



March 10, 2023
Juan Schaening, MD
First Coast Contractor Medical Director
Novitas Solutions
2020 Technology Pkwy
Suite 100
Mechanicsburg, PA 17050

RE: RPM/RTM Multi-Jurisdictional CAC Meeting held on February 28, 2023

Dear Dr. Schaening,

On behalf of the American Podiatric Medical Association (APMA), the national organization that represents the majority of the nation's estimated 15,000 doctors of podiatric medicine (DPMs), also known as podiatric physicians and surgeons, we would like to express our sincere appreciation for the opportunity to participate in your Multi-Jurisdictional CAC Meeting on RPM/RTM, held on February 28, 2023. Given the time constraints and the number of stakeholders involved, we would like to more fully address the questions asked and the literature provided in advance of the call. We would also like to provide some brief feedback about the process management of this type of meeting, anticipating that more meetings like it may arise given the new structure of the CAC and its role.

Background

Diabetic foot ulcers are a serious issue among many, resulting in high mortality rates. The US Department of Veterans Affairs recognizes the significance of preventive care using telemedicine to reach those at risk of chronic wound formation.¹ According to a 2017 study by Brennan et al, the mortality rate for patients with Diabetic Foot Ulcers (DFU) was 19% at one year, and only 29% survived beyond five years.² Additionally, about 60% of all foot ulcers become infected, and more than 20% of patients with a diabetic foot infection require amputation.³ In 2010, a retrospective study reported that over 3,400 veterans have a diabetes-related lower extremity amputation per year, with inpatient costs for each amputation exceeding \$60,000.⁴ These amputation-related costs represent only one component of the VA's expense for

¹ Rothenberg, Gary M, et al. "Remote Temperature Monitoring of the Diabetic Foot: From Research to Practice." *Federal Practitioner : for the Health Care Professionals of the VA, DoD, and PHS*, U.S. National Library of Medicine, Mar. 2020

² Brennan MB, Hess TM, Bartle B, et al. Diabetic foot ulcer severity predicts mortality among veterans with type 2 diabetes. *J Diabetes Complications*. 2017;31(3):556–561.

³ Glover JL, Weingarten MS, Buchbinder DS, Poucher RL, Deitrick GA, 3rd, Fyelling CP. A 4-year outcome-based retrospective study of wound healing and limb salvage in patients with chronic wounds. *Adv Wound Care*. 1997;10(1):33–38.

⁴ Franklin H, Rajan M, Tseng C-L, Pogach L, Sinha A. Cost of lower-limb amputation in U.S. veterans with diabetes using health services data in fiscal years 2004 and 2010. *J Rehabil Res Dev*. 2014;51(8):1325–1330.

diabetic foot disease (DFD). According to a systematic review, the mean annual costs in the year following a foot ulcer were \$44,200 to the public payer. The 2017 study by Chan et al in the *Journal of Wound Care* highlights the opportunity to shift focus from treatment to prevention of DFUs.⁵

In another report, the 2017 Skrepnik Hospitalization Odds Risk Report showed that the odds of hospitalization for DFUs were 3.4 times higher than for congestive heart failure and 6.7 times higher than for other diabetic foot infections.⁶ Furthermore, over 10% of hospital admissions are related to the foot (ulcer, infection, Charcot), and DFU is the number one cause of emergency room and inpatient admissions. DFU also increases the risk of death by 2.5 times in five years.⁷

Clinical Questions and Answers

APMA was appreciative that four podiatric physicians and RPM experts were given time to discuss the role and importance that RPM and RTM play in patient care, while addressing the questions that were provided in advance. For ease, we have compiled their answers to the questions you provided below:

1) Are you using Remote Physiologic Monitoring and/or Remote Therapeutic Monitoring, as defined by the AMA CPT code descriptors in your clinical setting for your Medicare patients? If yes, how do you identify potential patients (e.g., In what clinical situation would they benefit from this type of intervention? Are there specific diagnoses targeted?)

