



**Examining Two Approaches  
to U.S. Drug Pricing:  
*International Prices and  
Therapeutic Equivalency***

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# Executive Summary

Scientific advances in the biomedical research and pharmaceutical sectors have led to new drug treatments for a multitude of acute and chronic illnesses. While policymakers value the need to support continued innovation, they also seek ways to increase the affordability and accessibility of drugs. Evidence shows that the high prices of drugs are prompting difficult choices, as patients delay taking or don't access therapies they cannot afford. Most Americans, across party lines, see policy options to curb prescription drug costs as a top priority.

To date, many of the options to mitigate the high price of drugs have focused on increasing competition and transparency in the pharmaceutical sector as well as increasing value-based payments based on outcomes achieved. However, this report examines two additional tools: external reference pricing and internal reference pricing.

External reference pricing uses international prices as a benchmark to set or negotiate the price of drugs. Internal reference pricing, which could be used in various scenarios to ensure that therapeutically equivalent drugs are priced similarly, encourages the use of the least costly alternative therapy.

Agencies abroad commonly use both tools to restrain the high cost of drugs. While experts and officials have only recently proposed external reference pricing in the United States, it is currently employed in dozens of countries around the world, with many using the tool as the sole or main pricing policy. There is substantial heterogeneity among countries in how the tool is implemented with variation existing in the number of countries referenced, the calculation of the reference price, the specific sectors to which the policy applies, and the frequency of price revisions. While this variation makes it difficult to assess the overall impact on outcomes, studies generally demonstrate that external reference pricing leads to lower drug prices immediately, although this effect may diminish over time.

Studies also suggest that more frequent monitoring and systematic price revisions may lead to greater price reductions, and additional data suggest larger savings could be garnered if real prices paid by payers (discounted prices) were used. There are some studies that point to unintended consequences, such as potential encouragement of higher pricing in low-income countries, manufacturer launch delays in countries with lower prices, and short-term discouragement of investment in research and development.

Many countries around the world also use internal reference pricing to incentivize the uptake of therapeutically equivalent lower-cost drugs. Evidence suggests that internal reference pricing policies may reduce drug prices and expenditures by increasing the use of reference drugs rather than more expensive products. The U.S. government used internal reference pricing in a limited way, primarily through Medicare Part B policies, from 1995 to 2010. More recently, private-sector purchasers have been using this tool successfully to reduce employer spending on therapeutically equivalent prescription drugs.

The varied use of external and internal reference pricing schemes in developed, market-oriented countries such as Germany, Switzerland, and Denmark, all of which have a relatively short time-to-market for pharmaceutical drugs, demonstrates that these tools could be effective in the United States to mitigate high drug prices.

**This report proposes the following policy considerations:**

## **External Reference Pricing**

1. The U.S. Department of Health and Human Services (HHS) could consider implementing a pilot program using external reference pricing for a subset of Medicare Part B or D single-source brand-name drugs or biologics that are relatively expensive and face limited to no competition. Applying lessons learned from other countries and adhering to best practices have the potential to increase the affordability of drugs in the United States while minimizing unintended consequences.

Implementing any external reference pricing scheme would require building an infrastructure to collect and update comparable data from various countries.

### **Internal Reference Pricing**

2. To implement internal reference pricing for pharmaceuticals more systematically in the United States, policymakers could consider efforts to catalyze assessments of therapeutic equivalency in several ways:
  - a. Congress should support the reauthorization of the Patient-Centered Outcomes Research Institute (PCORI), while HHS should continue to deliberate on how to support assessments of “comparability” within its regulatory apparatus.
  - b. To supplement existing efforts, HHS could establish an advisory group or task an existing office to look at the added incremental benefit of any new brand-name drug or biologic. For drugs that have a potential existing therapeutic equivalent, comparative effectiveness research could be undertaken; whereas, for drugs without an existing comparable treatment course, a clinical assessment of the drug’s benefit to patient health could be undertaken and compared with the standard of care.
  - c. To inform HHS’s efforts, federal funding could be provided to multiple private-sector research organizations to undertake these studies. The office or advisory group could review the data received from these studies, including information from manufacturers and from other countries, and publish an expert assessment. This information would help inform private-sector price negotiation of drugs and public-sector internal reference pricing policies.
  - d. As the European Union moves forward to strengthen cooperation on health technology assessments, the United States could consider joining such an effort. This process would lead to common assessment methods and facilitate data-sharing to better ascertain the added comparative value of new medicines.
3. It is critical that implementation of any internal reference pricing scheme use a transparent process involving multi-sector stakeholders to accurately identify therapeutic classes and determine therapeutic equivalency. With respect to instituting specific internal reference pricing policies:
  - a. Congress could provide the Centers for Medicare and Medicaid Services (CMS) authority to implement least costly alternative policies for Medicare Part B and the functional equivalence standard in the hospital outpatient prospective payment system.
  - b. Congress could also provide the HHS secretary the authority to group biologics and their respective biosimilars into a common billing code to maximize price competition.
  - c. CMS could also consider updating the Medicare Plan Finder tool with real-time information on patient cost-sharing for drugs so that Part D plans can institute internal reference pricing, which has the potential to supplement efforts of Pharmacy Benefit Managers (PBMs) in reducing total prescription drug costs.

To be sure, reference pricing alone is not a panacea and will not address all the affordability and accessibility challenges in the pharmaceutical sector. However, in the right setting, focused on the most appropriate drugs, and in combination with additional pricing and reimbursement approaches, it could make a significant impact.

