

UnitedHealthcare® Medicare Advantage *Medical Policy*

Remote Physiologic Monitoring (RPM)

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Related Medicare Advantage Reimbursement Policies

- Telehealth and Telemedicine Policy, Professional
- <u>Time Span Codes Policy, Professional</u>

Coverage Rationale

Overview

Remote physiologic monitoring (RPM) allows a patient to collect their own health data (for example, blood pressure, pulse, and respiratory rate) using a connected Medical Device that automatically transmits the data to their provider. The provider then uses this data to treat or manage the patient's condition.

Remote physiologic monitoring (RPM) is structured around three key components that build upon one another to support effective patient care. It begins with patient education and device setup, where patients learn how to properly use monitoring devices and accurately collect health data. The next step involves device supply, which includes providing appropriate devices, ensuring they are correctly connected to transmit data, and guiding patients on how frequently to use them. Finally, treatment management focuses on reviewing the collected data to make informed clinical decisions aimed at improving patient health outcomes.

Mobile health (mHealth) represents a rapidly advancing area within technology-driven healthcare. According to the National Institutes of Health, mHealth involves the use of mobile and wireless technologies such as smartphones and tablets to enhance health outcomes, healthcare delivery, and medical research. Unlike traditional Medical Devices, mobile health applications are not subject to the same rigorous testing or clinical validation processes. They also do not require supervision by healthcare professionals. For the purposes of this policy, mobile health apps are categorized as tools for self-care, self-management, and self-monitoring.

CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for remote physiologic monitoring (RPM).

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the coverage rationale below.

Remote physiologic monitoring (RPM) is reasonable and necessary when the individual has one or more of the following conditions:

- Heart failure (HF)
- Hypertensive disorders of pregnancy (HDP)

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Remote physiologic monitoring (RPM) is not reasonable and necessary due to insufficient evidence of efficacy for all other indications not listed as reasonable and necessary, including but not limited to:

- Anxiety
- Bipolar disorder
- Chronic obstructive pulmonary disease (COPD)
- Depression
- Diabetes mellitus (DM)
- Gestational diabetes
- Hypertension (HTN) other than hypertensive disorders of pregnancy (HDP)
- Obstructive sleep apnea (OSA)
- Schizoaffective disorder

Note: For guidance on diabetes management, refer to the DME MAC LCD for Glucose Monitors (L33822).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Remote Physiolo	egic Monitoring (RPM)
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
99445	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
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); device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar 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 1 real-time interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes

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

Diagnosis Code	Description
150.1	Left ventricular failure, unspecified

Diagnosis Code	Description
150.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
150.22	Chronic systolic (congestive) heart failure
150.23	Acute on chronic systolic (congestive) heart failure
150.30	Unspecified diastolic (congestive) heart failure
150.31	Acute diastolic (congestive) heart failure
150.32	Chronic diastolic (congestive) heart failure
150.33	Acute on chronic diastolic (congestive) heart failure
150.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
150.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
150.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
150.814	Right heart failure due to left heart failure
150.82	Biventricular heart failure
150.83	High output heart failure
150.84	End stage heart failure
150.89	Other heart failure
150.9	Heart failure, unspecified
O10.011	Pre-existing essential hypertension complicating pregnancy, first trimester
O10.012	Pre-existing essential hypertension complicating pregnancy, second trimester
O10.013	Pre-existing essential hypertension complicating pregnancy, third trimester
O10.019	Pre-existing essential hypertension complicating pregnancy, unspecified trimester
O10.02	Pre-existing essential hypertension complicating childbirth
O10.03	Pre-existing essential hypertension complicating the puerperium
010.111	Pre-existing hypertensive heart disease complicating pregnancy, first trimester
010.112	Pre-existing hypertensive heart disease complicating pregnancy, second trimester
O10.113	Pre-existing hypertensive heart disease complicating pregnancy, third trimester
010.119	Pre-existing hypertensive heart disease complicating pregnancy, unspecified trimester
O10.12	Pre-existing hypertensive heart disease complicating childbirth
O10.13	Pre-existing hypertensive heart disease complicating the puerperium
010.211	Pre-existing hypertensive chronic kidney disease complicating pregnancy, first trimester
010.212	Pre-existing hypertensive chronic kidney disease complicating pregnancy, second trimester
010.213	Pre-existing hypertensive chronic kidney disease complicating pregnancy, third trimester
O10.219	Pre-existing hypertensive chronic kidney disease complicating pregnancy, unspecified trimester
010.22	Pre-existing hypertensive chronic kidney disease complicating childbirth
O10.23	Pre-existing hypertensive chronic kidney disease complicating the puerperium
010.311	Pre-existing hypertensive heart and chronic kidney disease complicating pregnancy, first trimester
O10.312	Pre-existing hypertensive heart and chronic kidney disease complicating pregnancy, second trimester
O10.313	Pre-existing hypertensive heart and chronic kidney disease complicating pregnancy, third trimester
O10.319	Pre-existing hypertensive heart and chronic kidney disease complicating pregnancy, unspecified trimester

