Medical Coverage Policy

Effective Date.....9/15/2024
Next Review Date.....5/15/2025
Coverage Policy Number..... 0563

Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM)

Table of Contents

Related Coverage Resources

Airway Clearance Devices in the Ambulatory Setting
Ambulatory External and Implantable Electrocardiographic Monitoring
Diabetes Equipment and Supplies
Home Ventilators
Ventricular Assist Devices (VADs), Percutaneous Cardiac Support Systems and Total Artificial Heart

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not

covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses remote physiologic monitoring (RPM) (also known as remote patient monitoring), self-measured blood pressure (SMBP), and remote therapeutic monitoring (RTM).

RPM involves the use of digital technologies to capture and monitor information regarding the physical or behavioral functioning of an individual. Examples of RPM include the monitoring of pulse, blood pressure, respiratory rate, blood glucose, weight, and/or oxygen saturation using automated digital technology.

SMBP monitoring is a subset of RPM and involves the collection of blood pressure data only, self-measured by the individual and reported to the physician or other qualified health care professional with subsequent communication of a treatment plan from the physician or other qualified health care professional back to the individual.

RTM refers to the management of an individual's non-physiologic information by a healthcare provider. An example of RTM is the monitoring of patient adherence to a treatment plan.

Technology used for remote monitoring includes software, use of a mobile device, and/or a wearable device. The information is electronically transmitted to the healthcare provider for assessment.

Information in this Coverage Policy is informed by the US Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Center for Medicare and Medicaid Services (CMS) and other published sources.

Coverage Policy

Coverage for Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) varies across plans. Refer to the customer's benefit plan document for coverage details.

Remote Physiologic Monitoring (RPM) (CPT® codes 99091, 99453, 99454, 99457, 99458, HCPCS code G0322) is considered medically necessary for ANY of the following indications:

- Chronic Obstructive Pulmonary Disease (COPD)
- Diabetes Mellitus
- Gestational Diabetes
- Heart Failure
- Hypertensive Disorders Of Pregnancy (HDP)

when ALL of the following criteria are met for the technology in question:

- Prescribed and administered by a board-eligible or board-certified medical provider or subspecialist (e.g., cardiologist, pulmonologist, endocrinologist), nurse practitioner (NP) or physician assistant (PA))
- physiologic data are electronically collected and automatically uploaded for analysis and interpretation.
- intended for the purpose of displaying or analyzing the physiological parameter(s) measured by the device
- used for remote communication, counseling and monitoring of acute or chronic health conditions

Self-Measured Blood Pressure (SMBP) Monitoring (CPT® codes 99473, 99474) is considered medically necessary for the following indication:

- Hypertension
- Hypertensive Disorders Of Pregnancy (HDP)

when ALL of the following criteria are met for the technology in question:

- Prescribed and administered by a board-eligible or board-certified medical provider or subspecialist (e.g., cardiologist, pulmonologist, endocrinologist), nurse practitioner (NP) or physician assistant (PA))
- physiologic data are electronically collected and automatically uploaded for analysis and interpretation.
- intended for the purpose of displaying or analyzing the physiological parameter(s) measured by the device
- used for remote communication, counseling and monitoring of acute or chronic health conditions

Remote Physiologic Monitoring (RPM) is not covered or reimbursable for any other indication, including isolated hypertension.

Remote Therapeutic Monitoring (RTM) (CPT codes 98975, 98976, 98977, 98978, 98980, 98981) is not covered or reimbursable for ANY indication.

Health Equity Considerations

According to HRSA (2022), health barriers to telehealth access remain, including the lack of video sharing technology, such as a smartphone, tablet, or computer, spotty or no internet access, few local providers who offer telehealth practices, language barriers and lack of adaptive equipment for people with disabilities.

Remote physiologic monitoring as a subset of telehealth services is proposed as a means to allow more equitable access to healthcare services to underserved communities such as low income individuals, those who live in rural areas, people of color, immigrants and others.

Gestational Diabetes
Preexisting diabetes and gestational diabetes can negatively affect maternal and infant health, including increased risk for preterm birth. Diabetes in pregnancy varies by race and ethnicity. Preexisting diabetes is highest among American Indian, Alaska Native and Native Hawaiian and Pacific Islander women. Gestational diabetes is a type of diabetes that first develops during

pregnancy. Among women with a live birth, gestational diabetes rates are highest among Asian women. Among women with any type of diabetes, high blood glucose during pregnancy increases women's risk of having a cesarean delivery. It also increases babies' risk of being born too large and developing obesity or type 2 diabetes in the future (Ely, et al., 2024).

Hypertensive Disorders of Pregnancy
Hypertensive disorders in pregnancy (HDPs), defined as pre-pregnancy (chronic) or pregnancy-associated hypertension, are common pregnancy complications in the United States. HDPs are strongly associated with severe maternal complications, such as heart attack and stroke and are a leading cause of pregnancy-related death in the United States. Compared with non-Hispanic White women, non-Hispanic Black women have higher odds of entering pregnancy with chronic hypertension and developing severe preeclampsia. Factors that contribute to racial and ethnic inequities in chronic and pregnancy-induced hypertension are varied and include higher prevalences of HDP risk factors, including diet, tobacco use, physical activity patterns, poverty and access to care. Rural counties are at higher risk for pregnancy-related mortality than metropolitan counties. In a study of racial and ethnic disparities in pregnancy-related deaths, those caused by HDP among Black and AI/AN women were found to be substantially higher than those among White women, highlighting the importance of addressing HDP to reduce inequities in pregnancy-related mortality. Risk factors for HDP, include advanced maternal age, obesity, and diabetes mellitus. Women with a history of pregnancy-associated hypertension are at increased risk for cardiovascular disease compared with women with normotensive pregnancies (Ford, et al., 2022).

General Background

Remote Physiologic Monitoring (RPM)
For the purpose of this Coverage Policy, RPM, also referred to as remote patient monitoring, involves the use of digital technologies such as software, or a mobile or wearable device to capture and monitor patient information related to physical or behavioral functioning of an individual. The term RPM does not refer to a single technology or intervention; multiple types of technologies may be used, depending on the condition(s) being monitored. The use of technology to monitor an individual’s chronic condition remotely allows patients and providers flexibility in the scheduling of in-person trips into the healthcare provider’s office. Other benefits include measurement and potential stabilization of acute symptoms.

Although devices used for RPM may be invasive or non-invasive, for the purpose of this Coverage Policy RPM refers to non-invasive interventions.