APMA recommends that the specific diagnoses for diabetes would include E08.- through E13.8; G60.0-G65.2; M12.571/2; M14.671/2, and for vascular disease patients I70.201-I73.9.

Are there certain clinical situations where you might choose Physiologic Monitoring versus Therapeutic Monitoring? Please explain.

APMA chooses to primarily comment on RPM utilization, which was only originally provided for physician use. Our observation is that podiatric physicians have been using temperature monitoring as one of the primary options. Additionally, podiatric physicians have also been using pressure monitoring. Due to the fact that RTM is very new, we can see practitioners potentially using it to improve therapeutic goals whether from injury or surgical interventions requiring improved function as quickly as possible from these treatments. The concern raised by many of the SME's as was related on the Webex was that it's too new to make determinations on RTM.

⁵ Chan B, Cadarette S, Wodchis W, Wong J, Mittmann N, Krahn M. Cost-of-illness studies in chronic ulcers: a systematic review. *J Wound Care*. 2017;26(suppl 4):S4-S14.

⁶ Skrepnek GH, Mills JL, Sr, Lavery LA, Armstrong DG. Health care service and outcomes among an estimated 6.7 million ambulatory care diabetic foot cases in the U.S. *Diabetes Care*. 2017;40(7):936-942.

⁷ Lazzarini PA, Hurn SE, Kuys SS, et al. Direct inpatient burden caused by foot-related conditions: a multisite point-prevalence study. *BMJ Open*. (6) 2016;6:e010811.

How do you determine how long to monitor the patient?

APMA recommends that no expiration date be implemented for diabetic patients at risk, so long as the patient is willing to participate. However, if the patient does not meet the minimum requirements of 16 days then they should be removed from RPM. Being involved in RPM, APMA feels there is a need to include podiatric physicians in Principal Care Management services.

If [you are not using RPM or RTM in your practice], what factors led to your decision not to use the monitoring?

If the patient does not have a qualifying diagnosis as discussed previously, the podiatric physician is not considering those patients for RPM in their treatment plan currently. APMA also has concerns that providers may be unfamiliar with RPM/RTM and have a general lack of experience utilizing these options, particularly as RPM/RTM is a relatively new technology for some physicians. There are only a few companies producing devices that could be part of the treatment protocol.

However, after reviewing the present information and technology available, peer-reviewed literature establishes that RPM/RTM is a beneficial and cost-effective option to reduce the development of ulcers, not just within the diabetic community but also for individuals with neuropathy due to other etiologies, especially when combined with significant foot deformities. By reducing plantar foot ulcerations, fewer patients will progress to lower extremity amputations (LEA). Overall this will reduce cost and burden to the healthcare system, along with a reduction in the number of emergency room visits and hospitalizations.

2) What is the advantage of using RPM or RTM over STANDARD PRACTICE for any given patient?

In 2017, the New England Journal of Medicine published a report titled "Diabetic Foot Ulcers and their Recurrence" authored by Drs. David Armstrong and Boulton.⁸ The study demonstrates that the use of home temperature recording devices led to a significant reduction in diabetic foot ulcers (DFUs) among patients. Previous research by Armstrong, Boulton, Lavery, and others had focused on diabetic patients with co-morbidities and a history of DFU, and had examined the use of less advanced devices that required active patient participation. Yet, even with these limitations, it was shown in the course of a very brief trial that home monitoring of skin temperature was an effective tool to predict ulcers prior to significant development. This shows that an effective strategy to reduce ulcerations and amputation is prevention. Home

⁸ Armstrong, et al. "Diabetic Foot Ulcers and Their Recurrence." *The New England Journal of Medicine*, U.S. National Library of Medicine, 2017

thermography and pressure-sensing devices are valuable to detect and monitor areas of the foot prone to ulceration. This otherwise would only be done during an office visit.

