# Devices for Remote Physiologic Monitoring

### With the advent of the COVID-19 pandemic, expect a rise in use of wearable gadgets.

**BY JEFFREY LEHRMAN, DPM**

During the COVID-19 public health emergency, we saw a dramatic increase in the acceptance and utilization of non-face-to-face services. Both providers and patients gained a greater appreciation for these services. Providers realized these services could help them remain engaged with their patients who were not coming in to the office, provide care for these patients, and help keep them and their communities safer. Patients realized the efficiency and convenience of these services and enjoyed the option to receive evaluation and care without having to travel anywhere. There is good reason to believe the wider acceptance of these services will continue well beyond this Public Health Emergency.

One non-face-to-face service type which many podiatrists have enjoyed implementing into their practices is remote monitoring of physiologic parameters. This allows us to dispense a device to a patient that is capable of monitoring certain physiologic parameters, reviewing the feedback provided by that device, and communicating with the patient, when necessary, regarding the results of that feedback.

Some physiologic parameters being monitored by podiatrists include pedal temperature, pressure to the feet during ambulation, and activity. Monitoring these parameters in at-risk patients can help to prevent ulceration or re-ulceration.[1] With wider acceptance and utilization of remote monitoring of physiologic parameters during and after the public health emergency, knowledge of proper coding and compliance is essential.

## CPT® Codes

The AMA CPT editorial panel published three new codes for remote physiologic monitoring in the 2019 CPT® Professional book. The proper use of these codes was covered in the September, 2019 edition of *Podiatry Management*.[2] These codes have since been updated and combined with a previously existing code; the CPT® code[3] options include:

CPT® 99453—Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment

CPT® 99454—Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.

CPT® 99457—Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes

CPT® 99458—Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure).

CPT® 99091—Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days.

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## Device Considerations

Before using the above CPT® codes, consideration must be given to the device that is providing the feedback. When using these CPT® codes, not only must the service be medically necessary and the parameters monitored be physiologic parameters, but there are also certain requirements that apply to the device that is providing the feedback. Some of these requirements come straight from CPT®, which means the requirement is a prerequisite for even using the code. Others come from individual payors.

## Device Must Be a Medical Device

CPT® informs on page 43 of the *2020 CPT Professional Book*[3] that the device used, "must be a medical device as defined by the FDA." The FDA provides its definition of a medical device with the following:

"Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines, and medical lasers."[4] The Centers for Medicare and Medicaid Services (CMS) mirror this guidance by stating, "The device used to capture a patient's physiologic data must meet the FDA definition of being a medical device."[5]

Do not use the remote physiologic monitoring CPT® codes unless the device providing the monitoring is defined as a "medical device" by the FDA. If a device has received the status of "medical device" by the FDA, the manufacturer of the device should be able to easily to provide this evidence from the FDA.

## Device Should Be a Covered Service

Medical directors from multiple different Medicare Administrative Contractors (MACs) have shared that they will only consider payment for remote physiologic monitoring if the device providing the data is itself a covered service. In order to be a considered a covered service, the first steps would be that a HCPCS code[6] exists that describes the device and, ideally, that the Pricing, Data Analysis, and Coding (PDAC) contractor has verified and assigned the use of that HCPCS code for that device. However, that does not complete the process. This HCPCS code needs to be assigned a dollar value and the payor would need to consider this medical device medically necessary and payable.

After these requirements have been satisfied, that medical device can be used with remote physiologic monitoring services. Therefore, the suggestion here is to not use the remote physiologic monitoring CPT® codes unless the device being used has a PDAC-assigned HCPCS code that is payable by the payor.

## Randomized Controlled Trials

Medical Directors from multiple different MACs have shared that they will not consider payment for remote physiologic monitoring CPT® codes unless there are randomized controlled trials of sufficient size to be statistically valid that support the medical necessity of the service being provided. Therefore, the suggestion here is to not use the remote physiologic monitoring CPT® codes unless the monitoring type being provided has randomized controlled trials of this type that support its medical necessity.

## Conclusion

Remote physiologic monitoring is a wonderful, useful service that can benefit both providers and patients. Its use increased during the COVID-19 public health emergency and is only expected to rise. When providing this service, be sure the device which is providing the monitoring is recognized by the FDA as a "medical device". Furthermore, multiple payors require that the device providing the monitoring be a covered service itself and that there are randomized

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controlled trials of sufficient quality to support the service. **PM**

## References

[1] Abbot CA, et al. Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomized, proof-of-concept study. Lancet Digital Health Oct. 2019; 1: e308–18.

[2] "What You Need to Know About Remote Patient Monitoring (RPM)"Podiatry Management September, 2019pgs. 39-42.

[3] 2020 CPT Professional.Current Procedural Terminology (CPT®) is copyright 1966, 1970, 1973, 1977, 1981, 1983-2019 by the American Medical Association. All rights reserved.CPT is a registered trademark of the American Medical Association (AMA).

[4] https://www.fda.gov/medical-devices

[5] Question #22 Section L COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing 5/27/20https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

[6] CMS HCPCS information https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo

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