Information that is collected and automatically transmitted to the healthcare provider for assessment may include measurement of blood pressure, weight, heart and respiratory rate, pulse oximetry, spirometry, temperature and blood glucose levels (American Telemedicine Association, 2006; Malasinghe et al., 2019).

According to the Centers for Medicare and Medicare Services ([CMS, 2021]) and the Health Resources and Services Administration ([HRSA], 2022) the following parameters apply to RPM:

- Physiologic data must be electronically collected and automatically uploaded to a secure location where the data can be available for analysis and interpretation by the billing practitioner.
- Devices must be FDA-approved as a medical device and they must be able to automatically transmit data and information to the provider without patient interference.
- Remote physiologic monitoring services must monitor an acute care or chronic condition.

- The services may be provided by auxiliary personnel under the general supervision of the billing practitioner.
- Monitoring must occur over at least 16 days of a 30-day period.
- When multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected.

Please see the appendix for a list of RPM CPT codes.

Self-Measured Blood Pressure (SMBP)
Similar to RPM, SMBP involves the use of a validated blood pressure device for home use to capture and monitor blood pressure measurements that have been self-measured, by the individual, and reported to the healthcare provider. It's proposed that SMBP plus clinical support can improve access to and quality of care by making blood pressure control more convenient and accessible (CDC, 2023).

Please see the appendix for a list of SMBP CPT codes.

Remote Therapeutic Monitoring (RTM)
Like RPM, RTM involves the use of digital technologies such as software, or a mobile or wearable device to capture and monitor patient information by a healthcare provider. However, the devices support the receipt of non-physiologic information, such as whether or not an individual is taking medication or participating in therapy as prescribed or to monitor the level of pain. Per CMS guidelines, the use of RTM in reporting an individual's non-physiologic information is limited to musculoskeletal and respiratory conditions.

Please see the appendix for a list of RTM CPT codes.

U.S. Food and Drug Administration (FDA)

A number of remote or wearable monitoring devices have received FDA approval, clearance, or emergency use authorization (EUA) status. These include non-invasive remote monitoring devices that measure or detect common physiological parameters and non-invasive monitoring devices that wirelessly transmit patient information to a health care provider or other monitoring entity. (FDA, 2023; FDA, 2024).

Literature Review

Remote Physiologic Monitoring (RPM)
RPM has been proposed for a wide variety of indications. Multiple peer-reviewed randomized controlled trials, meta-analyses and systematic reviews have been published. Limitations such as heterogeneous patient populations, variability in the type of monitoring performed, and diversity in study design have been identified. Additionally there is a lack of published professional society guidelines for RPM.

Although studies suffer from multiple limitations as previously noted, there is some evidence to support a reduction in the number of emergency department visits, inpatient hospital admissions or mortality rates with the use of RPM for the management of chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM) and heart failure (HF). An improvement in patient satisfaction with care management and quality of life is suggested by some study data (Kitsiou, et al., 2021; Cooper, et al., 2020; Hong, et al., 2019; Lee, et al., 2019; Koehler, et al., 2018; Olivari, et al., 2018; Vianello, et al., 2018; Walker, et al., 2018; Bollyky, et al., 2017; Conway, et al., 2014; Nakamura, et al., 2013; Inglis, et al., 2011; Klersy, et al., 2009).

Multiple Conditions
Flodgren et al. (2016) published results of a systematic review evaluating the effectiveness of telemedicine (TM) delivered in addition to, or as an alternative to, usual care as compared to usual care alone as reported in 93 RCTs (n =22,047). Clinical conditions included in eligible studies were heterogeneous and included cardiovascular disease (36 studies), diabetes mellitus (21 studies), respiratory conditions (9 studies), behavioral health (BH) conditions or substance abuse (9 studies). Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination. The type of data transmitted by the patient, the frequency of data transfer, (e.g. telephone, e-mail, SMS) and frequency of interactions between patient and healthcare provider varied across studies, as did the type of healthcare provider(s) and healthcare system involved in delivering the intervention. No difference was found between groups for all-cause mortality for patients with heart failure (16 studies; n = 5239, p = 0.12, moderate to high certainty of evidence) at a median of six months follow-up. Admissions to hospital (11 studies; n = 4529) ranged from a decrease of 64% to an increase of 60% at median eight months follow-up (moderate certainty of evidence). Data suggests some evidence of improved quality of life (five studies; P < 0.02, moderate certainty of evidence) for those allocated to TM as compared with usual care at a median three months follow-up. In studies recruiting participants with diabetes mellitus (16 studies; n = 2768) there were lower HbA1c levels in those allocated to TM than in controls (P < 0.00001, high certainty of evidence) at a median of nine months follow-up. Some evidence for a decrease in low density lipoprotein (LDL) (four studies; n = 1692; p=< 0.00001, moderate certainty of evidence), and blood pressure (four studies; n = 1770, p < 0.00001, moderate certainty evidence) was noted in TM as compared with usual care. Seven studies that recruited participants with various behavioral health and/or substance abuse reported no differences in the effect of therapy delivered over video-conferencing, as compared to face-to-face delivery. Findings from the other studies were inconsistent; there was some evidence that monitoring via TM improved blood pressure control in participants with hypertension, and a few studies reported improved symptom scores for those with a respiratory condition. Authors note the use of TM in the management of heart failure reflected similar health outcomes as face-to-face or telephone delivery of care; however, there is some evidence that TM can improve the control of blood glucose in those with diabetes.

Taylor et al. (2020) published a systematic review of 91 studies, including RCTs, cohort studies and case–controlled studies that compared acute hospital use by patients utilizing RPM with those not remotely monitored, and studies comparing acute hospital use pre-RPM and post-RPM. Of 91 studies, 15 were for cardiovascular disease, primarily heart failure, COPD (n=18) or co-morbid cardiovascular disease and COPD (n=4). Of the thirteen RCTs investigating RPM in COPD populations; seven trials showed no significant difference in hospital use between the intervention and control groups while 30% reported a reduction in hospital use. Two RCTs reported an increase in hospital admissions in the RPM group. Of the 15 RCTs reporting results for cardiovascular disease, eight trials reported no difference and seven trials (47%) reported a reduction in acute hospital use.Due to the limited number of studies evaluated, the benefit of RPM for other conditions, including behavioral health and neuromuscular conditions, could not be determined. Overall, the authors note that 50% of included studies reported decreased hospital admissions and 50% reported no change with the use of RPM. A smaller number of studies reported the effect of RPM on length of stay (n=47) and ED presentations (n=32), with around half reporting a decrease and half reporting no change for both. Studies were not limited to RCTs and P values were not reported. Systematic review suggests some decrease in rates of acute care hospital use in a subpopulation of individuals with cardiovascular disease, COPD or comorbid conditions of cardiovascular disease and COPD.

