

Molina Clinical Policy

Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2022

Next Review Due By: October 2023



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.¹ References included were accurate at the time of policy approval and publication.

OVERVIEW

Telehealth is broadly defined as the application of electronic information and telecommunication technology to facilitate long-distance clinical health care, patient and professional health-related education, health administration, and public health (HRSA 2022). The three primary types of telehealth applications include 1) real-time communication (enables patients to connect with providers via video conference, telephone, or a home health monitoring device), 2) store-and-forward (transmits data, images, sound, or video from one care site to another for evaluation), and 3) remote patient monitoring. Telehealth is either practiced in real time or as store-and-forward. Real-time telemedicine necessitates the presence of both the provider and the patient, or several providers, on a communications link that permits real-time engagement. Store-and-forward telemedicine involves the capture and transmission of medical data from a patient to a medical provider for evaluation and assessment later; it does not require the simultaneous presence of both parties and a real-time communication link.

Remote patient monitoring (RPM) is a subset of telehealth sometimes referred to as telemonitoring. RPM involves the “collection, transmission, evaluation, and communication of individual health data from a patient to their healthcare provider or extended care team from outside a hospital or clinical office (i.e., the patient's home) using personal health technologies including wireless devices, wearable sensors, implanted health monitors, smartphones, and mobile apps” (American Telemedicine Association 2022). The goal of RPM is to provide a more comprehensive understanding of a patient's health over a specific period, allowing clinicians to better evaluate patient compliance with recommended treatment(s) and respond more quickly when patient physiologic data deviates from the patient's established norms. RPM has the potential to enhance patient outcomes in chronic illnesses, including quality of life, mortality, hospitalization for chronic conditions, and all-cause hospitalization (Bashi et al. 2017). Remote monitoring has been associated with lower mortality for patients with heart failure and reduced hospital admissions for people with chronic disease (Walker et al. 2019).

COVERAGE POLICY

Please refer to the member's Plan benefit and any applicable Federal/State telehealth program requirements, including limits, definitions, eligibility, service authorization conditions, and data requirements.

Initial Requests for RPM

RPM may be considered medically necessary in accordance with the member's plan benefit and all applicable regulatory requirements, and when **ALL** of the following criteria are met:

1. RPM is prescribed by a qualified healthcare practitioner who is a network provider participating in telehealth AND licensed to practice in the state where the member is located; **AND**
2. Member has a diagnosis of **ONE** of the following chronic conditions as defined by applicable Federal/State Centers guidelines and member's Plan benefit (e.g., asthma, chronic obstructive pulmonary disease, diabetes, heart failure, hypertension); **AND**

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3. The Prescriber has determined the following of the member's condition:
 - a. High-risk for decompensation or complication that may lead to hospitalization, or another acute intervention and the provision of an RPM may reduce this risk (*e.g., member with recent hospitalization(s) or recurrent admissions for a chronic condition*)

OR

- b. Requires monitoring for a current or new treatment plan.

AND

4. RPM services prescribed is appropriate for the monitoring of member's condition and consistent with the provider's scope of practice; **AND**
5. Prescribed remote monitoring device must meet **ALL** the following:
 - a. Meet the *FDA definition of a "medical device" defined as:

Per Section 201(h) of the Federal Food, Drug, and Cosmetic Act as:

- "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.

NOTE: Personal devices such as Apple Watch® or Fitbit® are not approved for RPM.

AND

- b. Provide monitoring consistent with the symptoms or diagnosis and treatment of the Member's condition, illness, or injury.