Diagnosis Code	Description
O10.32	Pre-existing hypertensive heart and chronic kidney disease complicating childbirth
O10.33	Pre-existing hypertensive heart and chronic kidney disease complicating the puerperium
O10.411	Pre-existing secondary hypertension complicating pregnancy, first trimester
O10.412	Pre-existing secondary hypertension complicating pregnancy, second trimester
O10.413	Pre-existing secondary hypertension complicating pregnancy, third trimester
O10.419	Pre-existing secondary hypertension complicating pregnancy, unspecified trimester
O10.42	Pre-existing secondary hypertension complicating childbirth
O10.43	Pre-existing secondary hypertension complicating the puerperium
O10.911	Unspecified pre-existing hypertension complicating pregnancy, first trimester
O10.912	Unspecified pre-existing hypertension complicating pregnancy, second trimester
O10.913	Unspecified pre-existing hypertension complicating pregnancy, third trimester
O10.919	Unspecified pre-existing hypertension complicating pregnancy, unspecified trimester
O10.92	Unspecified pre-existing hypertension complicating childbirth
O10.93	Unspecified pre-existing hypertension complicating the puerperium
011.1	Pre-existing hypertension with pre-eclampsia, first trimester
011.2	Pre-existing hypertension with pre-eclampsia, second trimester
O11.3	Pre-existing hypertension with pre-eclampsia, third trimester
O11.4	Pre-existing hypertension with pre-eclampsia, complicating childbirth
O11.5	Pre-existing hypertension with pre-eclampsia, complicating the puerperium
O11.9	Pre-existing hypertension with pre-eclampsia, unspecified trimester
O13.1	Gestational [pregnancy-induced] hypertension without significant proteinuria, first trimester
O13.2	Gestational [pregnancy-induced] hypertension without significant proteinuria, second trimester
O13.3	Gestational [pregnancy-induced] hypertension without significant proteinuria, third trimester
O13.4	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating childbirth
O13.5	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating the puerperium
O13.9	Gestational [pregnancy-induced] hypertension without significant proteinuria, unspecified trimester
O14.00	Mild to moderate pre-eclampsia, unspecified trimester
O14.02	Mild to moderate pre-eclampsia, second trimester
O14.03	Mild to moderate pre-eclampsia, third trimester
O14.04	Mild to moderate pre-eclampsia, complicating childbirth
O14.05	Mild to moderate pre-eclampsia, complicating the puerperium
O14.10	Severe pre-eclampsia, unspecified trimester
O14.12	Severe pre-eclampsia, second trimester
O14.13	Severe pre-eclampsia, third trimester
O14.14	Severe pre-eclampsia complicating childbirth
O14.15	Severe pre-eclampsia, complicating the puerperium
O14.20	HELLP syndrome (HELLP), unspecified trimester
O14.22	HELLP syndrome (HELLP), second trimester
O14.23	HELLP syndrome (HELLP), third trimester
O14.24	HELLP syndrome, complicating childbirth
O14.25	HELLP syndrome, complicating the puerperium
O14.90	Unspecified pre-eclampsia, unspecified trimester
O14.92	Unspecified pre-eclampsia, second trimester
O14.93	Unspecified pre-eclampsia, third trimester

Diagnosis Code	Description
O14.94	Unspecified pre-eclampsia, complicating childbirth
O14.95	Unspecified pre-eclampsia, complicating the puerperium
O15.00	Eclampsia complicating pregnancy, unspecified trimester
O15.02	Eclampsia complicating pregnancy, second trimester
O15.03	Eclampsia complicating pregnancy, third trimester
O15.1	Eclampsia complicating labor
O15.2	Eclampsia complicating the puerperium
O15.9	Eclampsia, unspecified as to time period
O16.1	Unspecified maternal hypertension, first trimester
O16.2	Unspecified maternal hypertension, second trimester
O16.3	Unspecified maternal hypertension, third trimester
O16.4	Unspecified maternal hypertension, complicating childbirth
O16.5	Unspecified maternal hypertension, complicating the puerperium
O16.9	Unspecified maternal hypertension, unspecified trimester

Definitions

Auxiliary Personnel: Any individual who is acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician, or of the legal entity that employs or contracts with the physician. Likewise, the supervising physician may be an employee, leased employee or independent contractor of the legal entity billing and receiving payment for the services or supplies. Refer to the Medicare Benefit Policy Manual, Chapter 15, §110.1 – Incident To Physician's Professional Services.

Established Patient: An individual who has received any professional services, including Evaluation and Management (E/M) services or other face-to-face services (e.g., surgical procedures), from the same physician or another physician of the same specialty within the same group practice, within the past three years. Refer to New Patient vs Established Patient Visit - JE Part B - Noridian and New Patient vs Established Patients - CGS.

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- :Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- :Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its
 primary intended purposes through chemical action within or on the body of man or other animals and which is not
 dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not
 include software functions excluded pursuant to section 520(o):. Refer to How to Determine if Your Product is a Medical Device | FDA.

New Patient: One who has not received any professional services, [e.g., E/M service or other face-to-face service (e.g., surgical procedure)] from the physician or physician group practice (same physician specialty) within the previous 3 years. Refer to New Patient Visits: Incorrect Coding | CMS.

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the <u>Medicare Coverage Database</u>, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the <u>Coverage Rationale</u> section above.

Medicare Administrative Contractor (MAC) With Corresponding States/Territories		
MAC Name (Abbreviation)	States/Territories	
CGS Administrators, LLC (CGS)	KY, OH	
First Coast Service Options, Inc. (First Coast)	FL, PR, VI	

Medicare Administrative Contractor (MAC) With Corresponding States/Territories		
MAC Name (Abbreviation)	States/Territories	
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI	
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY	
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**	
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV	
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE	

Notes

*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers.

MLN Matters

CMS Booklet MLN901705, Telehealth & Remote Patient Monitoring: April 2025. CMS MLN Connects, Remote Patient Monitoring Use & Bill: July 2025.

Others

Code of Federal Regulations, § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Clinical Evidence

Heart Failure (HF)

Dawson et al. (2021) conducted a prospective, randomized controlled trial to compare 30-day readmission rates and mortality for patients at high risk for readmission who received home telemonitoring versus standard care. The intervention group received home-installed equipment to measure blood pressure, heart rate, pulse oximetry, weight if heart failure was present, and glucose if diabetes was present. Results were transmitted daily and reviewed by a trained nurse. Both groups received standard care. Standard care included but was not limited to teach-back education, medication reconciliation, and a follow-up phone call within 72 hours of discharge. The study included a total of 1380 participants. Patients were 1:1 randomized to standard care (n = 690) or telemonitoring (n = 690). Using a modified intention-to-treat analysis, the risk of readmission or death within 30 days among patients at high readmission risk was 23.7% (137/578) in the control group and 18.2% (87/477) in the telemonitoring group. Emergency department visits occurred within 30 days after discharge in 14.2% (81/570) of patients in the control group and 8.6% (40/464) of patients in the telemonitoring. The intensity of remote monitoring interventions was limited to daily business hours, although patient data was uploaded to a cloud-based system 24 hours per day. The authors concluded that the study demonstrated that thirty days of post discharge telemonitoring may reduce readmissions of high-risk patients.