Vegesna et al. (2017) reported on a systematic review of RPM utilizing non-invasive remote patient monitoring technology for various conditions in 62 studies. Study design was

heterogeneous and included RCT, systematic reviews, cohort and observational studies. The review noted whether a study reported positive or neutral results. The conditions reviewed most frequently were COPD (7 RCTs, 4 positive results, 3 neutral results and 1 cohort study with a neutral result), DM (4 RCTs with positive results and 2 cohort studies: one positive and 1 neutral result and 1 observational study with a positive result). Two RCTs with positive results were reviewed for HF. The lack of quantification of study results prohibits an assessment regarding impact on outcomes. Further research utilizing robust study designs is needed to assess the efficacy and value of RPM technology.

Castelyn et al. (2021) performed a systematic review and metaanalysis of 89 RCT, longitudinal studies and nonrandomized experimental studies investigating telehealth interventions, such as the remote monitoring of patient clinical data (e.g. blood pressure, blood glucose, heart rate, medication use) as a strategy to better manage chronic conditions and to reduce the impact on patients and healthcare system. Authors report variance in the quality, sample size and performance among the studies. The authors reported that overall, algorithms involved in diagnosis (n = 22, 47%) had superior performance to those involved in predicting a future event (n = 25, 53%). Detection of arrhythmia and ischemia using ECG data showed promising results; however, there was no evidence of a positive impact on healthcare utilization (p = .35) or mortality (p = .208). A positive effect was noted on health status (p = .010] and diabetes control (p < .001).

Data suggest telehealth interventions may have a positive impact on health outcomes for control of diabetes and general health status.

Chronic Obstructive Pulmonary Disease (COPD)
Vianello et al. (2018) reported results of a 12 month RCT involving 334 patients diagnosed with COPD. Patients were provided with a telemonitoring system consisting of a finger pulse-oximeter and a gateway device for data transmission over telephone line to a central data management unit. Clinical staff was alerted via a trained operator whenever variations in respiratory parameters fell beyond the individual's normal range. The study's primary endpoint was health related quality of life (HRQL). Secondary endpoints were scores on the Hospital Anxiety and Depression Scale (HADS), the number and duration of hospitalizations; the number of readmissions; the number of appointments with a pulmonary specialist; the number of visits to the emergency department; and the number of deaths. There was no significant difference in Physical and Mental Component Summary scores between the TM and control groups (p = 0). Variations in HADS were not significantly different in the two groups (p = 0.65, p = 0.71, respectively). The hospitalization rate was not significantly different in the two groups (p = 0.16, p = 0.16, respectively). The readmission rate was significantly lower in the TM group compared to control group (p = 0.01). Study data suggest tele-monitoring may result in decreased readmission rates for this subset of patients.

Walker et al. (2018) reported results of an RCT evaluating the efficacy of home monitoring compared with usual care for 312 patients with COPD and comorbidities. Patients on the telemonitoring arm used a device that measured within-breath respiratory mechanical impedance, a touch-screen computer, and a mobile modem. Patients with a comorbid diagnosis of congestive heart also used a wearable device to assess blood pressure, oxygen saturation, heart rate, and body temperature over a 4-minute period. An algorithm identified deterioration and a telephone contact was triggered. Primary outcomes were time to first hospitalization and change in the EuroQoL utility index score. Secondary outcomes included rate of antibiotic and corticosteroid prescription, hospitalization, COPD Assessment Tool, Patient Health Questionnaire-9 and Minnesota Living with Heart Failure questionnaire scores, quality adjusted life years and healthcare costs. Telemonitoring was associated with fewer repeat hospitalizations (p=0.017). No

effect on other outcomes was noted. Data suggest some improved outcomes related to hospitalization rate for this subset of patients.

Cooper et al. (2020) published results of a non-randomized trial of 17 patients receiving RPM who were trained in the use of novel software that recorded daily symptoms, medication use and self-reported activity level. They were also trained to use a handheld spirometer and pulse oximeter. The handheld spirometer was programmed with electronic diaries and the capability for recording pulse oximetry and included questions on daily symptoms, daily physical activities and daily medications. Various physiological values related to lung function were measured and were used to identify predictors of exacerbations. There was agreement between forced vital capacity and self-reported healthcare utilization events ($p<0.001$) as well as between increased use of inhaled short-acting bronchodilators and exacerbations. There was moderate agreement between forced expiratory volume and self-reported healthcare utilization events ($p<0.001$) and between oxygen saturation less than 90% and exacerbations. Although data are not high level evidence, there are some data to suggest a positive effect of RPM for COPD.

Department of Veterans Affairs/Department of Defense (VA/DoD): In a clinical practice guideline for the management COPD (2021), the VA/DoD gave a "weak" recommendation for the use of "telehealth support that includes telemonitoring and/or mobile applications". The work group indicated that "the quality of evidence for the evaluation fo telehealth support was low due to inconsistency" and that "most studies were either fair or poor quality, and studies varied with respect to their comparison groups and timing in which outcomes were assessed". Interventions were categorized as telephone only, mobile phone/interactive web-based support, video supported and remote monitoring. The workgroup concluded that the benefits increasing accessibility with telehealth support outweigh the harms and that such services should "be considered supportive in nature and not a replacement for usual medical care".

Diabetes Mellitus
Lee et al. (2019) reported on a RCT evaluating the effects of remote telemonitoring with team-based management on 240 people with uncontrolled type 2 diabetes mellitus. The intervention group received home glucose telemonitors and transmitted glucose data to a care team compared with routine healthcare services. The primary outcome was the change in HbA1c at 24 and 52 weeks. Secondary outcomes included change in fasting plasma glucose, blood pressure, lipid levels and health-related quality of life. At week 24, both groups showed reduction in the HbA1c levels from baseline; however this did not reach statistical improvement in glycemic control at 24 or 52 weeks ($p=0.226$). No differences in secondary outcomes were observed, including the number of adverse events and health-related quality of life. Data suggests limited benefit in the use of remote telemonitoring compared with self-monitoring of blood glucose.

