

Heart Disease and Stroke Prevention: Reducing Out-of-Pocket Costs for Cardiovascular Disease Preventive Services for Patients with High Blood Pressure and High Cholesterol

# **Task Force Finding and Rationale Statement**

## **Table of Contents**

Intervention Definition	2
Task Force Finding	
Rationale	
Basis of Finding	
Applicability and Generalizability Issues	
Data Quality Issues	
Other Benefits and Harms	
Economic Evidence	6
Considerations for Implementation	7
Evidence Gaps	7
Disclaimer	8

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# **Task Force Finding and Rationale Statement**

## **Intervention Definition**

Reducing out-of-pocket costs (ROPC) for patients with high blood pressure and high cholesterol involves program and policy changes that make cardiovascular disease preventive services more affordable. These services include medications, behavioral counseling (e.g., nutrition counseling), and behavioral support (e.g., community-based weight management programs, gym membership). Costs for these services can be reduced by providing new or expanded treatment coverage and lowering or eliminating patient out-of-pocket expenses (e.g., copayments, coinsurances, deductibles).

ROPC is coordinated through the health care system and preventive services may be delivered in clinical or non-clinical settings (e.g., worksite, community). ROPC can be implemented alone or in combination with additional interventions to enhance patient-provider interaction such as team-based care, medication counseling, and patient education. Program and policy changes may be communicated to patients and providers using targeted messages to increase awareness and use of covered services.

## Task Force Finding (November 2012; updated July 2015)

The Community Preventive Services Task Force recommends reducing patient out-of-pocket costs (ROPC) for medications to control high blood pressure and high cholesterol when combined with additional interventions aimed at improving patient—provider interaction and patient knowledge, such as team-based care with medication counseling, and patient education.

This recommendation is based on strong evidence of effectiveness in improving (1) medication adherence and (2) blood pressure and cholesterol outcomes. Limited evidence was available to assess the effectiveness of reducing patient out-of-pocket costs for behavioral counseling or behavioral support services independent of reducing patient costs for medications.

## **Rationale**

#### **Basis of Finding**

The Task Force finding is based on evidence from 18 studies that assessed effectiveness of reducing out-of-pocket costs for medications to treat high blood pressure, high cholesterol, or both (search period January 1980-July 2015). The table summarizes review results by outcome.

### **Summary Results from Review**

Review Outcome	Effectiveness Measurements	Suitability of Study Design	Summary Estimates
Medication adherence	Absolute percentage point change in patient adherence rates for blood pressure and cholesterol medications	Greatest	Median: increase of 3.0 pct pts (IQI: 2.3 to 4.5 pct pts) 6 studies with 15 study arms



Review Outcome	Effectiveness Measurements	Suitability of Study Design	Summary Estimates
Medication adherence	Absolute percentage point change in proportion of patients achieving 80% adherence	Greatest	Increase of 5.1 pct pts 1 study
Medication adherence	Absolute percentage point change in patient adherence by baseline adherence rate	Least	Patients with low adherence (≤55%): increase of 21.4 pct pts  Patients with high adherence (>55%): reduction of 2.2 pct pts 1 study
Blood pressure	Absolute percentage point change in proportion of patients achieving blood pressure goal (<140 mmHg/90 mmHg)	Greatest or moderate	6.0 pct pts (Range: -8.2 to 17 pct pts 3 studies
		Least	Median: increase of 30.1 pct pts (IQI: 20.3 to 46.5 pct pts) 4 studies
Blood pressure	Change in mean systolic blood pressure (mmHg)	Greatest or moderate	Median: decrease of 5.9 mmHg (Range: -10.7 to 3.83 mmHg) 4 studies
		Least	Median: decrease of 8.7 mmHg (IQI: -14.5 to -5.45 mmHg) 6 studies
Blood pressure	Change in mean diastolic blood pressure (mmHg)	Greatest or moderate	Median: decrease of 3.75 mmHg (Range: -6.1 to -2.1 mmHg) 4 studies



Review Outcome	Effectiveness Measurements	Suitability of Study Design	Summary Estimates
		Least	Median: decrease of 4.5 mmHg (IQI: -7.8 to -3.8 mmHg) 6 studies
Low density lipoprotein (LDL) cholesterol	Change in mean LDL (mg/dl)	Greatest or moderate	Median: decrease of 14 mg/dL (Range: -16.0 to -6.9 mg/dL) 3 studies
		Least	Median: decrease of 14 mg/dL (IQI: -18.9 to 10.9 mg/dL) 3 studies with 6 study arms
Low density lipoprotein (LDL) cholesterol	Absolute percentage point change in proportion of patients achieving LDL goal	Greatest or moderate	Increases of 13.0 and 24.0 pct pts 2 studies
		Least	Increase of 10 pct pts 1 study
Triglycerides (TG)	Change in mean TG (mg/dl)	Greatest or moderate	Decreases of 13.0 and 9.8 mg/dl 2 studies
		Least	Decreases of 38.4 and 25.0 mg/dl 2 studies
Total cholesterol (TC)	Change in mean TC (mg/dl)	Greatest or moderate	Decrease of 15.0 mg/dl 1 study
		Least	Decrease of 25 mg/dL 1 study



