Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/23**
(See policy history boxes for previous effective dates)

Title: Remote Patient Monitoring

Description/Background

Telehealth and telemedicine are terms that are frequently used interchangeably. Telehealth is an umbrella term that describes all the possible variations of healthcare services and education using telecommunications. Telehealth includes healthcare services such as telemedicine, telemonitoring and store and forward, in addition to healthcare education for patients and professionals and related administrative services.

Telemonitoring, or more specifically, remote patient monitoring, is the use of digital technologies to collect physiological and psychological health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment and clinical management recommendations. This allows a provider to continue to track healthcare data for a patient released from the hospital to home or to a care facility, potentially reducing readmission rates. Monitoring programs collect physiological signs such as temperature, respiratory rate, heart rate, blood pressure, blood sugar, blood oxygen levels, weight and electrocardiograms. Data for psychological health may include well-being information. The data is transmitted to healthcare professionals in office settings or hospitals, or the data may be transmitted to monitoring centers or centralized off-site case management programs. Healthcare professionals monitor these patients remotely and respond to the information received as part of the treatment plan.[1]

Remote monitoring is not a recent technological development. Dr. Willem Einthoven, who received a Nobel Prize for his work in electrocardiography, was most likely the first person to use telemonitoring. In 1905 Dr. Einthoven transmitted an ECG from his physiology laboratory to the Academic Hospital, about a mile away, by connecting immersion electrodes via telephone lines to a remote galvanometer.[2,3] An impressive example of telemonitoring involves the National Aeronautics and Space Administration. In the early 1960s, NASA developed medical monitoring systems which were used in animal test flights to assess circulation and respiration. The medical scientists' priority was understanding what effects spaceflight had on

the physiological and psychological processes of the human body. This drove the development of increasingly sophisticated monitoring technologies – the Integrated Medical and Behavioral Laboratories and Measurement Systems (IMBLMS). The advanced IMBLMS upgraded the existing technology, but it was also viewed as a support in longer human spaceflights, providing monitoring of biometric data as well as directing medical treatment by non-physicians. The IMBLMS validation testing was a result of a partnership between NASA and the Lockheed Missiles and Space Company. A program was developed and offered to the people of the Tohono O'odham (Papago) reservation, remotely located in Southern Arizona. The technology linked rural patients in mobile support units with physicians in Indian Health Service hospitals in Sells and Phoenix, Arizona. The program was operational from 1973 to 1977.[4]

Remote patient monitoring uses technology (a medical device) to collect patient data and then electronically transmits that data to a platform where it is reviewed by a healthcare provider, over a period of a month. Remote patient monitoring is a tool to monitor a particular condition, over a period of time, to identify possible patterns that can be acted upon to improve a patient's clinical outcome; it is one component of a plan of care.

As an example: a patient has uncontrolled hypertension with evidence of end organ damage; previous treatments have been unsuccessful. The provider begins a new treatment regimen, and feels RPM will be valuable in monitoring the patient's response. The physician's office gives the patient a blood pressure monitor that electronically takes the patient's blood pressure, downloads the blood pressure reading to an app on the patient's phone, and then uploads the blood pressure reading to a platform for the physician to review. The patient is educated on the use of the equipment, and is instructed to take his blood pressure reading every morning at 10am for the next 30 days. The physician reviews the patient's blood pressures and notes that the blood pressure readings are not reaching target goals. The physician contacts the patient and makes an adjustment to the medication dose. The blood pressure monitoring continues for the rest of the month.

Mobile health, mHealth, is a relatively new and rapidly evolving aspect of technology-enabled health care. The National Institutes of Health defines mHealth as the use of mobile and wireless devices (cell phones, tablets, etc.) to improve health outcomes, healthcare services, and health research.[5,6] Mobile health apps do not undergo the rigorous testing that is required by medical equipment, including validation through clinical trials. In addition, they do not require oversight by a healthcare provider. For the purpose of this policy, mobile health applications are considered to be self-care, self-management and self-monitoring tools.