Bollyky et al. (2017) reported on a trial of 330 adults with Type 2 DM who were current participants in the Livongo Diabetes Program and who had not yet achieved glycemic control and weight goals. Participants were randomized into one of four groups: no further intervention, a connected scale, a scale plus less-intensive coaching with a certified diabetes educator (CDE) or a scale plus intense coaching with a CDE. Primary study objectives were to determine if use of a connected scale plus intensive lifestyle coaching would be associated with greater improvements in glycemic control and weight goals compared with other study arms. Patient characteristics of those with the greatest engagement were also investigated. Participants were 64.2% white/Caucasian, 10.9% Black/African American, 0.9% Hispanic/Latino/Mexican and for 11.8% race was unknown. Baseline characteristics among groups were similar except that the participants randomized to the less intensive coaching intervention were significantly less likely to be on insulin than control participants ($p = 0\ 007$). The mean weight loss was greatest in the intensive coaching group compared with scale-only ($p = 0\ 005$). Mean improvement in blood glucose was highest in the intensive coaching group compared to scale-only group ($p = 0\ 02$).

There were no significant differences between the less-intensive and intensive lifestyle coaching groups on any of the outcomes of interest. Participants with the greatest improvements in glucose control at the end of the intervention had higher preintervention mean blood glucose levels. Age, gender, race/ethnicity, and insulin use were not associated with improvements in mean blood glucose. Data suggest that intervention with a connected scale and coaching with a CDE results in an improvement in weight loss and HbA1c compared to use of connected scale only or no intervention.

Department of Veterans Affairs/Department of Defense (VA/DoD): In a 2023 clinical practice guideline for the management of type 2 diabetes mellitus, the VA/DoD gave a "weak" recommendation for the use of telehealth interventions in adults with type 2 diabetes mellitus. The work group indicated that the quality of evidence is low to support telehealth interventions in this population with small sample sizes, confounding variables, and heterogeneity of telehealth interventions. The workgroup added that "no single study reported harm associated with the telehealth intervention, and outcomes ranged from neutral to moderately beneficial".

Gestational Diabetes
Peer-reviewed evidence regarding the efficacy of RPM for monitoring blood glucose levels in pregnant individuals is limited. However, systematic review and meta-analysis of randomized controlled trials and a retrospective cohort study reflect improvement in morbidity, achievement of glycemic control in the target range sooner, submission of more glucose values, and lower rates of neonatal hypglycemia in the first 24 hours of life. The evidence also suggests improved outcomes related to patient engagement, decreased number of face to face provider visits, and positive patient perception of RPM. Heterogeneity related to type of RPM used for individual studies exists, however, no harms were noted with use of RPM compared to in office measurement for blood glucose (Wei, et al., 2023; Ming, et al., 2016; Kantorowska, et al., 2023).

Heart Failure (HF)
Conway et al. (2014) conducted a systematic review and metaanalysis of RCTs to examine the effect of specific technology used for noninvasive remote monitoring compared with usual care for people with HF. Reductions in all-cause mortality and HF–related hospitalizations were evaluated. Separate metaanalyses were performed according to the specific type of technology used. Four different types of noninvasive remote monitoring technologies were identified (i.e., structured telephone calls, videophone, interactive voice response devices and telemonitoring). Telemonitoring involved transmission of physiological data, such as weight, heart rate and rhythm, oxygen saturations, and blood pressure, from the measuring device to a central server via telephonic, satellite, or broadband capabilities for interpretation by a healthcare team. Only structured telephone calls and telemonitoring were effective in reducing the risk of all-cause mortality ($p = 0.06$ and $p < 0.0001$, respectively) and heart failure–related hospitalizations ($p < 0.001$ and $p = 0.003$, respectively). Data suggest that there is positive health benefit with the use of tememonitoring for an individual with HF.

Inglis et al. (2011) published a systematic review and metaanalysis of 30 RCTS assessing the outcomes of structured telephone support (STS) or telemonitoring (TM) as the primary component of chronic heart failure management. STS was defined as monitoring and/or self-care management delivered using telephone technology where data may have been collected and stored by a computer. TM was defined as digital/broadband/satellite/wireless, or blue-tooth transmission of physiological data (e.g., electrocardiogram, blood pressure, weight, pulse oximetry, respiratory rate) and other data (e.g., self-care, education, lifestyle modification, and medicine administration). Of the 30 RCTs, thirteen studies of STS and four studies of TM examined the effect of these interventions on the risk of CHF-related hospitalization. STS reduced the proportion of patients hospitalized due to CHF by 23% ($p< 0.0001$) while TM reduced the risk of

hospitalization by 21% (p=0.008). Data suggests a positive health benefit with the use of RPM in a population of individuals with chronic heart failure.

Nakamura et al. (2013) published a metaanalysis of 13 RCTs using RPM compared with usual care for 3337 chronic heart failure patients. The primary outcome was mortality. In order to determine which RPM model was most effective, subgroup analyses were conducted by age, severity of illness, measurement frequency, medication management and speed of intervention. The group with rapid intervention had the lowest mortality compared with non-rapid risk intervention (p=0.05). The group with high measurement frequency had lower mortality compared with low measurement frequency (p=0.07). The group with medication management had lower mortality compared with the non-medication management group (p=0.19). Data suggests RPM may be effective in decreasing risk of mortality in chronic heart failure.

Olivari et al. (2018) performed an RCT comparing remote monitoring (RM) (n=229) with usual care (UC) (n=110) in patients with heart failure (HF) who were hospitalized in the previous three months. The primary end-point was the combined 12-month incidence of death by any cause or at least one hospital readmission for HF. The primary endpoint was reached in 101 (44.1%) and 51 (46.4%) patients in the RM and UC groups, respectively, (p=0.78). No difference was seen in mortality (p=0.097) or in the proportion of patients with at least one rehospitalization for HF (p=0.48). A secondary endpoint of quality of life was significantly improved in the RM group, both in physical (p<0.0001) and behavioral health components (p =0.04). Data suggest RM did not result in improved mortality or rehospitaliztion for HF; however, data suggest improved quality of life measures.

Koehler et al. (2018) published results of a RCT comparing RPM (n=796) or usual care (UC) (n=775) for HF. RPM intervention consisted of a daily transmission of physiologic data, including weight, blood pressure, heart rate, analysis of the heart rhythm, peripheral capillary oxygen saturation and a self-rated health status. The percentage of days lost due to unplanned cardiovascular hospital admissions and all-cause death was 4.88% in the RPM group and 6.64% in the UC group (p=0.0460). The all-cause death rate was 7.86 per 100 person-years of follow-up in the remote patient management group compared with 11.34 per 100 person-years of follow-up in the usual care group (p=0.0280). Cardiovascular mortality was not significantly different between the two groups (p=0.0560). Data suggest a positive effect on unplanned admission for cardiovascular conditions and all-cause death in the group who utilized RPM.