Review Outcome	Effectiveness Measurements	Suitability of Study Design	Summary Estimates
Total cholesterol (TC)	Absolute percentage point change in proportion of patients achieving cholesterol goal	Greatest	Increase of 7.0 pct pts 1 study

IQI=interquartile interval (calculated for ≥5 study arms); pct. pts. = percentage points

All 18 studies evaluated programs or policies that reduced patient out-of-pocket costs for medications to treat high blood pressure or high cholesterol. Thirteen studies combined ROPC for medications with one or more additional interventions. These interventions included team-based care with medication counseling (seven studies), pro-active follow-up (five studies), disease management (six studies), linkages to other resources and services (four studies), and patient education (four studies). Six studies were policy-based; four of these evaluated value-based insurance design (VBID). Ten of 18 studies assessed the impact of ROPC for medications on blood pressure and cholesterol outcomes. Nine studies assessed the impact of BOPC on adherence to blood pressure- and cholesterol-lowering medications. Only one of 13 studies evaluated the impact of both medication adherence and blood pressure and cholesterol outcomes.

The Task Force finding reflects (1) the focus of available studies on reducing patient out-of-pocket costs for medications, (2) modest improvements in medication adherence in studies with ROPC policy changes, (3) meaningful improvements in blood pressure and cholesterol outcomes in patients from studies in which most ROPC efforts were combined with additional interventions such as team-based care with medication counseling, and (4) the lack of studies including or evaluating ROPC for behavioral counseling or behavioral support services for patients with high blood pressure or high cholesterol, independent of ROPC for medications.

#### **Applicability and Generalizability Issues**

Fifteen of 18 included studies were conducted in the United States with study populations that were balanced by gender and included working-age adults. Studies examined outcomes in different racial and ethnic groups (i.e. Hispanic, white, and African-American) with similar results. Six studies found effectiveness of ROPC in improving treatment outcomes for low-income patients. Overall, results indicate that evidence of effectiveness is broadly applicable to patients with high blood pressure and high cholesterol in the U.S. health care system.

Included studies evaluated different types of implementers with evidence of effectiveness suggesting applicability to employers, health plans and insurers, and government agencies. Four studies examined VBIDs in which patient out-of-pocket costs for medications for high blood pressure and high cholesterol were reduced or eliminated based on assessments of importance of the clinical benefit (high-value service). All four studies assessed medication adherence and reported modest, but favorable results.

Eight of 18 studies eliminated copayments for medications (100% cost reduction), and were found to be effective in improving outcomes. None studies both eliminated and reduced costs with favorable results, but did not report outcomes by level of reduction (i.e., improvements among those prescribed free versus reduced-cost medications) or by drug patent type (i.e., generic versus brand-name drugs). Few studies reported the actual dollar amount of cost reductions.



Five studies evaluated the effectiveness of ROPC policy changes on medication adherence in large patient populations. Although improvements in adherence were modest, adherence rates were relatively high (53% to 89%) at baseline in these populations. Improvements in adherence were larger among the patients with low adherence prior to the policy change (Table 1).

### **Data Quality Issues**

Twelve included studies had a comparison group and the other six measured before-after changes without a comparison group. The most common limitations of included studies were incomplete descriptions of study population and lack of detailed information about the ROPC program or policy.

#### **Other Benefits and Harms**

Included studies did not describe or evaluate additional benefits of ROPC. The coordination of ROPC with additional interventions (such as team-based care with medication counseling) may increase opportunities for patient—provider interaction on treatment issues such as dealing with medication side effects. Neither the included studies nor the broader literature identified any harms to patients from these interventions.

#### **Economic Evidence**

The economic review included nine studies that evaluated ROPC for medications to treat high blood pressure or high cholesterol. Eight studies were conducted in the United States and one in Israel. Studies examined different approaches to reducing medication costs. In two studies, reductions in costs were for medications to treat specific conditions. In the other seven studies, costs for medications were reduced as part of VBID plans. Two of the nine studies combined reduced cost for medications with team-based care and three combined VBID with support for disease or lifestyle management. All monetary values are reported in 2014 U.S. dollars.

**Intervention Cost:** All nine studies reported information on the costs of providing reduced-cost medications to both existing and new users. The intervention cost per person per year of increased pharmacy spending by plans was provided by all 9 studies, with median = \$172 (IQI: \$70 to \$529, n = 10). The higher estimates included blood pressure-lowering and diabetes medications. Of the 5 studies that had interventions in addition to ROPC, only one also provided the cost of the additional team-based care component, \$45 per patient per year in medication costs and \$542 per patient per year for team-based care.