The Optimization of the Ambulatory Monitoring for Patients with Heart Failure by Tele-cardiology (OSICAT) study (Galinier et al., 2020) was a randomized, multicenter, open-label French study in 937 patients hospitalized for acute heart failure $(HF) \le 12$ months before inclusion. The primary goal of the study was to assess the effect of a telemonitoring program vs. standard care (SC) in preventing all-cause deaths or unplanned hospitalizations over 18 months of follow-up in patients with HF. Patients were randomized to telemonitoring (daily body weight measurement, daily recording of HF symptoms, and personalized education) (n = 482) or to SC (n = 455). In New York Heart Association (NYHA) class III or IV HF. median time to all-cause death or first unplanned hospitalization was 82 days in the telemonitoring group and 67 days in the SC group. The relative risk reduction was 29% in patients with NYHA class III or IV HF (hazard ratio 0.71, 95% CI 0.53-0.95; p = 0.02), 38% in socially isolated patients (hazard ratio 0.62, 95% CI 0.39-0.98; p = 0.043), and 37% in patients who were ≥ 70% adherent to body weight (hazard ratio 0.63, 95% CI 0.45-0.88; p = 0.006). There were statistically significant improvements in vitality (p-0.034) and social functioning (p-0.025) for telemonitoring vs. SC. The authors concluded that telemonitoring did not result in a significantly lower rate of all-cause deaths or unplanned hospitalizations in HF patients. Data on body weight and frequency of measurement were not collected in the SC group to avoid interference with routine management. The relative risk reduction of 30% used in the sample size estimation may have been overestimated and thus the study did not have sufficient power to detect a benefit from telemonitoring in the overall population. The primary outcome of all-cause deaths or unplanned hospitalizations at 18 months was broad based.

^{**}For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.

However, among the secondary outcomes, after adjustment for known predictive factors, telemonitoring was associated with a 21% relative risk reduction in first unplanned hospitalization for HF (hazard ratio 0.79, 95% CI 0.62-0.99; p = 0.044), the relative risk reduction was 29% in patients with NYHA class III or IV HF (HR 0.71, 95% CI 0.53-0.95; P-0.02), 38% in socially isolated patients (HR 0.62, 95% CI 0.38-0.98; p = 0.043) and 37% in patients who were ≥ 70% adherent to body weight measurement (HR 0.63, 95% CI 0.45–0.88; p = 0.006).

Olivari et al. (2018) conducted a randomized control trial (RCT) to explore the effectiveness of remote monitoring (RM) in individuals > 65 years old with heart failure (HF) after hospital discharge. The study included 339 participants that were randomized: RM group (n = 229) and usual care (UC) group (n = 110). The primary endpoint (PE) of the study was the combined occurrence of 12-month all-cause mortality or at least one hospitalization for HF. The secondary endpoints were: 12-month all-cause mortality, number of hospitalizations for all causes and for heart failure, duration of hospitalizations, number of scheduled and urgent outpatient controls and health related quality of life as measured by SF36v2. The authors identified in the intention-to-treat analysis, the PE occurred in 44.1% (RM) and 46.4% (UC) of participants in groups, respectively (p = 0.78). Additionally, there was no difference in all-cause mortality (p = 0.097) or in the proportion of patients with at least one rehospitalization for HF (p = 0.48). Secondary endpoint measured by SF36v2 scores, identified quality of life was significantly improved in the RM group, both in physical (2.63 score difference, p < 0.0001) and mental (1.69 score difference, p = 0.04) components. In the on-treatment analysis, comparing 190 individuals that ultimately received RM with the 149 remaining individuals, the primary end-point was reached in 40% vs 51% (p = 0.055), respectively. The authors concluded that RM did not improve the PE of all-cause mortality and hospital admissions for HF; however, RM improved the participants' quality of life (small improvements of SF36v2 score).

Conway et al. (2014) conducted a systematic review and meta-analysis on the effect of specific technology used for noninvasive remote monitoring of people with heart failure on all-cause mortality and heart failure—related hospitalizations. Four different modes of noninvasive remote monitoring technologies were identified among the 25 randomized controlled trials. The four different types of noninvasive remote monitoring technologies identified were structured telephone calls, videophone, interactive voice response devices, and telemonitoring (which 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 the healthcare team). The authors results showed structured telephone calls and telemonitoring were effective in reducing the risk of all-cause mortality (p = 0.06; p < 0.0001, respectively) and heart failure—related hospitalizations (p < 0.001; p = 0.003, respectively). The authors concluded that two of the four specific technologies (structured telephone calls and telemonitoring) used for noninvasive remote monitoring in heart failure improved outcomes. More research data is required to evaluate the effectiveness of videophone and interactive voice response technologies.

Hypertensive Disorders of Pregnancy (HDP)

Kalafat et al. (2020) conducted a systematic review and meta-analysis to investigate the safety and efficacy of home blood pressure monitoring (HBPM) during pregnancy. This meta-analysis included nine studies (four observational and five randomized trials) that met inclusion criteria. Eight of the 11 included studies used telemonitoring. The study identified categorical outcomes [labor induction, neonatal intensive care unit (NICU) admission, prenatal hospital admission, diagnosis of pre-eclampsia, preterm delivery, intrauterine growth restriction, composite maternal, fetal, and neonatal outcomes] and continuous outcomes (antenatal visits, gestational age at delivery, ultrasound scans). The author's findings identified the use of HBPM during the antenatal period was associated with reduced odds of labor induction (OR: 0.55, 95% CI: 0.36–0.82, 444 women, I² = 0%), prenatal hospital admissions (OR: 0.31, 95% CI: 0.19–0.49, 416 women, I² = 0%) and diagnosis of preeclampsia (OR: 0.50, 95% CI: 0.31–0.81, 725 women, I² = 37%). The number of antenatal visits was significantly less in the HBPM group (standard mean difference: -0.49, 95% CI: -0.82 to-0.16, 738 women, I² = 75%). Regarding composite maternal, fetal, or neonatal outcomes when used during the antenatal period, no significant differences were identified. The authors concluded HBPM in pregnancy appears to be a safe and effective method for reducing antenatal visits, prenatal hospital admissions, diagnosis of preeclampsia and induction of labor in pregnancies being monitored for HDP.

