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Pharmaceutical pricing policies to improve the population's access to pharmaceuticals in Georgia

Rapid Response product

October 2019



Acknowledgement

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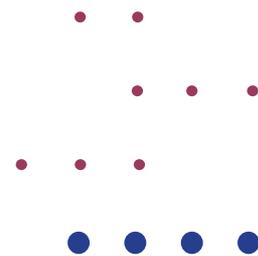


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Key messages

Pharmaceutical spending – heavy financial burden for Georgians

- In Georgia, 96% of total pharmaceutical spending is out-of-pocket (OOP) and the government contribution amounts to only 2%. In contrast, in OECD countries, the cost of pharmaceuticals, as with other health care functions, is predominantly covered by government financing or compulsory insurance schemes. On average, these schemes cover around 57% of all retail pharmaceutical spending, with OOPs paying for 39% and voluntary private insurance financing the remaining 4%.
- Public drug plans have a significant effect on patients' access to pharmaceuticals and adherence to treatment. Drug plans (coverage schemes) reduce financial barriers to access in Low- and Middle-Income Countries as they are associated with a decreased likelihood of paying for medicines and with slightly decreased consumer expenditures on medicines, leading to reduced financial barriers to purchasing medicines. Although Georgia implements a state funded health program to subsidize medicines for patients with chronic diseases for the poor and retired population, **outpatient drug benefit is still limited** and **access to medicines remains a challenge**:
- In Georgia, households' out-of-pocket payments for pharmaceuticals have contributed to the increased financial burden of healthcare and challenges to achieve universal health coverage among the population. At the same time, the less regulated pharmaceutical market and the scarcity of public funds to cover the population's need push patients into catastrophic health expenditures and inequitable access to essential medicines.

Pharmaceutical pricing policies

- There is no **single gold standard** of pharmaceutical pricing policies that has the potential to improve the population's access to pharmaceuticals and to control public and private expenditures on medicines. Instead, countries are using **a mix of policy options** to achieve their expected goals by adapting tools to the country-specific context.
- Successful pharmaceutical policies and pricing mechanisms have to be grounded on country-specific needs; aligned to the interests of stakeholders,

including providers and consumers; transparent; supported by a strong legal system and regulatory framework; and carefully monitored in order to achieve efficiency in medicine use.

- Although pharmaceutical pricing policies are associated with increased public drug expenditures, in settings where no or limited prior public drug plans existed, such increases might be offset by a corresponding reduction in overall healthcare costs by controlling the adverse health outcomes of poor medication adherence and access.
- Evidence suggests that the most commonly used mechanisms for pharmaceutical pricing policies are: *Reference Pricing*, *Tiered Co-payments* and *Cost-sharing Strategies* (Caps, Deductibles, Coinsurance).
- Prescription-drug insurance plans are one of the most powerful policy alternatives available for both controlling expenditures in a health system and effective compliance and management among patients. **Public drug insurance schemes are a critical precondition for countries to moves on to the other instruments presented below:**

Impact of different pricing interventions

- Impact of reference pricing on access to drugs and expenditures:
 - Reference pricing's overarching mechanism to influence access to pharmaceuticals comprises: a) shifting drug use from more expensive to less expensive drugs within the reference drug groups; b) reducing the prices of pharmaceuticals; and c) reducing the total use of drugs in the reference drug groups.
 - The effect of reference pricing on general health service utilization is that the rate of physician visits increases for a short period after policy implementation due to the practice of switching patients from more expensive to cheaper drugs. The longer-term effects on emergency department visits or hospitalization service use have not been examined. Overall, this policy appear to achieve cost savings without significant negative effects on resource consumption.
 - In order to set reference prices, ex-factory prices are used in Europe to avoid price differences caused by differences in distribution mark-ups. However, since Georgia is largely import

dependent, *Cost, Insurance and Freight*¹ (CIF) prices should be used if the reference pricing mechanism is applied, in order to minimize the increase in wholesale mark-up and decrease medicines prices.



Tiered formularies' impact on drug use and expenditure:

- With tiered co-payment (differential cost sharing), some patients switch to the cheaper drug options. In countries where most drug expenditure is paid by the government, overall public pharmacy spending decreases, and overall patients' OOP pharmacy spending slightly increases. Some patients continue to use more expensive options, which results in higher OOP expenditures. Although reports on patients' adherence have been mixed, they suggest decreased adherence to and utilization of the more expensive drugs.
- In the Georgian context, tiered co-payment could possibly encourage the use of generic drugs, leading to decreased OOP pharmacy spending. However, since the government's contribution to total pharmaceutical spending is currently small, tiered co-payment may not deliver its expected results unless the public share in the pharmaceutical sector increases significantly.



Cost-sharing strategies' impact on drug use and expenditure

- In markets where public or private insurers pay a significant proportion of pharmaceutical costs, cost-sharing strategies such as co-payments, caps, co-insurance or combinations of these reduces the use of medicines as they add a financial burden to patients by switching costs from insurers to patients. These policies place a potential financial barrier to the safe and timely use of prescription medicines and in some cases may be high enough to impair medicine use (for chronic patients, multi-medicine users, etc.).
- If public spending on drugs increases, cost-sharing strategies will have the opposite effect in Georgia as they will increase access to medicines, decrease household expenditure on pharmaceuticals and boost the government's contribution to total pharmaceutical

¹ Based on incoterms

spending (considering the fact that public expenditure on pharmaceuticals does not exceed 2%).

Implementation considerations

- Pharmaceutical pricing policies have their drawbacks and implementation risks. It is therefore important to have flexibility in mixing diverse policy alternatives such as placing exemptions and/or prior authorization in conjunction with tiered co-payments or cost-sharing strategies to reduce the policy burden for vulnerable populations (e.g. patients with chronic conditions, with low socio-economic status, etc.) during access to pharmaceuticals and address potential equity issues.
- In terms of reference pricing implementation, there are many factors that should be assessed prior to and during the introduction of this policy: the availability of, and access to, drugs; the presence of significant price differences between the drugs in the reference group before the reference price system is introduced, with relatively high prices on the drugs most used; the alignment of stakeholders' interests and the availability of adequate incentives for patients, physicians, pharmacists and pharmaceutical companies to comply with the reference price system; the provision of clinical and managerial information and support; the equivalence of drugs in the reference group; exemptions; the availability of electronic information systems; the existence of a regulatory framework allowing generic substitution or prescribing using international non-proprietary names; and quality control of generics to minimize perceived differences between the quality of generics vs. brand-name drugs that motivate patients to avoid generic equivalents.

Appropriate prescribing should also be supported in the country

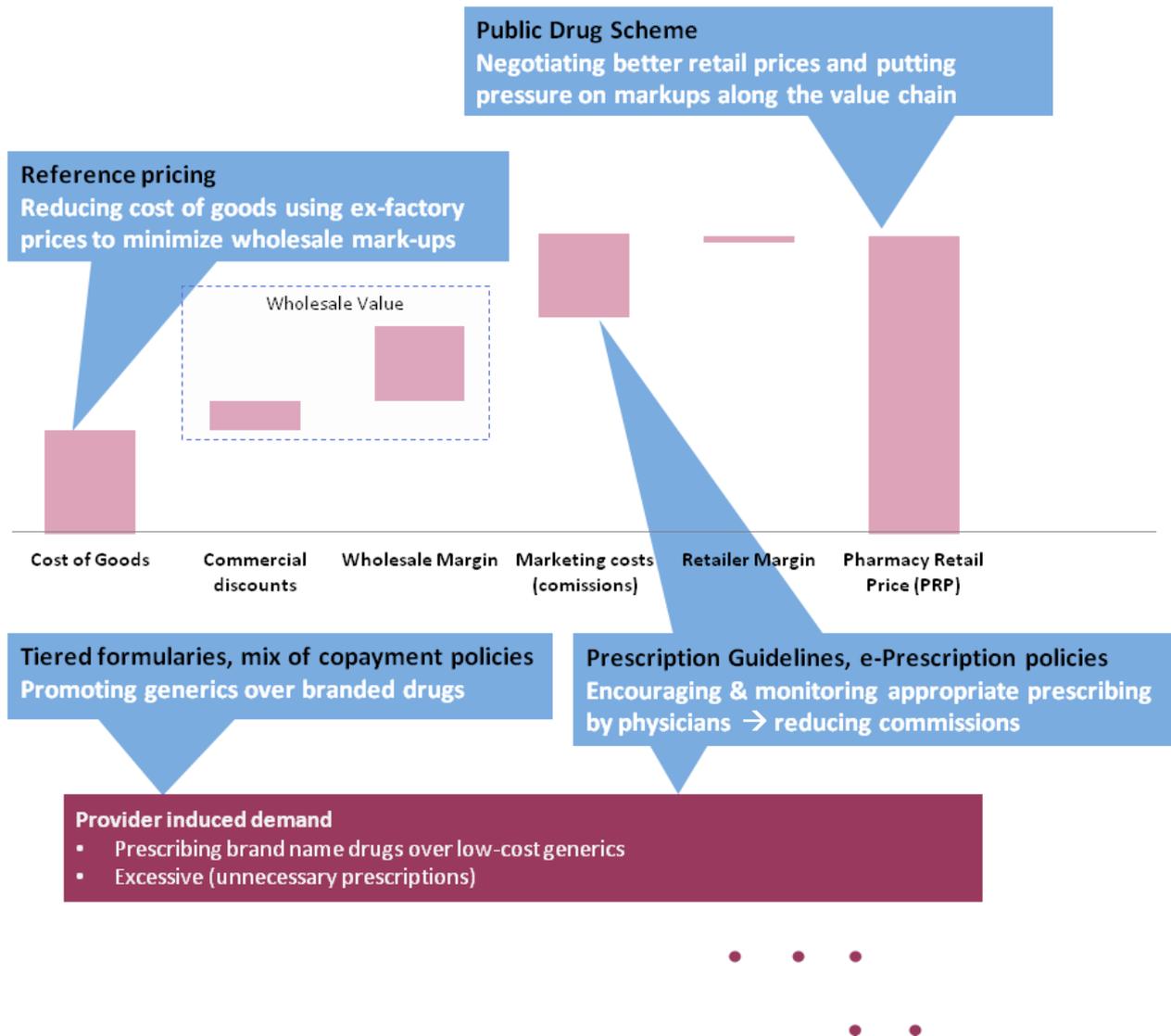
To effectively contain pharmaceutical expenditure in Georgia, it is necessary to enact regulations affecting not just the prices of pharmaceuticals but also reducing the volume of consumed medications. There are many mechanisms affecting provider behavior to improve prescribing patterns and quality: these policies can also be applied in Georgia to contain pharmaceutical spending as, to a significant extent, customer buying habits are driven by physicians' prescribing practices, which are effectively influenced by competitors through variable (and at times by unethical) marketing strategies.

In summary, in order to achieve current policy objectives and reduce the financial burden caused by high OOP expenditure on pharmaceuticals for the population along with reducing overall national expenditure on drugs, two parallel processes should be induced by policy-making institutions:

1. **Reducing average price per drug through:**
 - a. **A public drug scheme** that would realize economies of scale and introduce a 4th player in the market with significant purchasing power.
 - b. **Using reference pricing**, which reduces the cost of goods based on ex-factory prices (widely used in Europe) to avoid price differences caused by differences in distribution mark-ups.
 - c. **Tiered formularies and mix of co-payment policies** to promote the generic consumption of brands and thereby reduce the cost of treatment.
2. **Reducing overall (and to a degree unnecessary) drug consumption through:**
 - a. **Reducing excessive prescription** through the application of strategies encouraging appropriate prescribing guidelines; electronically monitoring prescription patterns and volumes and comparing them to others (e-prescriptions); and introducing administrative/enforcement mechanisms like incentives and/or sanctions.
 - b. **Promoting generics over branded drugs** through introducing tiered formularies and/or a mix of co-payment policies under publicly funded drug schemes with more financial benefits to vulnerable populations.

The illustration below attempts to explain the drivers of high pharmaceutical expenditures in Georgia and how the solutions proposed in this document would work on different price and demand elements:

Figure 1 Illustrative – Pharmaceutical Price Build-Up and Possible Influence of Proposed Policies²

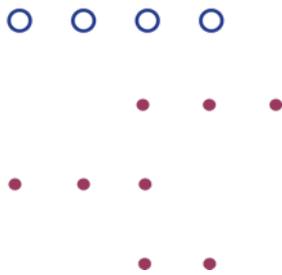


² The size of columns is for illustrative purposes only. Proportions are only indicative for the average price build-up across the value chain

Content

This Rapid Response document is structured as follows:

1. Current Issue and Question
2. Methods
3. Synthesis of the Evidence
4. What other countries are doing
5. Implementation Consideration



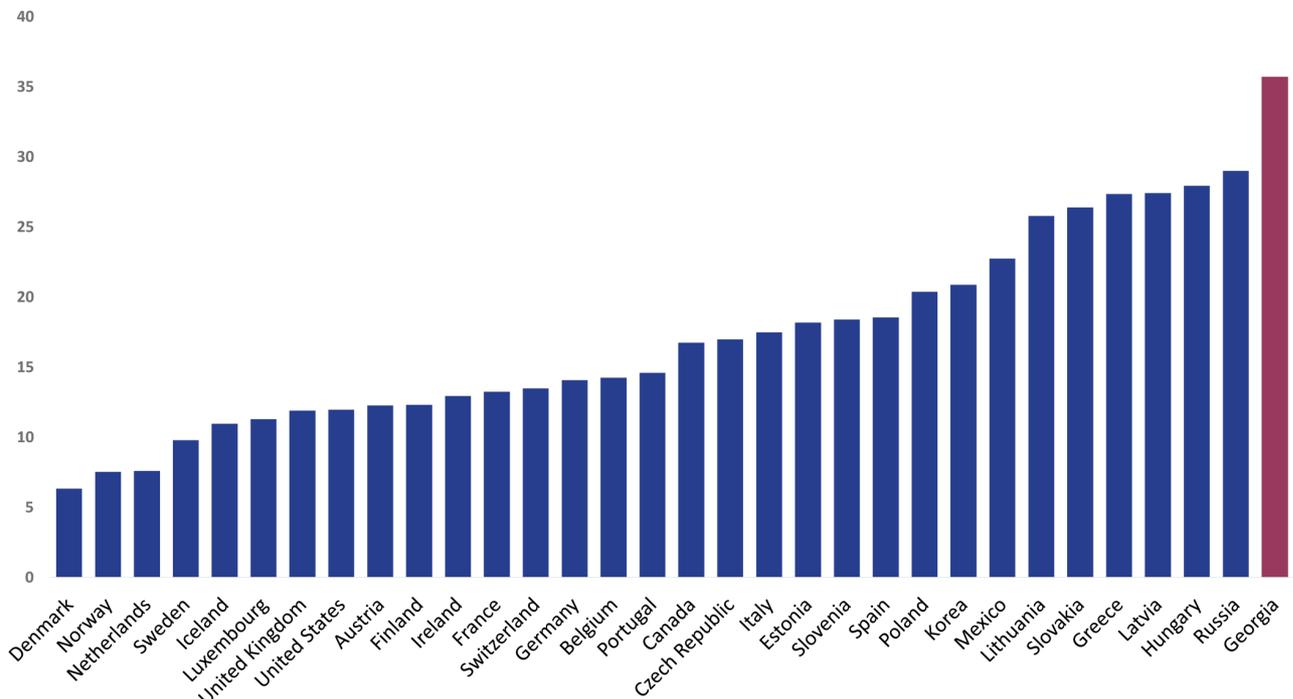


1. Current Issue and Question

Spending on Pharmaceuticals in Georgia and other countries

In OECD countries, after inpatient and outpatient care, pharmaceuticals represent the third largest expenditure item of health care spending, accounting for 16% of health expenditure. In contrast, pharmaceutical spending is the largest expenditure item in Georgia, constituting 35.7% of national health spending (see Figure 2).