# Introduction

A vibrant, innovative pharmaceutical market is vital to optimizing the health of all Americans. Scientific advances in the pharmaceutical sector have led to new treatments for a multitude of acute and chronic illnesses. While policymakers value the need to support continued innovation, they also seek ways to increase the affordability and accessibility of pharmaceuticals. The United States is the world's largest market for pharmaceuticals, with high prices and high utilization of new pharmaceuticals.<sup>1</sup> The United States spends more per capita on pharmaceutical drugs than any other high-income country.<sup>2</sup> (Hereafter, the term “drugs” refers to pharmaceutical drugs).

Many new types of drugs, such as biologics, gene therapies, and immunotherapies, require sophisticated, resource-intensive technologies for safe and reliable production. Often, these drugs are the first in their therapeutic class and have limited to no market competition. Patients' accessibility to these novel drug treatments is becoming more of a concern as rising drug prices affect patients' out-of-pocket costs as well as the budgets of private and public payers in the United States.<sup>3</sup>

For example, health professionals now treat many cancers, autoimmune diseases, and genetic disorders that previously resulted in death and/or a sharply curtailed life span as chronic conditions because of innovative drug treatments. However, the sustainability of paying thousands of dollars per month for such treatments on an ongoing basis is becoming a public concern.

Higher prices for existing drugs (whether generic drugs or brand-name drugs) are also an area of concern with respect to rising drug prices. There has recently been an unprecedented rise in the prices of generic drugs, thought to be largely secondary to manufacturer consolidation.<sup>4</sup> In addition, the trend of year-to-year increases in the price of brand-name drugs continues despite its length of time on the market and despite the presence of other drugs with therapeutic equivalency.<sup>5</sup>

As a result, an increasing number of Americans and their families must choose between paying for drugs or spending money on necessities such as food, housing, and transportation. About one-quarter of people taking a prescription drug in the United States report that it is either somewhat or very difficult to afford.<sup>6</sup> Evidence shows that high drug prices are forcing patients to either delay therapies or preventing them from accessing them at all.<sup>7</sup>

Policymakers are responding to the challenges in various ways with possible solutions generally falling into three categories: (1) increasing competition; (2) increasing transparency; and (3) increasing value-based payments based on outcomes achieved. This report examines two additional tools—external reference pricing and internal reference pricing—both of which are used more commonly abroad to curb the high prices of drugs.

These tools are generally consistent with the categories outlined above. External reference pricing uses the prices of drugs in other countries in order to potentially set or negotiate the price of drugs. It focuses largely on single-source brand-name drugs or biologics without therapeutic or generic competition. Internal reference pricing, which can ensure that therapeutically equivalent drugs are priced similarly, encourages the use of the least costly alternative therapy.

This report is organized in three parts. The background section describes prescription drug pricing and reimbursement in the United States and details current federal policymaker efforts to address challenges related to drug affordability and accessibility, including using various forms of reference pricing. The second section summarizes the experience of the United States and other countries in using both external and internal reference pricing. A final section lays out considerations for policymakers on how the United States could increasingly utilize these tools.

The Bipartisan Policy Center compiled this report through information and insights derived from extensive literature review; interviews with subject matter experts, Capitol Hill staff, and drug pricing stakeholders; and information shared at a BPC roundtable held in July 2019.

# Background

## DRUG PRICING AND REIMBURSEMENT IN THE UNITED STATES

People often describe prescription drug pricing and reimbursement as opaque due to confusion surrounding the drug pricing determinants. Although a drug's initial price is determined by manufacturers, a drug may eventually have several different prices for various payers and consumers. Prescribers and patients may not have access to these varying prices or to information on how the process for prices is determined. Therefore, making informed decisions about a therapeutically appropriate drug at the most economical price is challenging.

### Key Actors Influencing Drug Pricing

Drug manufacturers use gross (from here on referred to as “list”) prices to initiate the drug pricing process. List prices are known as an Average Wholesale Price or Wholesale Acquisition Cost and can be likened to sticker prices for cars, as the rationales for prices are not completely transparent.<sup>8</sup> Equally opaque to consumers are net drug prices, which are the true drug prices paid by third-party payers (that is, health insurers) and patients after the total value of manufacturers' discounts, rebates, and other price concessions are taken into account.

In addition to the pricing opacity, drug manufacturers can create a monopoly on specialty drugs, such as many single source brand-name drugs and biologics, through patent protection and FDA marketing exclusivity of their products.<sup>9</sup> These monopolies can lead to excessive drug prices in a market where other actors and consumers have little leverage.

Another key influencer of drug prices are intermediaries known as pharmacy benefit managers (PBMs) who support health care payers in managing pharmacy costs. PBMs use their ability to set drug formularies for private health insurance plans, including the private health plan formularies in Medicare Part D, as a tool for negotiating discounts from drug manufacturers.<sup>10</sup> Private payers, including those participating in Medicare Part D, pay a net (discounted) price to drug manufacturers plus some payment to PBMs.<sup>11</sup> This nontransparent price discount between manufacturers and PBMs creates confusion for those who aren't involved in the negotiating process when attempting to understand pharmaceutical pricing dynamics, as discounts may or may not change with changes in list prices.<sup>12</sup>

In recent years, PBMs have come under closer scrutiny from policymakers due to a perception that PBMs drive up drug prices in their negotiations with drug manufacturers and thereby interfere with patients' access to prescription medications. PBMs charge fees to pharmacies, for example, retail business pharmacies or community oncology practices, and in some cases, these fees have increased dramatically in recent years.<sup>13</sup> On the other hand, a recent Government Accountability Office study found that in the case of Medicare Part D drugs, PBMs retained less than 1 percent of the rebates they negotiated with Medicare Part D manufacturers.<sup>14</sup>

Each of these actors affect drug prices in different ways, some more clear-cut than others. One clear and prevailing theme is that drug spending is growing rapidly and is an ongoing issue area that policymakers are interested in addressing.