Regulatory Status

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a medical device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

The FDA document "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – Guidance for Industry and Food and Drug Administration Staff," March 2020, informed this policy review, specifically the "RPM Device Guidance" in the Inclusions section.[7]

Medical Policy Statement

The use of remote patient monitoring (RPM) to collect physiological or psychological data in the medical management of patients is considered established when criteria are met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Remote Patient Monitoring (RPM) is not intended to be an ongoing modality; it is intended to be an intervention in response to a complication, decompensation or instability of a medical condition. It may be used during the stabilization period, while a patient returns to the baseline of their condition, or establishes a new baseline. Once baseline is achieved, RPM is no longer an integral part of a plan of care.

When Blue Cross of Michigan has an existing medical policy that is specific to the technology or device being considered for RMP, that policy supersedes the information in this policy.

Inclusions:
Remote Patient Monitoring (RPM) is approved when both of the following are met:
- A physician or qualified healthcare practitioner (QHP) has determined that the patient's condition:
  - Is high-risk for decompensation or complication that may lead to hospitalization or another acute intervention, or
  - Requires monitoring for a current or new treatment plan
- There is an order written by a physician or QHP that specifies the medical condition and the length of time for RPM, up to 90 days

POLICY GUIDELINES

- RPM Data
  - Data may include common physiological parameters such as heart rate, blood pressure, temperature, respiratory rate, weight, oxygen saturation, peak flow, blood glucose levels, well-being information, etc.

- RPM Device Guidance*
  - The device used for data collection must be a medical device, as defined by the FDA
  - The device is non-invasive and has the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection
  - The device transmits a patient's measurements directly to their healthcare provider, or to a monitoring company affiliated with the healthcare provider
  - Some devices may have the potential to apply algorithms to the data, which result in notifications of parameters that are outside the ideal range for that patient
  - The device used must provide secure, HIPAA-compliant transmission of the data
    * Examples: devices may include wearable, hand-held, stationary in-home units and digital interfaces. A device may be a clinical electronic thermometer, electrocardiograph, cardiac monitor, pulse oximeter, non-invasive blood pressure monitor, etc.
- Services included in RPM:
  - Initial set-up and patient instruction of the monitoring device
  - RPM for up to 90 days
    - For RPM services beyond 90 days:
      - ✓ there is a physician/QHP order for the continuation of RPM; and
      - ✓ the medical record contains documentation that:
        - supports the medical necessity for continued RPM, and
        - reflects that the results of the monitoring are used in clinical decision-making and intervention; and
      - ✓ RPM (after the first 90 days) is billed with modifier KX (the provider attests that requirements specified in the medical policy have been met)
      - ❖ Complex patients with chronic conditions who are at high risk for intermittent exacerbations and poor long-term clinical outcomes may benefit from longer-term RPM within the context of a Provider-Delivered Case Management (PDCM), health plan-administered care management program, or an approved provider-organization or vendor-managed care management program. Participation may be determined on a case by case basis, subject to the judgment of the attending physician/QHP and care management program guidelines.
  - RPM treatment management services, when in response to physiological parameters that require intervention
  - Physician interpretation of the physiological or psychological data
- Remote patient monitoring should include daily monitoring or programmed alert transmissions
- Each 30-day billing cycle must include at least 16 days of monitoring
- Remote patient monitoring programs can be offered by health plans, hospital systems, medical specialty groups or clinical practices
- Reimbursement for remote patient monitoring is driven by current BCBSM payment policy

Exclusions:
- RPM is not separately billable if performed during a 90-day global payment period (eg, following surgery)
- The RPM device itself (including any additional apps, software, digital interfaces, etc.) is not covered

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

99453 99454 99457 99458 99091*

**99091 provided on the same date of service as E&M services (face-to-face or telemedicine) is considered included in the E&M service and should not be reported separately.*

Other codes (investigational, not medically necessary, etc.):

NA

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Remote patient monitoring may potentially be used as an adjunct to treatment of any condition. However, most of the research found in published literature focuses on the value of remote patient monitoring in those who have chronic diseases.