Figure 2. Total pharmaceutical spending as % of total health spending (2017)



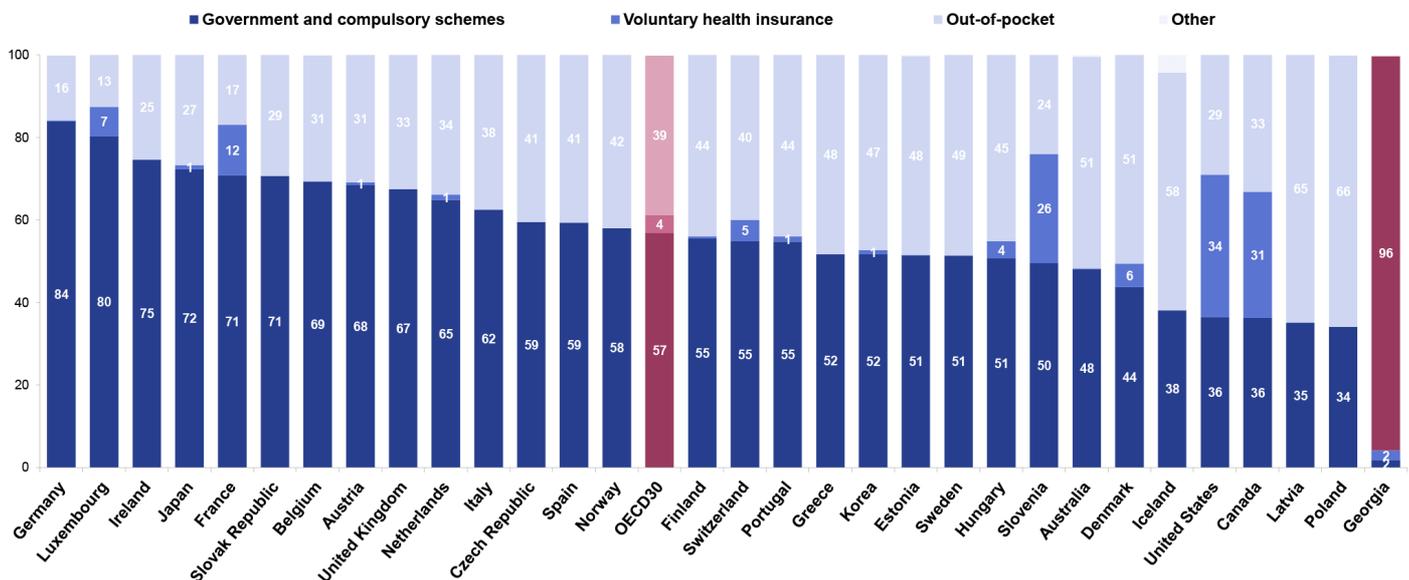
Source: OECD data health at a glance (“Pharmaceutical Expenditure in OECD Countries” 2017) (MoILHSA 2017)

Similar to other health care functions, in OECD countries the cost of pharmaceuticals is predominantly covered by government financing or compulsory insurance schemes (see Figure 3). These schemes on average cover around 57% of all retail pharmaceutical spending, with out of pocket payments (OOP) payments contributing 39% and

voluntary private insurance, 4%. Coverage is most generous in Germany and Luxembourg where government and compulsory insurance schemes pay for 80% or more of all pharmaceutical costs (“Pharmaceutical Expenditure in OECD Countries” 2017), while in Georgia pharmaceutical expenditures are primarily covered by households OOP - 96% (MoILHSA 2017).

Thus, Georgia is one of the highest spenders on pharmaceuticals in the world. Most of the money comes from households, placing a huge financial burden on their disposable income and creating significant financial access barriers, especially for poor people and for patients with chronic conditions (Gotsadze et al. 2017).

Figure 3. Expenditure on retail pharmaceuticals by type of financing, 2016 (or nearest year)



Source: OECD data health at a glance (“Pharmaceutical Expenditure in OECD Countries” 2017) (MoILHSA 2017)

Pharmaceutical spending – heavy financial burden for Georgians

Improving the population’s access to quality assured pharmaceuticals and protecting the citizens of Georgia from impoverishing expenditures when purchasing drugs has always been a challenge for national policy-makers (Chanturidze et al. 2009; Richardson and Berdzuli 2017). Out of pocket (OOP) payments for pharmaceuticals comprise 62.4% of total OOP spending for health; in 2017 they reached 983 million Georgian Lari (GEL) (MoILHSA 2017). High OOP spending on pharmaceuticals is associated with high wholesale and especially marketing/commission markups and provider induced demand i.e. promoting brand over generics and exercising over-

prescription. All of this forces households into catastrophic³ health care costs (which grew from 28% to 34% between 2010 and 2015) and diminished financial protection (Tan and Dolidze 2017). As a result, about 50% of households are unable to buy prescribed drugs because of their high costs and are at a high risk of unmet healthcare needs (NDI 2019).

This is further compounded by the following factors:

- A. **Limited drug benefit:** While medicines are covered under publicly funded schemes for vertical health programs (like TB, HIV, Hep C, Diabetes Type 1, etc.) and for inpatient use, the UHC Program has rather limited outpatient drug benefits.⁴ In 2017, the government introduced a new program offering subsidized drugs to chronic patients and covering the six most prevalent chronic conditions only (hypertension, COPD, diabetes type 2, thyroid diseases, Parkinson's and Epilepsy diseases), with two dozen drugs included in the reimbursement scheme (The Government of Georgia 2017);
- B. **Only a limited group of beneficiaries has access** to outpatient drug benefits under the stated program, which includes the poor (required to only pay a nominal 1 GEL at pharmacies for a prescription) and pensioners who are eligible for 50 percent reimbursement. In December 2018, the total size of the population eligible to access these benefits equaled around 30% of Georgians or 1,095,611 individuals (poor and pensioners), although only 9,334 individuals (0.9% out of those eligible candidates) benefited from this program in the same month (SSA 2018). Other population groups are not eligible for the drug benefit at all (The Government of Georgia 2017);
- C. **Limited public spending for outpatient pharmaceuticals:** Spending on outpatient medicines has consistently comprised less than 0.01 percent of the total UHC Program budget. Since 2017 public spending on outpatient medicines has increased but it only reached about 1.1 percent of the UHC program budget and 0.7 percent of total public health expenditure in 2018 (Ministry of Finance of Georgia 2018);

³ Catastrophic payment here is defined at the lower threshold of 10 percent of total expenditures.

⁴ Before introducing a new state funded health program for chronic conditions medicines reimbursement in April 2017, the UHC program covered some essential list of drugs for the poor, veterans and pensioners with 50% of co-payment and a limited annual cap of 100 GEL.

- D. **Drug spending is unnecessarily high** because of the poorly regulated pharma market:
- i. Prices for pharmaceuticals are not regulated and wild market forces drive pharmaceutical prices high. The wholesale and retail mark-ups are as high as can be borne by the market (Tokhadze 2016);
 - ii. The structure of the pharma market is oligopolistic, controlled by three vertically integrated firms with wholesale and retail networks, private health insurance and with a network of service providers (Richardson and Berdzuli 2017; CIF 2017);
 - iii. Low-cost generics are less available in pharmacies compared to the expensive originator products (CIF 2017) determined by the population's preferences and/or by behavior influenced by the marketing efforts of the suppliers;
 - iv. The 2014 pharmaceutical policies that introduced prescription requirements to support more rational pharmaceutical consumption have failed. Likewise, e-prescriptions introduced in Tbilisi in 2016 on a pilot basis were not compulsory and are not used on a large scale (CIF 2017);
 - v. Over-prescription of so called "polypragmasia" is a common practice caused by the perverse incentives created by pharmaceutical companies, using unethical marketing practices (Keller, Marczewski, and Pavlović 2016) and motivating doctors to prescribe certain medicines. This practice results in increased OOP on medicines (Richardson and Berdzuli 2017).

How the pharmaceutical price is build-up in Georgia

-  *Most pharmaceuticals are imported in the country (90%). While the share of domestic production has been growing in recent years, it is still limited to around 10%.*
-  *Most manufacturers supplying pharmaceuticals to Georgia provide volume related commercial discounts to Georgian importers/wholesalers, with variable rates between 3-20%⁵.*

⁵ Expert opinion collected by CIF through key-informant interviews

- *Due to the highly concentrated supply of pharmaceuticals among a handful of importers, wholesale markups are the highest and allow most revenue generation potential, mainly to market leaders.*
- *Marketing costs are rather high, mainly due to physician direct/indirect commissions, and form a significant part ($\approx 30-40\%$) of the drug Pharmacy Retail Price (PRP), causing cost increases.*
- *Retail markups by influential market players are the smallest portion of the PRP, coming in at around 1.5 – 3%⁶.*

Due to these reasons, Georgian health policy-makers have an interest in reforming the pharmaceutical system in a way that improves the population's access to pharmaceuticals and lowers the burden associated with high prices and high consumption.

The current rapid response product aims to answer a high priority research question, which is formulated as follows: (a) how to reduce the overall cost paid by the nation on pharmaceuticals; and (b) how to protect the public?



2. Methodology

What is a Rapid Response Product

A Rapid Response product responds to requests from policymakers and stakeholders by summarizing the research evidence drawn from systematic reviews and from primary research studies and provides them access to optimally packaged, relevant and best available research evidence.

The preparation of this rapid response involved the following steps:

⁶ Expert opinion collected by CIF through key-informant interviews

1. Formulating a clear review question on a high priority topic requested by policymakers and stakeholders;
2. Establishing what is to be done, and in what timeline;
3. Identifying, selecting, appraising and synthesizing the relevant research evidence about the question;
4. Drafting the Rapid Response in such a way that the research evidence is presented concisely and in accessible language;
5. Submitting the Rapid Response for Peer/Merit Reviews;
6. Finalizing the Rapid Response based on the input of the peer/merit reviewers; and
7. Final submission, validation, and dissemination of the Rapid Response

The quality of evidence is assessed using A Measurement Tool to Assess Systematic Reviews (AMSTAR), which uses 11 items to judge quality. AMSTAR characterizes quality of evidence at three levels: (1) 8 to 11= high quality; (2) 4 to 7 = medium quality; (3) 0 to 3 = low quality.

Evidence search and studies selection

A comprehensive search of the **systematic reviews** was performed using the PubMed, Health Systems Evidence and Cochrane databases for studies published between January 2000 and June 2019 that reported on the effects of pharmaceutical pricing policies on the population's access to pharmaceuticals and pharmaceutical expenditures.

Study selection, data abstraction and quality appraisal were performed by two reviewers simultaneously.

The streamlined steps followed in this document included limiting: the study design to systematic reviews, search dates to a period of 20 years and the language of publication to English.

From the database searches 1545 documents were retrieved. The titles of these papers were scanned and relevant abstracts (309) reviewed by 2 researchers. After abstract screening, 36 publications were selected for full-text screening. As a result, 22 systematic reviews met the inclusion criteria of the rapid response product.

Key terms and Boolean operators used for systematic reviews search: (drug OR drugs OR pharmaceutical* OR medicine OR medicines OR medication OR medications) AND (price OR prices OR pricing OR cost OR costs) OR ("health expenditures" OR "Health Care Costs" OR "cost control" OR "cost savings"). For more detailed description please see Annex 2. Search strategy.

Filters used during search in Health Systems Evidence: Decision-making authority about who is covered and what can or must be provided to them, Licensure & registration requirements, Patents & profits, Pricing & purchasing.

Exclusion: We excluded publications that were only focused on certain diseases or programs (oncology, TB, end of life palliative care, etc.); or population groups (e.g. children); or assessed the impact of patented and/or high price/ innovative drug policies or drug policies related to complementary medicines/biosimilars and orphan drugs; or systematic reviews in progress. Publications focusing on educational interventions for patients or prescribers and advertising/marketing were also outside of our scope.

In addition to the data synthesis from systematic reviews, we also used the OECD database to capture the pharmaceutical spending landscape across OECD countries. We present the charts built on these data at first and then move on to synthesize the best available evidence.



3. Synthesis of the evidence

In this section we present the findings from systematic reviews exploring the associations between pharmaceutical policies and access (use, utilization, adherence⁷) to pharmaceuticals on the one hand and the expenditures (costs, spending) of both patient and third party payers (public insurer), on the other. **Some of the articles assessed the impact of pharmaceutical policy on total health expenditures in addition to pharmaceutical expenditures.**

There is no **single gold standard** of pharmaceutical pricing policies that has the potential to improve the population's access to pharmaceuticals and to control public and private expenditures on medicines. Instead, countries are using **a mix of policy alternatives** to achieve their expected goals by adapting tools to the country-specific context. Evidence suggests that the most commonly used mechanisms for pharmaceutical pricing policies are: Reference Pricing, Tiered Co-payments and Cost-

⁷ Adherence to (or compliance with) a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers.

sharing Strategies (Caps, Deductibles, Coinsurance). We looked at other interventions as well. Specifically, the policies used in different countries can be found in the “What other countries are doing” section of this document.

Reference pricing impact on drug use and expenditures

Definition and its overarching mechanism

In accordance with World Health Organization (WHO) Glossary of Pharmaceutical Terms, **reference pricing** policy is “the practice of using the price(s) of a medicine in one or several countries (external reference pricing) or of identical medicines or similar products or even with therapeutically equivalent treatment in a country (internal reference pricing) in order to derive a benchmark or reference price for the purposes of **setting or negotiating the price** of the product in a given country.”

The introduction of external reference pricing policy entails three key stages: 1. Selection of reference countries, which is mainly based on geographic proximity, economic similarity, historical links, the availability of price information, the level of public health insurance for drugs, the level of investment in the pharmaceutical industry and the relative economic importance of domestic pharmaceutical production. 2. Determining the level at which prices are compared and the ‘price date’ in the reference country. **The ex-factory price is used in Europe to avoid price differences caused by differences in distribution mark-ups.** 3. Calculation of benchmark price. There are diverse methods of price calculation but the most used approach is to take a **price average**. Some countries use the following methods: reference price is set as the highest price generic product (Portugal), or the lowest price product (Canada), or the lowest price product accounting for at least 20% of the market (Spain), or the lowest price plus a proportion (Sweden). While some companies can choose to price at the reference price, others may price higher and rely on patients’ willingness to pay part of the cost.

