

# Molina Clinical Policy

## Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



### 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. References included were accurate at the time of policy approval and publication.

### OVERVIEW

**Telehealth** is broadly defined by the Health Resources and Services Administration (2022) 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. 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. The American Telemedicine Association (2022) reports that 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". 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**

# Molina Clinical Policy

## Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



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

## Molina Clinical Policy

### Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



- 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**

### **Asthma**

Almasi et al. (2022) conducted a systematic search of clinical trials that investigated the effectiveness of telemedicine in the management of asthmatic patients from 2005 to 2018. A total of 33 articles were included by researchers for review with 23 studies employing telemedicine for the promotion of patient compliance to treatment. Study inclusion criteria consisted of randomized trials in English; intervention tools for the diagnosis and management of asthma; any age group; and results of interventions that correlated to asthma management, symptom control, quality of life, costs, and adherence to prescribed treatment programs. Researchers separated telemedicine functions into five categories: consultation, communication, education, monitoring, and reminder. Remote patient monitoring functions identified were online asthma control, respiratory functions, data entry regarding asthma symptoms including physical data, medication dosage and monitoring, and disease progression. Reminders and alarms were the most frequent function employed using telemedicine interventions followed by communication with healthcare providers. Most studies did find that treatment adherence and quality of life improved when patients received telemedicine interventions, but the cost of care did not decrease. Patients did report that telemedicine interventions improved education on asthma, anatomy of the lungs, common asthma symptoms, medication compliance, device use (inhalers, peak flow meters, spacers, and telemedicine tools), following treatment programs, and the causes for asthma exacerbation. When multiple diverse types of telemedicine interventions are implemented overall asthma management does improve when compared to a single intervention. Currently the cost of care is not reduced with the use of telemedicine and RPM.

## Molina Clinical Policy

### Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



#### 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. This study was 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 exacerbations 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 control and rescue inhaler usage. Patients were notified when alarms indicated poor control 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.

Park et al. (2023) conducted a retrospective cohort study investigating patient adherence to daily diabetic protocols using RPM over a 180-day period between 2016 to 2018. Inclusion in this study consisted of Texas Medicaid patients on RPM who transmitted blood glucose levels for data collection after a 30-day training period. Initially a total of 2099 patients referred by their physician were enrolled in the study. Patients were assigned to either an adherence or nonadherence cohort group based on frequency required for data transmission. The adherence group consisted of 460 patients who agreed to transmit blood glucose data at least once daily for a minimum of 120 out of the 150-day study period. The remaining 382 patients were allocated to the nonadherent cohort and consented to a minimum of twice monthly testing. Both groups received adherence reminder calls when data was not transmitted. While both groups had improvements with blood glucose control, adherence calls improved data transmission in the adherent cohort by 50.7% and in the nonadherent cohort by 29.5%. Nearly half of the adherent cohort achieved adherence levels of approximately 90% that were sustained throughout the study period with the help of adherence calls. The study also faced challenges with 20.9% of the total group failing to transmit daily glucose levels despite reminder calls. The adherent cohort accounted for 8.1% of this group. This study did not include patient medications, activity levels, carbohydrate consumption, or other factors that may have affected glucose levels. Additionally, the type of diabetes (type 1 or type 2) and HbA<sub>1c</sub> data was not submitted for patients during the study. While RPM was identified with potential patient benefits, adherence calls significantly improved patient compliance in achieving better blood glucose control. Further studies are needed to identify all components that help diabetic patients attain optimal care.

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

## Molina Clinical Policy

### Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



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)

Ong et al. (2023) in an evidence-based systematic review and meta-analysis identified that the use of telemedicine has been shown to be beneficial for patients with HF. Although randomized trials of telemedicine with monitoring alone have not consistently indicated benefits for a reduction in hospitalization or mortality. When viewed from the broader perspective of overall care, remote monitoring does assist providers with disease management. The Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO) study found that when patients with HF who also had an implantable cardioverter-defibrillator (ICD) received remote monitoring of intrathoracic impedance (as a measure of fluid status), atrial arrhythmias, and ICD shocks the need for emergency and unscheduled physician visits was reduced. Telemedicine visits have limitations such as physical examination, difficulty with technology, and patient preference, and should be viewed as an addition rather than a replacement to current therapies. In addition, software and data security for telemedicine visits need to comply with the Health Insurance Portability and Accountability Act for all protected health information.

