August 2016 – SUPPORT Summary of a systematic review

How do pharmaceutical policies that restrict reimbursement for selected medications effect health outcomes, drug use and expenditures, and healthcare utilization?

Restrictions on reimbursement are defined as insurance policies that restrict reimbursement for selected drugs or drug classes, often using additional patient specific information related to health status or need.

Key messages

- **Restrictions on reimbursement in health insurance systems with substantial coverage for medicines probably decreases targeted drug use and expenditures on targeted drugs or drug classes.**
- **The effects of restriction on reimbursement vary by drug and drug class, and by how the restrictions are implemented and enforced.**
- **The impacts of restrictions on health outcomes and health service utilisation are uncertain.**
- **All the studies were done in high-income countries and participants were mainly senior citizens or low-income adult populations whose medications were being paid for in whole or part through publicly funded drug benefit plans.**
- **The effect of restrictions on reimbursement on equity has not been studied.**

Who is this summary for?

People making decisions about restrictions on reimbursement for medicines

! This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low-income countries

X Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

This summary is based on the following systematic review:

Green CJ, Maclure M, Fortin PM, et al. Pharmaceutical policies: effects of restrictions on reimbursement. Cochrane Database of Systematic Reviews 2010, Issue 8. Art. No.: CD008654.

What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies

SUPPORT was an international project to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries, funded by the European Commission (FP6) and the Canadian Institutes of Health Research.

Glossary of terms used in this report: www.supportsummaries.org/glossary-of-terms

Background references on this topic: See back page

Background

Pharmaceutical expenditures are a large component of health expenditures, accounting for an average of 17% of total health spending in Organization of Economic Cooperation and Development (OECD) countries in 2007 and exceeding 20% of health spending in eight countries. Restrictions on reimbursement are defined as the sets of insurance policies that restrict reimbursement for selected drugs or drug classes, often using additional patient specific information related to health status or need. Approval may be automatic (but subject to audit) if a reason is supplied. Included in this category are policies that are labelled as special authorization, special authority, special consideration, prior authorization, prior approval, pre-authorisation, restricted access, exemptions and for limited use.

How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low-income countries. The methods used to assess the reliability of the review and to make judgements about its relevance are described here: www.supportsummaries.org/how-support-summaries-are-prepared/

Knowing what's not known is important

A reliable review might not find any studies from low-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

A lack of evidence does not mean a lack of effects. It means the effects are uncertain. When there is a lack of evidence, consideration should be given to monitoring and evaluating the effects of the intervention, if it is used.

About the systematic review underlying this summary

Review objective: To determine the effects of a pharmaceutical policy restricting the reimbursement of selected medications on drug use, healthcare utilization, health outcomes and costs (expenditures).

Types of	What the review authors searched for	What the review authors found
Study designs & Interventions	Randomised and non-randomised trials, interrupted time series studies including repeated measures studies, and controlled before-after studies assessing prescribing policies - introduction of restriction to reimbursement, relaxation of previously instituted restrictions to reimbursement, or exemption from restrictive policies for targeted cost-effective drugs	24 studies evaluating restrictions to reimbursement policies. The majority of interventions were prior authorization. 5 studies evaluated policies of releasing or relaxing past restrictions to reimbursement. All of the studies were interrupted time series.
Participants	Healthcare consumers and providers within a large jurisdiction or system of care (regional, national or international)	Participants were predominantly the beneficiaries of publically subsidized or administered pharmaceutical insurance plans – most often senior citizens aged 65 years or over and low-income adult populations.
Settings	All settings	Health insurance systems with substantial coverage of medicines in the USA (14), Canada (11), Norway (2) and Denmark (2)
Outcomes	**Primary outcomes:** drug use (prescribed, dispensed or actually used), healthcare utilisation, health outcomes, costs (expenditures). **Secondary outcomes:** changes in equity of access to drugs, changes in access to medically necessary drugs by disadvantaged groups, changes in the distribution of financial burden	Drug use and drug expenditures (24 studies), health outcome data (2 studies), healthcare utilization (9 studies)
Date of most recent search: MEDLINE (2005 to January 2009) and other databases (2005 to October 2008)		
Limitations: This is a well-conducted systematic review with only minor limitations; however the most recent searches were in January 2009.		

Green CJ, Maclure M, Fortin PM, Ramsay CR, Aaserud M, Bardal S. Pharmaceutical policies: effects of restrictions on reimbursement. *Cochrane Database of Systematic Reviews* 2010, Issue 8. Art. No.: CD008654.

Summary of findings

Twenty-four studies evaluated restrictions on reimbursement. The majority of interventions were prior authorization policies where drug benefit plans required physicians to apply for exemptions from restrictions before permission was granted to have all or part of the cost of the targeted drug paid for by the insurance plan.

Restrictions to reimbursement

- **Restrictions on reimbursement probably decrease targeted drug use in the short and long term, and reduce expenditures on target drug or drug class. The certainty of this evidence is moderate.**
- **The effects of restrictions on reimbursement vary by drug and drug class and by how the restrictions are implemented and enforced.**
- **The impacts of restrictions on reimbursements on health service utilisation and health outcomes are uncertain because the certainty of this evidence is very low.**

About the certainty of the evidence (GRADE) *

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This is sometimes referred to as 'quality of evidence' or 'confidence in the estimate'.

† Substantially different = a large enough difference that it might affect a decision

See last page for more information.