Internal reference pricing involves price comparison between therapeutic equivalents within a country. Countries use this policy to price original products at market entry where therapeutic comparators are already available. In these instances, a medicine that has no added therapeutic value over an existing one is priced equivalently to its therapeutic comparators. However, if it is superior to the existing medication, a premium is applied that represents a percentage increase.

Considering the oligopolistic market structure of Georgia’s pharmaceutical market, internal reference pricing may entail significant risks unless the

public purchaser conducts international, open and transparent tendering engaging extra-territorial suppliers.

Reference pricing policy's overarching mechanism to influence access to pharmaceuticals includes the following: a) shifting drug use from more expensive to less expensive drugs within the reference drug groups; b) reducing the prices of pharmaceuticals; and c) reducing the total use of drugs in the reference drug groups (Aaserud et al. 2006; Acosta et al. 2014).

Reference pricing policy's impact on drug use and expenditures

Six systematic reviews emphasized the role of reference pricing in promoting switching behavior from expensive products to cheaper alternatives within the reference group, increasing the utilization of and adherence to targeted drugs (Aaserud et al. 2006; Acosta et al. 2014; J. L.-Y. Lee et al. 2012; Ogbechie and Hsu 2015; Morgan, Hanley, and Greyson 2009).

Three systematic reviews reported reference pricing's role in **decreasing medicines prices** (J. L.-Y. Lee et al. 2012, Aaserud et al. 2006, I.-H. Lee et al. 2015). However, according to the other systematic reviews, the effects of reference pricing on drug prices and patients' out of pocket payments remain uncertain (Acosta et al. 2014).

Internal reference pricing is assumed to **reduce third party drug expenditures** immediately and for six months and one or two years. The effects of reference pricing on drug use and expenditure beyond two years are uncertain. However, even if the short-term reductions in drug expenditure growth rates are not sustained, the absolute difference in drug expenditure could be sustained for many years (Acosta et al. 2014).

Reference pricing's effects on general health service utilization was examined in some of the systematic reviews, which concluded that **reference pricing had no significant effect on hospitalizations and physician visits**. One systematic review found a temporary **11% increase in physician visits (probably to switch to reference products) with no significant changes later on (3-10 months)**. Although the rate of physician visits increased for a short period after policy implementation, reductions in visits and hospitalizations over a longer time period were not consistently observed. Therefore, the policies appeared to achieve cost savings without negative effects on resource consumption (J. L.-Y. Lee et al. 2012). No clear evidence of increased healthcare utilization and adverse effects on health were found (Aaserud et al. 2006; Morgan, Hanley, and Greyson 2009).

The administrative expenditures related to the design, implementation, and ongoing support for the reference pricing policy were estimated to be approximately 7% (\$0.42 million / \$6.2 million) of the savings during the first year of the policy in British Columbia, Canada. The time costs for physicians and pharmacists related to a generic

reference pricing system in Norway were estimated to be approximately 60% of the public drug insurance savings (Aaserud et al. 2006).

Based on this, it can be assumed that reference pricing policies can help to increase the purchasing power (i.e. buy more drugs or serve more individuals) of Public Insurance schemes if they are well implemented.

Detailed results retrieved from the systematic reviews on the reference pricing effects on drug use and expenditures are presented in the table below:

Table 1. Reference pricing impact on drug use and expenditures.

Impact on drug use	Impact on drug prices and expenditure
<p>Six systematic reviews emphasized reference pricing's role in shifting drug use from more expensive to less expensive medications within the reference drug groups: The aggregate use of reference drugs increased while the utilization of drugs subjected to cost share arrangements decreased. The use of fully reimbursed drugs increased by 60% - 196% immediately after the policy started, while the use of cost share drugs (drugs from the reference group which cost more but for which patients pay the difference) decreased immediately by 19% - 42% (Aaserud et al. 2006)</p>	<p>Two systematic reviews reported reference price policies' impact on price reductions: Reference pricing reduced the prices of the targeted drug classes, with a mean reduction of 11.5% (range 7%-24%) (J. L.-Y. Lee et al. 2012) The prices of reference drugs reduced in the following drug categories: oral antibiotics decreased by 18%; generics - 11%, brand drugs - 26%; anti-ulcer drugs - 12% to 26% (Aaserud et al. 2006)</p>
<p>An updated version of the abovementioned systematic review reported a median relative increase of 15% in reference drug prescriptions at one year (range -14% to 166%), and a median decrease of -39% in cost share drug prescriptions at one year (range - 87% to -17%) (Acosta et al. 2014)</p>	<p>One systematic review reported uncertainty around the effects of reference pricing on drug prices. In three studies reference pricing appeared to reduce drug prices, and in one study co-payment prices decreased 13% for generic drugs and 23% for brand name drugs (Acosta et al. 2014)</p>
<p>According to (Morgan, Hanley, and Greyson 2009), between 9% and 34% of patients switched to fully covered (reference) products after reference pricing was implemented.</p>	<p>One systematic review found that reference drug pricing is an effective tool for controlling pharmaceutical</p>

Reference pricing policies increased the utilization of and adherence to targeted (reference) drugs, and promoted switching behavior from expensive products to alternatives at or below the reference price (J. L.-Y. Lee et al. 2012; Ogbechie and Hsu 2015).

Reference pricing policies have little impact on the overall use of pharmaceuticals, but they may reduce the volume of non-reference products while increasing the volume of reference products, linked to reductions in payers' expenditure (I.-H. Lee et al. 2015)

Reference pricing has no adverse effects on health. Nor did it increase the use of health services (Aaserud et al. 2006), with the possible exception of an increased number of consultations when reference pricing began (during the first 2 to 4 months after the policy change), when patients switched from a more expensive drug to a reference drug (Aaserud et al. 2006), which partially offset the savings in drug costs to the insurer. One systematic review found evidence of longer-term effects in terms of the increased use of physician services, which extended to over 4 months for 2 of the 3 categories studied (CCBs and ACE inhibitors) (Morgan, Hanley, and Greyson 2009).

expenditures for private and public payers. Unlike other cost-control mechanisms, reference pricing reduces expenditures without negatively affecting medication use or resource consumption. Reference price policies significantly decreased both patient and payer expenditures: OOP savings reached 12% - 18% per month; payer expenditure reductions ranged from 14% to 52% on targeted drug classes. These correspond to per capita savings of \$81 to \$650 (J. L.-Y. Lee et al. 2012).

Third party payer pharmaceutical expenditure reduction was seen in four other systematic reviews:

- ▶ Changes in utilization associated with reference pricing resulted in savings to insurers that ranged from 12% to 19% (\$1.67 million to \$6.7 million per year) of spending on related medicines (Morgan, Hanley, and Greyson 2009);
- ▶ Almost all studies reported decreasing third-party drug expenditures for the reference drug group (range 19% - 50%) for the third-party payer (Aaserud et al. 2006);
- ▶ Reference pricing has a demonstrable impact on payer expenditure, but this is a result of shifting costs to patients rather than reducing prices (I.-H. Lee et al. 2015). *However, this will not be the case for Georgia, where prices for pharmaceutical are mainly paid OOP.*
- ▶ Internal reference pricing may reduce third party drug expenditures immediately and for six months and one or two years (Acosta et al. 2014)

One systematic review showed an increase in patient OOP drug expenditure of 0% – 16% for senior citizens immediate after the policy's introduction (Aaserud et al. 2006).

Reference pricing seemed to be an effective intervention for decreasing pharmaceutical spending but was associated with increased nonpharmaceutical (health) expenditure (Ogbechie and Hsu 2015).

Importance of Insurance Schemes for drug coverage

Evidence suggests that drug coverage schemes reduce financial barriers to access in Low and Middle Income Countries (LMICs) in OECD countries as they are associated with a decreased likelihood of paying for medicines by consumers, leading to decreased OOP spending on medicines as a percentage of total health expenditure (Faden et al. 2011; Barnieh et al. 2014). The introduction of drug insurance for those without previous drug insurance appears to consistently increase adherence to medications. Moreover, increased costs on drug expenditures by the public payer may be offset by decreased costs in non-drug expenditures through preventing exacerbations of chronic conditions (Mann et al. 2014).

All systematic reviews indicate that in most of the countries where pharmaceutical policies were applied, public insurance plans for pharmaceuticals were in place. Pharmaceutical policies in these countries used different approaches to limit expenditures for their publicly-funded drug plans and placed different priorities on who should be able to access prescription drug insurance, and at what cost (Polinski et al. 2011).

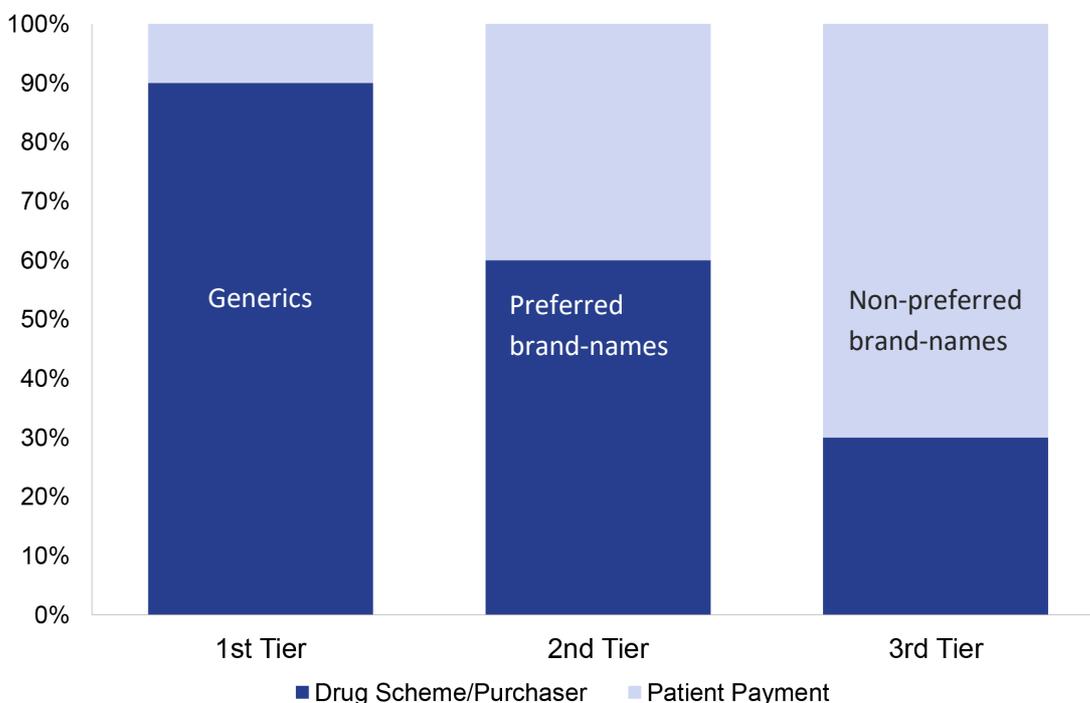
Prescription-drug insurance plans are one of the most powerful policy options available for both controlling expenditures in a health system and effective compliance and management among patients (Barnieh et al. 2014).

To conclude, having public drug insurance schemes functioning in overall health system is a critical precondition for a country to move to the other instruments presented below:

Tiered Formularies’ impact on drug use and expenditure

Tiered formularies, also known as tiered co-payment, are defined as a structure where certain drugs (either generic, particularly effective or cost-effective brand name drugs) are assigned a lower co-payment (first tier), with nonpreferred brand drugs assigned a higher co-payment (second tier). A third tier, with an even higher co-payment, may be assigned to less preferred brand drugs.

Figure 4. Illustrative – Conceptualization of Tiered Formularies



With tiered co-payment (differential cost sharing), some patients switch to the cheaper drug option, overall plans’ pharmacy spending decreases, and overall patients’ OOP pharmacy spending increases. Some patients continue to use the more expensive option, which results in high OOP expenditures (Ogbechie and Hsu 2015; Austvoll-Dahlgren et al. 2008).

Although using tiered formularies is expected to reduce third-party drug expenditures through increasing the financial burden of pharmaceutical spending for beneficiaries leading patients to use less expensive alternatives, it has the opposite effect (i.e. increasing third-party expenditures and medication use) when, prior to the

introduction of the policy, health systems lack any drug coverage for patients (Polinski et al. 2011).

The overarching mechanism of this policy is to shift some costs from insurer to patients; however, it will have the opposite effect in Georgia because there is nothing to shift from the public payer to a patient.

Systematic reviews on patients’ adherence were mixed but suggestive of decreased adherence to the more expensive drugs. Similarly, most articles found decreases in utilization of the expensive option (Ogbechie and Hsu 2015;(Morgan, Hanley, and Greyson 2009; I.-H. Lee et al. 2015).

Please see Table 2 below for more details.