In a cohort study, Kalafat et al. (2019) assessed the safety and efficacy of home blood pressure monitoring (HBPM) and office (traditional) blood pressure measurements in a cohort of pregnant women with gestational hypertension (GH). The study included 143 women (80 HBPM vs 63 standard care) with GH using the automated Microlife® "WatchBP Home" BP machine. Main endpoints measured were adverse fetal, neonatal, and maternal outcomes, and the number of antenatal hospital visits in comparison between HBPM and office (traditional) pathways. The authors identified there were no significant difference between the two groups in maternal high-dependency unit admission (p = 0.999), birthweight centile (p = 0.803), fetal growth restriction (p = 0.999), neonatal intensive care unit admissions (p = 0.507) and composite neonatal (p = 0.654), maternal (p = 0.999) or fetal adverse outcomes (p = 0.999). The HBPM group was significantly lower than the traditional pathway (p = 0.009) in the number of Day Assessment Unit (DAU) visits. The difference was greater when the number of visits was adjusted for the duration of monitoring in weeks (p < 0.001). No difference was observed

between the groups regarding the total number of outpatient (p = 0.357) and triage visits (p = 0.237). However, the total number of antenatal visits adjusted for the duration of monitoring was significantly lower for the HBPM group compared to the traditional pathway (p = 0.020). The authors concluded HBPM in women with GH results in significantly less antenatal visits compared to women on a traditional pathway of care. The two groups had comparable fetal, neonatal, and maternal adverse outcomes. In addition, large multicenter studies are needed to ascertain the safety of rare adverse pregnancy outcomes in women with HDP.

Clinical Practice Guidelines International Society for the Study of Hypertension in Pregnancy (ISSHP)

In the hypertensive disorders of pregnancy: ISSHP classification, diagnosis & management recommendations for international practice the following recommendations state:

- Diagnosis of hypertension and proteinuria.
 - 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.
 - 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.
- Chronic essential hypertension.
 - Home blood pressure monitoring is a very useful adjunct to clinic visits if available; about ³/₄ home BP devices are accurate so we recommend checking device accuracy against a sphygmomanometer for each woman (Brown, 2018).

Chronic Obstructive Pulmonary Disease (COPD)

There is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of RPM for chronic obstructive pulmonary disease (COPD). Identified studies reported conflicting findings and are insufficient to demonstrate the clinical usefulness of RPM compared to standard of care for this diagnosis.

Janjua et al. (2021) conducted a Cochrane systematic review to assess the effectiveness of telehealth interventions that allow remote monitoring and consultation and multi-component interventions for reducing exacerbations and improving quality of life, while reducing dyspnea symptoms, hospital service utilization, and death among people with COPD. Interventions included remote monitoring or consultation plus usual care, remote monitoring or consultation alone, and multi-component interventions from all care settings. Quality of life scales included St George's Respiratory Questionnaire (SGRQ) and the COPD Assessment Test (CAT). The dyspnea symptom scale used was the Chronic Respiratory Disease Questionnaire Self-Administered Standardized Scale (CRQ-SAS). Twenty-nine randomized controlled studies were included in the review (5654 participants). Most remote monitoring interventions required participants to transfer measurements using a remote device and later health professional review. Only five interventions transferred data and allowed review by health professionals in real time. No evidence of comparison of remote consultations with or without usual care was found. Remote monitoring plus usual care (8 studies, 1033 participants) with very uncertain evidence suggested that remote monitoring plus usual care may have little to no effect on the number of people experiencing exacerbations at 26 weeks or 52 weeks. There may be little to no difference in effect on quality of life (SGRQ) at 26 weeks (very low to low certainty) or on hospitalization. There may be little to no difference in deaths. No evidence of dyspnea symptoms or adverse events was found. Remote monitoring alone (10 studies, 2456 participants) with very uncertain evidence suggested that remote monitoring may result in little to no effect on the number of people experiencing exacerbations at 41 weeks. There may be little to no effect on quality of life. There may be little to no effect on dyspnea symptoms on the CRQ-SAS at 26 weeks (low certainty). There may be no difference in effects on the number of people admitted to hospital (very low certainty) or on deaths (very low certainty). No evidence of adverse events was found. Multicomponent interventions with remote monitoring or consultation component (11 studies, 2165 participants) with very uncertain evidence suggested that multi-component interventions may have little to no effect on the number of people experiencing exacerbations at 52 weeks. Quality of life at 13 weeks may improve as seen in SGRQ total score but not at 26 or 52 weeks (very low certainty). COPD assessment test (CAT) scores may improve at a mean of 38 weeks, but evidence is very uncertain, and interventions were varied. There may be little to no effect on the number of people admitted to hospital at 33 weeks (low certainty). There may be little to no difference in death at a mean of 40 weeks (very low certainty). There may be little to no effect on people experiencing adverse events (very low certainty). No evidence for dyspnea symptoms was found. The authors concluded that remote monitoring plus usual care may not be beneficial overall compared to usual care alone. Some benefit was seen in reduction of COPD-related hospital re-admissions, but moderate-certainty evidence is based on one study. Remote monitoring interventions alone are no better than usual care overall for health outcomes. Multi-component interventions are no better than usual care but may provide short-term benefit for quality of life and may result in fewer re-admissions to hospital for any cause. Studies were at high risk of bias

due to lack of blinding, and certainty of evidence ranged from moderate to very low. More studies are needed to determine whether telehealth provides any long-term benefits for people with COPD of varying severity. (Soriano et al. 2018, Walker et al. 2018 and Vianello et al. 2016, which are summarized below, are included in this systematic review).

Soriano et al. (2018) conducted a multicenter, randomized, 12-month trial. The principal objective was to estimate the effectiveness of a home telehealth (HTH) strategy in managing patients with severe-very severe COPD when compared to routine clinical practice (RCP). The main variable was changes in the number of severe exacerbations, defined as those resulting in a hospital admission or a visit to the hospital emergency services. Inclusion criteria for study participants were: aged 50-90 years old; diagnosis of COPD; with severe airflow obstruction defined as the forced expiratory volume in the first second (FEV1) below 50% of the predicted level, treated with chronic home oxygen therapy; and suffering two or more moderate or severe exacerbations in the previous year, but currently clinically stable (defined as 6 weeks without clinical symptoms since the last COPD exacerbation and separated by at least 4 weeks after finalizing treatment for the previous exacerbation). Blood pressure, oxygen saturation, heart rate, and spirometry were measured by the patient at home as per instructions. Respiratory rate (and oxygen adherence) data was passively collected by the Visionox® device. One hundred and fifteen patients were randomized to HTH and one hundred and fourteen to RCP. One hundred and sixty-nine completed the full follow-up period. There were no statistical differences at one year between groups in the proportion of participants who had a COPD exacerbation (60% in HTH vs. 53.5% in RCP; p = 0.321). There was a trend towards a shorter duration of hospitalization and days in ICU in the HTH group (18.9 ±16.0 and 6.0 ±4.6 days) compared to the RCP group (22.4 ±19.5 and 13.3 ±11.1 days). The number of all-cause deaths was comparable between groups (12 in HTH vs. 13 in RCP). Telehealth was evaluated highly positively by patients and doctors. The authors concluded that remote patient management did not reduce COPD-related ER visits or hospital admissions compared to RCP within 12 months. They noted that further evidence is needed to assess telehealth as an intervention strategy in COPD. (This study is included in the systematic review by Janjua et al., 2021).