### Prescription Drug Spending in the United States

The Centers for Medicare and Medicaid Services (CMS) defines prescription drug spending as “retail” sales of human-use dosage-form drugs, biological drugs, and diagnostic products that are available only by a prescription from a provider. A complete picture of spending on pharmaceuticals also includes the non-retail segment. The non-retail drug segment includes drugs that are purchased by providers such as hospitals, physician offices, nursing homes, and home health agencies and billed to patients as part of the provider bill.<sup>15</sup> U.S. retail prescription drug spending was \$333 billion in 2017.<sup>16</sup> Non-retail drug spending was estimated at \$148 billion (adjusted for rebates), for total U.S. prescription drug spending of \$481 billion in 2017.<sup>17</sup> After accounting

for rebates, the majority (82 percent) of U.S. retail prescription drug spending was incurred by the three major sources of health care payment in the U.S. health system: private health insurance, Medicare, and Medicaid. Among these three payers, private health insurance accounted for the largest share of drug spending, at 42 percent, followed by Medicare at 30 percent, and Medicaid at 10 percent. Patient out-of-pocket costs represented 14 percent of total retail drug spending.<sup>18</sup>

According to CMS's 2018-2027 projections of national health expenditures, the U.S. retail prescription drug spending will have grown 3.3 percent in 2018, due to faster than anticipated utilization growth partially driven by an increase in new drug introductions. CMS also projects that retail prescription drug spending growth will further accelerate to 4.6 percent in 2019, followed by a 6.1 percent per year on average growth for the years thereafter. Higher use of costly new drugs and efforts by employers and insurers to encourage patients with chronic conditions to consistently treat their diseases are driving factors contributing to projected retail prescription drug spending.<sup>19</sup>

## U.S. Federal Drug Spending

Medicare is the largest driver of federal drug spending. Medicare pays for drugs through the mechanisms of Medicare Parts B and D, which are described in the following paragraphs. Medicare Part B covers drugs and biologics that are bought and administered by infusion or injection in physician offices and hospital outpatient departments, and certain other drugs provided by pharmacies and suppliers.<sup>20</sup> Of total spending for Part B in 2017, about \$32.1 billion was spent on drug benefits,<sup>21</sup> and spending on Part D benefits totaled \$95 billion in 2017 (a sum of Medicare Parts B and D drug benefits totaling \$127.1 billion).<sup>22</sup> Medicare Part B concentrates drug spending in a small number of expensive products called biologics.

Health care providers use many biologics to treat cancer or its side effects, while others use them to treat macular degeneration, rheumatoid arthritis, and other inflammatory conditions.<sup>23</sup> Subsequently, the Medicare program compensates these providers for their acquisition costs. This is the so-called “buy and bill” system for financing physician-administered drugs. Medicare pays for most drugs covered under Part B using an average sales price (ASP) methodology. ASP is based on the weighted-average prices of drugs sold by manufacturers, which reflect discounts and rebates off list prices. The ASP calculation excludes certain types of sales, including sales to Medicare Part D plans and to entities covered by the Section 340B drug purchase program.<sup>24</sup>

The Medicare Modernization Act of 2003 established the Medicare statutory payment rate at 106 percent of ASP for most Part B drugs. The 6 percent add-on helps cover extra costs associated with these treatments, some of which involve special storage and handling protocols.<sup>25</sup> Physicians get a separate fee for administering drugs that must be injected or infused. Despite the statute setting Part B drug reimbursement at 106 percent of ASP, budget “sequestration” has reduced payment to 104.3 percent of ASP since 2013.<sup>26</sup> Intended to cover any added acquisition-related expenses, the percentage add-on can also have the unintended consequence of paying physicians more for prescribing drugs with higher costs than for prescribing less expensive therapeutic alternatives.<sup>27</sup>

Medicare Part D is a voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans approved by the federal government. Medicare Part D accounts for 3.4 times greater Medicare spending compared with Medicare Part B.<sup>28</sup> Beneficiaries can choose to enroll in either a stand-alone prescription drug plan to supplement traditional Medicare or a Medicare Advantage prescription drug plan, mainly HMOs and PPOs, that cover all Medicare benefits including drugs.<sup>29</sup> In 2018, more than 43 million of the 60 million people with Medicare were enrolled in Part D plans.<sup>30</sup>

Other federal drug plans require price discounts from manufacturers who wish to have their drugs covered.<sup>31</sup> Medicaid, the Veterans Health Administration, the U.S. Department of Defense, and the 340B drug program require price discounts from manufacturers with various tools (specific to each of these federal drug plans).<sup>32</sup> Price controls, usually in the form of required discounts from the average price paid by other purchasers and negotiated pricing, in which the government uses its market power to bargain for favorable rates from pharmaceutical suppliers, are some of the tools used to achieve price discounts.<sup>33</sup>



## High Prices Are Concerning to Policymakers

Despite the existing drug cost-management tools available to payers and PBMs, high drug prices continue to be of great concern to patients, taxpayers, employers, and the federal government. A defense of the status quo often invokes the concern that reducing drug prices may stifle innovation by discouraging research and development. However, others point to data suggesting that many of the largest pharmaceutical companies spend far more on sales and marketing than on research and development.<sup>34</sup>

The current dialogue taking place across the country, perhaps most notably the dialogue initiated by the Trump administration, reflects the growing burden of pharmaceutical costs on consumers.<sup>35</sup> Efforts at the federal and state levels and the vested interests of other stakeholders suggest that the opportunity may be ripe for collaboration on paths forward to address the challenge of high prices.

## FEDERAL POLICYMAKER RESPONSE

### Executive Branch

In May 2018, the U.S. Department of Health and Human Services (HHS) under the Trump administration released a Blueprint to Lower Drug Prices to address high drug prices in the United States. HHS identified four challenges in the U.S. drug market:

1. High list prices for drugs;
2. Seniors and government programs overpaying for drugs due to the lack of the latest negotiation tools;
3. High and rising out-of-pocket costs for consumers; and
4. Foreign governments benefiting from U.S. investment in drug manufacturing innovation without contributing toward the high costs of it.<sup>36</sup>

The HHS blueprint includes multiple policy proposals to lower drug prices and address these challenges. HHS then identified four key strategies for reform:

1. Improved competition;
2. Better negotiation;
3. Incentives for lower list prices; and
4. Lowering out-of-pocket costs.<sup>37</sup>

The HHS blueprint includes two phases: (1) actions President Donald Trump may direct HHS to take immediately; and (2) actions HHS is considering for which it has solicited feedback.<sup>38</sup>

Three blueprint policy proposals to reduce high drug prices via differing methods received considerable attention in the first half of 2019. A proposal to eliminate drug rebates in Medicare and Medicaid plans by excluding the rebates that drug manufacturers pay to PBMs was met with significant pushback from insurers and hospitals, who worried the proposal wouldn't force drug manufacturers to lower prices and would likely see higher profit margins from it. Due to projections that the elimination of drug rebates would significantly increase premiums, the administration withdrew the proposal in mid-July 2019.<sup>39</sup>

In mid-July 2019, a District of Columbia federal judge blocked a proposed requirement that drug manufacturers include in their television commercials the list price of any drug that costs more than \$35 a month. The ruling stated that HHS exceeded its regulatory authority in this requirement of drug manufacturers.<sup>40</sup>

The third proposal, published by the Trump administration in an Advance Notice of Proposed Rulemaking on October 30, 2018, requested comments on potential options for revamping the payment system for Part B-covered drugs. One of the demonstration projects is the International Pricing Index (IPI) and Targeted Savings. As an alternative to using ASP methodology, the demonstration project would use an IPI as a form of external reference pricing to allocate a targeted savings percentage across selected Part B drugs.<sup>41</sup>

Under the IPI model, the government would determine a payment rate for Medicare fee-for-service Part B drugs based on a target price linked to international prices (external reference).<sup>42</sup> The Office of the Assistant Secretary for Planning and Evaluation estimated in the first quarter of 2018 that list prices for 27 Part B drugs in the United States were, on average, about 1.8 times higher than prices paid for the same products in comparison countries. The IPI is the ratio of Medicare spending on selected Part B-covered drugs using the ASP methodology to spending on those same drugs using international prices. This calculation holds the volume and mix of drugs constant.<sup>43</sup> Over a five-year period, the IPI model would phase in a target price for Part B drugs, which HHS states would result in about a 30 percent reduction in spending achieved by smaller reductions for some drugs and substantially larger cuts for others, depending on the magnitude of the existing gap between the U.S. and international price for a drug.<sup>44</sup> The rulemaking status of the IPI model is pending as of October 2019.

## Legislative Branch

The high cost of drugs has been a primary focus of legislators during the 116<sup>th</sup> Congress. Members of Congress have introduced dozens of bills related to lowering the cost of drugs and the House and Senate committees of jurisdiction have held around a dozen hearings related to drug pricing.

### Efforts in the U.S. House of Representatives

In May 2019, the U.S. House of Representatives passed H.R. 987, the Strengthening Health Care and Lowering Prescription Drug Costs Act. This legislation included several bills intended to reduce prescription drug costs by making it easier to bring more generic drugs to the market. The package included the CREATES Act, language to limit “pay for delay” activities, and other language to make it easier to bring generic drugs to market. While the prescription drug portions of this legislation had bipartisan support, the bill passed 234 to 183, with only five Republican votes because lawmakers paired the prescription drug provisions with more partisan bills related to the Affordable Care Act.<sup>45</sup>

The House is continuing to work through the committees of jurisdiction on additional measures to reduce prescription drug prices, including legislation to increase transparency in the prescription drug supply chain; reduce additional hurdles for bringing generic drugs to market; reduce out-of-pocket costs for patients, particularly in Medicare Part D; and address the rising costs of specific drugs, including insulin. House Democratic leadership has also released additional drug pricing legislation (H.R. 3). The bill proposal, which the committees of jurisdiction will consider, would allow Medicare to directly negotiate drug prices for at least 25 and up to 250 drugs each year to be determined by the drugs that have the highest cost to Medicare and other payers and no additional competition. The bill would rely on an international pricing index to limit drug prices for those negotiated drugs. The bill would also cap out-of-pocket costs for seniors in Medicare Part D and make other changes to prevent drug prices from rapidly increasing above inflation.

### Efforts in the U.S. Senate

The U.S. Senate has adhered to many of the same themes as the House of Representatives. This summer, both the Senate Health, Education, Labor, and Pensions (HELP) and Finance Committees released bipartisan packages. The goal of the HELP package is to reduce health care costs in general, and the focus of the Finance Committee package is more specific to prescription drug prices. In addition, the Senate Judiciary Committee has held several hearings on legislation related to reforming the patent system for prescription medicines.

The HELP package, the Lower Health Care Costs Act of 2019, passed out of committee in June with a vote of 20 to 3. Regarding prescription drug prices, the bill focuses on improving the ability and authority of the Food and Drug Administration (FDA) to bring generic drugs and biosimilars to market more efficiently and includes provisions to increase transparency in the prescription drug supply chain. According to the Congressional Budget Office (CBO), the prescription drug title of this bill would save the federal government \$4.58 billion over 10 years.<sup>46</sup>

The Finance Committee legislation, the Prescription Drug Pricing Reduction Act of 2019, passed out of committee in July 2019 with a vote of 19 to 9. It includes many provisions, but a few of the most notable are described here.<sup>47</sup> First, the package aims to limit Medicare Part B and Medicare Part D price increases for drugs by requiring manufacturers to pay additional rebates to Medicare if they increase their prices above the inflation rate (an “inflationary cap”). Second, it would redesign Medicare Part D to reduce out-of-pocket costs for seniors by capping those costs at \$3,100 beginning in 2022 while shifting more responsibility to the insurance plans. Finally, it would better align incentives between Medicare and Medicaid on prescription drug pricing, improve information disclosure, and better facilitate innovative contracts between Medicaid and drug manufacturers. According to the CBO, this package would save the federal government \$100 billion, reduce out-of-pocket drug costs for Medicare beneficiaries by \$27 billion, and reduce Medicare premiums by \$5 billion.<sup>48</sup> While this package has moved out of committee, senators on both sides of the aisle have raised concerns about several provisions. The committee is continuing to work on updating the bill text.

The legislative future of these proposals is uncertain. While there is great focus on the issue, it is notoriously difficult to reach bipartisan consensus on such complex health care policies, and the policy debate will likely continue throughout the rest of the year.

## Specific Efforts Around Reference Pricing

Legislative conversations around external reference pricing as a tool to reduce prescription drug prices are limited, but there have been several legislative proposals introduced. These include bills that focus on establishing a system of reference pricing as well as bills that simply list reference pricing as an option that policymakers could use as a transition to, or as part of other efforts to, reduce prices.

- **The End Price Gouging for Medications Act** (H.R. 3523 & S. 1987), introduced by Reps. Peter Welch (D-VT) and Francis Rooney (R-FL) and Sen. Jeff Merkley (D-OR). The bill would require the HHS secretary to establish reference prices for drugs, limiting the price of a drug to the median price in 11 countries—Japan, Germany, the United Kingdom, France, Italy, Canada, Australia, Spain, the Netherlands, Switzerland, and Sweden. This price would be available to all individuals in the U.S. market.
- **Transparent Drug Pricing Act** (S. 977), introduced by Sens. Rick Scott (R-FL) and Josh Hawley (R-MO). The bill, which mirrors elements of the president’s IPI proposal, would limit the retail list price of drugs in the United States for all consumers to the lowest retail list price for the drug among Canada, France, the United Kingdom, Japan, or Germany. This provision would sunset after five years.
- **Prescription Drug Price Relief Act of 2019** (S. 102 & H.R. 465), introduced by Sen. Bernie Sanders (I-VT) and Rep. Ro Khanna (D-CA-17). The bill would require HHS to review all brand-name drugs for excessive pricing at least annually. A price is considered excessive if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan. If HHS finds that any such drugs are excessively priced, it must (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biologics.
- **Medicare Negotiation and Competitive Licensing Act** (H.R. 1046 & S. 377), introduced by Rep. Lloyd Doggett (D-TX-35) and Sen. Sherrod Brown (D-OH). The bill allows Medicare to directly negotiate Part D drug prices. If those negotiations fail, it allows other companies to develop generics; in the interim, one-year period, it limits what Medicare will pay to the average of the

prices available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the 10 Organisation for Economic Co-operation and Development (OECD) countries that have the largest GDP with a per capita income that is not less than half the per capita income of the United States.

- **The Affordable Medications Act** (S. 1801), introduced by Sen. Tina Smith (D-MN). The bill is wide-reaching and includes Medicare Part D negotiation, additional transparency, and changes to FDA approval. It lists reference pricing as a technique Medicare could use in their negotiations but does not dictate the terms.
- **The Choose Medicare Act** (H.R. 2463 & S. 1261), introduced by Rep. Cedric Richmond (D-LA-2) and Sen. Jeff Merkley (D-OR). The bill creates a public option via Medicare. It allows Medicare to directly negotiate prices for Part D prescription drugs and lists reference pricing as an optional tool.

# International and U.S. Experience With Reference Pricing

## EXTERNAL REFERENCE PRICING ABROAD

Most European countries use international reference pricing as a tool to determine payment strategies for pharmaceutical drugs. The World Health Organization (WHO) Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies defines external price referencing as “the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product in a given country.”<sup>49</sup>

A recent analysis found that 36 of 41 countries surveyed by WHO in the Europe region apply external price referencing for some medicines. Of those 36, 26 apply the tool as the sole or main pricing policy, although this could be limited to specific sectors, such as the outpatient sector. The number of reference countries ranged between one (Luxembourg) and 31 (Poland), with the selection criteria consisting largely of similarities in economic conditions and geographic proximity. The majority of countries (25) used the manufacturer (list) price when conducting external reference pricing. The most common formula used to calculate the reference price was to average the prices or to use the average of the three lowest prices of reference countries. Most countries surveyed monitor and revise prices on a regular basis; however, the duration of the intervals ranged from three months to five years. Countries dealt with challenges related to the non-availability of price information in various ways, including requiring data availability in at least a minimum number of reference countries. Beyond Europe, external reference pricing has also been applied, reportedly, in 23 countries worldwide; however, there is considerably less published information on its use.<sup>50</sup>

It should be stated that while there are several common practices among countries using external price referencing, overall, there is a significant amount of heterogeneity in its application. This variation makes it difficult to assess the overall impact of external reference pricing on outcomes such as the affordability and accessibility of medicines. Even within a country, impact analyses are limited because external reference pricing is often not the only approach used in pricing.<sup>51</sup> Other approaches include value-based pricing and internal reference pricing, to name a few.

