Navigating Medicare Coverage for Remote Patient Monitoring

By Rebecca Burke, Esq.

Remote patient monitoring (RPM) technology has been proven to enhance quality of care for patients with chronic conditions and to reduce hospital readmissions. During the COVID-19 pandemic it has become especially relevant as a strategy for ensuring vulnerable patients can be monitored at home without the need to visit their physician's office or the hospital.

During the last three years, the Centers for Medicare and Medicaid Services (CMS) has demonstrated a new interest in promoting RPM, exemplified by its decisions to extend coverage to five new generic RPM codes. Most recently, the agency clarified that RPM is covered for both chronic and acute conditions.

However, while new RPM technologies abound, many health care providers have been slow to offer these new services to their patients due to confusion and uncertainty surrounding Medicare coverage and payment.

Briefly, here is what we do know about RPM and Medicare:

- CPT Codes covered by Medicare for RPM are 99091, 99453, 99454, 99457 and 99458.
- Medicare national payment rates are as follows:

CPT Code	Payment
99091	$59
99453	$19
99454	$62
99457	$52
99458	$42

- CPT code 99091 is for treatment management and does not have a separate technical component.
- CPT Codes 99453, 99454, 99457 and 99458 describe, respectively, patient education; transmission of data, treatment management (first 20 minutes) and treatment management, each additional 20 minutes.
- At least 30 minutes per month of physician/QHP or clinical staff time is required for CPT Code 99091; twenty minutes plus an interactive communication is required for CPT Code 99457.
- RPM must be ordered by a physician or qualified health professional (QHP).
- Services are billable every 30 days or once per calendar month.
- General rather than direct supervision applies for all codes except 99091
- Monitoring must last at least 16 days in order to be billed (except when monitoring COVID-19 patients during the public health emergency)
- Technology used for RPM must, with the possible exception of 99091, meet the FDA definition of "medical device"

1501 M STREET, NW ■ SEVENTH FLOOR ■ WASHINGTON DC 20005 ■ PH 202.466.6550 ■ www.PowersLaw.com

Areas of Uncertainty

What is a "medical device?"

Many questions asked by RPM technology vendors and health care providers relate to whether RPM software or a device meets the FDA's definition of "medical device." CPT instructions for the RPM Codes (except 99091) state that "the device used must be a medical device as defined by the FDA." [1] CPT Code 99454 further specifies that the device used to monitor physiological parameters must supply "daily recording(s) or programmed alert(s) transmission."

Whether a device is a "medical device" as defined by the FDA can be a complex determination. Section 201(h) of the Food, Drug and Cosmetic Act defines a "medical device" broadly as one that is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." The 21st Century Cures Act, passed in 2016, identified certain medical software functions that are specifically excluded from the definition of a "medical device" and hence, from FDA regulation. They are:

- Software intended for administrative support of a health care facility
- Software intended for maintaining or encouraging a healthy lifestyle
- Software intended to serve as electronic patient records
- Software intended for transferring, storing, converting formats, displaying data and results

The FDA has provided guidance as to the types of software that do and do not fall within these exceptions. In *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* issued September 27, 2019, the agency identified 21 types of software functionality that are deemed not to be a "medical device" and 18 that may meet the definition of medical device but for which the FDA will exercise "enforcement discretion" because they pose lower risk to the public.[2]

Among those not considered medical devices are:

- Software functions that allow a user to record data such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with their health care provider or upload to an online (cloud) database or certified EHR.
- Software that enables patients or health care providers to interact with a certified personal health record (PHR) EHR.

Thus, RPM software that allows patients to collect and report their own data may not meet the definition of "medical device" and, as such, may not be reimbursable under CPT Codes 99453-99457. However, software that is combined with a sensor or other type of device that measures

[1] CPT 2020 Professional Edition, p.42-42.
[2] https://www.fda.gov/media/109622/download

physiological parameters may qualify for reimbursement. More guidance in this area would certainly be helpful.

In contrast, CPT Code 99091 describes ""collection and interpretation of physiologic date (e.g. ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver . . ." and does not appear to require use of a "medical device." In fact, the code descriptor seems to permit the physiologic data to be collected and transmitted by the patient perhaps using their own equipment or devices. Moreover, when Medicare valued this code, it did not include any costs related to the equipment or device.

Another area where clarity would be helpful is the use of the RPM treatment management codes (99091 and 99457) when the physiologic data originates from an implanted device. Although many implantable devices have specific CPT Codes that should be used when the device is interrogated (e.g., pulmonary artery pressure sensors, CPT code 93264 and implantable loop recorder/intracardiac monitors, G2066) it is unclear whether physicians/QHPs may report 99457 when engaging in treatment management decisions and communicating with the patient. [3] CMS has been largely silent on this issue.

