Published on *The National Law Review* https://natlawreview.com

Remote Monitoring Services Under Review: Update on Potential Medicare Coverage Policies

Article By:

Caroline Reignley

Deborah R. Godes

Michael W. Ryan

Dale Van Demark

Marshall E. Jackson, Jr.

Abby Higgins

On May 19, 2023, Novitas Solutions and First Coast Options sent an email to certain interested parties, with whom they had engaged following the multijurisdictional contractor advisory committee (CAC) meeting, explaining that they have decided to not pursue at this time a local coverage determination for remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM).

What does this communication mean for RPM/RTM service providers?

In the short term, the status quo remains (i.e., there is no proposed local coverage determination) for Novitas and First Coast. This communication is specific to Novitas and First Coast, and does not prevent the other Medicare Administrative Contractors (MACs) from developing local coverage determinations for their jurisdictions. Novitas and First Coast may change their mind at any time and decide to draft a proposed local coverage determination for RPM and/or RTM services. Further, if any of the MACs decide to issue a draft LCD, they are not obligated to hold another CAC meeting or to notify stakeholders in advance.

Accordingly, healthcare providers and digital health companies should continue their focus on compiling the evidence to support the clinical utility of their services. This action (or inaction) by Novitas and First Coast should not be misinterpreted as a justification for easing off evidence generation and collection.

IN DEPTH

SUMMARY

A recent multijurisdictional CAC meeting held by six of the seven MACs gave stakeholders an initial opportunity to provide feedback on the strength of clinical evidence to support Medicare coverage for RPM and RTM services for non-implantable medical devices. We previewed how this meeting may influence the development of Medicare local coverage determinations in a recent article.

Twenty-four subject matter experts (SMEs), both physicians and other stakeholders, including digital health company medical leaders and clinicians with extensive experience with remote monitoring programs participated in the CAC meeting. The questions posed during the CAC meeting included requests for examples of SME experience with remote monitoring technologies and opinions on the amount of high-quality evidence to support their use for various diagnoses and conditions.

Despite certain questions posed during the CAC meeting that demonstrated a skepticism for remote monitoring services outside certain use cases, the SMEs voiced overwhelming support for continued coverage of remote monitoring services and several SMEs expressed concern about the potential proposal of one or more local coverage determinations (each, a LCD). Several participants noted that literature and data not referenced in the meeting materials, together with pending research studies, could provide support for continued coverage of remote monitoring services for a variety of clinical uses.

BACKGROUND

Remote Monitoring Background

In recent years, the Centers for Medicare & Medicaid Services expanded payment for remote monitoring services, which generally use digital technologies (medical devices, together with software) to collect medical and other forms of health data from patients in one location and electronically transmit the information to the patient's healthcare provider in a different location for assessment and care management. The data collected is electronically transmitted to health professionals for review and can be used in patient management. In some cases, the technologies can either trigger direct patient engagement or facilitate that communication.

RPM services involve monitoring physiological conditions (e.g., weight, blood pressure, blood sugar) through medical devices, which transmit data obtained from patients automatically to healthcare providers for assessment and recommendations. In contrast to RPM services, RTM services involve the use of medical devices to monitor a patient's health or response to treatment using non-physiological data. RTM can be used to monitor medication adherence, response to therapy, musculoskeletal activity and respiratory activity. Unlike RPM, devices for RTM are not limited to transmitting data automatically obtained from patients but can also transmit data self-reported by patients.

Medicare Coverage Policies and Role of CACs

In determining whether to develop an LCD for particular services, MACs may, but are not required to, hold a CAC meeting as an opportunity for healthcare providers to provide feedback (i.e., evidence) that the MAC contract medical directors can consider when contemplating the potential development of future coverage policies. CACs provide a forum for communications between the MACs and the healthcare industry more broadly. CACs are advisory only, however, and the final decision on whether to proceed with a draft LCD remains at the discretion of the MAC. If a MAC decides to draft

an LCD, it will be published on the Medicare Coverage Database and on the MAC's websites. After the publication, the public will have at least 45 days to provide written comments, as well as an opportunity to deliver comments verbally during an "open meeting" before the LCD is finalized. A MAC will then consider the submitted evidence and comments before taking final action on the draft LCD. This final action must be taken within 365 days of the draft LCD being published, and it can be finalized, revised or withdrawn. MACs are required to respond to submitted comments in a comment/response document published alongside any final LCD. Once a MAC publishes a final LCD, there must be a minimum 45-day notice period prior to the policy becoming effective.

IN DEPTH

Key Takeaways

The recent CAC meeting focused on the clinical use of remote monitoring technologies and the quantity and extent of clinical literature supporting the use of RPM and RTM across specialties. The stated purpose of the CAC meeting was to examine the quality and strength of the clinical evidence supporting remote monitoring technologies, discuss the relevance of the evidence to the Medicare population, and obtain opinions from a variety of clinical backgrounds. The CAC meeting involved the MAC medical directors and certain SMEs on remote monitoring services.

The SMEs overwhelmingly supported the use of remote monitoring technologies and services across a wide variety of specialties. The SMEs advocated for continued Medicare coverage of this type of treatment and highlighted a variety of success stories. The SMEs were asked questions on their clinical use, and also on the evidence to support use, as detailed below.

Clinical Use of Remote Monitoring

The SMEs provided background on their clinical practice and reasoning for using RPM or RTM technologies. SMEs that utilize remote monitoring technologies were asked to discuss how they identify potential patients, how long patients are monitored, and what patient diagnoses are suitable for RPM or RTM services. The SMEs represented specialties including cardiology, physical therapy, internal medicine, podiatry, pediatrics, geriatrics, urology, anesthesiology, interventional pain management and orthopedics.