AND

6. A plan of care, signed and dated by the prescriber, includes **ALL** of the following:
 - a. Specific clinical patient data to be monitored and measured (*e.g., weight, blood pressure, pulse, respirations, blood glucose, pulse oximetry*), **and**
 - b. Date and duration of monitoring requested, **and**
 - c. The frequency a qualified practitioner will be performing a reading of the transmitted health information. **NOTE:** Must be monitored for at least 16 days of each 30-day billing cycle, OR as specified by the billing CPT, **and**
 - d. Intervention process by which the monitoring provider will address potential health concerns or abnormal data measurements to prevent avoidable hospital utilization, **and**
 - e. If medication adherence management services are ordered:
 - Medication regimen/plan
 - Medication adherence monitoring method to be used for timing, dosing, and frequency of medication/plan
 - Records to support a documented history of poor adherence to ordered medication regimen

AND

7. Prescriber attestation that the member meets **ALL** of the following conditions:
 - a. Member has consented to RPM services in writing or verbally, **and**
 - b. Cognitively intact and capable of operating the RPM device or has a willing and capable caregiver to assist

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- in the completion of electronic data transmission, **and**
- c. Has internet connections necessary to host the RPM device/equipment in the home.

AND

8. Duration of Initial Service Authorization: Initial duration should not exceed 90 days. This may rarely be extended on a case-by-case basis for complex members with chronic conditions at very high risk of exacerbation and documented compliance with RPM.

Continuation Requests for RPM

RPM serves as an intervention in the case of a medical condition's complication, decompensation, or instability, rather than as a continuous mode, according to the available published evidence. It is intended for use during the stabilization period, as the patient returns to baseline or establishes a new baseline.

For continuation of service requests: Authorization may be extended in increments up to 90 days provided ALL documentation noted above is submitted. This includes a written order for RPM and duration, updated plan of care, rationale/supporting evidence that the member's clinical condition requires ongoing monitoring.

Exclusion or Discontinuation of RPM Service

1. Molina Clinical Reviewer or Medical Director determines that ANY of the above criteria are not met
2. Prescriber has not submitted ALL documentation/records requested
3. Member is hospitalized or receiving duplicative services while under an RPM plan of care
4. Member's condition has returned to baseline, or the reached a new established baseline.
5. Continuation of service beyond 90 days without a submission of a new records meeting all continued eligibility criteria stated in policy and approval of authorization.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The **Agency for Healthcare Research and Quality** issued a brief (2016) to provide an overview of the vast and disparate body of evidence on telehealth. The reviewers found 1,494 telehealth-related citations, of which 58 systematic reviews met the inclusion criteria. There is a large body of research literature on telehealth utilization across clinical conditions and health care functions, including systematic reviews and various studies. RPM has the potential to be used as an adjunct to the treatment of any condition. The majority of published research focuses on the value of RPM for patients with chronic conditions as discussed below.

Asthma

In a Cochrane review, Kew et al. (2016) compared the efficacy and safety of home telemonitoring with healthcare professional input between clinic visits to standard treatment for 2,268 participants across 18 trials (12 trials in adults, 5 in children and 1 from both age groups). Inclusion criteria included parallel randomized controlled trials (RCTs) of adults or children with asthma in which any form of technology was used to measure and share asthma monitoring data with a healthcare provider between clinic visits, compared to other monitoring or standard care. Trials in which technologies were used for monitoring without the involvement of a doctor or nurse were excluded. Patients with mild to moderate persistent asthma were typically recruited and followed for 3 to 12 months in studies. Patients in the intervention group were given one of several technologies to record and share their symptoms (text messaging, Web systems, or phone calls), while those in the control group received either usual care or a control intervention. The evidence from these studies did not show whether asthma telemonitoring with feedback from a healthcare professional increase or decreases the odds of exacerbations requiring oral steroids (466 participants; four studies), a visit to the emergency department (1018 participants; eight studies), or a hospital stay (1042 participants; ten studies) when

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compared to usual care. Imprecision in all three primary outcomes limited the authors' confidence. The level of evidence quality ranged from moderate to very low. None of the studies separated severe and minor adverse events from asthma exacerbations. The evidence for asthma control measures was imprecise and inconsistent, revealing a potential benefit over standard care for quality of life (796 participants; six studies), but the effect was small and study results varied. Telemonitoring interventions may improve two measures of lung function, forced expiratory volume in one second and change in peak expiratory flow. However, overall, the data does not support the widespread use of telemonitoring with input from healthcare providers between asthma clinic appointments, according to the review. Additional telemonitoring measures have not yet been shown to improve asthma symptom management or minimize the requirement for oral corticosteroids, nor have any unintended consequences been ruled out. As the studies were not blinded, the benefits to quality of life identified by researchers are susceptible to bias.

