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Corporate Medical Policy

Remote Therapeutic and Physiologic Monitoring

File Name: remote_therapeutic_and_physiologic_monitoring
Origination: 2/2023
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Description of Procedure or Service

Remote therapeutic monitoring (RTM) refers to the remote monitoring and management of therapy services, for example, monitoring of respiratory or musculoskeletal status, and medication and therapy adherence and response. RTM involves remote managing and collection of non-physiological patient data.

Remote physiologic monitoring (RPM) refers to the monitoring of physiological data, for example, weight, blood pressure, pulse oximetry, respiratory flow rate, as well as associated physiologic monitoring treatment management services.

Related Policies:
Durable Medical Equipment (DME)
Continuous Monitoring of Glucose in the Interstitial Fluid

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Remote Therapeutic and Physiologic Monitoring when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

When Remote Therapeutic and Physiologic Monitoring is covered

Remote therapeutic monitoring (RTM) in a non-healthcare setting is considered medically necessary when ALL of the following criteria are met:

1. RTM is clinically appropriate, in terms of type, quantity, frequency, extent, site and duration and is considered effective for the individual's illness, injury or disease and in accordance with generally accepted standards of medical practice; and
2. RTM data is being regularly assessed to detect acute changes in clinical status and prompt intervention; and
3. RTM is not primarily for the convenience of the individual, physician, caregiver, or other health care provider; and

4. The individual is at risk of clinically significant changes in medical status which warrant enhanced monitoring based on current status and instability of the underlying clinical condition; and
5. The individual is unable to access regularly scheduled outpatient clinical care or therapeutic monitoring is required between visits due to potential changes in medical status; and
6. Monitoring is reasonably likely to prevent avoidable deterioration in the clinical condition and/or other adverse events relating to the underlying clinical condition.

Remote physiologic monitoring (RPM), in a non-healthcare setting is considered medically necessary when ALL the following criteria are met:

1. RPM involves an FDA-recognized medical device that directly measures member physiologic data (for example, sphygmomanometer, pulse oximeter, heart rate monitor, glucometer, thermometer, weight scale, respiratory flow rate monitor) used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition; and
2. RPM is clinically appropriate, in terms of type, quantity, frequency, extent, site and duration and is considered appropriate for the individual's illness, injury or disease and in accordance with generally accepted standards of medical practice; and
3. RPM data is being assessed to detect acute changes in clinical status and prompt intervention; and
4. RPM is not primarily for the convenience of the individual, physician, caregiver, or other health care provider; and
5. The individual is at risk of clinically significant changes in medical status which warrant enhanced monitoring based on current status and instability of the underlying clinical condition; and
6. The individual is unable to access regularly scheduled outpatient clinical care or physiological monitoring is required between visits due to potential changes in medical status; and
7. Monitoring is reasonably likely to prevent avoidable deterioration in the clinical condition and/or other adverse events relating to the underlying clinical condition.

When Remote Therapeutic and Physiologic Monitoring is not covered

RTM or RPM is considered not medically necessary when similar services are being provided concurrently, for example, home health services.

RTM or RPM is considered not medically necessary when the criteria above have not been met.

Policy Guidelines

Remote therapeutic monitoring (RTM) treatment management services are provided when a physician or other qualified healthcare professional uses the results of RTM to manage an individual's chronic condition under a specific treatment plan. The service must be ordered by a physician or other qualified healthcare professional. RTM services involve "general medicine" collection of data (that is: non-physiological patient data), for example monitoring of medication and therapy adherence, or respiratory or musculoskeletal status. RTM has the potential to prevent avoidable deterioration in the clinical condition in individuals at risk of clinically significant changes in medical status, thereby preventing rehospitalizations, or urgent care and emergency room visits.