Table 2. Tiered co-payment impact on drug use and expenditures

Impact on drug use	Impact on expenditure
<p>Three systematic reviews revealed that tiered co-payment increased switching to the cheaper option and decreased drug use (Ogbechie and Hsu 2015; Austvoll-Dahlgren et al. 2008). Tier co-payment structures reduced drug use across all tiers, including drugs used for treating chronic illnesses (Austvoll-Dahlgren et al. 2008). This policy may also reduce overall drug use if patients are not willing to substitute for other drugs or if the changes in the tier structure also include increased co-payments for generics (Luiza et al. 2015).</p> <p>Patients appear to respond to some financial cost-sharing incentives to switch to close drug substitutes:</p> <ol style="list-style-type: none"> 1) Nonpreferred vs Preferred Brand-name drugs - adding a third tier for nonpreferred brand-name drugs resulted in a decrease in the use of these 	<p>One systematic review showed that greater use of generic medications via tiered formularies could result in important health care savings while maintaining the quality of care. Formularies “channel” patients to a particular product and point out an apparent “best value” among many drugs of therapeutic category. Patients are offered financial incentives (e.g. lower co-payments) to buy drugs from a formulary. This has helped Pharmacy Benefit Managers to increase the purchase volume of the drugs and maximize rebates from drug manufacturers (Hermanowski, Drozdowska, and Kowalczyk 2015).</p> <p>Three systematic reviews found that tiered formularies are associated with reduced plan expenditures, greater patient costs and increased rates of non-compliance with prescribed drug therapy (Morgan, Hanley, and Greyson 2009; I.-H. Lee et al. 2015). <i>However, in Georgia the impact is expected to be the complete opposite, as</i></p>

<p>drugs and an increase in the use of preferred brand-name drugs (Gibson, Ozminkowski, and Goetzel 2005; Luiza et al. 2015). One systematic review reported switching toward “preferred” drugs on a formulary occurring among 5% to 49.4% of patients (Morgan, Hanley, and Greyson 2009);</p> <p>2) Generic Substitution - Four systematic reviews reported an increase in the number of generic drugs dispensed as a result of higher generic vs brand price differentials (Gibson, Ozminkowski, and Goetzel 2005; J. L.-Y. Lee et al. 2012; Hermanowski, Drozdowska, and Kowalczyk 2015; Howard et al. 2018).</p> <p>Changing OOP drug costs affected both the under- and over-use of medicines in the US. When Medicare Part D insurance coverage was available, drug use increased, especially among those who had previously lacked coverage. Conversely, as patients entered the Part D coverage gap and lost financial benefits, utilization rates decreased (Polinski et al. 2011).</p> <p>Two systematic reviews reported tiered a co-payment association with health service use.</p> <p>A significant impact on utilization was not observed in any of the studies.</p>	<p><i>currently 96% of costs for pharmaceuticals are paid by patients and tiered co-payments will increase expenditures on pharmaceuticals for the public plan and will decrease them for households.</i></p> <p>While the shift of cost from the insurer to patients in many cases led to savings for the insurer, the discontinuation of drugs may have had unintended effects. Direct payment interventions may also have adversely affected patients through the discontinuation of life-sustaining drugs or drugs that are important in treating chronic conditions.</p> <p>The deterioration of health in these vulnerable populations may in the end result in the increased use of healthcare services and overall plan expenditures (Morgan, Hanley, and Greyson 2009).</p> <p><i>The abovementioned describes the current situation in the Georgian pharmaceutical system, where there is nothing to shift from state to patients with regard to pharmaceutical expenditures and, as a result, the policy effects will be different.</i></p> <p>Direct payments are less likely to cause harm if only non-essential drugs are included or exemptions are built in to ensure that patients receive the necessary medical care.</p> <p>Only one systematic review reported tiered formularies' impact on total health expenditure, patient expenditure, plans' expenditure, and pharmacy spending,</p>
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<p>→ One systematic review stated that a significant impact on health service utilization was not observed (Austvoll-Dahlgren et al. 2008).</p> <p>→ The other systematic review found a short-term increase in physician visits immediately after the differential pricing intervention, but most found either no change or decreased longer-term physician utilization (Ogbechie and Hsu 2015).</p>	<p>where 9 out of 12 studies showed overall decreases.</p> <p>Most articles (4 out of 6) reporting on plans' nonpharmacy spending found increases, while all reporting on overall medical spending showed decreases (Ogbechie and Hsu 2015).</p>
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Cost-sharing strategies impact on drug use and expenditure

Three systematic reviews reported that cost-sharing strategies including **co-payments, caps, co-insurance** or combinations of the above reduced the use of both essential and non-essential medicines across studies. The findings suggest that patients may not have prioritized their medicine use when faced with a reimbursement restriction or they were not able to afford the increased cost, and/or that they prioritized their spending (e.g. for different medicines and other goods, like food) in ways that made sense to them. Therefore, these policies may have a disproportionate effect on the vulnerable population, including multi-medicine users (Luiza et al. 2015; Austvoll-Dahlgren et al. 2008; Gibson, Ozminkowski, and Goetzel 2005).

Co-payments provide significant opportunities for a prescription drug insurance plan to maximize its budget: evidence suggests that doubling a patient's co-payment in a given plan, regardless of the type of co-payment, reduces average annual drug spending by one-third (Barnieh et al. 2014; Luiza et al. 2015). Although cost-sharing policies decrease medicine expenditures for insurers, nevertheless it may increase the use of healthcare services, which may result in increased health expenditures for the insurer (Luiza et al. 2015; Austvoll-Dahlgren et al. 2008; Gibson, Ozminkowski, and Goetzel 2005). Evidence confirms that higher levels of prescription drug cost-sharing generally produce some of the intended effects of decreasing the effects of consumption of prescription drugs and steering patients away from nonpreferred brand-name drugs to preferred brand-name drugs. Although not consistently reported in the literature, the most troublesome effects associated with higher levels of cost sharing are reports of

treatment disruption for chronically ill patients who depend on a regular regimen of prescription drugs (Gibson, Ozminkowski, and Goetzel 2005).

In most cases, a small increase in cost sharing was not associated with increased utilization of low-intensity outpatient medical services, such as physician office visits, outpatient visits, and home health visits. Two studies reported an increase in high-intensity health services, such as inpatient visits, as cost-sharing rose. Patients reducing the consumption of less essential medications did not have a significant change in adverse events (Gibson, Ozminkowski, and Goetzel 2005).

To conclude, the shift of cost from insurers to patients may lead to savings for the insurer in terms of expenditures on medicines, while the discontinuation of medicines may have had unintended effects on healthcare utilization. The discontinuation of medicines might lead to (1) an increase in other healthcare expenditures for the insurer; and (2) to adverse health outcomes for patients.

Considering the Georgian context, where the list of publicly reimbursable medicines and the group of potential beneficiaries are limited and public expenditure on pharmaceuticals does not exceed 2% of total pharmaceutical spending, cost-sharing strategies are expected to have the opposite effect and result in increased financial access to pharmaceuticals for the population. Evidence about providing more benefits to the vulnerable population through lowering cost-sharing amounts compared to non-vulnerable groups should be taken into the consideration to avoid the undesirable effects of this policy intervention (risks of discontinuation of treatment).

Please see the table below describing the effects of cost-sharing strategies, which was prepared based on best available evidence.

Table 3. Cost-sharing strategies impact on drug use and expenditures

Impact on drug use	Impact on expenditures
<p>One systematic review found that increasing co-payments has been shown to decrease drug usage in an effort by the patient to maintain their overall costs. The concern is that patients are unlikely to only reduce the consumption of less effective medications. It was found that for each \$10 increase in co-payments, average compliance fell by 5% and that lower compliance resulted in greater use of other, more expensive medical services (Barnieh et al. 2014).</p>	<p>According to one systematic review, only the mix of cap with co-insurance and ceiling was assumed to decrease patient expenditures on medicines (Luiza et al. 2015).</p> <p><i>Below are the effects of the cost-sharing strategies found in other countries that do not seem relevant to Georgia considering</i></p>

<p>In high-income countries, where the willingness to pay is perhaps less likely to be affected by low fixed co-payment values, only a small decrease in medicine use was observed. Thus, setting the co-payment amount greatly affects its intended effect and may result in almost no or a significant change in drug use.</p> <p>Three systematic reviews revealed that other cost sharing strategies have a similar impact on drug use. Reimbursement policies by using a cap, fixed co-payments, ceiling with fixed co-payments or with co-insurance, prescription caps show that these policies reduced medicine use, even for medicines considered 'essential' (Dorman et al. 2018; I.-H. Lee et al. 2015; Luiza et al. 2015)</p> <p>Only one systematic review showed an increase in the overall use of medicines while using a mix of co-payment methods. A cap with co-insurance and a ceiling (deductible) vs heterogeneous but limited medicines coverage appeared the only mix of cost-sharing strategies that increased the overall use of medicines (Luiza et al. 2015).</p> <p>The use of deductibles/ceiling (up to \$350 per year) does not appear to have a significant impact on medication adherence. One study reported that a 100% co-payment (i.e. those who had not yet reached the deductible level) was associated with a two-fold reduction in drug adherence (Mann et al. 2014).</p> <p>In a publicly insured system where co-payments for medicines are required, patients have 11% increased odds of nonadherence to medicines. Reductions in</p>	<p>the current context, but are still worth presenting:</p> <ol style="list-style-type: none"> 1. Cost sharing/co-payments strategies provide significant opportunities to a prescription drug insurance plan to maintain its budget (Barnieh et al. 2014). The increase in cost-sharing results in pharmaceutical cost savings to health plans, as their cost per prescription is reduced by the increase in patient cost-sharing. 2. Cost sharing strategies (fixed co-payments, caps, ceilings with co-insurance, prescription caps) reduced medicine expenditures for insurers, although they increased the use of healthcare services (Dorman et al. 2018). 3. User charges reduce the utilization of pharmaceuticals and reduce public expenditure by shifting costs to patients. However, they can reduce the use of essential as well as non-essential drugs; without adequate exemptions, they affect vulnerable groups disproportionately and substantially increase non-drug expenditure in some populations (I.-H. Lee et al. 2015).
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<p>adherence to medicines, especially essential medicines, can be detrimental to health status and cause increases in expenditure via hospital admissions (Sinnott et al. 2013). Similar findings were found for the elderly and low-income individuals (Barnieh et al. 2014);(Dorman et al. 2018; I.-H. Lee et al. 2015; Gibson, Ozminkowski, and Goetzel 2005). In Georgia, cost-sharing strategies are assumed to have the opposite effect.</p>	
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Other interventions:

Competition policy

One systematic review suggests that competition can reduce prices for medicines. Even for patented medicines, competitive pressure from close therapeutic substitutes can place downward pressure on prices. Competition policy is a potentially important policy space to improve the use of generics in LMICs. The prices of generic medicines are lower compared to originator products if there is “enough” competition (not defined), and higher volume purchases are not, by themselves, sufficient to reduce the prices of generic medicines (Kaplan et al. 2012).

Considering the oligopolistic structure of the pharmaceutical market in Georgia, introducing the Government as a major player in the pharma market would increase the competition for government contracts and may create a better environment for reducing the prices.

Pharmaceutical budget caps or targets

Pharmaceutical budget caps or targets are the policy intervention where doctors and healthcare organizations are given a budget and the responsibility to stay within this budget (global budget decisions, where a proportion of a global budget is earmarked for prescribing pharmaceuticals). This policy may lead to a modest reduction in overall drug use per patient. All results reported in the studies almost uniformly showed a greater increase in the use of generic drugs among fund-holders (budget cap). Studies suggest a median of +15.0% (range -43.7% to 190.5%) increase at 12 months and +18.3% (13.6% to 23.0%) at 24 months. The effects of this policy on drug costs or on healthcare utilization are uncertain, as the certainty of the evidence has been assessed

as very low. The effects of this policy on health outcomes have not been measured (Rashidian et al. 2015).

Implementing restrictions to coverage and reimbursement of selected medications can decrease third-party drug spending without increasing the use of other health services. Relaxing reimbursement rules for drugs used for secondary prevention can also remove barriers to access. Exemption from restrictions to reimbursement provides a 'safety valve' allowing access to restricted drugs under some circumstances, thereby maintaining a range of therapeutic options and facilitating acceptance by physicians and patients (Green et al. 2010).

Where drugs have cheaper, effective alternatives and they target symptoms, reimbursement restriction policies can ensure the better use of the medications with reduced costs and without an increase in the use of other health services (as would be expected if there were negative health effects of the restriction policies) (Green et al. 2010).

Prior Authorization

The Impact of Prior Authorization (PA) policy is a cost-containment measure applied to high-cost medicines to control expenditure by substituting less expensive medicines for more expensive ones when therapeutically equivalent alternatives exist and/or to reduce inappropriate prescribing. This policy requires advance approval from drug reimbursement schemes before the medicine is dispensed based on the submissions of the clinical information from doctors. PA policy is grounded on a "fail-first" mechanism whereby patients have to fail a lower-cost treatment before the use of more expensive medicine is permitted. The application of this policy indicates that pharmaceutical use of drugs and /or expenditure per patient or enrollee is directly affected by PA restrictions and that overall drug expenditure significantly decreased (increased) after policy implementation (removal). The health outcome changes attributed to PA policies were not directly evaluated, although changes in the use of other health services may provide an indirect indication of any complications or adverse health effects. In most cases, PA implementation was not associated with significant changes in the utilization of other medical services (Puig-Junoy and Moreno-Torres 2007).

Although PA policies can support the sustainability of drug benefit plans and thereby preserve access to the necessary drugs for low-income populations, it may have unintended consequences. Appropriate use may decrease because: 1) some physicians charge for applying for exemptions and patients may be unwilling or unable to pay these charges; 2) patients may be unwilling to switch medications and may not renew the new drug prescriptions; or 3) physicians may be unwilling to take the time to apply for an exemption, leaving some patients unable to pay for additional coverage and

forgoing the needed therapy. Moreover, processing PA requests is associated with administration costs for third party insurers, prescribers and pharmacies. These costs may or may not be offset by the program savings (Green et al. 2010).

Pay-for-Performance policy

A pay-for-performance scheme initiated to provide incentives for physicians to reduce pharmacy costs and to increase the prescribing rate of generic medicines comprised a reward payment to the practice every 6 months dependent on the extent of cost-savings. This intervention did not increase the generic dispensing rate (Babar, Kan, and Scahill 2014). Similar results were found in another systematic review, which suggested that pay-for-performance did not result in major improvements in prescribing or health outcomes (Rashidian et al. 2015).

Educational interventions

Although **patient-related factors** such as patient demographics, patients' prior experience with generic drugs, and patients' communication with healthcare providers regarding generic drugs were outside of the scope of this rapid response, the literature indicates that such factors play a crucial role in generic drug use. For example, patients with lower incomes, or who are Caucasian, male, young, or otherwise healthy are less likely than their counterparts to utilize generic drugs and may need an additional or more targeted approach, including educational materials and information from healthcare professionals, in order to increase generic drug utilization.

Likewise, **educational interventions** directed towards prescribers/physicians were not considered in this review. Nevertheless, the evidence demonstrated that they can lower pharmaceutical utilization and expenditures when the focus of the intervention is on cost-effectiveness information, but that changes are likely to be modest (I.-H. Lee et al. 2015).

Comparisons between different pricing policy interventions

Reference pricing vs Tiered Formularies

Patients facing either reference pricing or tiered formularies often switched to medications with preferred coverage. These policies alter prescription drug use among patients and save on drug costs. Studies of reference pricing suggest that this approach is also associated with short-term increases in the use of physician services, which may be interpreted as a transaction cost associated with switching medications. Reference pricing is not associated with adverse health effects.

The evidence concludes that reference pricing has a slight evidentiary advantage, given that patients' health outcomes under tiered formularies have not been adequately studied and that tiered formularies were associated with increased rates of medicine discontinuation (Morgan, Hanley, and Greyson 2009).

However, as described above, it is assumed that in Georgia tiered formularies would have the opposite effect: namely, the subsidization of costs of medicines by a public payer will improve the affordability of pharmaceuticals.

Reference pricing vs Cap limits

Reference pricing appears to have different effects to many other strategies to contain prescription drug spending. While prescription cap limits protect payers from excessive cost, the limits cannot distinguish between medically necessary and unnecessary drug use and may prevent patients from purchasing the drugs that they need. Among frail, low-income, elderly patients, these caps lead to an increased risk of institutionalization (J. L.-Y. Lee et al. 2012)

Tiered formularies or co-insurance vs Fixed co-payments

The aim of a fixed co-payment is to reduce overall medicine expenditures and utilization. As co-payments are the same for every prescription or for the whole

medicine group, patients' co-payments are identical for both brand and generic medicines. Therefore, fixed co-payments do not provide incentives to choose cheaper substitutes, in contrast to co-insurance or tier co-payments. Tiered co-payments encourage consumers through financial incentives to choose products that are assumed to be more cost-effective for the insurer. Therefore, fixed co-payments do not provide incentives to choose cheaper substitutes, in contrast to co-insurance or tier co-payments.