Chronic Obstructive Pulmonary Disease (COPD)

Nagase et al. (2022) conducted a systematic review of the scholarly literature released in the last 10 years. The evaluation comprised 17 RCTs and two comparative observational studies. The key finding of this systematic review is that there is a substantial amount of evidence relating to the efficacy/effectiveness of remote home monitoring, however it is of poor quality. Although remote home monitoring is safe, it does not appear to improve Health related quality of life, lung function, or self-efficacy, or to reduce sadness, anxiety, or healthcare resource consumption (independent of the kind of remote home monitoring). Regular feedback from clinicians may help to decrease COPD-related hospitalizations. Though remote home monitoring adherence remains unknown, both patients and providers expressed high levels of satisfaction with the intervention.

Lu et al. (2021) conducted a systematic review and meta-analysis that included 3,001 patients from 17 trials with both telemonitoring intervention and a control group, based on a search of PubMed, Embase, and the Cochrane Library for RCTs published between 1990 and May 2020. The authors noted that although an increasing number of studies have reported that telemonitoring in patients with COPD can be useful and effective for hospitalizations and quality of life, its actual utility in detecting and controlling acute exacerbations of COPD is less well-established. The purpose of the meta-analysis was to identify the best available evidence regarding the efficacy of telemonitoring targeting early and optimized management of acute exacerbation COPD in patients with a history of previous acute exacerbation COPD versus a control group without telemonitoring intervention. Primary endpoints included emergency room visits and exacerbation-related readmissions. According to the evidence presented in this meta-analysis, telemonitoring reduced ER visits and acute exacerbation-related readmissions, as well as acute exacerbation-related hospital days and mortality in patients with acute COPD exacerbation, particularly when the telemonitoring intervention was carried out for more than 12 months. The rapid development and reform of telemonitoring in practice may necessitate further recurrent control studies to determine the efficacy and advantage of certain types of telemonitoring. Consequently, telemonitoring constitutes a novel approach for the management of the condition.

Alshabani et al. (2019) published a retrospective review of the pre- and post-analysis phases of a Cleveland Clinic quality improvement study. Thirty-nine COPD patients with high healthcare utilization were provided electronic inhaler monitoring devices for a year to measure controller and rescue inhaler usage. Patients were notified when alarms indicated poor controller inhaler adherence or an increase in the use of rescue inhalers. The study reported that electronic inhaler monitoring was associated with a reduction in COPD-related healthcare utilization per year when compared to the year before enrollment. It was not statistically significant, even though overall healthcare use had decreased.

Diabetes Mellitus

The use of telemedicine in chronic diabetes mellitus management is well established. Several studies demonstrate the benefits of telemedicine treatments for diabetes management, while many integrate multiple care modalities ranging from teleconsultation to RPM.

In a 2016 meta-analysis including 55 randomized trials and over 9000 patients, the greatest hemoglobin A1C (HbA1c) improvement was seen in patients with type 2 diabetes mellitus, among those over 40 years old, and in those receiving teleconsultation (Su et al. 2016). Furthermore, telemedicine interventions marginally decreased HbA1C at all time intervals assessed (range from -0.20 to -0.74 percent) in comparison to conventional care, according to a 2017 comprehensive review that included 111 RCTs and almost 24,000 patients (Faruque et al. 2017). The most significant effect was shown in patients with higher baseline HbA1C, as well as in trials that used text messaging or web portals for communication and applications that aided medication adjustment, according to meta-regression analysis.

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Lee et al. (2018) conducted a systematic review and meta-analysis of RCTs to establish the efficacy of telehealth interventions on the glycemic management of adults with type 2 diabetes. Two reviewers identified and reviewed eligible studies published between 1990 and 2016. Of 3,279 references retrieved, 4 systematic reviews reporting 29 unique studies were included. Pooled evidence indicated that telemedicine interventions resulted in a minor but substantial improvement in HbA1c levels when compared to standard care. Telephone-delivered interventions had the greatest benefit, followed by internet blood glucose monitoring system interventions, and finally, interventions including automatic transmission of self-monitoring of blood glucose via a mobile phone or a telehealth unit.