Nevertheless, several researchers have attempted to isolate the impact of external reference pricing within and across sectors. In general, these studies demonstrate that external reference pricing leads to lower medicine prices immediately, but this effect may diminish over time.<sup>52</sup> In addition, methodological specifications have a significant impact on reductions in pricing. For example, one study demonstrated that more frequent monitoring and systematic price revisions led to greater price reductions. Further modeling suggests that the size of the market basket of countries, the exclusion of either lowest-income countries or highest-income countries, and the calculation formula also impact the average external reference price.<sup>53</sup>

Research has also investigated potential unintended consequences of external reference pricing schemes. For example, one study demonstrated that external reference pricing policies may encourage higher pricing in low-income countries, directly undermining affordability of medicines in these countries.<sup>54</sup> Other studies suggest that external reference pricing may discourage incremental innovation and investment in research and development, particularly in the short-term.<sup>55,56</sup> Additional studies have pointed to external reference pricing leading to spillover effects, such as manufacturer launch delays, particularly in countries with lower prices and strict regulations.<sup>57</sup> Some researchers have proposed that governments consider compensating manufacturers for the overall small negative impact on manufacturer revenue.<sup>58</sup>

To support European countries implementing external pricing schemes, the European Integrated Price Information Database (EURIPID) collaboration maintains a database with information on national prices and pricing regulations of medicinal products in a standardized format.<sup>59</sup> In 2018, EURIPID, with funding support from the European Union Health Programme, jointly developed 12 “Guiding Principles,” which are meant to serve as best practices for countries in establishing external reference pricing schemes.

Table 1 lays out these Guiding Principles.

**Table 1. Guiding Principles: External Reference Pricing (ERP)**

1.	ERP is an important policy tool that should be used in a mix with other instruments and not as a stand-alone policy tool.
2.	ERP should take place on a single-product basis rather than by indices.
3.	The aim of the national pharmaceutical policy should determine the selection of reference countries.
4.	Evidence has shown that ERP is most effective when applied to pharmaceuticals without generic or therapeutic competition.
5.	The comparison of prices of medicinal products should be done on the first price (type) in the pharmaceutical distribution chain.
6.	Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered comparable.
7.	The pricing formula applied for ERP should reflect the national pricing policy objective.
8.	ERP procedures should be performed with the highest possible accuracy and completeness of data sources.
9.	If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner.
10.	ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring.
11.	The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness.
12.	Policymakers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies.

Source: European Union<sup>60</sup>

Of these principles, the one with the greatest debate involves the selection of price type (principle 5). The EURIPID collaboration argues that external reference pricing must be applied at the first possible price type, such as the “ex-factory,” or list price. Doing so negates the need to take into account the various price differentials along the pharmaceutical distribution chain (for example, tariffs, duties, taxes). It has also argued that the application of external reference pricing at the retail price level is challenging due to the frequent lack of transparency in supply chain negotiations.<sup>61</sup>

However, a previous study on enhanced cross-coordination in the area of pharmaceutical product pricing using a basic simulation model found that external reference pricing could garner larger savings if real prices paid by payers (discounted prices) were used. Many have questioned the political feasibility of such an approach given not only the likely opposition from the pharmaceutical industry, but perhaps from countries themselves, who may fear being granted fewer discounts.<sup>62</sup>

## INTERNAL REFERENCE PRICING ABROAD

Internal reference pricing is defined by the WHO as the “practice of using the price(s) of identical medicines or similar products or even with therapeutic equivalent treatment (not necessarily a treatment) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.”<sup>63</sup> While many countries apply this strategy to set generic prices in relationship to originator medicines (versus fostering generic competition in the United States), more relevant for American policymakers is the practice of reimbursing therapeutically equivalent drugs similarly by setting a reference price. The reference price is typically the maximum level of reimbursement for a group of drugs. Given that patients are often asked to pay the difference between the reference price and the price of more expensive drugs, they

are encouraged to opt for the lower-priced therapeutic equivalent. As of 2017, 22 out of 28 EU member states used this form of internal reference pricing.<sup>64</sup>

A *Cochrane* systematic review of 17 studies<sup>a</sup> focused on the impact of internal reference pricing on health outcomes, health care utilization, drug expenditures, and drug use. While the overall quality of evidence was low, the review found that internal reference pricing may reduce third-party drug expenditures immediately and up to two years. The review suggested that reference pricing may increase the use of reference drugs while reducing the use of more expensive drugs requiring patient cost-sharing. Effects on drug prices, patients' out-of-pocket payments, health outcomes, or health care utilization were uncertain due to lack of evidence. There is no documentation identified that the use of internal reference pricing could lead to disincentives to pharmaceutical innovation.<sup>65</sup>

A previous review of internal reference pricing policies in OECD countries found that internal reference policies led to price decreases, particularly for drugs that were already facing generic competition prior to reference pricing. The review found that brand-name drugs originally priced above the reference price decreased their prices to a greater extent. There was no association between clustering therapeutically equivalent drugs and health losses for patients.<sup>66</sup> Finally, a Harvard Medical School meta-analysis of 16 studies evaluated various internal reference pricing policies and found that this tool reduced drug prices and promoted switching from expensive products to alternatives at or below the reference price. These outcomes were associated with reductions in both patient out-of-pocket and total payer expenditures.<sup>67</sup>

## COUNTRY CASE STUDIES

In order to obtain further insights for U.S. drug pricing policy, BPC examined the utilization of external and internal reference pricing in three specific countries. These countries were preferentially selected based on how quickly drugs are available to patients (time-to-market) and whether they employed reference pricing schemes. Table 2 below shows the results of four studies on time-to-market in European countries. The combined studies show that in the time-to-market ranking across countries studied, Germany, Denmark, and Switzerland are among those in which prescription drugs have the fastest time-to-market and are therefore available to patients most quickly (of note, the United Kingdom and Sweden do not employ reference pricing).<sup>68</sup> Each of these three countries has a unique drug pricing and reimbursement system. The unique country systems are described in case studies in Table 3.

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<sup>a</sup> The Cochrane Database of Systematic Reviews is a leading journal and database for systematic reviews in health care. A systematic review attempts to identify, appraise, and synthesize all the empirical evidence that meets prespecified eligibility criteria to answer a specific research question. Researchers conducting systematic reviews use explicit, systematic methods that are selected with a view aimed at minimizing bias to produce more reliable findings to inform decision-making.

**Table 2: Time-to-Market (TTM) for European Countries in Four Different Studies<sup>69</sup>**

Vernier (2011) <sup>70</sup>		EFPIA (2018) <sup>71</sup>		HST (2016) <sup>72</sup>		CIHI (2015) <sup>73</sup>	
Country	TTM	Country	TTM	Country	TTM	Country	TTM
Germany	0	Germany	3.5	Germany	3.5	Sweden	5
Denmark	0.8	U.K.	3.7	Denmark	5	U.K.	7
U.K.	0.8	Switzerland	4.1	U.K.	5	Germany	8
Austria	1.5	Denmark	5.2	Finland	5	Switzerland	11
Switzerland	1.7	Netherlands	7.6	Austria	6	France	13
Ireland	2.6	Finland	8.3	Sweden	6	Italy	14
Sweden	3.5	Sweden	9.4	Ireland	7		
Netherlands	3.7	Norway	9.7	Netherlands	9		
Finland	4.2	Austria	11	Greece	9		
Norway	4.8	Spain	12	France	10		
Spain	6.6	Italy	13	Spain	11		
Belgium	7.2	Ireland	14	Belgium	12		
Portugal	9	Belgium	14	Italy	12		
Italy	9.6	France	17	Portugal	12		
France	10	Portugal	21				
Greece	13						

**Sources:** The Verniers (2011) study reviewed time-to-market in 50 countries globally for 58 new substances between 1994 and 2008. The study sets out TTM as a deviation from the average. Therefore, in the table above, Germany has been normalized to zero. In HST (2016), time-to-market is defined as the month when sales amount to 1 percent of the maximum sales during the 24 months following market approval by the European Medicines Agency for pharmaceuticals approved during 2006-2011. The 2018 EFPIA assessment looks at administrative times after market approval, for new substances during 2014-2016. The CIHI study compares time-to-market from 2009-2014 for new drugs for Canada compared with several European countries.



**Table 3: Three Country Case Studies\***

Country	Drug Pricing System Used	Role of Internal Reference Pricing	Number of Countries Used for External Reference Pricing <sup>74</sup>
Germany	<p>Combines manufacturer determined pricing for a certain period (for new drugs), internal and informal external reference pricing, and value-based pricing.</p> <p>Price determined by drug manufacturer for newly introduced drug for first year. National-level organizations evaluate and determine additional benefits of new drugs.</p> <p>If no incremental therapeutic benefit determined, then internal reference pricing used.</p> <p>If positive incremental benefit determined, then price negotiations between the manufacturer and health insurers initiated, sometimes with external reference pricing used in informal manner.</p>	<p>Most generics and some other drugs are included in reference price groups. These include drugs:</p> <ul style="list-style-type: none"> <li>(1) with the same active substance and similar use;</li> <li>(2) with comparable therapeutic or pharmacologically active substances; and</li> <li>(3) with comparable therapeutic effect (usually used for fixed combinations).</li> </ul> <p>The G-BA (Federal Joint Committee) determines which pharmaceuticals should be included in a reference price group. The GKV-SV (National Association of Statutory Health Insurance Funds) then sets the price in the group. The price is set administratively, using a statistical model. Drugs in a reference price group are assigned a maximum reimbursement amount for the benefits scheme.</p> <p>If the price of a drug exceeds the reference price, patients pay the difference. Manufacturers often lower their prices to match the maximum price for compensation. If they do not, patients may ask their prescriber for an alternative.</p>	<p>15</p> <p>(Austria, Belgium, Cyprus, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Netherlands, Portugal, Sweden, Slovakia, and the United Kingdom)</p>
Switzerland	<p>Government requires that drugs be deemed cost effective. Analyses incorporate external and internal reference pricing equally (each weighted 50 percent).</p>	<p>Internal reference pricing involves a comparison with other products that already have subsidy status in Switzerland for the same or similar indication.</p> <p>If a generic drug alternative is available but not selected by the patient, the patient pays an additional cost after the usual amount covered by insurance.</p>	<p>9</p> <p>(Belgium, Austria, Germany, Denmark, Finland, France, the Netherlands, Sweden, and the United Kingdom)</p>

Country	Drug Pricing System Used	Role of Internal Reference Pricing	Number of Countries Used for External Reference Pricing
Denmark	<p>In the outpatient drug sector, free competition exists between manufacturers of drugs in the same therapeutic groups, and publicly posted prices change every two weeks.</p> <p>In the hospital (inpatient) drug sector, price negotiations are used (price-capping agreements).</p> <p>Proposed external reference pricing for those hospital drugs that are not already covered by voluntary price-cap agreements. Measure has not yet taken place.</p>	The product with the lowest price in the respective group becomes the price that is paid for by insurers.	9  (Austria, Belgium, Germany, Finland, Ireland, the Netherlands, Norway, Sweden, and the United Kingdom)

\*Citations for information in Table 3 are included in the content of the country case studies presented below.