Fixed co-payments with a ceiling and tiered fixed co-payments may be less likely to reduce the use of essential medicines or to increase the use of healthcare services (Luiza et al. 2015).

4. What other countries are doing

As noted above, there are different types of pharmaceutical pricing policies that countries apply according to their needs and priorities. Pricing and reimbursement strategies are a vital part of the pharmaceutical system. In most European and OECD countries, public pharmaceutical schemes are a precondition for implementing further pricing policies. In general, reimbursable medicines are subject to state price control while non-reimbursable medicines prices are not regulated (free pricing).

The two tables below compare the mechanisms used for pharmaceutical expenditure control across OECD countries. As seen in Table 4, countries use a combination of different price control mechanisms rather than a single one. The most commonly used mechanism to determine medicine prices across Europe and OECD countries is price referencing (external and/or internal reference pricing). Co-payment strategies are also widely used in publicly funded prescription drug-plans in these countries. The magnitude of co-payment varies across countries and within countries by prevalence of chronic conditions, age or socioeconomic class. For example, five countries have co-payments that vary depending on the type of drug or its indication for use. In Portugal, the co-payment for drugs is dependent on the deemed essential nature of the pharmaceutical or class of medications, while in Greece and Sweden, there are no co-payments explicitly for insulin. In Iceland and Slovakia, all pharmaceuticals deemed vital by the agency are reimbursed in full. Co-payments vary by socio-economic status (either income or employment status), or by age in 15 countries (Australia, Belgium, Czech Republic, England, Estonia, Greece, Hungary, Italy, Japan, New Zealand, Norway, Slovenia, South Korea, Spain, and Turkey) (Barnieh et al. 2014).



Table 4. Use of reference pricing, cost-sharing and cost-containment policies within included OECD countries

Policies: Countries	External reference pricing	Internal reference pricing	Use of co-payment	Co-payments vary by				Maximum OOP Limit (a fixed amount or % of income after which insurer pays 100%)	Cap	Deductible	Public spending on drugs (2017)
				Condition	Type of drug	Soc-econ status	Fixed or %				
Germany	√	√	√	X	X	X	Both	2% of net income; 1% of net income for chronically ill patients	X	X	83.9%
Luxemburg	X	X	√	√	X	X	%	2.5% of net income	X	X	80.2%
Ireland	√	√	√	X	X	X	Fixed	19.50€ per month per month	X	X	74.6%
Japan			√	X	X	√	%	80,000 yen monthly	X	X	72.3%
France	√	√	√	X	X	X	Both	X	X	X	70.9%
Slovakia	√	√	√	X	√	X	Both	X	X	X	70.7%
Belgium	√	√	√	√	X	√	%	Varies by patient type	X	X	69.2%
Canada	√	√	Varies by plan	X	X	Varies by plan	Varies by plan	Varies by plan	Varies by plan	Varies by plan	69.2%
Austria	√	x	√	X	X	X	Fixed	2% of annual income	X	X	68.4%
England			√	√	X	√	Fixed	X	X	X	67.4%
Netherlands	√	√	√	X	√	X	Difference between reference price & retail	X	X	√	64.8%
Italy	√	√	√	√	X	√	Fixed	X	X	X	62.5%
Czech Republic	√		√	√	X	√	Fixed	200€ for children under 18 and at 100€ for adults over 65	X	X	59.5%
Spain	√	√	√	√	X	√	%	X	X	X	59.3%

Pharmaceutical pricing policies to improve the population's access to pharmaceuticals in Georgia

Norway		√	√	√	X	√	Both	216€ & 63€ per prescription	X	X	58.0%
Finland	√	√	√	√	X	X	%	Set 672€, subsequent costs are reimbursed in full after a fixed 1.50€ co-payment	X	X	55.5%
Switzerland			√	X	X	X	%	700 CHF for adults & 350 CHF for children	√	√	54.8%
Portugal	√	√	√	X	√	X	%	X	X	X	54.7%
Greece	√	√	√	√	√	√	%	X	X	X	51.7%
Estonia		√	√	√	X	√	Both	X			51.4%
Sweden	x	x	√	X	√	X	%	X	X	X	51.3%
Hungary	√		√	√	X	√	%	X	X	X	50.6%
Slovenia		√	√	√	X	√	%	X	X	X	49.5%
Australia	√	√	√	X	X	√	Fixed	Fixed, dependent on type of patient	X	X	48%
Denmark	x	√	√	√	X	X	Both	406€ for chronically ill patients	X	√	43.7%
Iceland	X	X	√	X	√	X	%	X	X	X	38.1%
US	No (except for Medicare& Medicaid)	x	Varies	X	X	X		Co-payment reduces to 5% after limit	Varies. Step therapy, PA&cost tiers		36.5%
Poland	√	√	√	√	X	X	Both	X	X	X	34.1%
Mexico			X					X	X	X	
New Zealand			√	√	X	√	Fixed	X	X	X	
Scotland			X		√				X	X	
South Korea			√	√	X	√	%	2,3 or 4 mln KRW by insurance plan	X	X	
Tukey			√	√	X	√	%	X	X	X	

In parallel to the above-mentioned policies, countries use strategies to encourage appropriate prescription by physicians to reduce volume and/or expenditures. Guideline-based prescription, either compulsory or non-compulsory, is enforced in 16 countries. Physician prescription patterns and volume are monitored in 19 countries; in several of these countries, the patterns and volume of physician prescription are benchmarked against others (Austria, Belgium, Denmark, England, Estonia, Finland, Hungary, Slovenia). Incentive structures in the form of rewards have been used in four countries (Austria, Belgium, England, Spain), while sanctions for over-prescribing can be seen in three countries (Austria, Belgium, Luxembourg) (Barnieh et al. 2014).

Table 5. Strategies to increase appropriate prescription

Country	Compulsory prescription guidelines	Non-compulsory prescription guidelines	Prescription pattern and volume monitored	Prescription pattern and volume compared to others	Incentives	Sanctions	Other
Belgium	x	√	√	√	√	√	
Austria	x	x	√	√	√	√	
England	x	√	√	√	√	x	
Denmark	x	√	√	√	x	x	Interactive database to facilitate self-monitoring
Estonia	√	x	√	√	x	x	Only one pharmaceutical per prescription
Finland	x	√	√	√	x	x	Rational prescribing program for doctors
Luxemburg	x	√	√	x	x	√	
France	√	x	√	x	x	x	
Hungary	x	x	√	√	x	x	
Netherlands	x	√	√	x	x	x	
Scotland	x	√	√	x	x	x	

Pharmaceutical pricing policies to improve the population's access to pharmaceuticals in Georgia

Country	Compulsory prescription guidelines	Non-compulsory prescription guidelines	Prescription pattern and volume monitored	Prescription pattern and volume compared to others	Incentives	Sanctions	Other
Slovakia	√	x	√	x	x	x	Insurance companies monitor the ratio of prescribed originals vs generics for contract doctors
Slovenia	x	x	√	√	x	x	Only one pharmaceutical per prescription, for a one-month supply
Sweden	x	√	√	x	x	x	County councils are responsible for prescribing policies in their respective region
Ireland	x	√	x	x	x	x	Certain insurance schemes have the right to influence the prescribing of doctors
Spain	x	x	√	x	√	x	Bonuses to physicians if pharmaceutical expenditure does not exceed forecasted growth at the regional level
Tukey	√	x	x	x	x	x	Guidelines for no. of items, dose & treatment time
Germany	√	x	x	x	x	x	
Israel	x	x	√	x	x	x	
Italy	√	x	x	x	x	x	
Japan	x	x	√	x	x	x	
Norway	x	x	√	x	x	x	
Portugal	x	√	x	x	x	x	
South Korea	x	x	√	x	x	x	
Czech Republic	x	x	x	x	x	x	Only specialists can prescribe new and more expensive pharmaceuticals
US	x	x	x	x	x	x	Step therapy & prior authorization used

5. Implementation considerations

The applicability of reference pricing interventions to low- and middle-income countries depends on:

- The availability of and access to drugs;
- The presence of significant price differences between the drugs in a reference group before the reference price system is introduced, with relatively high prices on the drugs most used;
- The alignment of stakeholders' interests and the availability of adequate incentives for patients, physicians, pharmacists and pharmaceutical companies to comply with the reference price system;
- The provision of clinical and managerial information and support;
- The equivalence of drugs in a reference group;
- Exemptions;
- The availability of electronic information systems;
- The existence of a regulatory framework allowing generic substitution or prescription by international non-proprietary names;
- Quality control of generics to minimize perceived differences between the quality of generic drugs and brand-name drugs that motivate patients to avoid generic equivalents (Aaserud et al. 2006; Acosta et al. 2014).

Many factors might modify the effects of policies, including: the magnitude of the increase in direct payments (size of cap/co-payment); the medicines included; the vulnerability of the populations affected; how the changes are implemented and enforced; the availability of exemptions; and the information provided to patients and providers (Luiza et al. 2015).

Containing expenditure effectively requires regulation not just of pharmaceutical prices but also of the volume of prescribed medication (I.-H. Lee et al. 2015). Although the policies affecting prescription behavior are outside of the scope of this rapid response, we have captured these policies in **Table 5**.

Price controls, unless they are linked to carefully monitored economic evaluation, may not necessarily promote efficiency in the use of medicines (I.-H. Lee et al. 2015).

Annexes

Annex 1. Glossary of used terms

Cap	A limit below which a patient does no pay or has reduced payments for prescriptions. After the cap is reached, payment is required by the patient. All caps are assumed to be annual unless otherwise specified
Ceiling same as Deductible	A limit up to which a patient pays the full cost of the drug. After the deductible is reached, the patient either does no pay or has reduced payments for prescriptions. All deductibles are assumed to be annual unless otherwise specified
Cost share drugs	Drugs in the same group as the reference drugs that cost more. Patients have to pay the difference between reference price drugs and the price of these (cost share) drugs
Fixed co- payment	A system where a patient pays a fixed, or set, amount per drug or per prescription
Formulary	A list of prescription drugs chosen for their clinical and cost-effectiveness and is used to determine plan coverage and patient cost share. It is also known as a preferred products list
Maximum out-of- pocket limit	A limit that is set as a fixed dollar amount or as a percentage of income after which the insurer pays 100% of the drugs. Co-payments are in place prior to the limit being reached. All maximum out-of-pocket limits are assumed to be annual unless otherwise specified.
Percentage co-payment same as Co- insurance	A system where a patient pays a set percentage of the amount per drug or per prescription
Price elasticity	The price elasticity for a medicine is the percentage change in its consumption related to one percentage change in the price or charge that patients pay for that medicine. This is a measure of how sensitive pharmaceutical consumption is to changes in pharmaceutical prices, and indirectly to changes in co-payments
Reference drugs	Drugs that determine the reference price level. There is no cost share by the patients for these drugs
Reference pricing	The practice of using the price(s) of a medicine in one or several countries (external reference pricing) or of identical medicines or

	similar products or even with therapeutically equivalent treatment in a country (internal reference pricing) in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country
Tiered co-payments	A structure where certain drugs (either generic, particularly effective or cost-effective brand name drugs) are assigned a lower co-payment (first tier), with nonpreferred brand drugs assigned a higher co-payment (second tier). A third tier, with an even higher co-payment, may be assigned to less preferred brand drugs

Annex 2. Search strategy

Main databases used for evidence search:

1. [Health Systems Evidence](#),
2. [Cochrane](#),
3. [PubMed](#)

Below we present search strategies applied for each database:

1. Health Systems Evidence

Free search terms used: (drug OR drugs OR pharmaceutical* OR medicine* OR medicat*)

Then apply the below filters:

Filters by domains

- Decision-making authority about who is covered and what can or must be provided to them
- Pricing and purchasing;
- Marketing
- Licensure & registration requirements
- Sales and dispensing
- Patents & profits

Filters by date range:

- Publication date range: 2000-2019

2. Cochrane database

In Cochrane, we only used free search terms. We experimented with Mesh terms and we did not find any additional studies (this is not unusual in Cochrane database).

We went to “Advanced search” and entered the search developed for each of the 3 concepts:

(drug OR drugs OR pharmaceutical OR pharmaceuticals OR medicine OR medicines OR medication OR medications)

AND

(price OR prices OR pricing OR cost OR costs OR expenditure OR expenditures OR economic OR economics OR reimbursement OR reimbursements OR fee OR fees OR expense OR expenses OR spending OR procurement OR procurements OR procuring OR sale OR sales OR finance OR financing)

AND

(policy OR policies OR politics OR plan OR plans OR planning OR program OR programs OR regulation OR regulations OR legislation OR legislations OR reform OR reforms) in Title Abstract Keyword - (Word variations have been searched)

3. PubMed

For PubMed we combined Mesh terms and free search terms as below

Line #1 reflects the free search terms whereas line #2 reflects the MESH terms. We then combined them with "OR" and limit to both systematic reviews and date of publications...