**Intervention Benefits:** Seven studies estimated change in health care cost, with median = -\$127 (IQI: -\$632 to -\$18, n = 8). All but two of these studies included interventions in addition to ROPC, and the estimated change in healthcare cost are the result of the combined interventions and not due to ROPC alone.

None of the studies examined the effect of the intervention on productivity of the patients at their worksites.

**Net Benefit:** Three VBID studies reported information on net benefits, with 2 showing the cost of intervention exceeded averted health care costs by \$337 and \$90 per patient per year, and the third showing the intervention was cost-neutral. Hence, the evidence for net benefit was mixed.

**Summary:** The available studies do not provide sufficient assessments of economic cost and benefits to reach an overall economic conclusion regarding the intervention.



## **Considerations for Implementation**

The Task Force finding supports incorporation of policies or programs to reduce or eliminate out-of-pocket costs for medications to treat patients with high blood pressure or high cholesterol as one part of a cardiovascular disease prevention effort. Although team-based care and disease management programs were common additional interventions evaluated in the included studies, broader health system efforts such as Patient-Centered Medical Homes could also provide a useful infrastructure for coordination of prevention activities. In addition, partnerships with employers, providers, and community-based organizations may provide resources and settings that enhance access and use of preventive services.

Potential implementers include healthcare providers and plans, government agencies, and self-insured and fully-insured employers. The results of this review suggest opportunities for innovative application of ROPC policies, coordination of programs, and partnerships for delivery of services. Linking medical and pharmacy claims data and other information systems across settings may enhance coordinated service delivery, monitoring of service use, and assessment of program effectiveness for multiple outcomes of interest.

To increase awareness and use of ROPC covered services, it is critical to promote ROPC benefits to patients and providers. Only three of the 18 included studies described communicating ROPC for medications benefits to patients. Benefits were communicated to patients via letter, newsletter, and company intranet. None of the studies evaluated or reported changes in awareness as a result of activities related to communicating ROPC benefits.

The evidence indicates that a combination of interventions including ROPC for medications is effective in improving blood pressure and cholesterol outcomes for low-income patients. Innovative, culturally appropriate, and targeted promotion strategies to increase awareness among low-income groups with low medication adherence should be considered. Partnering with community organizations may also provide opportunities to increase awareness and use of ROPC benefits among underserved populations.

Reducing or eliminating copayments for generic medications is one ROPC policy approach. Increasing appropriate use of generic drugs may require additional efforts to inform preferences and decisions patients make with their providers. Price-sensitivity may be a function of patient income as well as medication cost. Prescribing providers can be important advocates for patients who are not aware of ROPC benefits. Providers can (1) actively ask patients about their ability to pay for medications and (2) be familiar with the medications covered by patients' health insurance plans and their costs to patients.

Reducing out-of-pocket costs for patients with high blood pressure and high cholesterol could be implemented as part of a broader effort to increase use of effective cardiovascular disease preventive services. A comprehensive approach would coordinate these policies with ROPC for evidence-based tobacco cessation treatments, and coverage to improve management of patients with diabetes. Evidence in this review, including studies evaluating VBID, indicates that ROPC interventions are effective in increasing adherence to medications in patients with different cardiovascular risk conditions.

#### **Evidence Gaps**

Although the evidence indicates that reducing patient out-of-pocket costs for medications to control high blood pressure and high cholesterol is effective, evidence is limited for assessing effectiveness of ROPC for behavioral counseling and behavioral support services. Additional studies could examine ROPC programs and policies to evaluate these cardiovascular disease preventive services, especially when coordinated with ROPC for medications. Future studies



should include and describe efforts to effectively communicate the presence and availability of covered ROPC benefits, and evaluate both the reach and effectiveness of different communication techniques.

Although eliminating patient out-of-pocket costs for cardiovascular disease preventive services is likely to maximize patient uptake, additional research could examine relationships between cost reduction and patient use, providing evidence on thresholds and differential effectiveness.

Additional research could also describe and examine effectiveness of ROPC by total medication cost, proportional cost-reduction, patient income, or drug patent type. In general, policy studies included in this review examined the impact of adding ROPC for medications for an entire patient population, but only evaluated changes in medication adherence. Conversely, the studies evaluating multicomponent programs that include ROPC for medications examined clinical outcomes for patients in the program, but did not report on changes in medication adherence. Both outcomes provide useful information to potential implementers and should be reported.

Where ROPC is combined with other interventions, studies need to provide the cost for both the ROPC and the intervention with which it is combined. Cost-effectiveness could not be calculated because many studies did not report clinical outcomes such as changes in blood pressure. The cost of communicating the ROPC benefits to providers and patients was not discussed or estimated in any of the economic studies.

### **Disclaimer**

The findings and conclusions on this page are those of the Community Preventive Services Task Force and do not necessarily represent those of CDC. Task Force evidence-based recommendations are not mandates for compliance or spending. Instead, they provide information and options for decision makers and stakeholders to consider when determining which programs, services, and policies best meet the needs, preferences, available resources, and constraints of their constituents.

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