Heart Failure

Jayram et al (2017) reported on telemonitoring's impact on health status in those with heart failure. Among the 1,521 patients with recent heart failure hospitalization who were randomized in the Telemonitoring to Improve Heart Failure Outcomes trial, 756 received telephonic monitoring and 765 received usual care. Health status was measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ) within 2 weeks of discharge and at 3 and 6 months. Over the 6-month follow-up period, there was a statistically significant, but clinically small, difference between the two groups in their KCCQ overall summary and subscale scores. The average KCCQ overall summary score for those receiving telemonitoring was 2.5 points (95% confidence interval [CI], 0.38 to 4.67; p=.02) higher than usual care, driven primarily by improvements in symptoms (3.5 points; 95% CI, 1.18 to 5.82; p=.003) and social function (3.1 points; 95% CI, 0.30 to 6.00; p=.03). The authors concluded that telemonitoring results in statistically significant, but clinically small, improvements in health status when compared with usual care. Additional studies were recommended.[8]

A Cochrane Review (2015) investigated randomized controlled trials of structured telephone support or non-invasive home telemonitoring compared to standard practice for people with heart failure, in order to quantify the effects of these interventions over and above usual care. This was an update to a previous 2010 review and included 17 new studies. The reviewers concluded that for people with heart failure, structured telephone support and non-invasive home telemonitoring reduced the risk of all-cause mortality and heart failure-related hospitalizations. These interventions also demonstrated improvements in health-related quality of life, heart failure knowledge and self-care behaviors.[9]

Kitsiou et al (2015) performed a review of systematic reviews on the effects of home telemonitoring interventions in patients with chronic heart failure. Fifteen reviews published between 2003 and 2013 were selected. Evidence from high-quality reviews with meta-analysis indicated that home telemonitoring interventions reduced the relative risk of all-cause mortality (0.60 to 0.85) and heart failure-related hospitalizations (0.64 to 0.86) compared with usual care. Absolute risk reductions ranged from 1.4% to 6.5% and 3.7% to 8.2%, respectively. Improvements in heart failure-related hospitalizations appeared to be more pronounced in patients with stable heart failure: hazard ratio (HR) 0.70 (95% credible interval [CrI] 0.34 to 1.5]). Risk reductions in mortality and all-cause hospitalizations appeared to be greater in patients who had been recently discharged (≤28 days) from an acute care setting after a recent heart failure exacerbation: HR 0.62 (95% CrI, 0.42 to 0.89) and HR 0.67 (95% CrI, 0.42 to 0.97), respectively. However, the reviewers noted that quality of evidence for these outcomes ranged from moderate to low suggesting that further research is likely to have an impact on the confidence in the observed estimates of effect and may change these estimates.[10]

Hypertension

Milani et al (2017) evaluated blood pressure control in 156 patients with uncontrolled hypertension who were enrolled in a home-based digital-medicine blood pressure program, and compared them with 400 patients (matched to age, sex, body mass index, and blood pressure) in a usual-care group after 90 days. Digital-medicine patients completed questionnaires online, were asked to submit at least 1 blood pressure reading/week, and received medication management and lifestyle recommendations via a clinical pharmacist and a health coach. Blood pressure units transmitted data directly to the electronic medical record. Digital-medicine patients averaged 4.2 blood pressure readings per week. At 90 days, 71% of digital-medicine versus 31% of usual-care patients had achieved target blood pressure control. Mean decrease in systolic/diastolic blood pressure was 14/5 mm Hg in digital medicine, versus 4/2 mm Hg in usual care (p<.001). Excess sodium consumption decreased from 32% to 8% in the digital-medicine group (p=.004). Mean patient activation increased from 41.9 to 44.1 (p=.008), and the percentage of patients with low patient activation decreased from 15% to 6% (p=.03) in the digital-medicine group. The authors concluded that a digital hypertension program is associated with significant improvement in blood pressure control rates and lifestyle change.[11]