3) How has the use of RPM/RTM altered your plan of care for your Medicare patients?

RPM/RTM alerts practices sooner to at-risk patients, allowing time relevant intervention which can

prevent ulcerations, infections, and hospitalization. Patients without this technology are frequently seen much later, resulting in more complications and adverse outcomes. As Dr. Kesselman discussed on the multi-jurisdictional CAC meeting, it is encouraged that patients at the highest risk for DFU (those with previous ulceration experience or those with high risk for ulceration due to loss of protective sensation (LOPS) or those with previous amputations) utilize a device which can record and actively report temperatures to a digital platform in order to engage patients earlier prior to the onset of an ulceration. He would not limit the use of these RPM devices to patients with only diabetes as there are other pathologies which cause profound neuropathy resulting in patients with compromised immune systems who are susceptible to the development of significant foot pathologies and ulcers. These include but are not limited to patients with history of neuropathies due to but not limited to chemotherapy, autoimmune disorders, and spinal fractures.

4) What outcome measures are you using to demonstrate improved patient outcomes with RPM or RTM OVER standard of care?

The literature has shown that patients using RPM have reduced incidence of foot ulcers, hospitalizations or reduced hospital stays due to foot ulcers contributing to reduced incidence of amputations. The literature also demonstrates that patients using RPM experienced reduced incidences and costs related to ancillary services and products that are frequently part of treating patients with these diagnoses (e.g. surgical dressings, cellular tissue products, hyperbaric oxygen, etc.).

5) Do you use a third-party vendor to assist you with the use of RPM or RTM code requirements?

Some of APMA's members work with companies like Siren and helped to develop the model by which a CPT-compliant model was developed to monitor patients using RPM. These members suggested that they would utilize such a platform and encourage others to do so.

6) Do you use RPM or RTM in conjunction with any of the Chronic Care Management CPT codes? If so, when, and how would you use them in tandem?

Podiatric physicians are currently precluded from Chronic Care Management (CCM) because of the nature of podiatric physician practice. The statute, however, does not preclude DPMs from Principal Care Management (PCM). NGS has determined that DPMs should not be reimbursed for PCM. APMA has made several efforts to date to address this oversight, however, NGS has

determined that the evidence to support DPMs capability to provide PCM were insufficient even though we could meet their litmus test. NGS stated that the decision was final, and no appeal was possible. APMA is of the belief this is unfair and prevents APMA from providing clear information that DPMs (as any other physician providing PCM for any single medical issue) are sufficiently trained to provide PCM. We would respectfully ask that CMS further investigate this matter.

Literature Review:

Based on any currently available literature, is there high-quality evidence to support RPM and RTM as medically reasonable and necessary for any other patient outcomes. Please provide a copy or link of any supporting additional literature.

In a review of the following articles,^{9,10,11,12} evidence suggests that relatively cost-effective RPM provides significant positive outcomes. Some attributes to be considered:

- Decreased time to heal
- Decreased disability
- Decreased recurrence
- Patient involvement with increased proactive role
- Increased access to professional monitoring and guidance
- Ability to be proactive vs reactive
- Overall savings to the Medicare Trust Fund to lower costs.
- Statistically this high-risk patient population is likely to encounter greater medical challenges if proactive measures are not instituted. (i.e., hospitalization, rehab, infection, amputation, compromised activities of daily living etc.)
- The increased health care dollars to treat the condition with associated complications is far greater than the anticipated cost of RPM.

Additional Supporting Articles

The *Preventing Diabetic Foot Ulcer Recurrence in High-Risk Patients* study suggested that when equipping patients with diabetes at high risk for foot ulceration, with a relatively simple skin temperature device, it can significantly reduce the incidence of foot ulcers.⁸ By evaluating the effectiveness of a temperature monitoring instrument, the study found that patients who did not utilize this therapy were over 4 times more likely to develop ulcers. The use of infrared temperature home monitoring used in the study served as an early warning in preventing diabetic foot ulcerations, providing a simple tool available to the user.