Bhatia et al. (2020) reviewed RPM for heart failure (HF) and identified inconsistencies that lacked evidenced-based data for clinical management. Research reviewed existing options for RPM and found that a framework was needed that included the following components: patient data collection, data transmission including analysis and presentation, and team care review with clinical action. Current modalities of RPM comprise both noninvasive and invasive devices. Noninvasive devices such as blood pressure cuffs, scales, and other wearable devices present minimal patient risk and are less expensive than invasive devices. The clinical benefit is mixed for noninvasive devices and requires more research that establishes effectiveness in specific patient populations. Implantable invasive devices present a greater risk to the patient at a significantly higher cost. That said, for specific patient populations there is potential to optimize better HF care. Research is needed for all types of RPM that clearly establishes specific patient care needs and treatment options that enhances monitoring for clinical HF decompensation. Moving forward, specific patient selection criteria is necessary for HF RPM and will need to identify when incorporating this type of intervention will provide the greatest patient benefit.

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 **Agency for Healthcare Research and Quality (AHRQ)** (2023) reviewed the evolution of remote patient monitoring (RPM) as a specific type of telehealth that rapidly advanced during the Covid-19 pandemic. Prior to the pandemic RPM was utilized primarily for patients with chronic health conditions that required frequent monitoring through digital medical devices such as weight scales, blood pressure monitors, pulse oximeters, and blood glucose meters. Disease management for patients with specific medical conditions such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and diabetes reduced emergency visits, hospital readmissions, and hospital length of stay with the use of RPM.

The Covid-19 pandemic quickly increased the use of RPM to include both acute and chronic conditions. Telehealth in general was found to be a safe mechanism to monitor patients and reduce potential exposure to infected patients. RPM services also helped to reduce hospital burden due to earlier detection of a change in patient status and more rapid intervention of treatment. The rapid expansion of RPM also identified potential patient safety concerns including

# Molina Clinical Policy

## Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



misdiagnosis or failure to identify when patients needed increased attention from providers. With the end of the pandemic mitigation of patient safety issues with the development of robust protocols and guidelines has been identified as a priority for continued safe use of RPM. Further research is needed to identify appropriate use of RPM with defined guidelines that focus on patient safety, potential adverse effects, and overall improvement in patient care.

The **American Heart Association (AHA)** (2017) issued a Recommendation for the Implementation of Telehealth in Cardiovascular and Stroke Care: A Policy Statement from the American Heart Association. The intent of this policy statement is to provide a comprehensive review of current scientific evidence evaluating the use of telemedicine in cardiovascular and stroke care. These policy suggestions provide ways that will advance healthcare quality, identify legal and regulatory concerns, propose strategies for overcoming barriers to care, and identify future areas of telehealth research that ensures quality of care for cardiovascular and stroke patients. The goal of the AHA is for telehealth to achieve its full potential by providing integration into current delivery care models while fostering better patient engagement.

The AHA acknowledges that cardiovascular disease and stroke present a significant health burden. The broader view of telehealth is to implement the Institute of Medicine STEEP acronym of care that is Safe, Timely, Effective, Efficient, Equitable, and Patient-centered. Expansion of telehealth for larger patient populations has identified legal/regulatory, technological, and financial barriers that will need to be addressed. Gaps in research were also identified including usability and other human factors, efficacy, and cost-effectiveness data that will require additional research to determine how telehealth interventions should be implemented. Further advancement of telehealth services for cardiovascular and stroke patients will require that healthcare providers, researchers, legislators, and regulators work toward the advancement of telehealth initiatives at the state and federal level. The AHA would like to partner with other organizations with the goal of making progress toward the expansion of telehealth initiatives.

### 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 (Current Procedural Terminology) 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 (e.g., 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

# Molina Clinical Policy

## Remote Patient Monitoring: Policy No. 419

Last Approval: 10/12/2023

Next Review Due By: October 2024



### HCPCS (Healthcare Common Procedure Coding System) Code

HCPCS	Description
G0322	The collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (i.e., remote patient monitoring)

**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

10/12/2023	Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References.
10/12/2022	New policy.