Search Query

#5 Search #1 OR #2 Filters: Systematic Reviews; Publication date from 2000/01/01 to 2019/12/31

#4 Search #1 OR #2 Filters: Systematic Reviews

#3 Search #1 OR #2

#2 Search ("pharmaceutical preparations"[MeSH Terms] OR "pharmacy"[MeSH Terms]) AND ("commerce"[MeSH Terms] OR "costs and cost analysis"[MeSH Terms] OR "health expenditures"[MeSH Terms] OR "economics"[MeSH Terms] OR "fees and charges"[MeSH Terms]) AND ("policy"[MeSH Terms] OR "politics"[MeSH Terms] OR "social control, formal"[MeSH Terms] OR "legislation as topic"[MeSH Terms])

#1 Search (drug[TIAB] OR drugs[TIAB] OR pharmaceutical[TIAB] OR pharmaceuticals[TIAB] OR medicine[TIAB] OR medicines[TIAB] OR medication[TIAB] OR medications[TIAB]) AND (price[TIAB] OR prices[TIAB] OR pricing[TIAB] OR cost[TIAB] OR costs[TIAB] OR expenditure[TIAB] OR expenditures[TIAB] OR economic[TIAB] OR economics[TIAB] OR reimbursement[TIAB] OR reimbursements[TIAB] OR fee[TIAB] OR fees[TIAB] OR expense[TIAB] OR expenses[TIAB] OR spending[TIAB] OR procurement[TIAB] OR procurements[TIAB] OR procuring[TIAB] OR sale[TIAB] OR sales[TIAB] OR finance[TIAB] OR financing[TIAB]) AND (policy[TIAB] OR policies[TIAB] OR politics[TIAB] OR plan[TIAB] OR plans[TIAB] OR planning[TIAB] OR program[TIAB] OR programs[TIAB] OR regulation[TIAB] OR regulations[TIAB] OR legislation[TIAB] OR legislations[TIAB] OR reform[TIAB] OR reforms[TIAB])

Annex 3. Systematic reviews used for evidence synthesis

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
A Systematic Review of Cost-Sharing Strategies Used within Publicly-Funded Drug Plans in Member Countries of the Organisation for Economic Co-Operation and Development (Barnieh et al. 2014) (7/9)	33 OECD countries (5 studies; 98 reports)	Access to drugs and drug expenditure	<p>Co-payment impact on drug use and expenditure:</p> <p>Cost sharing/co-payments strategies provide significant opportunities in a prescription drug insurance plan to maximize their budget: one study found that doubling a patient’s co-payment in a given plan, regardless of the type of co-payment, reduces average annual drug spending by one-third. Increasing co-payments, however, has been shown to decrease drug usage in an effort by the patient to maintain their overall costs; of concern, patients are unlikely to reduce consumption of only less effective medications. One study found that for every \$10 increase in co-payments, average compliance fell by 5 percentage points and that lower compliance resulted in greater use of other more expensive medical services.</p> <p>Co-payment impact on health service utilization</p> <p>Evidence on decreased drug use impact on clinical outcomes is conflicting. Although no evidence that co-payments affect clinical outcomes for patients overall, but in lower income population co-payment is a barrier to seeking care; Studies have noted similar findings for the elderly, and low-income</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>individuals, where the introduction of a cost-sharing policy decreased the use of essential drugs and increased the incidence of serious adverse events.</p> <p>co-payment impact on drug expenditures</p> <p>Despite evidence indicating that increasing co-payments for patients may negatively affect clinical outcomes for chronic conditions, potential impact of these measures on pharmaceutical expenditures is unknown at the health system level;</p> <p>Cap impact on drug use</p> <p>One study found that among the chronically ill, patients who had reached their benefit cap are more likely to stop taking their medications than those who haven't. Further, of those who stopped their medications, only a minority resumed therapy in the first three months after their coverage returned.</p> <p>Cap impact on health service utilization and cost</p> <p>The impact of Caps on clinical outcomes and overall costs is uncertain.</p>
<p>Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies (Review) (Acosta et al. 2014) (9/10)</p>	<p>Canada, Germany, USA, Spain, Norway (17)</p>	<p>Drug use and drug expenditure</p>	<p>Reference Pricing impact on drug use:</p> <p>Four reference pricing studies reported a median relative change of 15% in reference drug prescriptions at one year (range -14% to 166%). Three reference pricing studies reported a median relative change of -39% in cost share drug prescriptions at one year (range -87% to -17%).</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Reference pricing impact on Drug expenditures:</p> <p>Change in expenditures caused by the following effects, a) a shift in drug use from more expensive to less expensive drugs within the reference drug groups; b) patients or their private insurers paying a larger part of the expenditures; c) reduced prices; d) reduced total use of drugs in the reference drug groups (immediately, for six months and one or two years)</p> <p>Reference pricing may reduce expenditures related to effects on reference drugs, and the effect on expenditures of cost share drugs is uncertain. Reference pricing may increase the use of reference drugs and may reduce the use of cost share drugs. Two studies reported median relative insurer's cumulative expenditures on both reference drugs and cost share drugs of -18%, ranging from -36%to 3%.</p> <p>Reference pricing policy compared to no reference pricing</p> <ul style="list-style-type: none"> • drug use (prescribed, dispensed or actually used); <p>Drug use - one year after the transition period Reference drugs: Median relative change in prescriptions of 15% (range: from -14% to 166%) (4 studies)</p> <p>Cost share drugs: Median relative change in prescriptions of - 39% (range: from -87% to -17%) (3 studies)</p> <ul style="list-style-type: none"> • costs (expenditures), including drug costs and prices, other healthcare costs and policy administration costs. <p>Insurer's cumulative drug expenditures one year after the transition period - Reference drugs + cost share drugs: Median relative cumulative drug expenditures of -18% (range: from -36% to 3%)</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Index pricing may reduce the use of brand drugs and increase the use of generic drugs. index pricing may slightly reduce the price of generic drugs (evidence limited).</p> <p>Index pricing compared to no index pricing Drug use 6 months after policy start date - Generic citalopram: 55% (95% CI 11 to 98%) Brand citalopram: -43% (95% CI -67 to -18%) Drug prices 6 months after policy start date - Generic drug prices: -5.3% (95% CI NA) Brand drugs prices: -1.1% (95% CI NA)</p> <p>Maximum prices compared to no maximum prices for drug expenditures Drug expenditure one year after the transition period 21.4% (95% CI 19.0 to 23.7%) in volume of sales for total statins</p>
Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies (Aaserud et al. 2006) (9/10)	Canada (British Columbia), the USA (Maryland), Australia, Germany, Sweden (11)	Drug use (prescribed, dispensed or actually used), Healthcare utilization, Health outcomes, Costs (expenditures), including drug costs and prices, other health care costs and policy administration costs.	<p>Drug use Use of reference drugs increased while the use of cost-share drugs decreased. Total use of drugs decreased slightly. Four studies demonstrated an increase in reference drug use immediate after the transition period following the policy start. The increases were between 60% and 196%. The use of cost share drugs decreased immediately by between 19% and 42%. No or statistically non-significant decrease (7%) was found in the use of other drugs (drugs beyond the reference group).</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Health Service use</p> <p>Reference pricing was not found to have adverse effects on health. Nor did it increase the use of health services, with the possible exception of an increased number of visits when reference pricing is started, when patients switch from a more expensive drug to a reference drug.</p> <p>Expenditures</p> <p>Reference pricing decreases drug expenditures for third party payers. The change in expenditures can be decomposed to: a) a shift in drug use from more expensive to less expensive drugs within the reference drug groups; b) patients or their private insurers paying a larger part of the expenditures; c) reduced prices; d) reduced total use of drugs in the reference drug groups.</p> <p>Patient drug expenditures - One study reported an increase from 0% to approximately 16% of the total drug expenditures of reference drug class. However, this was related to that there were no co-payment on the drugs before reference.</p> <p>Index-pricing</p> <p>The effects on prices of generic and brand drugs (though not statistically significant for the latter category) as well as on the use of generic and brand citalapram were all in the intended direction.</p> <p>Drug use</p> <p>The effects on use of drugs in the index pricing groups were not analyzed appropriately in the report. Based on graphs ITS analysis was conducted of</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>the effect on use of brand and generic citalopram. The use of brand citalopram decreased, relatively, by 29 % (immediate) and 43% (after six months) after a transition period following the introduction of the index pricing system.</p> <p>The use of generic citalopram increased by 114% (immediate) and 55% (six months).</p> <p>Drug prices</p> <p>Brand and generic drug prices were both reduced. Reduction in brand drug prices was not statistically significant. The generic drug prices were reduced more (relatively) than the brand drugs. The long-term effects were slightly larger than the short-term effects (-1.1% vs -0.8% for brand drugs; -5.3% vs -4.0% for generic drugs).</p> <p>Healthcare utilization - no clear evidence of increased health care utilization</p> <p>Health outcomes - no evidence of adverse effects on health found.</p>
<p>Pharmaceutical policies: effects of cap and co-payment on rational use of medicines (Luiza et al. 2015) (9/9)</p>	<p>Australia, Canada, Sweden, United States (32)</p>	<p>Effects of cap and co-payment (cost-sharing) policies on use of medicines, healthcare utilization, health outcomes and costs (expenditures)</p>	<p>Cap</p> <p>Reimbursement by using a cap: may decrease the use of medicines for symptomatic conditions and overall use of medicines; it may also decrease insurers' expenditures on medicines; this policy has unintended effect of reducing the use of necessary medicines when applied to "essential" medicines, and puts extra strain on already vulnerable populations which (1 study) resulted in increased use of healthcare services and deterioration of health in vulnerable populations.</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Cap policies are expected to have greater effects for multi-medicine users (1 study);</p> <p>Cap policies reduced medicine use, even for medicines considered 'essential'. Medicine expenditures for insurers were also reduced, although use of healthcare services tended to increase.</p> <p>Cap with co-insurance and ceiling vs heterogeneous but limited medicines coverage</p> <p>Impact on drug use and costs</p> <p>This intervention may increase overall use of medicines as well as use of medicines for symptomatic and asymptomatic conditions, and may decrease patient expenditures on medicines.</p> <p>Fixed Co-payments vs lower value of fixed co-payment or full medicines coverage</p> <p>Impact on drug use and costs</p> <p>Effect of intervention on overall use of medicines is uncertain. However, it may decrease use of medicines for symptomatic and asymptomatic conditions.</p> <p>Intervention may slightly decrease insurer expenditures on medicines. Effect on patient expenditures and insurer expenditures on health care was not reported.</p> <p>Tier with fixed co-payment vs full medicine coverage or 2-tier</p> <p>Impact on drug use</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Implementation of, or an increase in, tier combined with fixed co-payment may lead to little or no difference in overall use of medicines.</p> <p>Impact on healthcare utilization</p> <p>Effect of the intervention on use of emergency department, hospitalization and outpatient care is uncertain. Effect on overall healthcare utilization was not reported.</p> <p>Tiered co-payments are intended to prompt patients to choose more cost-effective medicines or to cover the extra expenses themselves. However, tiered co-payments may also reduce overall medicine use if patients are not willing to substitute other medicines, or if changes in the tier structure also include increased co-payments for generic medicines.</p> <p>Ceilings with fixed co-payments vs full medicines coverage, lower fixed co-payment and ceiling amounts</p> <p>Impact on drug use</p> <p>This intervention may slightly decrease the overall use of medicines for symptomatic and asymptomatic conditions. It may lead to little or no difference in emergency department, hospitalization and outpatient care.</p> <p>Impact on cost</p> <p>Effect of the intervention on insurer medicine expenditures is uncertain. Effect on patient medicine expenditures or insurer expenditure on health care was not reported.</p> <p>Impact on healthcare utilization</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Intervention may lead to little or no difference in emergency department, hospitalization and outpatient care.</p> <p>Ceiling with co-insurance vs full medicines coverage, fixed co-payment and lower co-insurance</p> <p>Impact on drug use</p> <p>Implementation of, or an increase in, the value of the ceiling combined with co-insurance probably slightly decreases the overall use of, and insurer expenditures on, medicines. It may also decrease the use of medicines for symptomatic conditions, although its effect on the use of medicines for asymptomatic conditions remains uncertain.</p> <p>Impact on Cost</p> <p>Intervention probably slightly decreases insurer expenditures on medicines. Effects on patient expenditure or insurer expenditures on health care were not reported.</p> <p>Impact on healthcare utilization</p> <p>Intervention may lead to an increase in emergency department utilization and hospitalization. Effects of the intervention on outpatient care are uncertain. Effects on overall healthcare utilization were not reported</p>
The Effects of Prescription Drug Cost Sharing: A Review of the Evidence (Gibson,	Canada, United States (30)	Use (nonpreferred vs Preferred Brand-name Drugs, Generic vs brand name drugs essential vs less essential drugs.) expenditures (total	Higher levels of prescription drug cost sharing generally decreases the effects of consumption of prescription drugs and steer patients away from nonpreferred brand-name drugs to preferred brand-name drugs. However, patients do not consistently appear to be switching to generic substitutes, which are considerably less expensive than brand-name drugs.