⁹ Lavery LA, Higgins KR, Lanctot DR, et al. Preventing Diabetic Foot Ulcer Recurrence in High-Risk Patients: Use of temperature monitoring as a self-assessment tool. *Diabetes Care*. 2007;30(1):14-20. doi:10.2337/dc06-1600.

¹⁰ Lavery LA, Higgins KR, Lanctot DR, et al. Home Monitoring of Foot Skin Temperatures to Prevent Ulceration. *Diabetes Care*. 2004;27(11):2642-2647. doi:10.2337/diacare.27.11.2642.

¹¹ Gollidge et al (2020) "The Potential Role of Sensors, Wearables and Telehealth in the Remote Management of Diabetes-Related Foot Disease"

¹² Brooks et al (2021) "Remote Diabetic Foot Temperature Monitoring for Early Detection of Diabetic Foot Ulcers: A Cost-Effectiveness Analysis"

The study also concluded that under the ideal circumstance, the high-risk patient likely will be evaluated in specialty clinics 4-6 times a year. However, self-monitoring provides the ability for a more frequent assessment, making it critical in the prevention of lower extremity ulcerations. In fact, the study concluded that self-care may be the “single most important factor in preventing complications in individuals with high risk for diabetic foot ulceration.” The results of this study suggested that when equipping patients with diabetes at high risk for foot ulceration, with a relatively simple skin temperature device, a significant reduction in foot ulceration is to be expected. Additionally, it was noted that high-risk patients with diabetes in the study who developed foot ulcers did not comply with measuring their foot temperatures.

The *Home Monitoring of Foot Skin Temperatures to Prevent Ulceration* study indicated that using structured temperature monitoring in therapy groups can significantly reduce diabetic foot complications/ulcerations.⁹ The study concluded that monitoring foot temperatures at home on a daily basis could be an effective method to prevent foot ulcerations. Furthermore, temperature measurements can aid in diagnosing and monitoring treatment of Charcot’s neuroarthropathy.

The study was particularly important for patients who were either legally blind and/or suffered from peripheral neuropathy/LOPS, as they were at a higher risk of developing complications. Providing these patients with a self-assessment tool that was relatively easy to use provided “actionable information” that otherwise would likely not be available. Without such a tool, patients may have been at an increased risk of ulcerations.

In conclusion, the study concluded that personal thermometers can be an effective means to reduce the risk of diabetic foot ulcers.

In the Golledge article,¹³ a review article of sensors, wearables, and telehealth approaches to Diabetic foot disease (DFD) it states “*We believe that the utilization of sensors, wearables and telemedicine approaches outlined in this review—and those currently under development—will offer an innovative means to approach the assessment of risk factors in people with DFD*” making a note that even though the study was small in size, the results were promising.

In the Brooks article,¹¹ a decision-tree analysis was conducted to compare expected DFU occurrence rates and costs between standards of care (SoC) alone vs RTFM plus SoC for early detection of DFUs in patients with diabetic neuropathy at a moderate-to-high risk of DFU (i.e., with a history of DFUs, calluses, or Charcot foot). The study found that RTFM is cost-effective with compliance as low as 13%, and the average compliance was 78% (Compliance = wearing RTFM 1hr/d for at least 16d/mo). Furthermore, the expected ulcer rate with SoC alone is 2.1 more than SoC+RTFM. The cost savings associated with RTFM + SoC were \$38,593 per additional ulcer avoided versus SoC alone, and \$8,027 per patient per year on average compared to SoC alone.

¹³ Golledge et al (2020) “The Potential Role of Sensors, Wearables and Telehealth in the Remote Management of Diabetes-Related Foot Disease”

Other recent literature^{14,15,16,17} documents the significant cost savings associated with RPM and veterans with a history of diabetic foot ulcers. There are also several unpublished collaborative studies being conducted by several major health insurance companies including Cigna, Kaiser, and Blue Cross. All these studies have shown that RPM for patients with a history of neuropathic foot ulcers have been an effective measure in reducing the incidence of ulcer recurrence infections, amputations, hospitalizations, and other costs associated with treating neuropathic ulcers.