### REFERENCES

1. Almasi S, Shahbodaghi A, Asadi F. Efficacy of Telemedicine for the Management of Asthma: A Systematic Review. *Tanaffos*. 2022 Feb;21(2):132-145. PMID: 36879729; PMCID: PMC9985125.
2. Alshabani K, Attaway AA, Smith MJ, et al. Electronic inhaler monitoring and healthcare utilization in chronic obstructive pulmonary disease. *J Telemed Telecare*. 2020 Aug-Sep;26(7-8):495-503. doi: 10.1177/1357633X19850404. Epub 2019 May 16. PMID: 31096842.
3. American Heart Association (AHA). Recommendation for the implementation of telehealth in cardiovascular and stroke care: A policy statement from the American Heart Association. Published February 14, 2017. Accessed September 14, 2023. <https://www.heart.org>.
4. American Telemedicine Association (ATA). Telehealth: Defining 21st century care, remote patient monitoring. Published: 2022. Accessed September 14, 2023. <https://www.americantelemed.org/resource/why-telemedicine/>.
5. Bashi N, Karunanithi M, Fatehi F, et al. Remote Monitoring of Patients with Heart Failure: An Overview of Systematic Reviews. *J Med Internet Res*. 2017 Jan 20;19(1):e18. doi: 10.2196/jmir.6571. PMID: 28108430; PMCID: PMC5291866.
6. Bhatia A, Maddox TM. Remote Patient Monitoring in Heart Failure: Factors for Clinical Efficacy. *Int J Heart Fail*. 2020 Nov 30;3(1):31-50. doi: 10.36628/ijhf.2020.0023. PMID: 36263114; PMCID: PMC9536717.
7. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database – no National Coverage Determination identified (search: “telemedicine” or “telehealth” or “remote patient monitoring”). Accessed September 20, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
8. Health Resources and Services Administration (HRSA). What is telehealth? Updated March 2022. Accessed September 14, 2023. <https://www.hrsa.gov/telehealth/what-is-telehealth>.
9. Jayaram NM, Khariton Y, Krumholz HM, et al. Impact of Telemonitoring on Health Status. *Circ Cardiovasc Qual Outcomes*. 2017 Dec;10(12):e004148. doi: 10.1161/CIRCOUTCOMES.117.004148. PMID: 29237746; PMCID: PMC5776725.
10. Lee PA, Greenfield G, Pappas Y. The impact of telehealth remote patient monitoring on glycemic control in type 2 diabetes: a systematic review and meta-analysis of systematic reviews of randomised controlled trials. *BMC Health Serv Res*. 2018 Jun 26;18(1):495. doi: 10.1186/s12913-018-3274-8. PMID: 29940936; PMCID: PMC6019730.
11. Lu JW, Wang Y, Sun Y, et al. Effectiveness of Telemonitoring for Reducing Exacerbation Occurrence in COPD Patients With Past Exacerbation History: A Systematic Review and Meta-Analysis. *Front Med (Lausanne)*. 2021 Sep 10;8:720019. doi: 10.3389/fmed.2021.720019. PMID: 34568376; PMCID: PMC8460761.
12. Nagase FI, Stafinski T, Avdagovska M, et al. Effectiveness of remote home monitoring for patients with Chronic Obstructive Pulmonary Disease (COPD): systematic review. *BMC Health Serv Res*. 2022 May 14;22(1):646. doi: 10.1186/s12913-022-07938-y. PMID: 35568904; PMCID: PMC9107164.
13. Ong MK, Pfeffer M, Mullur, RS. Telemedicine for adults. Updated September 11, 2023. Accessed September 20, 2023. <http://www.uptodate.com>.
14. Park S, Kum HC, Zheng Q, Lawley MA. Real-World Adherence and Effectiveness of Remote Patient Monitoring Among Medicaid Patients With Diabetes: Retrospective Cohort Study. *J Med Internet Res*. 2023 Aug 22;25:e45033. doi: 10.2196/45033. PMID: 37606977; PMCID: PMC10481216.
15. United States Food and Drug Administration (FDA). Classification of products as drugs and devices & additional product classification issues: Guidance for industry and FDA staff. ID No. FDA-2011-D-0429-0025. Updated July 12, 2018. Accessed September 20, 2023. <https://www.fda.gov/combination-products>.
16. Walker RC, Tong A, Howard K, et al. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. *Int J Med Inform*. 2019 Apr;124:78-85. doi: 10.1016/j.ijmedinf.2019.01.013. Epub 2019 Jan 29. PMID: 30784430.