Kitsiou et al. (2021) reported results of a metaanalysis and systematic review of 16 RCTs (n=4389) utilizing remote monitoring and clinical feedback for patients with HF. Primary outcomes included all-cause mortality, cardiovascular mortality, HF–related hospitalizations and all-cause hospitalizations compared with usual care. Remote monitoring intervention was heterogeneous between studies. Four trials involved the use of dedicated mobile app. Summary statistics regarding race or ethnicity were provided in four trials. Of these one study included 75% Hispanic/Latino and 25% African American with HF. The other three trials included a majority of white participants (≥67%). Compared with usual care, remote monitoring and clinical feedback reduced the risk of all-cause mortality (risk reduction (p=0.02, high-quality evidence), cardiovascular mortality (p=0.009, high-quality evidence) and heart failure hospitalization (p=0.001, high-quality evidence). No effect was noted on all-cause hospitalizations. Data suggest a positive effect of remote monitoring methods on heart failure.

Klersy et al. (2009) published a metaanalysis of 20 RCTs and twelve cohort studies assessing the effect of RPM compared with usual care on the outcome of patients with chronic HF. RPM was defined as regularly scheduled structured telephone contact between patients and health care providers or electronic transfer of physiological data using remote access technology via remote external, wearable, or implantable electronic devices. Both RCTs and cohort studies demonstrated

a significantly lower number of deaths (RCTs: p=0.006; cohort studies: p<0.001) and hospitalizations (RCTs: p=0.030; cohort studies: p<0.001) with the use of RPM. Data suggest a positive health benefit of RPM on an individual with chronic HF compared with usual care.

Other Conditions
Research utilizing robust study designs is needed to assess the efficacy and value of RPM technology for other conditions. Data are not yet available to determine improved patient outcomes compared to standard of care clinical practice for additional indications.

Asthma
Kew et al. (2016) conducted a systematic review of randomized controlled trials to assess the safety and efficacy of home telemonitoring (i.e., text messaging, web systems, phone calls) with healthcare professional feedback between clinical visits compared with usual care (i.e., educational session, personalized asthma action plan, peak flow meter to encourage self-monitoring at home). Eighteen studies with follow-up times ranging from 3–12 months were included in the review. The number of participants in each study ranged from 16–288 adults and/or children. The authors concluded that "Current evidence does not support the widespread implementation of telemonitoring with healthcare provider feedback between asthma clinic visits. Studies have not yet proved that additional telemonitoring strategies lead to better symptom control or reduced need for oral steroids over usual asthma care, nor have they ruled out unintended harms. Investigators have reported small benefits in quality of life, but these are subject to a risk of bias, as the studies were unblinded. Similarly, some benefits for lung function are uncertain owing to possible attrition bias."

Self-Measured Blood Pressure (SMBP) Monitoring
Evidence in the published, peer-reviewed literature assessing the efficacy of SMBP monitoring compared to usual care is lacking. However, multiple professional society policy statements, practice guidelines, and recommendations support the use of SMBP monitoring for the management of hypertension and hypertensive disorders of pregnancy.

Professional Societies/Organizations
American Heart Association (AHA) and American Medical Association (AMA): In a 2020 joint policy statement (Shimbo, et al. 2020), the AHA and AMA stated that the use of self-measured BP monitoring without cointerventions vs usual care is associated with moderate reductions in SBP and DBP at 6 months and moderate reductions in SBP and DBP and improved BP control at 12 months with cointerventions. They provided the following indications for SMBP monitoring:

- "Diagnosing white-coat hypertension and masked hypertension and identifying white-coat effect and masked uncontrolled hypertension
- Evaluating BP in response to treatment
- Confirming the diagnosis of resistant hypertension
- Detecting morning hypertension"

In their joint policy statement, the AHA and AMA summarize the following professional society statements, guidelines, and position papers that include SMBP monitoring:

American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines:

- In adults with an untreated SBP >130 but <160 mmHg or DBP >80 but <100 mmHg, it is reasonable to screen for the presence of white-coat hypertension by using daytime ABPM or self-measured BP monitoring before diagnosis of hypertension (COR IIa; LOE B-NR).

- In adults with white-coat hypertension, periodic monitoring with either ABPM or self-measured BP monitoring is reasonable to detect transition to sustained hypertension (COR IIa; LOE C-LD).
- In adults with untreated office BPs that are consistently between 120 and 129 mmHg for SBP or between 75 and 79 mmHg for DBP, screening for masked hypertension with self-measured BP monitoring (or ABPM) is reasonable (COR IIa; LOE B-NR).
- In adults on multiple-drug therapies for hypertension and office BPs within 10 mmHg above goal, it may be reasonable to screen for white-coat effect with self-measured BP monitoring (or ABPM) (COR IIb; LOE C-LD).
- It may be reasonable to screen for masked uncontrolled hypertension with self-measured BP monitoring in adults being treated for hypertension with office readings at goal in the presence of target-organ damage or increased overall cardiovascular disease risk (COR IIb; LOE C-EO).

American Heart Association:
- Indications for self-measured BP monitoring include assessing for the presence of white-coat hypertension or masked hypertension, monitoring of antihypertensive medication efficacy in treated patients, assessing for white-coat effect, and assessing for masked uncontrolled hypertension.
- Self-measured BP monitoring can be used to exclude white-coat effect and to confirm the diagnosis of resistant hypertension.

USPSTF:
- Recommended to confirm a diagnosis of high BP when ABPM is not feasible. The USPSTF acknowledged the current barriers, including the availability and affordability of ABPM.

American Society of Hypertension:
- Recommended to confirm diagnosis of high BP and to evaluate white-coat hypertension and masked hypertension. Evaluating BP in response to treatment. Self-measured BP monitoring is preferred over ABPM because performing multiple ABPM sessions in the same patient is impractical.

The authors reported that "SMBP monitoring is a validated approach to measure out-of-office BP and is recognized to be part of hypertension diagnosis and treatment."