RPM proved to be a valuable tool in reducing the incidence of neuropathic foot ulcers, As demonstrated by both the literature and clinical experience The reduction in foot ulcer incidence amongst patients being provided with RPM tools has been an effective means by which to reduce the associated significant costs of treating neuropathic foot ulcers. However, it is premature to set a policy or LCD at this specific time, as more information is needed post-pandemic. It is essential to avoid creating bad policies and capture the benefits of these services. Despite this, the literature clearly shows that there is a significant advantage for intervention when treating these complicated patients, and thus, RPM has to be here to stay.

As alluded to above, the attributes of RPM demonstrate favorable outcomes. The health and financial value of RPM services will be beneficial not only during the PHE but after, as clearly suggested by the literature. There was an observed increase in the incidence of diabetic and non-diabetic ulcers with comorbidities during and after the PHE crisis. This further supports and demonstrates the efficacy and need to have this option available. It affords patients an additional resource that reduces the burden of patient and physician office visits with the associated commensurate challenges. RTM has also been used recently to monitor patients with DFU. A recent study conducted at Baylor College of Medicine, just released for publication, studied patients using non-removable boots, removable boots, and smart removable boots.¹⁸ This study illustrated those who used a smart boot had fewer falls and tended to rate their offloading boot more favorably.

Findings from this study suggest that smart offloading with a remote patient monitoring solution may help promote adherence among older adults to wear offloading boots prescribed for DFUs

¹⁴ Robbins, et al. “Reducing Hospital Admissions and Amputation Prevention: Remote Temperature Monitoring.” Diffusion Marketplace, 2022

¹⁵ Frykberg, et al “Feasibility and Efficacy of a Smart Mat Technology to Predict Development of Diabetic Plantar Ulcers.” Diabetes Care, U.S. National Library of Medicine

¹⁶ Isaac, et al. “Lower Resource Utilization for Patients with Healed Diabetic Foot Ulcers during Participation in a Prevention Program with Foot Temperature Monitoring.”

¹⁷ Yaqoob, et al. “Trends in Avoidable Hospitalizations for Diabetes: Experience of a Large Clinically Integrated Health Care System.” Journal for Healthcare Quality : Official Publication of the National Association for Healthcare Quality, U.S. National Library of Medicine, 2019

¹⁸ Finco, et al. “Taking a Load Off: User Perceptions of Smart Offloading Walkers for Diabetic Foot Ulcers Using the Technology Acceptance Model.” 2023

Process Management Considerations for Future Multijurisdictional CAC Calls

Given the likelihood of future calls in this format for both these specific issues and other concerns, APMA would like to briefly discuss possible areas of improvement that might result in more focused and efficient collaboration. As evidenced by the hundreds of observers on the call, and the dozens of Subject Matter Experts (SMEs) present, it is clear this is an important issue to a number of stakeholders. One way to manage this level of interest and engagement in the future may be to more aggressively manage the time given to each speaker and pre-schedule the order of speakers in advance of the meeting. Additionally, for this specific topic, APMA would recommend that future meetings addressing RPM and RTM have separate calls for each subject. These small changes will allow the SMEs and CAC members to have sufficient time to contribute to the discussion in a more effective and meaningful way

Conclusion

Thank you for the opportunity to comment and for your attention to this matter. APMA looks forward to the possibility of participating in future meetings on RPM/RTM. We welcome the opportunity to discuss these issues further, and if you need additional information, please contact APMA's Senior Director of Health Policy and Practice, Scott Haag, JD, MSPH at shaag@apma.org or (301) 581-9233.

Sincerely,



Laura J. Pickard, DPM
President