Walker et al. (2018) conducted a multicenter, randomized control trial (RCT), to evaluate the efficacy of home monitoring of lung mechanics by the forced oscillation technique and cardiac parameters in older patients with COPD and comorbidities. A total of 312 individuals were randomized to usual care (n = 158) or telemonitoring (n = 154) and followed for 9 months. Primary measurements included time to first hospitalization (TTFH) and change in the EuroQoL EQ-5D utility index score. Secondary measurements included: rate of antibiotic/corticosteroid prescription; hospitalization; the COPD Assessment Tool, Patient Health Questionnaire-9, and Minnesota Living with Heart Failure questionnaire scores; quality-adjusted life years; and healthcare costs. The authors stated there were no significant differences between intervention and control groups in the baseline characteristics. There was no difference between groups in the TTFH (primary study endpoint), however, there was a 54% decrease in repeat hospital admissions, a post hoc secondary outcome. The authors concluded that telemonitoring of older patients with COPD, using forced oscillation technique and cardiac monitoring, did not change TTFH and EQ-5D. There were a lower-than-expected number of hospitalizations and there was variation in the pattern of health care between healthcare systems, which precluded mandating specific interventions in response to an alert. The authors concluded that although this was a negative clinical trial, future investigations focusing on patients with COPD at risk of hospitalizations using objectively defined criteria for clinical deterioration may be of value. While telemedicine appeared to be associated with fewer repeated hospitalizations, this was a post hoc analysis. Therefore, the finding could be due to chance and multiple comparisons. (This study is included in the systematic review by Janjua et al., 2021).

Vianello et al. (2016) conducted a study to investigate the benefits of a telemonitoring (TM) system in managing acute exacerbations (AE) in patients with advanced-stage COPD to improve their Health-Related Quality of Life (HRQL) and to reduce utilization of healthcare services. In a 12-month RCT, 324 individuals were enrolled and randomized into 2 groups, TM group (n = 234) vs control group (n = 104). The authors' findings in the SF36 Physical and Mental Component Summary scores did not significantly differ between the TM and control groups [-2.07 (8.98) vs -1.91 (7.75); p = 0.889 and -1.08 (11.30) vs -1.92 (10.92); p = 0.5754, respectively]. Variations in Hospital Anxiety and Depression Scale (HADS) were not significantly different between the two groups [0.85 (3.68) vs 0.62 (3.6); p = 0.65 and 0.50 (4.3) vs 0.72 (4.5); p = 0.65 and 0.50 (4.5); p0.71]. The hospitalization rate for AECOPD and/or for any cause was not significantly different in the two groups [IRR = 0.89 (95% CI 0.79 - 1.04); p = 0.16 and IRR = 0.91 (95% CI 0.75 - 1.04); p = 0.16, respectively]. TM does not significantly improve HRQL in patients with COPD and develop AE. Nor is it effective in reducing hospitalizations. TM was associated with a lower rate of hospital readmission for AECOPD and/or any cause during the first 30 days after hospitalization [IRR: 0.43 (0.19-0.98); p = 0.04 and 0.46 (0.24-0.89); p = 0.02, respectively]. Findings were conflicting with most pre-specified outcomes showing no benefit and one secondary outcome (readmission) being statistically significant. Considering multiple comparisons, this could be due to chance and would need to be confirmed in a study designed to test this outcome specifically. The authors concluded that this study had a number of limitations. First, although COPD has been recently regarded as a heterogeneous disease characterized by high phenotype variability, phenotypic distinctions in the patients were not considered during the randomization process. In particular, since patients' history of previous exacerbations was unavailable, the possibility that the distribution of "frequent exacerbators" was unbalanced between the groups, with a confounding effect on the impact of TM on HRQL cannot be excluded. "Frequent exacerbators" have, in fact, been recognized as a distinct clinical subgroup characterized by poorer HRQL as a result of a high exacerbation rate irrespective of the degree of airflow limitation. In addition, TM to manage AE should not be generalized across the entire population of patients with COPD and efforts should be made to identify specific subgroups that could most benefit from telehealth care. (This study is included in the systematic review by Janjua et al., 2021).

Clinical Practice Guidelines

Veterans Affairs and Department of Defense (VA/DoD)

The VA/DOD 2021 Clinical Practice Guideline on the management of chronic obstructive pulmonary disease stated a weak recommendation for offering telehealth support that includes telemonitoring and/or mobile applications.

Diabetes Mellitus (DM)

There is insufficient evidence to establish the safety and efficacy of RPM for treating diabetes mellitus (DM). Well-designed, randomized controlled trials (RCTs) with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes. For guidance on diabetes management, refer to the DME MAC <u>LCD for Glucose Monitors (L33822)</u>.

A 12-month randomized crossover trial (n = 119) was conducted by Amante et al. (2021) to evaluate 6 months of a diabetes remote monitoring program facilitated by cellular-connected glucose meter, access to a diabetes coach, and support responsive to abnormal blood glucose recordings greater than 400 mg/dL or below 50 mg/dL in adults with poorly controlled T2D in a diabetes center of excellence. There were two arms: the intervention (IV) arm included a cellular connected glucose meter and phone-based diabetes coaching provided by Livongo Health, and the usual care arm (UC). The coach answered questions, assisted in goal setting, and provided support in response to abnormal glucose levels. One group received the intervention for 6 months before returning to usual care (IV/UC). The other group received usual care before enrolling in the intervention (UC/IV) for 6 months. Change in hemoglobin A1c (HbA1c) was the primary outcome and change in treatment satisfaction was the secondary outcome. At study enrollment, participants had an HbA1c test drawn. Participants were scheduled to return at 3, 6, 9, and 12 months ±1 week post-study enrollment for HbA1c testing. Participants completed paper questionnaires at baseline, 6 months (prior to treatment crossover), and 12 months (study completion). Of the 119 study participants, 97 (81.5%) returned for the 6-month HbA1c lab, and 92 (77.3%) completed the 6-month follow-up survey. After treatment crossover, 86 (72.3%) participants returned for the 12-month HbA1c test, and 92 (77.3%) participants completed the 12-month follow-up survey. Improvements in mean HbA1c were seen in both groups during the first 6 months. After crossover, there was no meaningful change in HbA1c in IV/UC; however, those in UC/IV showed further improvement. A mixed-effects model showed no significant treatment effect (IV vs UC) over 12 months (p = .06). Both groups reported similar improvements in treatment satisfaction throughout the study. The authors concluded that patients enrolled in the diabetes remote monitoring program intervention experienced improvements in HbA1c and treatment satisfaction similar to usual care at a specialty diabetes center. Future studies on diabetes remote monitoring programs should incorporate scheduled coaching components and involve family members and caregivers. Study limitations noted were the short intervention time period (6 months) the limited exposure to the intervention did not allow for evaluation of a sustained intervention effect and the frequency of blood glucose testing during intervention compared to usual care was not compared. More research is needed with longer durations of intervention treatment and in more centers. Future studies should include other patient populations, as this study only focused on patients with poorly controlled diabetes and did not collect data on duration of diabetes at time of enrollment.

Lee et al. (2020) conducted a randomized control trial (RCT) on the effects of remote telemonitoring with team-based management on people with uncontrolled type 2 diabetes. A total of 240 participants met the inclusion criteria with 120 assigned to the telemonitoring (TG) group and 120 assigned to the usual care (UC) group. The primary outcome was the change in HbA1c at 24 weeks and 52 weeks. Secondary outcomes included changes in fasting plasma glucose, blood pressure, lipid levels, health-related quality of life, and diabetes self-efficacy. The authors reported TG demonstrated larger improvements in glycemic control compared with control at the end of study (week 24, – 0.05%; 95% CI – 0.10 to 0.00%) and at follow-up (week 52, – 0.03%; – 0.07 to 0.02%, p = 0.226). Secondary outcomes were observed, including the number of adverse events and health-related quality of life, however, no differences were identified. The authors concluded that the addition of telemedicine in replacement of self-monitoring in diabetes care had limited clinical benefits in improving glycemic control. Limitations in the study include additional coaching sessions which increased the cost of intervention. Also, there was limited internet connectivity and usage of older smartphones that led to a high rejection rate. In addition, there was a lack of information on medication titration and escalation by the clinicians. Lastly, there was a lack of information on the long-term effects after 12 months.

Bollyky et al. (2018) evaluated an RCT on individuals with Type 2 diabetes (T2D) and were on the Livongo Diabetes Program. The RCT focused on 330 participants who had T2D, HbA1c > 7.5%, BMI ≥ 25. Livongo provides connected,

two-way messaging glucose meters, unlimited blood glucose (BG) test strips, and access to certified diabetes educators. The participants were randomized into four different groups: Livongo program with no further intervention (control group, n = 75), Livongo program with a connected scale (n = 115), Livongo program with a scale plus lightweight coaching provided by Restore Health (n = 73), or Livongo program plus a connected scale plus intense coaching (n = 67) for 12 weeks. The lifestyle coaching interventions focused on nutrition, exercise, sleep, and stress. The authors identified that the Livongo program alone is sufficient to achieve desired blood glucose control for some participants. Livongo participation resulted in improved BG control (mean HbA1c declined: 8.5% to 7.5%), (p = 0.01) across all groups prior to the Restore Health lifestyle modification intervention. Mean weight loss and additional BG decreases were higher in the intensive coaching group compared with the lightweight coaching and scale-only groups (weight change (lb): -6.4, -4.1, and -1.1 resp., p = 0 01; BG change (mg/dL): -19.4, -11.3, -2.9, resp., p = 0 02). The authors concluded that future research should be directed at understanding the key elements of the intensive lifestyle coaching program. Limitations in the study include blood glucose value calculations versus HbA1C values and external interventions from other health care providers may have contributed to improving glucose control. As the interventions included multiple components (2 intensities of coaching, CDE, scale, glucometer, text messaging) it does not permit isolation of the effect of the remoting monitoring component on the outcomes studied.

Clinical Practice Guidelines

Veterans Affairs and Department of Defense (VA/DoD)

The VA/DOD 2023 Clinical Practice Guideline on the management of type 2 diabetes mellitus stated a weak recommendation for health care delivered through telehealth interventions to improve outcomes in adults with type 2 diabetes mellitus.

Gestational Diabetes

There is insufficient evidence to establish the safety and efficacy of RPM for treating gestational diabetes. Well-designed, randomized controlled trials (RCTs) with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes. For guidance on diabetes management, refer to the DME MAC <u>LCD for Glucose Monitors (L33822)</u>.

In a retrospective cohort study, Kantorowska et al. (2023) conducted a study to determine if remote patient monitoring (RPM) for outpatient management of diabetes mellitus in pregnancy could lead to improvement in maternal and neonatal outcomes. A total of 533 patients met inclusion criteria. A comparison was conducted between 173 patients managed with paper logs to 360 patients managed with remote patient monitoring (176 device integration and 184 manual entry). The primary outcomes were maternal morbidity and neonatal morbidity. Secondary outcomes measured glycemic control and individual obstetrical and neonatal outcomes. The authors' findings identified maternal baseline characteristics did not differ significantly between the RPM group and paper groups (p = .011). No significant difference was identified between the groups for primary outcomes. RPM patients submitted more glucose values and were more likely to achieve glycemic control in target range (79.2% vs 52.0%; p < .0001) and achieved the target range sooner (p = .025) than patients managed with paper logs. Study limitations included retrospective design and the study was performed at a single institution versus multiple sites. Additional prospective studies at multiple institutions are needed.