American Heart Association (AHA): In a 2022 scientific statement on hypertension in pregnancy (Garovic, et al., 2022), the AHA stated that "out-of-office BP measurements are widely endorsed as more accurate and better predictors of cardiovascular morbidity and mortality" for the general population. "Available information does not demonstrate a systematic difference between self-measurements and office BP measurements in pregnancy, which suggests that appropriate treatment and diagnostic thresholds for self-monitoring during pregnancy may be equivalent to standard clinic thresholds."

International Society for the Study of Hypertension in Pregnancy (ISSHP): In a practice recommendation document (Brown, et al., 2018) on hypertensive disorders of pregnancy, the ISSHP gives the following recommendations related to SMBP monitoring:
- "Home blood pressure monitoring is a useful adjunct in the management of chronic hypertension and is mandatory in the management of white-coat hypertension."
- "Transient gestational hypertension is not a benign disorder; it is associated with approximately 20% chance of developing preeclampsia and a further 20% chance of developing gestational hypertension. Therefore, such women should receive extra monitoring throughout their pregnancy, ideally including home BP measurements."

American College of Obstetricians and Gynecologists: In a report on hypertension in pregnancy (Roberts, et al., 2013), the ACOG provided the following recommendations related to SMBP monitoring during pregnancy:

- "For women with gestational hypertension, monitoring BP at least once weekly with proteinuria assessment in the office with an additional weekly measurement of BP at home or in the office is suggested (Quality of evidence: Moderate; Strength of recommendation: Qualified."
- "For pregnant women with chronic hypertension and poorly controlled BP, the use of home BP monitoring is suggested (Quality of evidence: Moderate; Strength of recommendation: Qualified."

Center for Disease Control and Prevention: In a morbidity and mortality weekly report on hypertensive disorders in pregnancy (Ford, et al., 2022), the CDC stated that "A strategy to address disparities in HDP and pregnancy-related mortality can include strengthening regional networks of health care facilities providing risk-appropriate maternal care through telemedicine. Recommendations for identifying and monitoring pregnant persons with hypertension include measuring blood pressure throughout pregnancy, including self-monitoring."

Remote Therapeutic Monitoring (RTM)
There are limited published, peer-reviewed data regarding the effect of RTM on health outcomes. At this time there is insufficient evidence to support improved health outcomes with remote therapeutic monitoring compared to standard of care clinical practice.

Cystic Fibrosis (CF)
In a 2023 systematic review, Pinto et al. sought to evaluate the benefits and harms of digital health technologies for delivering and monitoring exercise programs, adherence to exercise programs, and improving clinical outcomes in individuals with CF. Interventions and comparators included:

Digital health technologies for monitoring physical activity:

- Wearable fitness tracker plus personalized exercise prescription compared to personalized exercise prescription alone
- Wearable fitness tracker plus text message for personalized feedback and goal setting compared to wearable fitness tracker alone
- Web-based application to record, monitor, and set goals on physical activity plus usual care compared to usual care alone

Digital health technologies for delivering exercise programs:

- Web-based versus face-to-face exercise delivery

The authors concluded that there were methodologic concerns with the RCTs including insufficient information regarding study design, non-blinding of outcome assessors, missing outcome data, short term follow-ups, and small patient populations which led to a rating of low- to very low-certainty of evidence.

Professional Societies/Organizations
Published professional society consensus guidelines are lacking regarding the use of RTM.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No National Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

Remote Physiologic Monitoring (RPM) CPT codes:

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
99453	Remote monitoring of physiologic parameter(s) (eg, 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) (eg, 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)
G0322	The collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (i.e., remote patient monitoring)

Self-Measured Blood Pressure (SMBP) CPT codes:

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

Remote Therapeutic Monitoring (RTM) CPT codes:

98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment

98976	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	**Description**
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
99453	Remote monitoring of physiologic parameter(s) (eg, 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) (eg, 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

CPT®* Codes	Description
	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

HCPCS Codes	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)

ICD-10-CM Diagnosis Codes	Description
E08-E13	Diabetes mellitus
I50.1-I50.9	Heart failure
J44.0-J44.9	Chronic obstructive pulmonary disease
O10.0-O10.9	Pre-existing hypertension complicating pregnancy, childbirth and the puerperium
O11.1-O11.9	Pre-existing hypertension with pre-eclampsia
O13.1-O13.9	Gestational [pregnancy-induced] hypertension without significant proteinuria
O14.0-O14.9	Pre-eclampsia
O15.0-O15.9	Eclampsia
O16.1-O16.9	Unspecified maternal hypertension
O24.0-O24.9	Diabetes mellitus in pregnancy, childbirth, and the puerperium

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other diagnosis codes

Not Covered or Reimbursable:

CPT®* Codes	Description
98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)

References

1. Auener SL, Remers TEP, van Dulmen SA, Westert GP, Kool RB, Jeurissen PPT. The Effect of Noninvasive Telemonitoring for Chronic Heart Failure on Health Care Utilization: Systematic Review. J Med Internet Res. 2021 Sep 29;23(9):e26744.

2. Bollyky JB, Bravata D, Yang J, Williamson M, Schneider J. Remote Lifestyle Coaching Plus a Connected Glucose Meter with Certified Diabetes Educator Support Improves Glucose and Weight Loss for People with Type 2 Diabetes. J Diabetes Res. 2018 May 16;2018:3961730.

3. Blum K, Gottlieb SS. The effect of a randomized trial of home telemonitoring on medical costs, 30-day readmissions, mortality, and health-related quality of life in a cohort of community-dwelling heart failure patients. J Card Fail. 2014 Jul;20(7):513-21.

4. Brown MA, Magee LA, Kenny LC, Karumanchi SA, McCarthy FP, Saito S, Hall DR, Warren CE, Adoyi G, Ishaku S; International Society for the Study of Hypertension in Pregnancy (ISSHP). The hypertensive disorders of pregnancy: ISSHP classification, diagnosis & management recommendations for international practice. Pregnancy Hypertens. 2018 Jul;13:291-310.

5. Calvache-Mateo A, López-López L, Heredia-Ciuró A, Martín-Núñez J, Rodríguez-Torres J, Ortiz-Rubio A, Valenza MC. Efficacy of Web-Based Supportive Interventions in Quality of Life in COPD Patients, a Systematic Review and Meta-Analysis. Int J Environ Res Public Health. 2021 Dec 2;18(23):12692.

6. Castelyn G, Laranjo L, Schreier G, Gallego B. Predictive performance and impact of algorithms in remote monitoring of chronic conditions: A systematic review and meta-analysis. Int J Med Inform. 2021 Dec;156:104620.

7. Centers for Disease Control and Prevention (CDC). Million Hearts. Self-Measured Blood Pressure (SMBP) Monitoring. Sep 29, 2023. Accessed Apr 4, 2024. Available at URL address: https://millionhearts.hhs.gov/tools-protocols/tools/smbp.html

8. Center for Medicare and Medicaid Services. Department of Health and Human Services. Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-payment Medical Review Requirements. Accessed April 3, 2024. Available at URL address: https://public-inspection.federalregister.gov/2021-23972.pdf

9. Conway A, Inglis SC, Clark RA. Effective technologies for noninvasive remote monitoring in heart failure. Telemed J E Health. 2014 Jun;20(6):531-8.

10. Cooper CB, Sirichana W, Arnold MT, Neufeld EV, Taylor M, Wang X, Dolezal BA. Remote Patient Monitoring for the Detection of COPD Exacerbations. Int J Chron Obstruct Pulmon Dis. 2020 Aug 24;15:2005-2013.

11. Ely DM and Driscoll AK. Infant Mortality by Selected Maternal Characteristics and Race and Hispanic Origin in the United States, 2019–2021. National vital statistics reports; vol 73 no 3. Hyattsville, MD: National Center for Health Statistics. 2024.

12. Flodgren G, Rachas A, Farmer AJ, Inzitari M, Shepperd S. Interactive telemedicine: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2015 Sep 7;2015(9):CD002098.

13. Ford ND, Cox S, Ko JY, et al. Hypertensive Disorders in Pregnancy and Mortality at Delivery Hospitalization — United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2022;71:585–591.

14. Galinier M, Roubille F, Berdague P, Brierre G, Cantie P, Dary P, et al. Telemonitoring versus standard care in heart failure: a randomised multicentre trial. Eur J Heart Fail. 2020 Jun;22(6):985-994.

15. Garovic VD, Dechend R, Easterling T, Karumanchi SA, McMurtry Baird S, Magee LA, Rana S, Vermunt JV, August P; American Heart Association Council on Hypertension; Council on the Kidney in Cardiovascular Disease, Kidney in Heart Disease Science Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; and Stroke Council. Hypertension in Pregnancy: Diagnosis, Blood Pressure Goals, and Pharmacotherapy: A Scientific Statement From the American Heart Association. Hypertension. 2022 Feb;79(2):e21-e41.

16. Health Resources and Services Administration (HRSA). Telehealth for chronic conditions. Mar 25, 2022. Accessed Apr 3, 2024. Available at URL address: https://telehealth.hhs.gov/providers/telehealth-for-chronic-conditions/getting-started/

17. Hong Y, Lee SH. Effectiveness of tele-monitoring by patient severity and intervention type in chronic obstructive pulmonary disease patients: A systematic review and meta-analysis. International Journal of Nursing Studies. 2019;92:1-15. PubMed PMID: 30690162.

18. Inglis SC, Clark RA, Dierckx R, Prieto-Merino D, Cleland JGF. Structured telephone support or non-invasive telemonitoring for patients with heart failure. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD007228.

19. Inglis SC, Clark RA, McAlister FA, Stewart S, Cleland JG. Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Cochrane Review. Eur J Heart Fail. 2011 Sep;13(9):1028-40.

20. Janjua S, Carter D, Threapleton CJ, Prigmore S, Disler RT. Telehealth interventions: remote monitoring and consultations for people with chronic obstructive pulmonary disease (COPD). Cochrane Database Syst Rev. 2021 Jul 20;7(7):CD013196.

21. Jenneve A, Lorenzo-Villalba N, Courdier G, Talha S, Séverac F, Zulfiqar AA, et al. Benefit of Ambulatory Management of Patients with Chronic Heart Failure by Protocolized Follow-Up Therapeutic Education and Remote Monitoring Solution: An Original Study in 159 Patients. J Clin Med. 2020 Sep 25;9(10):3106.

22. Kantorowska A, Cohen K, Oberlander M, Jaysing AR, Akerman MB, Wise AM, Mann DM, Testa PA, Chavez MR, Vintzileos AM, Heo HJ. Remote patient monitoring for management of diabetes mellitus in pregnancy is associated with improved maternal and neonatal outcomes. Am J Obstet Gynecol. 2023 Jun;228(6):726.e1-726.e11.

23. Kew KM, Cates CJ. Home telemonitoring and remote feedback between clinic visits for asthma. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD011714.

24. Kitsiou S, Vatani H, Paré G, Gerber BS, Buchholz SW, Kansal MM, et al. Effectiveness of Mobile Health Technology Interventions for Patients With Heart Failure: Systematic Review and Meta-analysis. Can J Cardiol. 2021 Aug;37(8):1248-1259.

25. Klersy C, De Silvestri A, Gabutti G, Regoli F, Auricchio A. A meta-analysis of remote monitoring of heart failure patients. J Am Coll Cardiol. 2009 Oct 27;54(18):1683-94.

26. Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Kirwan BA, et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. Lancet. 2018 Sep 22;392(10152):1047-1057.

27. Lee JY, Chan CKY, Chua SS, Ng CJ, Paraidathathu T, Lee KKC, et al. Telemonitoring and Team-Based Management of Glycemic Control on People with Type 2 Diabetes: a Cluster-Randomized Controlled Trial. J Gen Intern Med. 2020 Jan;35(1):87-94.

28. 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.

29. Leo DG, Buckley BJR, Chowdhury M, Harrison SL, Isanejad M, Lip GYH, Wright DJ, Lane DA; TAILOR investigators. Interactive Remote Patient Monitoring Devices for Managing

Chronic Health Conditions: Systematic Review and Meta-analysis. J Med Internet Res. 2022 Nov 3;24(11):e35508.

30. Ming WK, Mackillop LH, Farmer AJ, Loerup L, Bartlett K, Levy JC, Tarassenko L, Velardo C, Kenworthy Y, Hirst JE. Telemedicine Technologies for Diabetes in Pregnancy: A Systematic Review and Meta-Analysis. J Med Internet Res. 2016 Nov 9;18(11):e290.

31. Nakamura N, Koga T, Iseki H. A meta-analysis of remote patient monitoring for chronic heart failure patients. J Telemed Telecare. 2014 Jan;20(1):11-7. doi: 10.1177/1357633X13517352. Epub 2013 Dec 18. PMID: 24352899.

