podiatrists include socks and/or pressure mats which allow podiatric physicians to remotely monitor their patients for early signs of inflammation (via temperature spikes).

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[1] Armstrong, D. et al. (March 2020) Five-year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer, Journal of foot and ankle research. Available at: https://pubmed.ncbi.nlm.nih.gov/32209136/ (Accessed: 15 November 2023).
[2] *Id.*

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An upcoming peer-reviewed study that will be published at a later date, titled "Continuous Remote Temperature Monitoring Program Reduces Foot Ulcers and Amputations: A Multicenter Post- Market Registry Study" submitted to JMR Diabetes illustrates that using digital wearable stocking technology has the potential to provide significant savings to the third-party payer for the average patient with diabetes in an outpatient setting.[3] This includes the expenditures for the device and costs for remote monitoring of the patient. By detecting temperature spikes at least two or more weeks before ulceration occurs in patients and intervening early, many DFU and their associated sequela can be prevented.

Other digital technology available to the podiatrist in treating patients with diabetes are ankle-foot orthosis (AFO) and prosthetic devices which are implanted with pedometers and sensors either implanted in the shell and/or foot bed of the device. This is done to detect compliance with the use of these devices. By providing real time data, the treating podiatric physician can provide feedback regarding offloading compliance and corrective gait measures needed for specific patients. By ensuring proper offloading and instituting corrective gait measures, the podiatric physician can assist in healing current DFUs and reduce patients' risk of developing additional DFUs. This can reduce the risk of developing more severe complications such as osteomyelitis and Charcot foot, all of which often lead to significant expense and may lead to limb amputation.

The management of chronic wounds has emerged as a major health care challenge during the 21st century consuming significant portions of health care budgets. Chronic wounds such as diabetic foot ulcers often require multiple daily or weekly dressing changes. There are several confusing standards by which to determine which dressings are appropriate for a specific wound. Medicare's Surgical Dressing LCD is in part based on the amount of drainage with little considerations for other factors such was wound pH, microbiological flora, and other factors. The advent of "Smart Dressings," that is dressings with the ability to monitor in real time the quantity and quality of exudate, microflora, wound pH, and quality of granulation vs. necrotic tissue have an enormous potential for cost savings. Having access to this real time data has the potential to increase the efficacy of dressings and accelerate wound closure time, reduce infection, negating the need for multiple antibiotics and their common side effects, reduce hospitalizations, surgery, and other expensive therapies.

Having these technologies will have a cost which both manufacturers and providers need to account for and must be affordable to provide. If CMS does not change the current structure for payment, then there will be no incentive for manufacturers to produce these wearables nor for providers to supply their patients with these advanced technologies.

Wearable technology products must have their own HCPCS codes and not be included as they are with the current Remote Physiologic or Remote Therapeutic (RPM/RTM) CPT codes. The monitoring of patients using wearables while shown to be cost effective and reimbursable, does not account for the costs of the products themselves and has been an hinderance to adaptation.

[3] Shih, Chia-Ding, et al. Continuous Remote Temperature Monitoring Program Reduces Foot Ulcers and Amputations : A Multicenter Post- Market Registry Study (Publication TBD)

Therefore, the wearable RPM/RTM must be paid separately from the product and also allow for separate entities to provide the wearables and possibly another to monitor the patient.
In certain instances, a new HCPCS code family will need to be created (e.g., smart socks). In others, a new HCPCS code will be required for the sensor while the CAM Walker (e.g., L4386/L4387 or L4360/L4361) is separately reimbursable. In addition, the AFO policy which does not allow for the use of AFO's (other than Crow Boot L4631) will need to be re-evaluated to permit reimbursement for offloading DFUs. This policy is both antiquated and poses challenges to providers and is perilous to patients.

Additionally, under the guidance set forth in CMS' recently released final rule for services reimbursed under the Medicare Physician Fee Schedule for the 2024 calendar year, only one practitioner may bill under RPM or RTM codes during a 30-day period when at least 16 days of data are collected on at least one medical device. RPM and RTM technology should be expanded from this current single provider limitation to as many providers as medically necessary. Otherwise, leaving this limitation in place forces both patients and clinicians into priorities that may result in worse outcomes for the patient overall.

Smart sensor embedded dressings will also require new HCPCS codes by which to designate their additional features over their current non-smart entities.

Most health care practitioners understand we are on the precipice of a whole new dimension of therapies. These technologies must be affordable to manufacture and affordable for providers to acquire. Despite these costs there is the potential to save taxpayers billions of dollars, CMS must take action to incentivize both manufacturers and providers to embrace these technologies. Embracing earlier access to care and reducing the associated morbidities and mortalities associated with diabetic foot pathology can only save our health care system significant expenditures and reduce needless suffering for millions of patients with diabetes.

APMA is here to serve as a valuable resource for further information on the podiatric medical profession. For inquiries and additional details, please feel free to contact APMA Senior Director, Health Policy and Practice, Scott Haag, JD, MSPH, at shaag@apma.org.