In contrast, remote physiologic monitoring (RPM) involves monitoring of physiological data only. RPM services involve data from monitoring devices which have the capability to transmit clinical data for physician review and for the intended use of managing the individual's condition using these results under a specific treatment plan. This enables the clinician, the individual being treated, or both, to respond and adjust treatment regimens in a more immediate way than what would be possible with, for example, routine clinic visits. Some RPM systems may be designed with automated voice

response software to give instructions to the monitored individual; others may alert health professionals and/or the individual being monitored to clinical values outside an acceptable range, and, in other systems, a health professional may respond immediately. Home-based technologies enable healthcare professionals to monitor physiological (for example, blood pressure) and psychological (for example, depression and mood) variables more routinely than is possible through face-to-face office visits. It has been reported that ambulatory blood pressure monitoring is more predictive of clinical outcomes than office blood pressures, and its use leads to improved blood pressure control. These technologies change the communication channel between the provider and the treated individual, in order to minimize barriers to care and improve delivery of medical services. The increased surveillance, support, and enhanced communication afforded by remote technology have significant potential to improve the individual's attention to, and adherence with, disease treatment and to facilitate patient-provider communication.

A large and diverse number of monitoring devices are currently cleared by the FDA and on the market with remote technology monitoring capabilities. The device used must be a medical device as defined by the U.S. Food and Drug Administration (FDA). Remote technology services require a live, interactive communication between the physician and the monitored individual or caregiver. Data transmission must be accomplished using a HIPAA-compliant network, with sufficient bandwidth and screen resolution to permit adequate interaction with the individual being treated and assessment of behavioral and physical features. The system must maintain a log of connections, with time, date, and duration. The applicable codes are specific to initial device set-up, the individual's education on its use, daily recordings, and the professional's time in communication with the monitored individual. RTM currently deals with musculoskeletal and respiratory systems (for system status, therapy adherence [such as inhaler use], and therapy response). Additional indications for this type of monitoring are anticipated in future (for example for hypertension [HTN], heart failure [HF], and diabetes mellitus [DM]). It is purported that RTM can help physicians to protect individuals at risk of heart attack or stroke; improve blood pressure management; and identify hypertensive crisis and heart failure exacerbations, which may enable early intervention. Home monitoring devices automatically upload readings to the online portal for the provider to monitor between office visits while the individual is out of the office thereby enabling faster response times when an abnormal value is picked up by the monitoring device.

The Agency for Healthcare Research and Quality (AHRQ) conducted a research project between September 13, 2007, and August 31, 2011 entitled, Digital Healthcare Research using Health Information Technology to Improve Ambulatory Chronic Disease Care. This project was designed to test strategies for clinician use of health information technology (HIT) in ambulatory settings to improve outcomes through more effective clinical decision support, medication management, or care delivery. The initiative encouraged consideration of the role of workflow and effective use of clinical alerts and reminders, with an emphasis on prevention and chronic illness management. Medication management was a particular focus, as medication therapy is a significant source of medical errors, cost, and missed opportunities for health care coordination, and health IT can be a potent intervention to address these issues.

The study took place in the primary care practices of the Department of Family and Community Medicine (FCM) and the Division of General Internal Medicine (GIM) of the Department of Internal Medicine at the University of Missouri Health System (UMHC). This project sought to leverage collaborative efforts between the University of Missouri (MU) Department of Family and Community Medicine and its electronic medical record (EMR) vendor, the Cerner Corporation, to create new tools and functionalities to improve chronic disease care.

In 2005, FCM Department leaders began to collaborate with the Cerner Corporation to develop an enhanced ambulatory HIT system to support chronic disease care. Of multiple proposed components, several were anticipated within the time frame of the proposed evaluation including:

- Condition summary screens which were specially designed dashboards, accessible from a tab within the electronic record, that included key information needed for managing that

condition, such as blood pressure (BP) readings in diabetes mellitus (DM), as well as indicators of whether quality metrics were being achieved for that individual.
- Easily accessible condition algorithms outlining standard care management.
- Electronic templates for creating visit notes, that would facilitate data acquisition for performance reports; and
- Performance reports on chronic condition quality indicators (for example, having a glycohemoglobin during the past year in subjects with DM) for those participants assigned to individual providers as well as the entire practice, including a list of subjects with out-of-range values.

Additionally, tied to this effort, the Health System planned introduction of a web-based participant interface, IQ Health, to enhance connectivity and secure communication between trial subjects and clinicians. It was anticipated to enable individuals to access information in their electronic health record, to upload clinical data and to verify medications. It was anticipated that "smart" devices that could directly upload readings, such as BP and blood glucose, would interface with IQ Health to upload data directly into the electronic health record. For those without Internet access, the "smart" devices would be able to upload data over an ordinary phone line. Diabetes performance reports were phased in at 10 UMHC primary care practices. In 3 practices, a portal for secure communications was implemented. A trial of home monitoring of blood glucose and BP occurred in 108 subjects.

Multiple studies included: a usability study of a diabetes dashboard; a quasi-experimental study of two kinds of performance reports distributed in a factorial design for one year; a qualitative analysis of differences between clinics with different patterns of performance; surveys of interest and experience with the participant web portal; testing accuracy and response to individuals electronically reporting medication inconsistencies; and a randomized trial of 3-months of home monitoring of BP and BP with electronic reporting. Results showed that the diabetes dashboard was efficient and improved accuracy. A composite measure improved in practices able to access performance information in the electronic record. Practices improving in the second year showed strong leadership, sharing of information, and exhibited adaptive reserve. Initial use of the participant portal was relatively limited; however, physicians felt better about its impact after use. In-home medication reconciliation was potentially limited by incomplete information from trial subjects and failure to update records by providers. Home monitoring did not improve outcomes, but qualitative findings pointed to important implementation principles. The investigators concluded that the effectiveness study of use of remote monitoring did not demonstrate an impact on clinical outcomes but did lead to the identification of important themes that will inform practices who are considering a remote monitoring intervention for individuals with chronic illness. Such practices need to understand the capabilities and limitations of the technology. Additionally, they should seek independent references to evaluate the vendor's performance on technical troubleshooting. Practices should design and understand the workflow and consider protocols for the flow of information. Additionally, the human side of the equation, patient-provider relationships, remained a crucial component of working with remote monitoring data. Buy-in by all participants appears important. Lastly, integration of the data transmission system with the EMR and electronic personal health record is key to the intervention's sustainability in real practices (Mehr, 2011).

Additional indications for RTM and RPM have been reported in limited studies. In 2011 Kohler and colleagues enrolled 710 subjects with stable chronic HF in New York Heart Association (NYHA) functional class II or III HF with a left ventricular ejection fraction (LVEF) of ≤ 35% and a history of HF decompensation within the previous 2 years or with a LVEF ≤ 25%. Trial subjects were randomly assigned (1:1) to remote monitoring or usual care. Remote telemedical management used portable devices for ECG, BP, and body weight measurements connected to a personal digital assistant that sent automated encrypted transmission via cell phones to the telemedical centers. The primary end point was death from any cause. The first secondary end point was a composite of cardiovascular death and hospitalization for HF. Baseline characteristics were similar between the RTM (n=354) and control (n=356) groups. Of those subjects assigned to RTM, 287 (81%) were at least 70% compliant with daily data transfers and no break for > 30 days (except during hospitalizations). The median

follow-up was 26 months (minimum 12) and was 99.9% complete. The authors concluded that, compared with usual care, RTM had no significant effect on all-cause mortality (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.67 to 1.41; p=0.87) or on cardiovascular death or HF hospitalization (HR, 0.89; 95% CI, 0.67 to 1.19; p=0.44).