32. Olivari Z, Giacomelli S, Gubian L, Mancin S, Visentin E, Di Francesco V, et al. Erratum to "The effectiveness of remote monitoring of elderly patients after hospitalisation for heart failure: The renewing health European project" [Int. J. Cardiol. 257 (2018) 137-142]. Int J Cardiol. 2018 Jul 15;263:189.

33. Ong MK, Romano PS, Edgington S, Aronow HU, Auerbach AD, Black JT, et al. Better Effectiveness After Transition–Heart Failure (BEAT-HF) Research Group. Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition -- Heart Failure (BEAT-HF) Randomized Clinical Trial. JAMA Intern Med. 2016 Mar;176(3):310-8.

34. Pandor A, Thokala P, Gomersall T, Baalbaki H, Stevens JW, Wang J, et al. Home telemonitoring or structured telephone support programmes after recent discharge in patients with heart failure: systematic review and economic evaluation. Health Technol Assess. 2013 Aug;17(32):1-207, v-vi. doi: 10.3310/hta17320. PMID: 23927840; PMCID: PMC4781365.

35. Pinto ACPN, Piva SR, Rocha A, Gomes-Neto M, Atallah ÁN, Saconato H, Trevisani VFM. Digital technology for delivering and monitoring exercise programs for people with cystic fibrosis. Cochrane Database of Systematic Reviews 2023, Issue 6. Art. No.: CD014605 (Summary).

36. Rahimi K, Nazarzadeh M, Pinho-Gomes AC, Woodward M, Salimi-Khorshidi G, Ohkuma T, et al. Home monitoring with technology-supported management in chronic heart failure: a randomised trial. Heart. 2020 Oct;106(20):1573-1578.

37. Roberts JM, August PA, Bakris G, Barton JR, Bernstein IM, Druzin ML, Gaiser RR, Granger JP, Jeyabalan A, Johnson DD, et al. Hypertension in pregnancy: report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy. Obstet Gynecol. 2013;122:1122–1131.

38. Shimbo D, Artinian NT, Basile JN, Krakoff LR, Margolis KL, Rakotz MK, Wozniak G; American Heart Association and the American Medical Association. Self-Measured Blood Pressure Monitoring at Home: A Joint Policy Statement From the American Heart Association and American Medical Association. Circulation. 2020 Jul 28;142(4):e42-e63.

39. Soriano JB, García-Río F, Vázquez-Espinosa E, Conforto JI, Hernando-Sanz A, López-Yepes L, Galera-Martínez R, Peces-Barba G, Gotera-Rivera CM, Pérez-Warnisher MT, Segrelles-Calvo G, Zamarro C, González-Ponce P, Ramos MI, Jafri S, Ancochea J. A multicentre, randomized controlled trial of telehealth for the management of COPD. Respir Med. 2018 Nov;144:74-81.

40. Taylor ML, Thomas EE, Snoswell CL, Smith AC, Caffery LJ. Does remote patient monitoring reduce acute care use? A systematic review. BMJ Open. 2021 Mar 2;11(3):e040232.

41. U.S. Food and Drug Administration (FDA). Devices@FDA. Product codes: HPT, POS, GYD, JWH, MHX. Accessed Apr 4, 2024. Available at URL address: https://www.accessdata.fda.gov/SCRIPTS/cdrh/devicesatfda/index.cfm

42. U.S. Food and Drug Administration (FDA). Remote or Wearable Patient Monitoring Devices EUAs. Content current as of: Nov 8, 2023. Accessed April 4, 2024. Available at URL address: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas#:~:text=The%20FDA%20has%20issued%20EUAs,during%20the%20COVID%2D19%20pandemic.

43. VA/DoD Clinical Practice Guideline. (2021). The management of chronic obstructive pulmonary disease. Accessed Apr 4, 2024. Available at URL address: https://www.healthquality.va.gov/guidelines/CD/copd/VADoDCOPDCPGFinal508.pdf

44. VA/DoD Clinical Practice Guideline. (2023). The management of type 2 diabetes mellitus. Accessed Apr 4, 2024. Available at URL address: https://www.healthquality.va.gov/guidelines/CD/diabetes/VADoD-Diabetes-CPG_Final_508.pdf

45. Vegesna A, Tran M, Angelaccio M, Arcona S. Remote Patient Monitoring via Non-Invasive Digital Technologies: A Systematic Review. Telemed J E Health. 2017 Jan;23(1):3-17.

46. Vianello A, Fusello M, Gubian L, Rinaldo C, Dario C, Concas A, Saccavini C, Battistella L, Pellizzon G, Zanardi G, Mancin S. Home telemonitoring for patients with acute exacerbation of chronic obstructive pulmonary disease: a randomized controlled trial. BMC Pulm Med. 2016 Nov 22;16(1):157.

47. Walker PP, Pompilio PP, Zanaboni P, Bergmo TS, Prikk K, Malinovschi A, Montserrat JM, Middlemass J, Šonc S, Munaro G, Marušič D, Sepper R, Rosso R, Siriwardena AN, Janson C, Farré R, Calverley PMA, Dellaca' RL. Telemonitoring in Chronic Obstructive Pulmonary Disease (CHROMED). A Randomized Clinical Trial. Am J Respir Crit Care Med. 2018 Sep 1;198(5):620-628.

48. Wei HX, Yang YL, Luo TY, Chen WQ. Effectiveness of mobile health interventions for pregnant women with gestational diabetes mellitus: a systematic review and meta-analysis. J Obstet Gynaecol. 2023 Dec;43(2):2245906.

49. Wei NJ, Nathan DM, Wexler DJ. Glycemic control after hospital discharge in insulin-treated type 2 diabetes: a randomized pilot study of daily remote glucose monitoring. Endocr Pract. 2015 Feb;21(2):115-21.

50. Zakeri R, Morgan JM, Phillips P, Kitt S, Ng GA, McComb JM, Williams S, Wright DJ, Gill JS, Seed A, Witte KK, Cowie MR; REM-HF Investigators. Impact of remote monitoring on clinical outcomes for patients with heart failure and atrial fibrillation: results from the REM-HF trial. Eur J Heart Fail. 2020 Mar;22(3):543-553.

Revision Details

Type of Revision	Summary of Changes	Date
Focused Review	• Added policy statement for gestational diabetes and hypertensive disorders of pregnancy.	9/15/2024
Annual Review	• Title change • Added policy statement for self-measured blood pressure monitoring • Removed policy statement criteria requiring FDA approval/clearance. • Revised policy statement for RPM for any other indication.	5/15/2024
New Policy	New policy created.	5/15/2023