Heart Failure (HF)

Telemonitoring is used in patients with chronic HF to predict and prevent acute decompensation episodes by tracking symptoms that require therapy optimization. Ong et al. (2022), in an evidence-based peer review, noted that the use of telemedicine has been shown to be beneficial for patients with HF in systematic reviews and meta-analyses (Polisena et al.; Inglis et al). However, in randomized trials, telemedicine monitoring alone did not consistently indicate benefits for hospitalization or mortality reduction in patients with HF (Ong et al.; Chaudhry et al.). Ong et al. also reported that telemonitoring combined with scheduled in-person visits can minimize both health care utilization and acute care visits in HF patients with implantable cardioverter-defibrillators (ICD). Remote monitoring of intrathoracic impedance (as a measure of fluid status), atrial arrhythmias, and ICD shocks reduced emergency and unscheduled physician visits in the Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO) study.

Inglis et al. (2015), in a Cochrane Review, analyzed RCTs using structured telephone assistance or non-invasive home telemonitoring compared to conventional practice for individuals with HF to assess the impact of these interventions in addition to standard of care. This review, which was an update of one from 2010 and included 17 new papers, The reviewers concluded that organized telephone support and non-invasive home telemonitoring decreased the risk of all-cause mortality and HF-related hospitalizations for patients with HF. Additionally, these therapies showed increases in self-care practices, HF knowledge, and health-related quality of life.

Jayram et al. (2017) evaluated the impact of telemonitoring on the health status of patients with HF. The Telemonitoring to Improve Heart Failure Outcomes trial randomized 1,521 patients with recent HF hospitalization to either telephonic monitoring or standard treatment. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess health status within 2 weeks of discharge, as well as 3 and 6 months later. The KCCQ overall summary and subscale scores between the two groups over the 6-month follow-up period showed a statistically significant, although clinically insignificant, difference. In comparison to patients receiving standard care, those receiving telemonitoring had an average KCCQ overall summary score that was 2.5 points higher (95% confidence interval, 0.38 to 4.67; P=0.02). This difference was primarily due to improvements in symptoms (3.5 points; 1.18 to 5.82; P=0.003) and social function (3.1 points; 0.30 to 6.00; P=0.03). The authors concluded that telemonitoring improves health status statistically but clinically minimal compared to standard treatment. Further research was suggested.

National and Specialty Organizations

The **American Heart Association (AHA)** (2019) issued a Guidance, Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes indicating: "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."

Although recent systematic reviews and meta-analyses have indicated a positive effect on HF-related admissions and mortality rates as well as all-cause mortality rates, the AHA states that the bulk of the literature consists of low-quality and inconsistent evidence about the positive effects of RPM (AHA 2019). RPM, for example, has been shown in cohort studies and non-randomized trials to reduce the risk of all-cause and HF mortality, as well as all-cause and HF hospital admissions; however, results from larger-scale RCTs have been inconsistent, with some showing no or negative effects and others showing decreases in HF-related admissions and emergency department visits. Future research should focus on understanding the process by which RPM improves HF-related outcomes, identifying optimal strategies and the duration of follow-up for which it confers benefits, and determining whether effectiveness varies between chronic HF patient groups and types of RMP technologies.

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SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

Diagnostic, consultative and treatment services should be reported with the appropriate Category I or Category III CPT code and the HCPCS modifier -GT (via interactive audio and video telecommunication systems) or CPT modifier-95 (synchronous telemedicine service rendered via a real-time interactive audio and video telecommunications system).

CPT Codes

CPT	Description
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
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
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
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)
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
99091	Collection and interpretation of physiologic data (eg, 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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022 New policy.

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Government Agencies

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Peer Reviewed Publications

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Asthma

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.