The majority (if not all) of the SMEs had extensive experience with either RPM or RTM, with many clinicians leveraging both technologies. The SMEs discussed at length the benefits of having data regularly collected by remote technologies and the value of being able to engage patients both sooner and more regularly when compared to in-person care. SMEs highlighted more regular contact with patients and access to data on patients' clinical status in particular as beneficial with respect to chronic conditions and patients who may receive less regular in-person care because of limited access to regular care. As one expert from Mount Sinai remarked, having access to data from high-risk patients allows for higher intensity care in a cost-effective manner.

Another area where there was broad agreement related to the need to accommodate variation in the length of monitoring for patients. The SMEs stated that the duration of remote monitoring was dependent on the patient's condition and the treating practitioner's particular evaluation. Ranges between four weeks and up to six months were offered, depending on the patient and the ongoing utility of remote monitoring, although other participants noted that remote monitoring can be of use for longer periods of time for patients with chronic conditions or for patients receiving RTM as part of a physical therapy plan of care.

Remote Physiologic Monitoring Use Cases

RPM was discussed across the majority of specialties, with specific discussions on the advantages of filling in data points for patients that are not seen often. The most frequently mentioned clinical uses of RPM services included the following:

- Patients diagnosed with the below conditions where consistent monitoring can aid in medical decision making:
    - Diabetes
    - Neuropathy
    - Musculoskeletal traumatic arthropathy
    - Vascular disease
    - Hypertension
    - Chronic heart failure
- Patients with more than one hospital stay in one year
- Patients who utilize healthcare resources or visit emergency departments frequently
- Patients who have had an escalation of their condition in the last 24 months
- Patients who are geographically disadvantaged to seek in-person care
- Patients with obstructive sleep apnea who use CPAP machines
- Patients with chronic obstructive pulmonary disease (COPD) exacerbation
- Chronic heart failure patients, specifically in relation to reducing hospital readmissions.

Remote Therapeutic Monitoring Use Cases

Similarly, RTM was widely discussed. The clinical use cases noted to have particular advantages included medication adherence and physical therapy monitoring. The clinical use cases for RTM included the following:

- Ensuring patients are adherent with therapy plans of care and are following therapist directions with respect to physical therapy exercises
- Medication adherence monitoring, specifically for identifying and monitoring the development of substance use disorders for chronic pain patients
- Providing ongoing monitoring to patients recovering from total knee replacements and to reduce the number of in-person physical therapy visits

- Monitoring the use of inhalers for patients with asthma and COPD.

Evidence-Supported Outcomes

The SMEs were asked to provide opinions on the amount and quality of literature supporting the use of RPM and RTM. The SMEs felt existing literature supported the use of RPM and RTM over established standards of care in several areas, including elevating patient engagement, improving patient care and reducing overall healthcare utilization. Several SMEs highlighted ongoing studies in the following areas:

- The value of RPM for hypertension and hyperlipidemia patients
- The correlation between the use of remote monitoring and improvements in health equity
- Use of remote monitoring in orthopedics and musculoskeletal treatment
- Improvements over the standard of care for treatment of patients with diabetic ulcers.

During the meeting, participants were asked whether there is high-quality evidence to support the use of remote monitoring for patient diagnoses other than chronic heart failure, hypertension, COPD, hemoglobin A1c (blood glucose monitoring for diabetes), back/knee pain and musculoskeletal conditions. Based on this question, the CAC may believe that the clinical evidence is stronger for these conditions, and views the evidence as less robust with respect to other conditions or use cases. Due to the number of SMEs participating in the meeting (and the extensive responses to certain questions provided by the SMEs), the MAC medical directors did not weigh in or provide additional insight as to how they are viewing the clinical support for various conditions or use cases.

Several individuals raised concern about the MACs implementing coverage policies before currently pending studies have been published, stating that these programs need time to finish and develop. Some commenters suggested that the timing of the availability of these codes—either shortly before (in the case of RPM) or shortly after (in the case of RTM) the start of the public health emergency—hindered efforts to collect data effectively on many of the remote monitoring services. Other commenters raised concern about implementing restrictive coverage policies before RPM services in particular have a chance to demonstrate value through published studies for use cases other than the conditions noted above. There were specific concerns over the implementation of LCDs by MACs that negatively impact coverage and payment for remote monitoring services more broadly, particularly in the Medicaid population.

Practical Impact

As discussed above, the CAC meeting is one of the first steps before an LCD may be proposed. If a MAC (or MACs) do propose an LCD, potential coverage limitations may relate to the particular conditions for which remote monitoring services are viewed as reasonable and necessary and the duration of remote monitoring that may be provided. Although the CAC meeting did not include meaningful discussion on the types of devices furnished to Medicare beneficiaries in connection with remote monitoring services, an eventual LCD could also potentially implement limitations on the types of devices for which remote monitoring services are considered reasonable and necessary.

Digital health companies that furnish these services (or help providers furnish these services) and have access to persuasive literature or have concerns about potential limitations in an eventual LCD should strongly consider submitting feedback and literature for consideration. The most persuasive literature or information will include evidence on what specific medical devices are used and which patient diagnoses are supported by clinical data, and how the use of RPM or RTM services impacts patient management and improves patient outcomes (for example, lowers the likelihood of side effects post-surgery, reduces the incidence of chronic condition exacerbation, or reduces recurrent hospitalizations or office visits). Healthcare providers with evidence to support the clinical utility of RPM and RTM services should similarly focus on compiling such evidence. This evidence will be crucial for establishing that the use of particular devices for certain diagnoses provides clinical benefit to the patient.

CAC participants are permitted to submit additional comments and/or literature to medicalaffairs@guidewellsource.com no later than March 10, 2023. The audio and transcript of the recording will be posted publicly on MAC websites within four weeks.

National Law Review, Volumess XIII, Number 145