Asthma

A Cochrane Review (2016) investigated whether home telemonitoring added benefits for people with asthma compared with their usual monitoring. Eighteen studies (12 included adults, 5 included children, 1 included both age groups) and a total of 2,268 individuals were studied. The intervention groups were given 1 of a variety of technologies to record and share their symptoms and were compared with a control group who received usual care. Evidence from these studies did not show clearly whether asthma telemonitoring with feedback from a healthcare professional increases or decreases the odds of exacerbations that require a course of oral steroids (odds ratio [OR]=0.93, 95% confidence Interval [CI]=0.60 to 1.44; 466 participants; 4 studies), a visit to the emergency department (OR=0.75, 95% CI, 0.36 to 1.58; 1018 participants; 8 studies) or a stay in hospital (OR=0.56, 95% CI, 0.21 to 1.49; 1042 participants; 10 studies) compared with usual care. Confidence was limited by imprecision in all 3 primary outcomes. Evidence quality ratings ranged from moderate to very low. Evidence

for measures of asthma control was imprecise and inconsistent, revealing possible benefit over usual care for quality of life (mean difference [MD]-0.23, 95% CI, 0.01 to 0.45; 796 participants; 6 studies; I^2 = 54%), but the effect was small and study results varied. Telemonitoring interventions may provide additional benefit for two measures of lung function: FEV1 and peak expiratory flow.[12]

Chronic Obstructive Pulmonary Disease

Alshabani et al (2019) reported on a retrospective pre- and post-analysis of a quality improvement project at the Cleveland Clinic. Thirty-nine patients with COPD and high healthcare utilization were provided with electronic inhaler monitoring devices for controller and rescue inhaler utilization for 1 year. Patients were contacted when alerts indicated suboptimal adherence to controller inhaler or increased use of rescue inhalers. Compared with the year prior to enrollment, electronic inhaler monitoring was associated with a reduction in COPD-related healthcare utilization per year (2.2 (±2.3) versus 3.4 (±3.2), p=0.01). Although there was a reduction in all-cause healthcare utilization, this was not statistically significant (3.4 (±2.6) versus 4.7 (±4.1), p=0.06).[13]

Kruse et al (2018) performed a systematic review of literature to determine how telemonitoring has been used to manage COPD. In a search from 2011 to 2017. Twenty-nine articles were selected for analysis. In examining outcomes of these studies, the authors found mixed results. Positive outcomes included reduced hospitalization rates, improved patient satisfaction, lower patient reported anxiety and depression as well as better clinical outcomes. Others found no significant improvement or actual reduced patient outcomes. Specifically, 31% of the studies showed a reduced number of clinical visits including primary care and emergency department visits. One study showed improvement, especially among rural patients. Three studies found that adding videoconferencing and phone support to monitoring services reduced admissions for exacerbations.[14]

Diabetes

Lee et al (2018) performed a systematic review and meta-analysis systematic reviews of RCTs to create an evidence-base for the effectiveness of telehealth interventions on glycemic control in adults with type 2 diabetes. Two reviewers selected and reviewed eligible studies published between 1990 and 2016. Of 3,279 references retrieved, 4 systematic reviews reporting 29 unique studies were included. Evidence from pooling found that telehealth interventions produced a small but significant improvement in hemoglobin A1c (HbA1c) levels compared with usual care (mean difference: -0.55, 95% CI: -0.73 to -0.36). The greatest effect was seen in telephone-delivered interventions, followed by internet blood glucose monitoring system interventions and lastly, interventions involving automatic transmission of self-monitoring if blood glucose using a mobile phone or a telehealth unit.[15]

Michaud et al (2018) examined the relationship between hemoglobin A1c outcomes in type 2 diabetic patients and participant characteristics. The study sample included 955 patients with type diabetes who were admitted to an urban Midwestern medical center for any reason from 2014 to 2017, and used remote patient monitoring for 3 months after discharge. Clinical outcomes included HbA1c, weight, body mass index (BMI), and patient activation scores. Most patients experienced decreases in HbA1c (67%) and BMI (58%), and increases in patient activation scores (67%) (p<.001 in all 3 cases) at the end of RPM. Logistic regression analyses

revealed that among patients who had HbA1c >9% at baseline, men (OR = 3.72; 95% CI, 1.43 to 9.64), those who had increased patient activation scores after intervention (OR = 1.05; 95% CI, 1.01 to 1.09), those who had higher baseline patient activation scores, and those who had a greater number of biometric data uploads during the intervention (OR = 1.02; 95% CI, 1.00 to 1.04) were more likely to have reduced their HbA1c to <9% at the end of RPM. The authors concluded that RPM for post-discharge patients with type 2 diabetes might be a promising approach for HbA1c control with increased patient engagement.[16]

Depression

Although there is an abundance of published literature regarding the management of depression via telemedicine, information regarding the use of remote patient monitoring in those with depression is lacking.