Even more ambiguity surrounds software which may be a medical device but for which the FDA will exercise enforcement discretion. Some of these include:

- Software functions that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider
- Software functions that enable a patient or caregiver to create and send an alert or general emergency notification to first responders
- Software functions that keep track of medications and provide user-configured reminders for improved medication adherence
- Software functions that allow a user to collect blood pressure data and share this data through email, track and trend it, or upload it to a personal or electronic health record.

Since these types of software functionality may or may not be "medical devices", there is no guarantee that patient physiologic data obtained from these sources for treatment management purposes can be billed to Medicare as RPM. CMS has not indicated how it intends to treat "enforcement discretion" technology.

In contrast, there are a number of software functions that transform a mobile platform into a regulated "medical device." These include those with build-in features such as light, vibrations, camera or other sources that perform medical device functions. For example, software functions that use a sensor or lead that is connected to a mobile platform to measure and display EKG data is clearly a "medical device." Similarly, software functions that connect to an existing device type for purposes of controlling its function, such as an implantable or body worn medical device are also clearly "medical devices."

[3] A June 2019 CPT Assistant Article seems to indicate that CPT Code 99457 can be used in connection with implantable device interrogation codes.

Another gray area is the definition of "physiologic parameter." All five of the generic CPT RPM codes refer to physiologic data and provide specific examples such as weight, blood pressure, pulse oximetry, respiratory flow rate, glucose monitoring, and ECG. But these are provided only by way of example and are not a definitive list.

It is unclear, for example, whether a mobile app that allows a patient to report subjective information such as pain levels would be considered monitoring of "physiologic data." Likewise, it is unclear whether mobile apps that measure activity levels or whether a patient is adhering to instructions that he/she restrict weight bearing activities would be considered "physiological parameters."

What is an Interactive Communication?

Health care providers that have implemented RPM and want to bill CPT code 99457 or 99458 for treatment management services must have at least one "interactive communication" with the patient per calendar month which can be performed by clinical staff under general supervision. However, it is unclear whether the interactive communication must be in "real-time" or whether it can be performed by messaging through a patient portal.

What types of providers can furnish and bill for RPM?

CMS has not provided any official guidance on the types of providers that can provide and bill for RPM services. We do know that Medicare will pay claims for RPM from physicians and other "qualified health professionals" such as nurse practitioners. However, it does not appear that physical and occupational therapists, for example, can bill these codes to Medicare.

Many Medicare-enrolled independent diagnostic testing facilities (IDTFs) that furnish other types of remote patient diagnostic testing and monitoring (e.g., cardiac monitoring) are well-equipped to provide the technical portion of the RPM service described by CPT Codes 99453 and 99454. However, Medicare Administrative Contractors (MACs) are not permitting IDTFs to provide and bill for these services. Unofficial guidance from CMS indicates that while IDTFs could provide RPM services under contract to physician practices, they cannot bill for the services directly. Any such contract would, of course, need to comply with federal anti-kickback laws and should also be analyzed under the Medicare anti-markup rules.

Hospital outpatient departments can also provide and be reimbursed for RPM technical component services under the Medicare Outpatient Prospective Payment System (OPPS),. Hospitals are permitted to contract with outside providers, including IDTFs, for services to hospital outpatients; thus, it may be possible for RPM vendors to provide these services to hospitals provided they comply with the Medicare "under arrangements" rules. Medicare OPPS does not reimburse for the professional treatment management RPM services (CPT Codes 99457, 99458 and 99091) which must be billed by physicians or qualified health professionals.

Chronic Care Management Services and RPM

RPM can also play a role in chronic care management (CCM) and complex chronic care management services. Although those services do not require the use of RPM, RPM can play a role in meeting the CCM required elements of "systematic assessment of the patient's medical, functional, and psychosocial needs" or "oversight of patient self-management of medications."[4] CMS has also acknowledged the role that third-party entities can play in assisting in CCM, provided the Medicare incident-to supervision rules are met. [5] The CCM codes (99487-99491) do not impose specific requirements related to RPM such as requiring programmed alerts or use of devices that are "medical devices" as defined by the FDA. Nor would RPM be used for the purpose of meeting the requirements of the chronic care management codes be limited to "physiological parameters." Although the requirements for CCM are more onerous that RPM overall, the use of the CCM codes may be a better option for certain types of remote monitoring. CMS rules also allow for reimbursement of both RPM and CCM when the requirements for both code sets are met.

In short, there are many more questions than answers when it comes to RPM. It is possible CMS will issue proposed regulations or guidance on this subject in the 2021 proposed Medicare Physician Fee Schedule, which is expect in early July of 2020. Powers will continue to monitor developments in this area. Watch for updates on our website at www.powerslaw.com.

For questions about this article please contact Rebecca Burke, Esq. at rebecca.burke@powerslaw.com or the Powers attorney with whom you normally work.

[4] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf
[5] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf