EVIDENCE SUMMARY Control High Blood Pressure



Implement strategies that improve adherence to anti-hypertensive and lipid-lowering prescription medications via expanded access to:

- low (\$5 or less) or no medication copayments
- fixed-dose medication combinations (two or more medications combined into a single tablet) with low or no copayments
- 90-day supply or longer medication fill supply
- innovative pharmacy packaging (e.g., calendar blister packs)
- improved care coordination within networked primary care teams using:
 - standardized protocols to manage blood pressure and cholesterol
 - electronic prescribing (e-prescribing) with 2-way information exchange between prescriber and pharmacy
 - medication therapy management (MTM) programs
 - self-monitoring of blood pressure with clinical support interventions.

CURRENT STATUS BY PAYER TYPE REGARDING MEDICATIONS IN FIXED-DOSE MEDICATION COMBINATIONS OR FILLS WITH LOW OR NO CO-PAYMENT (AS OF 2014)

Percentage of fills for fixed-dose blood pressure medication combinations and percentage of blood pressure medication fills with low (\$5 or less) or no copayment, by payer type (Medicare Part D, Medicaid, Commercial), in 2014¹⁸:

MEDICARE (PART D)

- ✓ 10.7% of blood pressure medication fills were for fixed-dose combinations of blood pressure medications.
- ✓ 84.8% of blood pressure medication fills had a copayment of \$5 or less.

MEDICAID

- ✓ 10.3% of blood pressure medication fills were for fixed-dose combinations of blood pressure medications.
- ✓ 99.5% of blood pressure medication fills had a copayment of \$5 or less.

WHAT IS CDC'S 6|18 INITIATIVE?

The CDC is partnering with health care purchasers, payers, and providers to improve health and control health care costs. CDC provides these partners with rigorous evidence about high-burden health conditions and associated interventions to inform their decisions to have the greatest health and cost impact. This initiative aligns evidence-based preventive practices with emerging value-based payment and delivery models.

FAST FACTS

Heart disease and stroke are the first and fifth leading causes of death in the United States. Heart disease, stroke, and other vascular diseases contribute to approximately 800,000 deaths per year and 200,000 preventable deaths (among those younger than 75).¹ Hypertension (high blood pressure) is one of the key risk factors for heart disease and stroke and is costly in terms of lives lost and health outcomes; however, it is highly treatable.

About 75 million U.S. adults have high blood pressure that's 1 in every 3 adults.² Among those with high blood pressure, about 64 million are aware of their condition and 57 million are taking blood pressure-lowering medication; however, only about half have their blood pressure under control.^{3, 4} In 2011 high blood pressure was associated with \$45 billion in direct medical costs.⁵

Emerging healthcare payment models are rewarding high performance and health improvement outcomes on a set of high-priority cardiovascular measures called the Million Hearts® ABCS. The Million Hearts® ABCS include: Aspirin use when appropriate, Blood pressure control, Cholesterol management, and Smoking cessation.⁶ The use of blood pressure control in these types of outcome-focused care models can help health practitioners ensure their patients get the care they need to manage their high blood pressure and improve their overall health outcomes.

COMMERCIAL

- ✓ 16.1% of blood pressure medication fills were for fixed-dose combinations of blood pressure medications.
- ✓ 76.5% of blood pressure medication fills had a copayment of \$5 or less.

KEY HEALTH AND COST INFORMATION FOR PAYERS AND PROVIDERS

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PAYERS

The Community Preventive Services Task Force provides strong evidence that reducing patient out-of-pocket costs for medications to control blood pressure improves medication adherence and blood pressure outcomes. This is especially true when lower medication costs are combined with additional interventions aimed at improving patient-provider interaction and patient knowledge (e.g., team-based care with medication counseling, patient education).¹⁹

To improve medication adherence, payers have used administrative claims data to identify the following possible gaps in care among their members and provide the appropriate healthcare professionals with timely and actionable information regarding these potential opportunities for intervention:

- Noncompliance with blood pressure, lipid-lowering, or tobacco cessation medication regimens (e.g., discontinued with no apparent medication switch).
- Non-use of blood pressure or lipid-lowering medications among members with documented hypertension, hyperlipidemia, myocardial infarction, peripheral artery disease, or stroke.

Health benefit managers are uniquely positioned to influence the adoption of medical innovation and services, so they can improve access to and the quality of health care, including the use of networked primary care teams to promote medication adherence. The proposed 6|18 strategies for medication adherence can improve interactions between the patient and the health care system, the community pharmacist and the patient, and the community pharmacist and the health care system.²⁰

Payers have considered requiring participating healthcare professionals and practices to implement protocols for hypertension treatment,

FAST FACTS

Creating an environment that supports patients' adherence to blood pressure medication regimens may help health plans improve rates of blood pressure control among members.⁷ In terms of the topic of medication adherence, two or more blood pressure medications are increasingly used to control blood pressure in hypertensive patients. Fixed-dose combinations of two blood pressure agents in a single tablet may provide greater benefits via a simpler regimen—than using separate medications.⁸

Calendar blister packaging (CBP) that incorporates a day or date feature is a simple medication packaging method designed to improve medication adherence and persistence. Using CBP for medication prescribed for daily, self-administered long-term use has been associated with modest improvement in prescription refill adherence and persistence.⁹

Strong evidence from the Community Preventive Services Task Force suggests that providing cardiovascular care using a team-based care model is most effective in improving blood pressure outcomes. The team based model includes the patient, the primary care provider, and other professionals such as nurses and pharmacists.¹⁰ New findings indicate the team-based care model is also effective in preventing cardiovascular disease when it engages community health workers in interventions.¹¹ Certified hypertension specialists, medical assistants, dietitians, and social workers have played significant roles in this teambased care model as well.¹² cholesterol management, and tobacco cessation.²¹ Prescribing evidencebased treatment regimens and routine screening by health professionals, including pharmacists, to reconcile medications, synchronize prescription fills, and assess the efficacy of and patient adherence to the prescribed treatment helps support effective communication among team members.²²

Payers have considered incentivizing healthcare providers and pharmacies to use e-prescribing, which has been shown to increase the percentage of prescriptions that are picked up by 10% compared with written prescriptions. Moreover, use of e-prescribing has been shown to decrease costs for patients and payers by encouraging substitution of generic medications or less costly formulary options.²³ Finally, e-prescribing can be used to identify patients who do not take their prescribed medication (e.g., a blood pressure medication prescription is ordered but is never picked up). Closing the communication loop, by sending confirmation to the prescriber that the prescribing on improving adherence.

Implementing a MTM Program that aligns with Centers for Medicare & Medicaid Services guidance—which, at a minimum, targets members with multiple chronic conditions such as hypertension and includes targeted medication reviews—has been shown to increase members' rates of reaching their blood pressure and other cardiovascular health goals.²⁴

Million Hearts[®] developed *Medication Adherence: Action Steps for Health Benefit Managers*²⁵ as a call to action that demonstrates where health benefit, employee, and pharmacy benefit managers have implemented evidenceand practice-based medication adherence strategies that improve blood pressure control, cholesterol management, and smoking cessation.

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PROVIDERS

The Million Hearts[®] Hypertension Control Change Package for Clinicians²⁶ lists evidence- and practice-based interventions for improving hypertension control. These interventions include change concepts such as providing blood pressure checks without appointment or co-payment, flowcharts for how hypertensive patients can be tracked and managed, the systematic use of evidence-based hypertension treatment protocols, and the use of direct care staff to facilitate patient self-management. This package also includes case studies showing how physicians have used systematic team-based approaches, along with specific tools to enhance information flow and workflow, to achieve significant improvements in their patients' blood pressure control. The Community Preventive Task Force found strong evidence to suggest that implementing these and other interventions is most effective in improving blood pressure outcomes when delivered in a team-based care model.^{27, 28}

FAST FACTS

In terms of coordinating care within networked primary care teams:

- E-prescribing is a process that allows physicians and other prescribers to send prescriptions to a pharmacy electronically instead of faxing them or giving hand-written prescriptions to patients.¹³ The federal standards for e-prescribing recommend that the process include the bidirectional exchange of information, allowing the prescriber to be notified when a patient has picked up a prescribed medication.¹⁴
- According to April 2014 data from Surescripts, an e-prescription network used by the majority of community pharmacies in the United States, 7 in 10 physicians e-prescribed through an electronic health record and 96% of community pharmacies were enabled to accept e-prescriptions. However, these data do not reflect the ability of pharmacies to send information back to the prescriber.¹⁵
- E-prescribing was formerly part of the Meaningful Use electronic health records program but is now one of the considerations for the Merit-Based Incentive Payment System for clinician payment.¹⁶
- Medicare-eligible beneficiaries who are in a Medicare drug (Part D) program may be eligible for other programs that can help those who take multiple medications for different medical conditions. Under federal regulation 423.153(d), a Medicare Part D plan sponsor must have established a Medication Therapy Management (MTM) program that:
 - Ensures optimum therapeutic outcomes for targeted beneficiaries through more effective medication use.
 - Reduces the risk of adverse events.
 - Is developed in cooperation with licensed and practicing pharmacists and physicians.
 - Describes the resources and time required to implement the program if using outside personnel and establishes the fees for pharmacists or others.
 - May be furnished by pharmacists or other qualified providers.
 - May distinguish between services in ambulatory and institutional settings.
 - Is coordinated with any care management plan established for a specific person under a chronic care improvement program.¹⁷

SUPPORTING HEALTH AND COST EVIDENCE: SCIENCE BEHIND THE ISSUE

COPAYMENTS

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Researchers conducting a 2012 study found that reducing or eliminating copayments for generic drugs for hypertension and hyperlipidemia, combined with disease management support as part of a value-based payment program, increased patient compliance from 1.4% to 3.2% after 1 year. Two years after value-based payments were started, patient medication adherence showed an additional 2.1% gain, increasing to 5.2%. These researchers observed that adherence changes were most notable among patients who were not consistently taking their medications before a value-based system was implemented.²⁹



A simulation study conducted by Goldman et al. found that implementation of a pharmacy benefit that varies copayments for cholesterol-lowering therapy based on expected therapeutic benefit will improve patient medication compliance and reduce use of other services (e.g., hospitalizations, emergency department services). In this study, copayments for high- and medium-risk patients were eliminated but increased (from \$10 to \$22) for low-risk patients. This simulation revealed that, assuming 6.3 million privately insured or Medicare-insured US adults were on cholesterol-lowering therapy, varying the copayments resulted in the avoidance of 79,837 hospitalizations, 31,411 emergency department admissions, and over \$1 billion in spending annually.³⁰



A systematic review of 13 studies assessing the effects of value-based insurance design programs with reduced medication copayments found a consistent association with improved adherence (average change of 3.0% over 1 year) and lower out-of-pocket spending for medication. Findings suggest that generous coverage did not lead to significant changes in medical spending by patients and insurers. Research is needed to clarify how best to structure value-based programs to improve quality of healthcare and reduce spending.³¹ **The Post-Myocardial Infarction Free Rx Event and Economic Evaluation,** a prospective trial of a cohort of 2,387 people (41% of the trial population), assessed whether reducing patients' out-of-pocket costs increased medication adherence among those discharged from the hospital after a heart attack. This study found that rates of medication adherence were significantly lower and rates of adverse clinical outcomes were significantly higher for nonwhite patients than for white patients. Providing full drug coverage increased medication adherence in both groups. However, the overall adherence rates remained low even when there was no cost-sharing for the medications and the patients had just suffered a myocardial infarction. Among nonwhite patients, full drug coverage contributed to lowering the rates of major vascular events or revascularization by 35% and reducing total health care spending by 70%. Providing full coverage had no effect on clinical outcomes and costs for white patients. This study concluded that lowering copayments for medications after heart attacks may reduce racial and ethnic disparities for cardiovascular disease.³²

Additional research is still needed to identify and collect the key strategies that should be implemented to achieve the largest improvement in health outcomes and the most desirable reductions in healthcare spending. These strategies will likely have to be tailored to the specific population of the health plan or provider. Suggested research areas include determining the strategies needed to reduce costs for patients and insurers and whether medication costs affect adherence for primary (no heart- or stroke-related events) versus secondary (post-cardiac or stroke event) prevention. Additional research could also foster a better understanding of 1) how socioeconomic variables (e.g., race, income) and selection of pharmacy plan are integrated with claims and administrative data and 2) the effect on medication cost sharing.³³

CARE COORDINATION WITHIN NETWORKED PRIMARY CARE TEAMS

In a review of the use of team-based care to treat blood pressure, the proportion of patients with controlled blood pressure improved (median increase by 12%); systolic blood pressure decreased (median reduction by 5.4 mmHg); and diastolic blood pressure also decreased (median reduction by 1.8 mmHg). This review concluded that team-based care increased the proportion of people with controlled blood pressure and reduced systolic and diastolic blood pressure, especially when pharmacists and nurses were part of the team.³⁴

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A CDC Community Guide Task Force review found that there is strong evidence of effectiveness for interventions that engage community health workers in a team-based care model to improve blood pressure and cholesterol in patients at increased risk for heart disease. Findings suggest that the use of community health workers alongside physicians and nurses in team-based care was associated with large improvements blood pressure and cholesterol outcomes. In the studies reviewed, community health workers used more than one mode of delivery to communicate with clients, the most common combination being face-to-face sessions accompanied by telephone contact. As most of the review studies evaluated outcomes at 12 months, more evidence is needed on programs evaluated over a longer time period. It also would be useful to have research on larger-scale interventions (i.e., more than 500 patients) and how these programs can be funded and continued in ways other than public grants.³⁵

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A CDC Community Guide review examining cost estimates (31 studies; search period, January 1980-May 2012) of team-based care found most cost-effectiveness estimates below the conservative threshold of \$50,000 per quality-adjusted life year (QALY) saved.³⁶

SMBP plus clinical support was more effective than usual care in lowering blood pressure and improving control among patients with hypertension.³⁷

PHARMACISTS AS PART OF CARE COORDINATION TEAMS

In another study lasting 6 months, pharmacists provided a variety of MTM services to patients with heart disease at no cost to the patients as part of their employer's health plan. Researchers compared clinical and economic outcomes for those who received MTM (n=63) with a matched group of patients who did not receive MTM (n=62).³⁸ Economically, the MTM group's total direct healthcare expenditures were significantly lower (\$359/patient) and revealed a return on investment of \$1.67 per \$1 spent. Clinically, those who received MTM were more successful at meeting their blood pressure and body mass index goals. The specific scope of MTM service provided was adapted according to individual patient needs, and it showed that in less than 1 year, pharmacists had a positive financial and clinical impact on patients with cardiovascular disease.

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A study of a pharmacist-physician collaborative approach to managing high blood pressure showed that within 18 months, nearly twice as many patients whose pharmacists helped manage their medications had control of their blood pressure than those not assisted by pharmacists.^{19, 39}

EVIDENCE-BASED INTERVENTIONS: PAYERS

Provide patients with known or suspected hypertension validated home blood pressure monitors and reimburse for the clinical support services required for self-measured blood pressure monitoring (SMBP).

FAST FACTS

National and international organizations and agencies are promoting SMBP with clinical support as an evidence-based strategy for improving blood pressure control.⁴⁰ By definition, SMBP is the regular measurement of a patient's own blood pressure, often using a personal blood pressure measurement device, outside a clinical setting.⁴¹

It is important to note that the delivery of SMBP interventions requires a team-based care model to ensure the patient receives the appropriate clinical support needed to take and send accurate blood pressure measurements. A care team includes the patient, the primary care provider, and other clinical professionals such as nurses, community health workers, social workers and pharmacists.⁴²

CURRENT PAYER COVERAGE (AS OF NOVEMBER 2016)

MEDICARE

- ✓ Medicare Part B (traditional fee-for-service): Home blood pressure monitors used for SMBP are not covered.
- ✓ Medicare Part C (Medicare Advantage): Coverage is not mandated but may include supplemental coverage of home blood pressure monitors or additional support programs for enrollees.⁴³

MEDICAID

- Coverage varies by state.
- States offering Medicaid expansion plans: Medicaid plans that are offered for non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level—or opting to cover recommended preventive services without cost-sharing in their standard Medicaid benefit package— may cover home blood pressure monitors as per the United States Preventive Services Task Force (USPSTF) recommendation.⁴⁴
- ✓ Select state Medicaid agencies cover SMBP as part of their experimental, pilot, or demonstration projects.^{45, 46, 47}

COMMERCIAL

- Non-grandfathered private insurance plans may cover home blood pressure monitors as per the USPSTF recommendation.⁴⁸
- Decision to cover home blood pressure monitors and additional support is made by individual private health insurance plans.
- Some private insurance plans provide these benefits only for beneficiaries enrolled in disease-management programs for high blood pressure or other medical conditions that increase the risk for heart disease and stroke.⁴⁹

KEY HEALTH AND COST INFORMATION FOR PAYERS AND PROVIDERS

The current USPSTF recommendation for blood pressure screening in adults, released in October 2015, is as follows:

"The USPSTF recommends screening for high blood pressure in adults aged 18 years or older. The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment.⁵⁰"

While SMBP is an evidence-based intervention for both diagnosis and treatment of hypertension, having coverage of home blood pressure cuffs and monitoring to help with elevated blood pressure follow-up provides an inroad to get home blood pressure monitors into the hands of adults with or at risk for hypertension.

Blood pressure control is a priority clinical quality measure universally recognized by quality reporting programs, including the Quality Payment Program.^{51,52}

SMBP plus clinical support is more effective than usual care in lowering blood pressure and improving control among patients with hypertension.⁵³

The Community Preventive Services Task Force found that there is **strong** evidence that SMBP interventions, when combined with additional support (i.e., patient counseling, education, or web-based support), are effective in improving blood pressure outcomes in patients with high blood pressure.⁵⁴

The Community Preventive Services Task Force found that there is **sufficient** evidence that SMBP interventions, when used alone, are effective in improving blood pressure outcomes in patients with high blood pressure.⁵⁵

SMBP interventions are cost-effective when used with either additional support or within team-based care.⁵⁶

SUPPORTING HEALTH AND COST EVIDENCE: SCIENCE BEHIND THE ISSUE

SMBP is defined as the regular measurement of blood pressure by the patient outside the clinical setting, either at home or elsewhere.⁵⁷ A 2008 Joint Scientific Statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association encourages clinicians to increase the regular use of SMBP among the majority of their patients with known or suspected hypertension as a way to increase their engagement and ability to self-manage their condition.⁵⁸ However, a 2013 study using 2009-2010 National Health and Nutrition Examination Survey data found that among people with hypertension, only 36.6% engaged in monthly or more frequent SMBP.⁵⁹



A 2012 comparative effectiveness review by the Agency for Healthcare Research and Quality (AHRQ) examined the effectiveness of usual care compared with SMBP plus additional clinical support. This review found strong evidence that SMBP plus additional clinical support was more effective than usual care in lowering blood pressure and improving control among patients with hypertension.⁵³ Based on the AHRQ comparative effectiveness review, in 2015 the Community Preventive Services Task Force conducted a systematic review evaluating the effectiveness of interventions using SMBP with additional support to manage high blood pressure and SMBP alone.⁶⁰ Results of this review demonstrated strong evidence of effectiveness for interventions using SMBP plus additional support to improve

high blood pressure outcomes and sufficient evidence of effectiveness for SMBP interventions used alone.⁶¹ The Task Force identified "additional support" as:

- One-on-one patient counseling on medications and health behavior changes (e.g., to improve diet and exercise).
- Educational sessions on high blood pressure and blood pressure self-management.
- Access to electronic or web-based tools (e.g., electronic requests for medication refills, text or email reminders to measure blood
 pressure or attend appointments, direct communications with healthcare providers via secure messaging).⁶²

The Task Force also stated that SMBP interventions are often used with team-based care.⁶³

The summary blood pressure improvements demonstrated by the studies evaluating SMBP plus additional support included 1) an increased proportion of patients with their blood pressure at goal, 2) a median 4.6-point reduction in systolic blood pressure during a median duration of 12 months, 3) a median 2.3-point reduction in diastolic blood pressure during a median duration of 9 months, and 4) consistent and meaningful improvements in blood pressure that were sustained at 12 months when compared with usual care.⁶⁴ These results and the findings of other core studies demonstrate the significant impact and value that SMBP can have, particularly in conjunction with additional clinical support, on reducing high blood pressure and controlling hypertension.

Additionally, the Task Force concluded that "SMBP interventions are cost-effective when used with additional patient support or within team-based care." The Task Force did not find sufficient evidence to make a determination on the cost-effectiveness of SMBP when used alone, but the averted cost of medications and outpatient visits was found to exceed the intervention cost.⁶⁶



One economic analysis study employing a decision-analytic model concluded that reimbursement of home monitoring of blood pressure (HBPM) is cost beneficial, from an insurer's perspective, for diagnosing and treating hypertension. The study estimated net savings associated with the use of HBPM ranging from \$33 to \$166 per member in the first year and from \$425 to \$1364 in the long run (10 years), with return on investment ranging from \$0.85 to \$3.75 per dollar invested in the first year and from \$7.50 to \$19.34 per dollar invested in the long run.⁶⁷

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