Raman et al. (2017) conducted a systematic review to compare the effects of different methods and settings for glucose monitoring for women with gestational diabetes mellitus (GDM) on maternal and fetal, neonatal, child and adult outcomes. and use and costs of health care. The study included 11 RCTs (n = 1272). Five different comparisons in the study included: telemedicine (transmission of glucose concentrations from home to healthcare professionals for review) versus standard care for glucose monitoring (face-to-face review in a clinic/hospital); self-monitoring versus periodic glucose monitoring (less frequently at face-to-face visits); continuous glucose monitoring system versus self-monitoring of glucose; modem (transmitting glucose concentrations directly from glucose meters to healthcare professionals) versus telephone transmission for glucose monitoring; postprandial versus pre-prandial glucose monitoring. The author's findings stated there was no clear difference between telemedicine and standard care, self-monitoring versus periodic glucose monitoring, nor continuous glucose monitoring system (CGMS) versus self-monitoring of glucose. Modem versus telephone transmission for glucose monitoring reported no primary outcomes. Postprandial versus pre-prandial glucose monitoring observed no clear differences between the postprandial and pre-prandial glucose monitoring groups for the mother, however, there were fewer large-for-gestational-age infants born to mothers in the postprandial compared with the pre-prandial glucose monitoring group. The authors concluded there were no clear differences for the primary outcomes or other secondary outcomes assessed in this review. However, there were limitations found in the study. Limitations include the small number of RCTs for the comparison, small sample sizes, and the variable methodological quality of the RCTs. Future large, high-quality RCTs evaluating the effects of different methods or settings for glucose monitoring for women with GDM are required.

Ming et al. (2016) conducted a systematic review and meta-analysis to determine whether telemedicine solutions offer any advantages compared with the standard care for women with diabetes in pregnancy. A total of seven RCTs were identified and included 579 women [496 with gestational diabetes mellitus (GDM) and 83 with type 1 DM]. The author's findings state a significant improvement in HbA1c associated with the use of telemedicine technology. The mean HbA1c of women using telemedicine was 5.33% compared with 5.45% in the standard care group, representing a mean difference of -0.12%. When this comparison was limited to women with GDM only, the mean HbA1c of women using telemedicine was 5.22% compared with 5.37% in the standard care group, mean difference-0.14%. There were no differences in other maternal and neonatal outcomes reported. The authors concluded there is currently insufficient evidence to conclude that for women with diabetes in pregnancy, telemedicine systems produce superior clinical outcomes when compared with standard care. Limitations in the study include no agreement between the trials on the screening method and the definition of GDM, or standard treatment protocols. Therefore, patient groups across trials may not be precisely comparable. With the rapid development of advances in communication technology, the same system has not been compared in different populations, and there has been no evidence of sustained scale-up of any of these technologies. A further limitation of this review is that some of the outcomes examined, such as Cesarean section rates, gestational age at delivery, and admission to the NICU, may be more influenced by local practice, rather than being directly influenced by the intervention itself. High-quality research is still needed to determine the efficacy of telemedicine systems compared to the standard of care for this population.

Hypertension (HTN)

There is insufficient evidence to establish the safety and efficacy of RPM for treating hypertension (HTN). Well-designed, randomized controlled trials (RCTs) with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Mehta et al. (2024) conducted a randomized clinical trial (RCT) to evaluate the effectiveness of a bidirectional text messaging program focused on BP control and medication adherence with and without social support in adults with hypertension. Patients were randomized to one of 3 study arms: remote monitoring of BP and medication adherence (RM), remote monitoring of BP and medication adherence with feedback provided to a social support partner (SS), or usual care (UC). The primary outcome was systolic BP at 4 months measured during the final follow-up visit. Secondary outcomes included achievement of normotension and diastolic BP. In all, 246 patients were included in the intention-totreat analysis: 100 patients in the RM arm, 97 in the SS arm, and 49 in the UC arm. Compared with the UC arm, there was no significant difference in systolic or diastolic BP at the 4-month follow-up visit in the RM arm [systolic BP adjusted mean difference, -5.25 (95% CI, -10.65 to 0.15) mm Hg; diastolic BP adjusted mean difference, -1.94 (95% CI, -5.14 to 1.27) mm Hg] or the SS arm [systolic BP adjusted mean difference, -0.91 (95% CI, -6.37 to 4.55) mm Hg; diastolic BP adjusted mean difference, -0.63 (95% CI, -3.77 to 2.51) mm Hg]. Of the 206 patients with a final BP measurement at 4 months, BP was controlled in 49% of patients in the RM arm, 31% of patients in the SS arm, and 40% of patients in the UC arm; these rates did not differ significantly between the intervention arms and the UC group. The authors concluded that neither remote BP monitoring nor remote BP monitoring with social support improved BP control compared with UC in adults with hypertension. A limitation identified in the study is that there may not have been sufficient power to detect smaller improvements in BP control. Additional studies are warranted.

Choi et al. (2020) conducted a systematic review and meta-analysis to examine the effect of remote home blood pressure monitoring (RBPM) in patients with hypertension in urban contexts. A total of 27 RCTs fit the inclusion criteria and were included in this meta-analysis. The main outcomes targeted mean differences in SBP and DBP between baseline measurements and follow-up points and the target BP achievement rate. The authors identified significant standardized mean difference (SMD) was observed for RBPM for systolic BP, but the effect size was small compared to face-to- face care and was clinically irrelevant in avoiding cardiovascular events (p < 0.001). For diastolic BP, the SMD between the two groups was small (p < 0.001) and the effect of RBPM was irrelevant in preventing cardiovascular events. The effect on the rate of BP control was significantly high for the intervention group (p = 0.018). The authors concluded that RBPM performed on urban hypertensive patients has limited value and seems not to be superior to ordinary care in avoidance of cardiovascular events. Further studies are needed to provide more reliable information about the effectiveness of RBPM in preventing hypertensive cardiovascular complications.