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
Ozminkowski, and Goetzel 2005) (1/10)		expenditures, health plan expenditures and patient expenditures) and outcomes (1) healthcare service utilization and (2) health status and mortality)	<p>Cost sharing is not always a benign instrument, and at times it may come at a price. Although not consistently reported in the literature, the most troublesome effects associated with higher levels of cost sharing are reports of treatment disruption for chronically ill patients who depend on a regular regimen of prescription drugs. In addition, higher levels of cost sharing can have significant effects on the use of essential or maintenance medications, the outcomes of care, and the process of care.</p> <p>Higher levels of cost sharing transfer a larger financial burden to the patient. As co-payments rise, concerns emerge about equity and fairness between different groups of patients, especially those with low incomes and those who are chronically ill.</p> <p>Tiered formulary</p> <p>Drug substitution: patients appear to be responding to some, but not all, financial cost-sharing incentives to switch to close drug substitutes</p> <p>1) Nonpreferred vs Preferred Brand-name Drugs - adding a third tier for nonpreferred brand-name drugs resulted in a decrease in the use of these drugs and an increase in the use of preferred brand-name drugs</p> <p>2) Generic Substitution - Few studies reported an increase in the number of generic drugs dispensed as a result of higher generic vs brand price differentials. Conversely, one study evaluated the effects of a switch to a generic-only benefit from a generic vs brand benefit and reported a 20% rise in generic prescriptions per person.</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Value of prescription drugs:</p> <p>1) Essential medications - higher levels of prescription drug cost sharing was associated with a reduction in the consumption of essential medications. Significant association between cost sharing and a reduction in the use of essential medications was found in studies of broad population. Smaller reductions were found among chronically ill patients or active users of essential medications, who are less likely to be price sensitive.</p> <p>2) Less essential medications - in studies of relationships between cost sharing and the use of individual therapeutic classes of medications, there were no clear trends for less essential compared with more essential medications. Larger reductions in the use of less essential medications were reported in 3 studies in which medications were aggregated into the 2 classes of more essential and less essential medications.</p> <p>Healthcare utilization</p> <p>In most cases, higher levels of cost sharing were not associated with changes in the utilization of low-intensity outpatient medical services, such as physician office visits, outpatient visits, and home health visits. However, these studies assessed small changes in prescription drug cost sharing. As cost sharing continues to rise, it is plausible that the utilization of outpatient visits may change. Two studies reported an increase in high-intensity health services, such as inpatient visits, as cost sharing rose. Patients reducing the consumption of less essential medications did not have a significant change in adverse events.</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Health Status and Mortality</p> <p>No studies were found measuring the effects of cost sharing on direct measures of health status, such as self-reported health status and empirical measures of clinical health status. A significantly large decline in a claims-based score of health status found with co-payment increases from \$1 to \$3 to \$5 but not with a co-payment increase from 50% with a \$25 maximum to 70% with a \$30 maximum. Introduction of the 25% coinsurance charge in Quebec reported that higher levels of cost sharing had no effect on mortality rates among patients discharged after acute MI.</p> <p>Direct and indirect costs</p> <p>Studies that estimated the effects of an increase in cost sharing on direct prescription drug costs found that higher levels of prescription drug cost sharing were associated with a reduction in total prescription drug expenditures. No or inconsistent effects found among privately insured individuals.</p> <p>Consistent finding - increase in cost sharing results in pharmaceutical cost savings to a health plan as its cost per prescription is reduced by the increase in patient cost sharing.</p> <p>Little is known about the cost effects of an increase in cost sharing, beyond the effects on prescription drug costs. Based on 1 study changes in cost sharing did not have a significant effect on medical expenditures.</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Cost shifting to patients via an increase in out-of-pocket payments was a consistent finding.</p> <p>Another possible reason for the observed lack of movement toward generic drugs may be that patients perceive differences between the quality of generic drugs and brand-name drugs that motivate them to avoid generic equivalents.</p>
<p>Policies to promote use of generic medicines in low and middle income countries: A review of published literature, 2000-2010 (Kaplan et al. 2012) (4/9)</p>	<p>Global, Brazil, South America, Thailand (79)</p>	<p>Prices, consumption of generic medicines</p>	<p>Educational interventions and reference pricing can increase the consumption of generic medicines, whereas free-trade agreements, and policies permitting physicians to dispense medicines can reduce the use of generics.</p> <p>Insurance systems can successfully promote the use of generic medicines (based on literature of high-income countries).</p> <p>Competition</p> <p>HIC Evidence - competition can reduce prices for medicines. Even for patented medicines, competitive pressure from close therapeutic substitutes can place downward pressure on prices. Competition policy is a potentially important policy space to improve use of generics in LMICs.</p> <p>Prices of generic medicines are lower compared to originator products if there is “enough” competition (not defined), and higher volume purchases are not, by themselves, sufficient to reduce prices of generic medicines.</p>
<p>A Systematic Review of Reference Pricing: Implications for US Prescription Drug</p>	<p>Canada, United States, Norway,</p>	<p>Drug Prices; Utilization and Switching;</p>	<p>Impact of 9 reference pricing policies suggests that this strategy reduced drug prices, increased utilization of and adherence to targeted drugs, and</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
<p>Spending (Morgan, Hanley, and Greyson 2009) (4/10)</p>	<p>Germany, Spain (16)</p>	<p>Expenditures and Resource Consumption</p>	<p>promoted switching behavior from expensive products to alternatives at or below the reference price.</p> <p>Reference drug pricing appears to be an effective tool for controlling pharmaceutical expenditures for private and public payers. Unlike other cost-control mechanisms, reference pricing reduces expenditures without negatively affecting medication use or resource consumption.</p> <p>Drug Prices Four of the 9 reference price policies were associated with significant reductions in the price of the targeted drug classes, with a mean reduction of 11.5% (range 7%-24%)</p> <p>Utilization and Switching The reference pricing policies had varying effects on utilization of the targeted drug classes (both increase and decrease in use). It has led to an increase in switching from more expensive drugs to those that fell in price because of reference pricing and a decrease in switching away from referent drugs to more expensive drugs.</p> <p>Expenditures and Resource Consumption Reference price policies significantly decreased both patient and payer expenditures: OOP savings - 12% - 18% per month (3 studies) Payer expenditure reductions of 14% to 52% on targeted drug classes. These correspond to per capita savings of \$81 to \$650 (4 studies).</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Effects of reference pricing on hospitalizations and physician visits had no significant changes (3 studies). One study found temporary 11% increase in physician visits (probably to switch to reference products) with no significant changes later on (3-10 months)</p> <p>Although the rate of physician visits increased for a short period after policy implementation, reductions in visits and hospitalizations over a longer time period were not consistently observed. Thus, the policies appeared to achieve cost savings without negative effects on resource consumption</p> <p>Tiered formularies result in lower spending on drugs by payers but increase spending for patients and lead to gaps in use in some cases. (US)</p> <p>Caps</p> <p>Reference pricing appears to have effects different from many other strategies to contain prescription drug spending. While prescription cap limits protect payers from excessive cost, the limits cannot distinguish between medically necessary and unnecessary drug use and may prevent patients from purchasing drugs that they need. Among frail, low-income, elderly patients, these caps lead to increased risk of institutionalization.</p>
<p>Pharmaceutical policies: effects of restrictions on reimbursement (Green et al. 2010) (10/11)</p>	<p>Belgium, Canada, Denmark, Norway, United States (29)</p>	<p>Drug use, health care utilization, health outcomes and costs</p>	<p>Implementing restrictions to coverage and reimbursement of selected medications can decrease third-party drug spending without increasing the use of other health services; Relaxing reimbursement rules for drugs used for secondary prevention can also remove barriers to access;</p> <p>exemption from restrictions to reimbursement provides a 'safety valve' allowing access to restricted drugs under some circumstances, thereby</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>maintaining a range of therapeutic options and facilitating acceptance by physicians and patients.</p> <p>Where drugs have cheaper, effective alternatives and they target symptoms, reimbursement restriction policies can ensure better use of the medications with reduced costs and without an increase in the use of other health services (as would be expected if there were negative health effects of the restriction policies).</p> <p>Prior Authorization (PA) policies can support sustainability of drug benefit plans and thereby preserve access to necessary drugs for low income populations</p> <p>Unintended consequences: Appropriate use may decrease because 1) some physicians charge for applying for exemptions and patients may be unwilling or unable to pay these charges; 2) patients may be unwilling to switch medications and may not renew the new drug prescriptions, or 3) physicians may be unwilling to take the time to apply for an exemption, leaving some patients unable to pay for additional coverage and forgoing the needed therapy; 4) Processing PA requests is associated with administration costs for third party insurers, prescribers and pharmacies. These costs may or may not be offset by the program savings.</p>
Pharmaceutical policies: effects of cap and co-payment on rational	Germany, United Kingdom (21)	Drug use, healthcare utilization, health outcomes and costs (expenditures)	Introducing or increasing direct co-payments reduced drug use and saved plan drug expenditures. Although insufficient data on health outcomes were available, substantial reductions in the use of life-sustaining drugs or drugs that are important in treating chronic conditions may have adverse effects

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
<p>drug use (Austvoll-Dahlgren et al. 2008) (10/10)</p>			<p>on health, and, as a result, increase the use of healthcare services and overall expenditures. Direct payments are less likely to cause harm if only non-essential drugs are included or exemptions are built in to ensure that patients receive needed medical care.</p> <p>One study found adverse effects on health through increased healthcare utilization when a cap was introduced in a vulnerable population.</p> <p>Tiered co-payments Fixed co-payments do not provide incentives to choose cheaper substitutions, in contrast to coinsurance or tier co-payments.</p> <p>Cap Possible adverse effects on health through increased healthcare utilization were found when a cap was introduced in a vulnerable population (low-income patients with chronic conditions).</p> <p>No statistically significant change in use of healthcare services found in other studies when a cap was introduced on a drug considered over-prescribed in a vulnerable population, or following a shift from a two-tier to a three-tier system with increased co-payments for tier-1 drugs in a general population.</p> <p>An increase in volume per prescription for “essential” drugs nearly offset the drop-in number of prescriptions (Canada)</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Stockpiling was another factor in the Canadian study. The abrupt and marked reduction in number of prescriptions that took place immediately after the policy may have been due to the stockpiling of drugs that took place prior to implementation of the co-payment policy.</p> <p>PA policy Education or prior authorization, might be better suited to address inappropriate use of drugs.</p>
<p>International experience in controlling pharmaceutical expenditure: influencing patients and providers and regulating industry – a systematic review (I.-H. Lee et al. 2015) (7/10)</p>	<p>Australia, Canada, Denmark, Finland, Germany, Iran (Islamic Republic of), Ireland, Israel, Italy, Korea (Republic of), Nepal, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Taiwan, United Kingdom (England), United Kingdom (Northern Ireland), United Kingdom</p>	<p>Use of drugs, expenditures</p>	<p>Influencing patients Prescription caps lower drug expenditure by reducing utilization, but they reduce the use of essential drugs in vulnerable populations, and in some populations substantially increase non-drug expenditure. User charges reduce utilization of pharmaceuticals and reduce public expenditure by shifting costs to patients. But they can reduce the use of essential as well as non-essential drugs, and without adequate exemptions they affect vulnerable groups disproportionately.</p> <p>Influencing prescribers Educational interventions can lower pharmaceutical utilization and expenditure when the focus of the intervention is on cost-effectiveness information, but that changes are likely to be modest. Reimbursement restriction policies can lower spending on drugs and switch use between categories, such as increasing generics use, but some studies revealed potential unintended consequences. Simple withdrawal of</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
	(Wales), United States		<p>reimbursement without other interventions such as guidance on alternatives can mean that prescribers switch to even more undesirable options.</p> <p>Incentive systems</p> <p>Overall, incentives for prescribers have been demonstrated to achieve modest savings, but there are transactions costs and rewards for prescribers that should be included in any estimate of the overall cost-effectiveness of these interventions.</p> <p>Regulating industry:</p> <p>Price controls - reference-pricing policies have little impact on overall use of pharmaceuticals, but they may reduce the volume of non-reference products while increasing the volume of reference products, linked to reductions in payers' expenditure.</p> <p>Reference pricing has minimal impact on pharmaceutical prices, but patients' out-of-pocket payments increase, implying consequent effects on equity of access to medicines.</p> <p>Reference pricing has a demonstrable impact on payer expenditure but this is a result of shifting costs to patients rather than reducing prices.</p> <p>Licensing and reimbursement is known as the most powerful economic control as it can exclude products from the market, but is also associated with prolonged time lag before reimbursement decisions or decreased proportion of drugs listed (two studies)</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Pharmaceutical Price Regulation Scheme (PPRS) (UK) regulates pharmaceutical prices indirectly, by controlling company profits.</p> <p>Companies are allowed freedom of pricing but negotiate target profits from pharmaceutical sales to the NHS, with a target rate of return on historic capital of 21%. Manufacturers earning excessive profits may be required to reduce prices of products sold to the NHS. One study explored the effect of changes in the rate of return cap and found little impact on pharmaceutical prices: a 1% change in the maximum rate of return generated only a 0.15% change in the aggregate price index overall.</p>
<p>Systematic Review of Benefit Designs With Differential Cost Sharing for Prescription Drugs (Ogbechie and Hsu 2015) (6/9)</p>	<p>31</p>	<p>1) behavioral responses, 2) spending, and 3) health outcomes.</p>	<p>To date, insurance plans have applied incentive-based designs most often to prescription drugs, such as through mechanisms including tiered formularies, reference pricing, or free drugs for chronic diseases.</p> <p>With tiered co-payment (differential cost sharing), some patients will switch to the cheaper drug option, overall plans’ pharmacy spending decreases, and overall patients’ OOP pharmacy spending increases. Some patients continue using the more expensive option, which results in high OOP expenditures. Reports on patients’ adherence were mixed but suggestive of decreased adherence to the more expensive option. Similarly, most articles found decreases in utilization of the expensive option.</p> <p>Tiered co-payment impact on drug use 15 studies reported increased switching to the cheaper option and 9 reported decreases in use of the drug use.</p>

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			<p>15 studies reported that patients changed their use of any drug in the affected drug class regardless of whether they used the more or less expensive option.</p> <p>According to the 16 articles that reported using higher-priced drug found decreases in use.</p> <p>Tiered co-payment impact on spending</p> <p>All articles reporting on spending examined the effects for at least 1 year.</p> <p>Out of 14 articles reporting patients' OOP pharmacy spending after introducing or increasing pricing differentials among drug substitutes, 13 found increases in patient spending. Conversely, among the 21 articles reporting on plan pharmacy spending, 19 found decreases.</p> <p>Only 12 articles assessed total, patients', plans', and pharmacy spending, and 9 of these reported overall decreases.</p> <p>Most articles (4 of 6) reporting on plans' nonpharmacy spending found increases, while all reporting on overall medical spending showed decreases.</p> <p>Tiered co-payment impact on health outcomes / health service utilization</p> <p>2 articles found short-term increases in physician visits immediately after the differential pricing intervention, but most found either no change or decreased longer-term physician utilization.</p> <p>All 6 articles that assessed Emergency Department visits and 5 of 6 that assessed in-patient hospitalizations found no change compared to controls after the differential drug-pricing intervention.</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Reference pricing:</p> <p>Reference pricing affected patient behavior by switching the use of more expensive to less expensive drugs.</p>
<p>Influencers of Generic Drug Utilization: A Systematic Review (Howard et al. 2018) (5/9)</p>	<p>67</p>	<p>Generic drug use</p>	<p>Formulary Management and Cost Control Factors</p> <p>An increase in drug costs and shift to more costly 3-tier formularies from 2-tier or other formulary designs results in a decline in brand drug utilization and increase in generic drug use. Likewise, as consumer out-of-pocket costs for brand-name drugs increase, so does generic drug use.</p> <p>Formulary management or cost containment measures positively influence generic drug use. An adjustment in cost sharing mechanisms influences drug use with decreased generic drug co-payments increasing generic drug use, shifts away from two-tier or other formularies to more costly 3-tier formularies decreasing brand drug use, and Medicare Part D enrollees in plans requiring prior authorization with a greater likelihood of using generic antidepressants, antidiabetics, and statins than their counterparts in plans without a prior authorization requirement.</p> <p>Medicare beneficiaries are more inclined to utilize generic drugs while in the Medicare Part D coverage gap when much of the cost for drug-related expenses are out-of-pocket.</p> <p>Generic substitution laws show that policy changes intended to encourage generic drug use have been successful. It may also lower drug expenditures under Medicaid. These results show that many recent policy changes have</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>been effective in altering generic drug use patterns broadly across Medicare and Medicaid populations.</p> <p>Patient related factors Patient-related factors, including insurance coverage type, patient demographics, patients' prior experience with generic drugs, and patients' communication with healthcare providers regarding generic drugs were the most frequently discussed in the literature, suggesting that patient-related factors play a crucial role in generic drug use. Patients with lower incomes, Caucasian, male, young, or who are otherwise healthy are less likely than their counterparts to utilize generic drugs and may need additional or more targeted educational materials and information from healthcare professionals in order to increase generic drug utilization.</p> <p>Promotional activities by pharmaceutical companies have been shown to increase brand name drug use. The impact of promoting generic drugs in healthcare settings showed that those activities were effective in increasing generic drug use as well.</p> <p>Educational initiatives, technological advances, and physician characteristics have impact on generic drug use. Evidence suggests that educational initiatives related to generic drugs should be focused on men, individuals with lower socio-economic status, and individuals belonging to a minority group. These groups were seen as less likely to take generics or have negative impressions of generic drugs and may benefit from targeted outreach. Targeted outreach or additional training may also benefit younger</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>physicians, as they may be greatly influenced in their prescribing patterns by their use of technology (e-prescribing) and their training (attending physicians prescribing patterns).</p>
<p>Association between Drug Insurance Cost Sharing Strategies and Outcomes in Patients with Chronic Diseases: A Systematic Review (Mann et al. 2014) (8/10)</p>	<p>Canada, Taiwan, United States (11)</p>	<p>Drug use/adherence</p>	<p>Addition of drug insurance for those without previous drug insurance appears to consistently increase adherence to medications, and that increased costs on drug expenditures may be offset by decreased costs in non-drug expenditures</p> <p>Cost-sharing mechanism</p> <p>One mechanism reducing the financial burden to insurance plans is to shift the burden from the insurer to patients. This shift of financial responsibility may lead to underuse of potentially important medications in people with chronic conditions.</p> <p>Small co-payment (up to 25%) does not appear to impact adherence, while large co-payments (95% copay) may have a substantial impact on medication adherence.</p> <p>The use of deductibles (up to \$350 per year) does not appear to have a significant impact on medication adherence, one study reported that 100% co-payment (i.e. those who had not yet reached the deductible level) was associated with a two-fold reduction in drug adherence.</p> <p>In a high-risk group of US Veteran's Administration patients with coronary heart disease, there was a slight decline in adherence in patients without an</p>