Lawes-Wickwar et al (2018) performed a systematic review with the aim of identifying various uses and efficacy of telehealth technology for severe mental illness. Literature was searched from inception to 2016; 31 articles describing 29 trials were selected as eligible for the review. Many of the study interventions focused on improving management. Monitoring strategies included telephones for prompting medication use and remote sensors to monitor medication use. Telephone support was found effective in improving medication adherence and reducing the severity of symptoms and inpatient days.[17]

Dickerson et al (2011) introduced a novel real-time depression monitoring system for the home. The integrated system, Emotional Monitoring for PATHology (EMPATH), consisted of sensors and analysis code. Data that was continuously monitored and collected included sleep quality by a novel monitoring sensor system, weight, speech analysis and activity. The authors performed a week-long case study, concluded that the sleep monitoring system was accurate and that EMPATH could be useful to both the patient and caregivers. Follow-up studies with this technology could not be found.[18]

The Department of Veterans Affairs reported on telehealth services offered by the Veterans Administration. They defined that home telehealth “monitors patients and manages diseases through video into the home and use of mobile devices for acute and chronic case management and health promotion/disease prevention.” It was reported that in fiscal year 2013, chronic disease management provided via home telehealth devices supported 7,340 patients with chronic mental health conditions to live independently in their homes. The devices used to support the patients were not specified.[19]

Summary

Remote patient monitoring captures data relevant to the patient’s medical condition. The data points can be tracked for trends that may reflect deterioration of the condition, and real-time interventions can be implemented that may prevent further decline or hospitalization. The technology is advancing quickly and it is clear that the objective data obtained is useful in medical management. However, more rigorous studies are needed to determine its effect on clinical outcomes, cost effectiveness and impact on utilization of health services. Even though we do not yet have strong empirical evidence, many health systems, including the Department of Veterans Affairs, are effectively integrating RPM into patient management. RPM appears to be an effective adjunct to care that is provided virtually.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Agency for Healthcare Research and Quality
The Agency for Healthcare Research and Quality published a brief (2016) to provide an overview of the large and disparate body of evidence about telehealth. One of the key messages from the review included the following:
•There is sufficient evidence to support the effectiveness of telehealth for specific uses with some types of patients, including remote patient monitoring for patients with chronic conditions.[20]

American Heart Association
The American Heart Association (2019) issued a Guidance, Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes, which states:

> "Remote patient monitoring (RPM) can empower patients to better manage their health and participate in their health care. When used by clinicians, RPM can provide a more holistic view of a patient's health over time, increase visibility into a patient's adherence to a treatment, and enable timely intervention before a costly care episode. Clinicians can strengthen their relationships with, and improve the experience of, their patients by using the data sent to them via RPM to develop a personalized care plan and to engage in joint decision-making to foster better outcomes. The American Heart Association supports initiatives that increase access to and incentivize the appropriate design and use of evidence-based remote patient monitoring technologies."[21]

Government Regulations

National:
There is no National Coverage Document on this topic.

Local:
There is no Local Coverage Document on this topic.

The 2022 Medicare Physician Fee Schedule has reimbursement for codes 99453, 99454, 99457, 99458 and 99091.

Federal Register, A Rule by the Centers for Medicare & Medicaid Services on 12/28/20:
Remote physiologic monitoring treatment management services were added to the general care management services.

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CMS is making it clear that clinicians can provide remote patient monitoring services to patients with acute and chronic conditions and for patients with only one disease. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Telemedicine
Home Cardiorespiratory Monitoring – Pediatric
Home Monitoring Device for Age-Related Macular Degeneration
Home Spirometry

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/1/22, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/21	2/17/21		Joint policy established
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (ls)

Next Review Date: 4th Qtr, 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: REMOTE PATIENT MONITORING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered
BCNA (Medicare Advantage)	See Government Regulations section.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.