The TASMINH4 study (McManus et al. 2018) was a parallel unmasked randomized controlled trial done in 142 general practices in the UK and included 1182 hypertensive participants with blood pressure higher than 140/90, who were willing to self-monitor their blood pressure. The aim of the study was to assess the efficacy of self-monitored blood pressure, with or without telemonitoring, for antihypertensive titration in primary care, compared with usual care. The primary outcome was a clinic that measured systolic blood pressure at 12 months from randomization. The 1182 participants were randomly assigned to the self-monitoring group (n = 395), the telemonitoring group (n = 393), or the usual care group (n = 394), of whom 1003 (85%) were included in the primary analysis. After 12 months, systolic blood pressure was lower in both intervention groups compared with usual care [self-monitoring, 137.0 (SD 16.7) mm Hg and telemonitoring, 136.0

 $(16\cdot1)$ mm Hg vs usual care, $140\cdot4$ $(16\cdot5)$; adjusted mean differences vs usual care: self-monitoring alone, $-3\cdot5$ mm Hg (95% CI $-5\cdot8$ to $-1\cdot2)$; telemonitoring, $-4\cdot7$ mm Hg $(-7\cdot0$ to $-2\cdot4)$]. No difference between the self-monitoring and telemonitoring groups was recorded. Adverse events were similar between all three groups. The authors concluded titration of antihypertensive medication in primary care using self-monitoring, with or without telemonitoring, results in significantly lower blood pressure after one year and recommended that self-monitoring be used for the ongoing management of hypertension in primary care in all patients who wish to use it. They also recommended that general practitioners incorporate self-monitored readings into their titration of blood pressure medications. However, the trial failed to demonstrate superiority of telemonitoring compared to self-monitoring, which was one of the *a priori* primary aims of the study (Franssen, 2017).

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)

The American College of Cardiology and American Heart Association 2025 Joint Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults states that there is insufficient evidence to recommend the use of technology-based remote monitoring in managing hypertension (Jones et al., 2025).

Veterans Affairs and Department of Defense (VA/DoD)

The VA/DOD 2020 Clinical Practice Guideline on the management of hypertension stated a weak recommendation for the use of technology-based interventions that include telemonitoring and/or mobile applications.

Mental Health Conditions

A review of current literature shows insufficient evidence to support the safety and effectiveness of remote physiologic monitoring (RPM) for mental health conditions including but not limited to anxiety, depression, schizoaffective disorder, and bipolar disorder. Well-designed randomized controlled trials (RCTs) are needed to understand RPM's impact on mental health outcomes.

A Hayes (2025) evidence analysis research brief sought to summarize the volume of publications and to determine whether there is adequate published peer-reviewed literature to assess remote patient monitoring (RPM) for evaluation of physiologic mental health information. Hayes findings suggest that currently there is not enough published peer-reviewed literature to evaluate the evidence related to RPM for evaluation of physiologic mental health information in a full assessment. One abstract on RPM for evaluation of physiologic mental health information for individuals with a diagnosis of major depressive disorder, bipolar disorder, or other mood disorders was identified in the Hayes literature search.

Obstructive Sleep Apnea (OSA)

There is insufficient evidence to establish the safety and efficacy of RPM for treating obstructive sleep apnea (OSA). Well-designed, randomized controlled trials (RCTs) with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Murphie et al. (2019) conducted a systematic review to assess the effectiveness of teleconsultation plus telemonitoring in the review of people with obstructive sleep apnea hypopnea syndrome (OSAHS) receiving continuous positive airway pressure therapy versus face-to-face care. The study identified five randomized controlled trials (n = 269 patients) that met inclusion criteria. The outcome measures included CPAP adherence, Epworth sleepiness scale, patient/clinician satisfaction/acceptability, and costs of providing the telemonitoring/teleconsultation intervention. The author's findings stated that teleconsultation/telemonitoring improved continuous positive airway pressure adherence in two trials (n = 19; n = 75); two (n = 114 and n = 75) trials reported no differences between groups. Two studies with moderate/high risk of bias showed no between-group difference in the Epworth Sleepiness Score. In all five trials, satisfaction was generally reported as positive; one trial reported that the teleconsultation/telemonitoring patients were more likely to continue with continuous positive airway pressure therapy treatment. The authors concluded evidence for teleconsultation/telemonitoring in continuous positive airway pressure users is limited. Adequately powered trials at low risk of bias will be needed to establish whether telehealth (combining remote consultation and real time telemonitoring) is a clinically viable, acceptable, and effective option for people with OSAHS using CPAP therapy. (Fox et al. 2012, which is summarized below, is included in this systematic review).

Fox et al. (2012) performed a single center, randomized controlled trial (RCT) of a telemedicine system versus standard care in patients with moderate to severe OSA. Seventy-five patients were enrolled in the study (39 randomized to telemedicine) and (36 to standard care). The primary outcome was PAP adherence after 3 months (minimum used per day), using an intention-to-treat approach (unpaired 2-tailed t-test). A variety of secondary outcomes were analyzed, including time spent with the patient, Epworth Sleepiness Score (ESS), sleep quality, side effects, and adherence on days

PAP was used. After 3 months, there was no difference in percent of days with PAP use; mean PAP adherence (average monthly minutes per day) was significantly greater in the telemedicine arm (191 min per day) versus the standard arm (105 min per day; p = 0.006, unpaired t test); on days when PAP was used, mean adherence was 321 min in the telemedicine arm and 207 min in the standard arm (p < 0.0001); there was no difference in ESS change or Apnea Hypoxia Index on treatment. There was no significant difference in the percentage of nights PAP was used (46% versus 56% in the standard versus telemedicine arm). Significant independent predictors of adherence included age, baseline ESS score, and use of telemedicine. On average, an additional 67 min of technician time was spent on patients in the telemedicine arm compared with the standard arm (p = 0.0001). The authors concluded PAP adherence (minutes per night with any use) can be improved with the use of a web-based telemedicine system at the initiation of treatment. The study has many limitations. First, only patients with moderate to severe disease were included in the study. Second, this was a single-center study with less than 40 patients per study arm. Third, adherence in the standard care arm was relatively low (1.75 hr/night) and may explain the low baseline ESS scores. Fourth, there was no sham telemedicine control group. Future studies are necessary to determine whether monitoring alone or the interventions may have contributed to the positive findings. Additional studies are needed to evaluate individuals with less severe disease; and reproduce these findings in other patient populations and other centers with longer follow-up. (This study is included in the systematic review by Murphy et al., 2019).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

There are several devices used for RPM. Refer to the following website for more information: <u>Devices@FDA</u>.

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Policy History/Revision Information

Date	Summary of Changes
01/01/2026	New Medicare Advantage Medical Policy

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the <u>Administrative Guide</u>.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.