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			<p>annual maximum out-of-pocket expenditure, compared to those with a maximum out-of-pocket expenditure.</p> <p>In Quebec, a change from minimal co-payment (\$2 CDN per prescription; annual maximum of \$100 CDN) to 25% coinsurance, with a \$250-\$750 CDN annual maximum OOP expenditure had x apparent change in medication use.</p> <p>When patients exceed a pre-defined annual threshold limit and enter a period of a coverage gap the use of medications decreases, particularly when patients were responsible for 100% of medication costs compared to those who had some form of drug coverage.</p>
<p>Institutional framework for integrated Pharmaceutical Benefits (Hermanowski, Drozdowska, and Kowalczyk 2015) (4/9)</p>	<p>USA, Canada, UK, Germany, Italy, Denmark, Poland (9)</p>	<p>Expenditure, quality of care</p>	<p>According to research by the Centers for Medicare and Medicaid Services, Pharmacy Benefit Manager tools contributed to the containment of the growing prescription drug expenditure from 5.3% in 2009 to 3.5% in 2010.</p> <p>Introduction of independent institutions – such as Pharmacy Benefit Managers in the USA – to coordinate functions associated with pharmaceutical care/drug policy has led to significant savings and increased quality of health care.</p> <p>Through promoting the use of generic drugs, Pharmacy Benefit Manager tools lower the costs for payers and consumers. The most prominent tool was the tiered co-payment that moved medication prescription and administration towards less expensive generic drugs.</p> <p>Electronic prescribing systems in the USA are expected to generate savings of about 29 billion dollars as a result of fewer prescription duplications, more generic prescriptions, elimination of drug–drug interactions and dosing</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>errors, and other medicine-related problems and the resulting decreased number of consultations with physicians or inpatient hospital days.</p> <p>Greater use of generic medications, via tiered formularies could result in important health care savings while maintaining quality of care. Formularies serve Pharmacy Benefit Managers to “channel” patients to a particular product and to point out an apparent “best value” among many drugs of therapeutic category. Patients are offered financial incentives (e.g. lower co-payments) to buy drugs from a formulary. This has helped Pharmacy Benefit Managers increase purchase volume of the drugs and maximize rebates from drug manufacturers.</p> <p>Significant savings in medical expenses from reducing the number of physician visits among chronically ill patients could be achieved through the use of automatic prescriptions renewing mechanism, with which chronically ill patients would be able to renew prescriptions without actually visiting the doctor in-person.</p>
<p>Medicare Part D’s impact on the under- and over-use of medications: a systematic review (Polinski et al. 2011) (6/10)</p>	<p>USA (19)</p>	<p>Drug use (over and under use of specific drugs and classes) (at three time periods in the Part D benefit: 1) the year(s) since Part D implementation, when many patients newly obtained drug</p>	<p>Increasing drug coverage led to increased use of both under-used essential medications and inappropriate, or over-used, medications under Medicare Part D. Despite efforts to do so, the Part D benefit did not sufficiently discriminate between essential and non-essential medication use.</p> <p>Increased use of specific drugs and classes after Part D implementation often occurred with little regard for the appropriateness of therapy. Rather, changes in medication use were more strongly correlated with shifting out-of-pocket costs and protections/restrictions for specific drugs and classes.</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
		<p>coverage; 2) the early months of 2006, known as the transition period, during which dual-eligible faced change as Medicare Part D, not Medicaid, became the primary payor for drugs; and 3) the coverage gap, when beneficiaries became responsible for 100% of drug costs)</p>	<p>In the year(s) since Part D's inception, as many previously uninsured elderly gained drug insurance, there was increased use of essential medications in accordance with legislative goals. However, use of often over-used medications also increased.</p> <p>In the transition period, when dual-eligible had their drug coverage shifted from Medicaid to Medicare, no changes were observed using claims data, but self-report-based studies reported acquisition difficulties for psychotropic and essential antiretroviral medications among the dual-eligible population.</p> <p>In the coverage gap, patients who were suddenly responsible for 100% of their drug costs decreased use of under- as well as over-used medications.</p> <p>Changing out-of-pocket drug costs affected both under- and over-use. When Part D insurance coverage was available, drug use increased, especially among those patients who previously lacked coverage. Conversely, as patients entered the Part D coverage gap and lost financial assistance, utilization rates decreased.</p> <p>Initial prescription of generic or plan-preferred medications has been associated with lower costs and better adherence over time.</p> <p>Value-based insurance designs, in which patients' cost-sharing is reduced for medications that provide high benefits relative to costs, have been shown to modestly improve essential medication adherence.</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
<p>The Effect of Co-payments for Prescriptions on Adherence to Prescription Medicines in Publicly Insured Populations; A Systematic Review and Meta-Analysis (Sinnott et al. 2013) (9/11)</p>	<p>USA (7)</p>	<p>Risk of non-adherence</p>	<p>This meta-analysis has found an 11% increase in odds of nonadherence when publicly insured patients are required to copay for their prescription medicines. This is a pertinent result because the question regarding adherence to medicines in a cost sharing environment was still inconclusively quantitatively answered by prior reviews.</p> <p>Reductions in adherence to medications, especially essential medicines, can be detrimental to health status and causes increases in expenditure via hospital admissions.</p>
<p>Pharmaceutical policies: effects of financial incentives for prescribers (Review) (Rashidian et al. 2015) (8/10)</p>	<p>Germany, Sweden, Taiwan, United Kingdom, United Kingdom (England), United Kingdom (Northern Ireland) (18)</p>	<p>Drug use, healthcare utilization, health outcomes and costs (expenditures)</p>	<p>Pharmaceutical budget caps or targets:</p> <p>This policy may lead to a modest reduction in overall drug use per patient (low-certainty evidence).</p> <p>All results reported in the studies almost uniformly showed a greater increase in use of generic drugs among fund-holders (budget cap). CITS studies suggest a median of +15.0% (range -43.7% to 190.5%) at 12 months and +18.3% (13.6% to 23.0%) at 24 months. (UK)</p> <p>Effects of this policy on drug costs or on healthcare utilization are uncertain, as the certainty of the evidence has been assessed as very low.</p> <p>Effects of this policy on health outcomes have not been measured.</p>

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Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>Pay for performance policies:</p> <p>Pay for performance policy did not result in major improvements in prescribing or health outcomes. As a result, review findings did not provide a favorable picture for the effects of pay for performance.</p> <p>Effects on drug use or health outcomes are uncertain, as the certainty of the evidence has been assessed as very low.</p> <p>Effects of this policy on drug costs or on healthcare utilization have not been measured.</p> <p>Reimbursement rate policies:</p> <p>Effects of reimbursement rate policies are uncertain because the quality of the evidence has been assessed as very low</p>
<p>Value-Based Insurance Design: Quality Improvement But No Cost Savings (J. L. Lee et al. 2013) (7/11)</p>	<p>USA (13)</p>	<p>Medication adherence (use) and medical expenditures, health services use</p>	<p>Although Value-Based Insurance Design (VBID) might not significantly reduce health spending in the short term—that is, within 1 to 3 years—some VBID plans improve medication adherence and reduce patients' out-of-pocket expenses.</p> <p>VBID programs were consistently associated with improved adherence (average change of 3 % over one year), as well as with lower out-of-pocket spending for drugs. Providing more generous coverage did not lead to significant changes in overall medical spending for patients and insurers.</p> <p>Improvements in medication adherence associated with VBID were not accompanied by significant reductions in overall medical or total insurer spending.</p>

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			<p>The primary benefit of VBID may be in its ability to improve the quality of care for patients with chronic diseases.</p> <p>Expenditures</p> <p>VBID policies were associated with significant increases in drug spending for insurers in the five studies that examined this outcome.</p> <p>Four studies did not observe statistically significant changes in overall insurer expenditures, which suggests that the VBID policies may have increased prescription spending without increasing overall spending.</p> <p>Health Services Use</p> <p>One study found that the policy was associated with significant decreases in emergency department visits (-36 %, p < 0:01), physician office visits (-5 %), and hospitalizations (-13 %) at two years</p>
<p>Comparison of tiered formularies and reference pricing policies: a systematic review (Morgan, Hanley, and Greyson 2009) (4/10)</p>	<p>Canada, USA (11)</p>	<p>Utilization/compliance, expenditures, health outcomes (use of physician services, adverse health outcomes, effects on treatments for acute and chronic conditions)</p>	<p>Introduction of reference reduced plan spending through switching to preferred medicines, reduced overall drug utilization and short-term increases in the use of physician services.</p> <p>Reference pricing was not associated with adverse health impacts.</p> <p>Tiered formularies</p> <p>Associated with reduced plan expenditures, greater patient costs and increased rates of non-compliance with prescribed drug therapy.</p> <p>The single study of the effects of tiered formularies on the use of medicines by children was the only study not to find an association between the policy and medicine discontinuation. In the single study that assessed differences in</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
			<p>effects on treatments for acute and chronic conditions, there were greater relative reductions in the utilization of and persistence with treatments for acute conditions.</p> <p>Under a tiered formulary, patients generally face incrementally higher co-payments for different treatment options: a relatively low co-payment applies to “preferred” drugs within a class (e.g., \$5 for generics), a higher co-payment to second tier products within a class (e.g., \$10 for “preferred brands” for which the insurer has negotiated a rebate) and an even higher co-payment to other drugs on the formulary (e.g., \$25 for other brands within a drug class). Tiered formularies are used most extensively in the United States.</p> <p>Most studies found that adding tiers to co-payments for prescription drugs in the US private insurance market was associated with a reduction in total spending (decreases of 5%–20%). One study did not find statistically significant associations between adding tiers to formularies and changes in total spending.</p> <p>Adding tiers to co-payment structures was associated with increased switching within drug classes in all 8 included studies (switching toward “preferred” drugs on formulary occurring among 5% to 49.4% of patients), decreased overall utilization of affected medicines, and either no change or an increase in the rate of discontinuation of prescribed drug treatments.</p> <p>Studies that investigated the distribution of costs, found that employing tiered formularies was associated with lower spending by the drug plan and greater spending by patients.</p>

Systematic review (AMSTAR score)	Countries (number of studies)	Outcome	Impact
<p>Impact of pharmaceutical prior authorization policies: a systematic review of the literature (Puig-Junoy and Moreno-Torres 2007) (5/9)</p>	<p>Not reported</p>	<p>Drug use, healthcare utilization, healthcare expenditures, health outcomes</p>	<p>Impact of Prior Authorization (PA) policies indicates that pharmaceutical use and /or expenditure per patient or enrollee of drugs directly affected by PA restrictions and overall drug expenditure significantly decreased (increased) after policy implementation (removal).</p> <p>Health outcome changes attributed to PA policies were not directly evaluated, although changes in the use of other health services may provide an indirect indication of complication or adverse health effects. In most cases PA implementation was not associated with significant changes in the utilization of other medical services.</p>
<p>Active pharmaceutical management strategies of health insurance systems to improve cost-effective use of medicines in low- and middle-income countries: A systematic review of current evidence (Faden et al. 2011) (3/9)</p>	<p>China, Europe, Ghana, India, Indonesia, Iran (Islamic republic), Jamaica, Korea, Latin America (67)</p>	<p>Access to and Use/utilization of pharmaceuticals and health outcomes in LMIC</p>	<p>Effects of insurance coverage on access, utilization, and health outcomes</p> <p>Health insurance can improve consumer access to and utilization of pharmaceuticals as well as health outcomes. Several studies have shown that being insured was associated with an increased use of medicines, and one found that insurance is a key determinant in the use of medicines.</p> <p>Health insurance reduces financial barriers to access in LMIC: insurance is associated with a decreased likelihood of paying for medicines, slightly decreased consumer expenditures on medicines, decreased OOP spending on medicines as percent of total health expenditure, and decreased reported financial barriers to purchasing medicines. However, one study (Mexico) found the insurance system had not improved medicines access and affordability for the poor as it only covered low-cost outpatient medicines for the poor.</p>

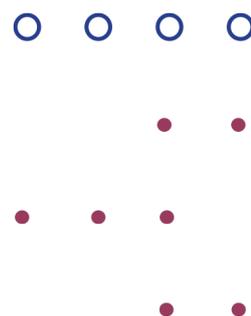
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			<p>The use of insurance as a strategy to improves access to pharmaceuticals in LMIC. However, most studies do not address whether the increased utilization is appropriate (i.e., pentup demand) or undesirable (i.e., moral hazard). There is limited, but positive, evidence supporting the use of health insurance to improve health outcomes</p> <p>Evidence from Kyrgyzstan, Mexico, Taiwan, and South Africa suggests that strategies such as generic reference pricing, direct or indirect price negotiation with suppliers, and better price information to members have the potential to stabilize market prices for medicines and improve access.</p> <p>In several Asian countries, strategies to reduce medicines costs have been unsuccessful under Fee For Service (FFS) systems since providers respond by increasing prescription volume or shifting to more costly medicines.</p> <p>Evidence from China, Thailand, Taiwan, and South Korea suggests that cost containment policies were more successful under capitated or case-based payment systems where hospitals and providers shared risk for medicines costs.</p>
Interventions promoting the acceptance and uptake of generic medicines: A narrative review of the literature	Spain, Taiwan, United Kingdom (England), United Kingdom (Northern Ireland),	Acceptance and uptake of generic medicines	The financial incentives category included in this review covered the changes in co-payment for consumers and reward payment for physicians.

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(Babar, Kan, and Scahill 2014) (3/9)	United Kingdom (Scotland), United States (18)		<p>Removing and/or off-setting financial barriers for consumers (co-payments) has been reported to improve generic switching for some medicines but not others.</p> <p>There is the potential to encourage a significant change to generic medicines if combined with other initiatives such as education but policy-makers, and health funders and planners need to be aware that one financial strategy may not be able to be applied to all classes of medicines or disease states.</p> <p>Pay-for-performance policy for physicians</p> <p>A pay-for-performance scheme was initiated to provide incentives for physicians to reduce pharmacy costs and to increase the prescribing rate of generic medicines. The incentives comprised a reward payment to the practice every 6 months dependent on the extent of cost-savings. The intervention did not increase the generic dispensing rate.</p>

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