Outcomes	**Impact**	Number of participants (studies)	Certainty of the evidence (GRADE)
Target drug use, immediately after introduction	Median relative effect (range) -26% (-.04 to -92%)	7 studies	⊕⊕⊕◯ Moderate
Target drug use, at 2 years after introduction	Median relative effect (range) -17% (-9% to -70%)	4 studies	⊕⊕⊕◯ Moderate
Expenditures on target drug or drug class at 6 months after introduction	Median relative effect (range) - 57% (-36% to -85%)	3 studies	⊕⊕⊕◯ Moderate
Expenditures on target drug at 2 years after introduction	Median relative effect (range) - 49% (-18% to -79%)	2 studies	⊕⊕⊕◯ Moderate
Health outcomes	One study found little or no difference in blood pressure control. The results of the other study were confounded.	2 studies	⊕◯◯◯ Very low
Health service utilization	Reported impacts on health service utilization varied.	9 studies	⊕◯◯◯ Very low
p: p-value GRADE: GRADE Working Group grades of evidence (see above and last page)			

Relevance of the review for low-income countries

➔ Findings	▷ Interpretation*
APPLICABILITY	
➔ **All of the included studies were conducted in high-income countries. Thus there is uncertainty regarding the transferability of the results to low-income country settings.** ➔ **Participants were mainly senior citizens or low-income adult populations in publicly subsidized or administered pharmaceutical benefit plans.** ➔ **Only two of the studies included in this review reported health outcome data.**	▷ *Applicability of these interventions to low-income countries depends on there being a:* *–Regulatory framework* *–Administrative and managerial system which support the implementation of the policy* *- Insurance system with relatively broad coverage of medicines* *- Efficient, timely access to patient-specific information* *- Availability of preferred products that are incentivized by the reimbursement policy* *- Product quality assessments and prescriber and patient trust in the quality of preferred products*
EQUITY	
➔ **Overall, the targeted population was mainly senior citizens or low-income adult populations in publicly subsidized or administered pharmaceutical benefit plans. The included studies provided little data regarding differential effects of the interventions for disadvantaged populations within the studied beneficiaries.**	▷ *These policies should be designed to minimize the risk of adverse effects on disadvantaged populations with poor access to medicines, and potential adverse effects on disadvantaged populations should be monitored.*
ECONOMIC CONSIDERATIONS	
➔ **None of the studies provided a full analysis of cost-effectiveness.**	▷ *Evaluations of the economic impact of the interventions at the system and household level are needed.*
MONITORING & EVALUATION	
➔ **Most of the studies did not evaluate effects on health outcomes.**	▷ *Consideration should be given to monitoring and evaluating potential impacts on health outcomes, as well as impacts on system and household expenditures, and on drug utilisation.*

*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low-income countries. For additional details about how these judgements were made see: www.supportsummaries.org/methods

Additional information

Related literature

Acosta A, Ciapponi A, Aaserud Met al. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database of Systematic Reviews 2014, Issue 10. Art. No.: CD005979.

Luiza VL, Chaves LA, Silva RM, et al. Pharmaceutical policies: effects of cap and co-payment on rational use of medicines. Cochrane Database of Systematic Reviews 2015, Issue 5. Art. No.: CD007017.

Wagner AK, Ross-Degnan D. The potential for insurance systems to increase access to and appropriate use of medicines in Asia-Pacific countries. In: K. Eggleston, ed. Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific. Brookings Press 2009.

Carapinha J, Ross-Degnan D, Desta A, Wagner AK. Health insurance systems in five Sub-Saharan African countries: Medicines benefits and data for decision making. Health Policy 2011; 99: 193-202.

This summary was prepared by

Taryn Young, South African Cochrane Centre, South African Medical Research Council, Cape Town, South Africa.

Conflict of interest

None declared. For details, see: www.supportsummaries.org/coi

Acknowledgements

This summary has been peer reviewed by: Anita Wagner and Carolyn Green.

This review should be cited as

Green CJ, Maclure M, Fortin PM, Ramsay CR, Aaserud M, Bardal S. Pharmaceutical policies: effects of restrictions on reimbursement. Cochrane Database of Systematic Reviews 2010, Issue 8. Art. No.: CD008654.

The summary should be cited as

Young T. How do pharmaceutical policies that restrict reimbursement for selected medications effect health outcomes, drug use and expenditures, and healthcare utilization? A SUPPORT Summary of a systematic review. August 2016. www.supportsummaries.org

This summary was prepared with additional support from:

The **South African Medical Research Council** aims to improve South Africa's health and quality of life through promoting and conducting relevant and responsive health research. www.mrc.ac.za/

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About certainty of the evidence (GRADE)

The "certainty of the evidence" is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By "substantially different" we mean a large enough difference that it might affect a decision. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the study design (randomised trials versus observational studies), factors that reduce the certainty (risk of bias, inconsistency, indirectness, imprecision, and publication bias) and factors that increase the certainty (a large effect, a dose response relationship, and plausible confounding). For each outcome, the certainty of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE: www.supportsummaries.org/grade

SUPPORT collaborators:

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is part of the Cochrane Collaboration. The Norwegian EPOC satellite supports the production of Cochrane reviews relevant to health systems in low- and middle-income countries . www.epocoslo.cochrane.org

The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking in low- and middle-income countries. www.evipnet.org

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration that promotes the generation and use of health policy and systems research in low- and middle-income countries. www.who.int/alliance-hpsr

Norad, the Norwegian Agency for Development Cooperation, supports the Norwegian EPOC satellite and the production of SUPPORT Summaries. www.norad.no

The Effective Health Care Research Consortium is an international partnership that prepares Cochrane reviews relevant to low-income countries. www.evidence4health.org

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