Extended results of the above trial (the telemedical interventional management in patients with heart failure II [TIM-HF2] randomized trial) were reported by Koehler and colleagues in 2020. TIM-HF2 was a prospective, randomized, multicenter trial done in 43 hospitals, 60 cardiology practices, and 87 general practitioners' offices in Germany. Trial participants included those with HF, in NYHA functional class II or III HF who had been hospitalized for HF within 12 months before randomization. Trial subjects were randomly assigned to either the RPM intervention or usual care (UC). At the final study visit (main trial), the RPM intervention was stopped, and the 1-year extended follow-up period started, which lasted 1 year. The primary outcome was percentage of days lost due to unplanned cardiovascular hospitalizations and all-cause mortality. Analyses were done using the intention-to-treat principle. Results at 1 year post RPM intervention showed that, compared with UC, a structured RPM intervention done over 12-months reduced the percentage of days lost, due to unplanned cardiovascular hospitalizations and all-cause death. However, when data from the main trial and the extended follow-up period were combined, the percentage of days lost due to unplanned cardiovascular hospitalization or all-cause death was significantly less in subjects allocated to the RPM group (382 [50%] of 765; weighted mean 9.28%; 95% CI, 7.76-10.81) than in the usual care (UC) group (398 [51%] of 773; 11.78%; 95% CI, 10.08-13.49; ratio of weighted average 0.79; 95% CI, 0.62-1.00; p=0.0486). The positive effect of RPM intervention on morbidity and mortality over the course of the main trial was no longer observed 1 year after stopping the RPM intervention. However, because the TIM-HF2 trial was not powered to show significance during the extended follow-up period, these results are considered preliminary and require further research.

In 2021 Dawson and colleagues conducted a prospective, randomized controlled trial to assess whether home 30-day telemonitoring after discharge for individuals at high risk of readmission would reduce readmissions or mortality. A total of 1380 participants (mean [SD] age, 66 [14] years; 722 [52.3%] men and 658 [47.7%] women) participated in this study; participants were defined as high risk for readmission based on criteria assessed during hospitalization, including payer source, poor health literacy, lack of social support or the inability to self-care, an admission within the previous 12 months, emergent admission, a hospitalization of greater than 5 days, or history of a major medical comorbid condition (diabetes mellitus, myocardial infarction, stroke, peripheral artery disease, congestive heart failure, chronic obstructive pulmonary disease, substance abuse, depression, acute delirium, receiving dialysis, previous or active cancer, end-stage liver disease, or HIV). They compared 30-day readmission rates and mortality for those who received home telemonitoring versus standard care between November 1, 2014, and November 30, 2018, in two tertiary care hospitals. The intervention group received home-installed equipment to measure BP, heart rate, pulse oximetry, weight if heart failure was present, and glucose if diabetes was present. Results were transmitted daily and reviewed by a nurse; changes in vital signs outside a preset range, determined by a standard protocol provided by the device company, triggered an alert for the nurse. Both groups received standard care. Using a modified intention-to-treat analysis, the risk of readmission or death within 30 days among subjects at high readmission risk was 23.7% (137/578) in the control group and 18.2% (87/477) in the telemonitoring group (absolute risk difference, -5.5% [95% CI, -10.4 to -0.6%]; relative risk, 0.77 [95% CI, 0.61 to 0.98]; p=0.03). Emergency department visits occurred within 30 days after discharge in 14.2% (81/570) in the control group and 8.6% (40/464) in the telemonitoring group (absolute risk difference, -5.6% [95% CI, -9.4 to -1.8%]; relative risk, 0.61 [95% CI, 0.42 to 0.87]; p=0.005). The authors concluded that 30 days of post discharge telemonitoring may reduce readmissions of high-risk individuals but further study is needed (NCT02136186; Dawson, 2021).

Additional small studies of impact of RTM and RPM yielded similar results. Most investigators agree that additional study is needed to inform clinical decisions about which populations will potentially benefit most from RTM and RPM. Given that currently published studies have generally shown that RTM and/or RPM provides no additional clinical benefit over usual care, use of RTM and/or RPM may be appropriate for individuals who are unable to access regularly scheduled outpatient clinical

care for chronic conditions that are typically managed using evidence-based coordinated care strategies (for example, HF or chronic kidney disease).

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 98975, 98976, 98977, 98980, 98981, 99453, 99454, 99457, 99458

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Medical Director Review 2/2024

Specialty Matched Consultant Panel review 2/2024

Policy Implementation/Update Information

2/7/23 New policy developed. BCBSNC will provide coverage for Remote Therapeutic and Physiologic Monitoring when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director Review 2/2023. **Notification given 2/7/2023 for effective date 4/18/2023.** (tt)

3/6/24 References updated. Medical Director Review 2/2024. Specialty Matched Consultant Panel review 2/2024. No change to policy statement. (tt)