## GERMANY

Germany is Europe's largest pharmaceutical market and usually the country with the earliest market entry for new pharmaceuticals in Europe. Germany has a price and reimbursement system that combines manufacturer determined pricing for a certain period, internal and informal external reference pricing, and value-based pricing.<sup>75</sup> By German statute, new drugs must have incremental clinical benefit over existing drug treatments in order to have an incrementally higher price. The final negotiated prices are not confidential.<sup>76</sup> Therefore, other countries are able to reference the final German prices when administering or negotiating their own rates.

In Germany's decentralized system, the GKV-SV (National Association of Statutory Health Insurance Funds) negotiates on behalf of the public and private health insurance funds on pharmaceutical prices with the manufacturers. The public legislatively mandated health insurance plans (referred to as sickness funds) numbered 110 in 2018. These sickness funds cover health expenses for most of the German population (90 percent), and private health plans cover the remaining 10 percent of the population.<sup>77</sup>

By German law, all drugs are covered and available for physician prescription in Germany immediately upon receiving market authorization by the European Medicines Agency (EMA). The German pricing system follows a guideline of 12 months for assessment of a new drug. Within those 12 months (the first year following EMA approval or following marketing authorization), a new drug is available at a price determined solely by the manufacturer.<sup>78</sup> During that year, comparative assessments of the new drug are made by IQWiG (the Institute for Quality and Efficiency in Healthcare), a national-level institute that, among other tasks, evaluates the additional therapeutic benefit of new pharmaceuticals. IQWiG's assessments are based on patient-relevant clinical endpoints, such as functional ability, reduction of symptoms, survival time, therapeutic effect compared with comparators, and results for specific patient subgroups.<sup>79</sup>

The IQWiG's comparative assessment informs the formal decision of the new prescription drug's additional therapeutic benefit by the G-BA (Federal Joint Committee), the highest decision-making entity in the self-governance of the German health system, composed of physicians, dentists, hospitals, sickness funds, and patient advocates. Orphan drugs, which often have no direct comparator and for which the clinical evidence may be based on very small patient samples, usually are awarded a nonquantifiable benefit without having to undergo a full additional benefit assessment.<sup>80</sup>

For those innovative drug treatments that are assessed as having incremental clinical benefit over existing drug treatments, external reference pricing is one of many factors used as supportive information in price negotiations.<sup>81</sup> All health plans pay the same collectively negotiated prices.<sup>82</sup> If a pricing agreement cannot be negotiated between the GKV-SV and the drug manufacturer, the drug's price is established by arbitration. In arbitration, the manufacturer, GKV-SV, and outside experts participate. The arbitration board decides on the price and the new price applies retrospectively to the 12-month date. The manufacturer can refuse the arbitrators' price and withdraw its product, but then it forgoes all sales in Germany, Europe's largest market. Another consequence of such a decision would be that a manufacturer may enter price negotiations in Germany for its next drug with a reputation for being uncooperative and therefore has an incentive to be cooperative in the first place.<sup>83</sup>

If it is decided that a new drug has no additional benefit compared with existing alternatives within a therapeutic class, the drug is to be assigned to one of the therapeutic classes covered by internal reference pricing. Manufacturers are permitted to set whichever price they feel is appropriate for drugs falling into these classes, but the GKV-SV, the umbrella organization of health insurers, establishes a limit to what individual insurers will contribute toward payment. The GKV-SV sets its payment limit near the 30th percentile in the distribution of prices within each therapeutic class, high enough to ensure that patients have more than one choice but low enough to ensure that the payer is not responsible for paying the highest prices within the class. Most generic drugs fall into the reference pricing system. For new drugs without added benefit and without sufficient equivalents for the formation of a reference cluster, prices are negotiated in the same manner as described above, but the annual costs of the new therapy cannot exceed those of the already available comparator. Since the introduction of this pricing system in 2011, most drugs without incremental benefit have followed this path.<sup>84</sup>

Patients pay out of pocket for the difference between the price set by the manufacturer and the reference-based reimbursement limit set by the purchaser organization. Many patients are unwilling to contribute out of pocket and prefer drugs priced below the reference limit, and their physicians will prescribe drugs at or below the limit.<sup>85</sup>

Table 4 below outlines the steps and time line of drug evaluation, pricing process, and associated new pharmaceuticals in Germany.

**Table 4. Drug Evaluation and Pricing Process Timeline of New Pharmaceuticals in Germany**

	Process	Time
1.	Market approval: After the Federal Institute for Drugs and Medical Devices or the EMA has approved a new pharmaceutical, the manufacturer can launch it. In connection with the launch, the manufacturer presents documents to the G-BA showing the therapeutic properties of the pharmaceutical. The pharmaceutical is included in the benefits scheme of the health insurance funds at a price determined by the manufacturer.	0-3 months
2.	The G-BA normally sends the documentation to the IQWiG, which conducts a benefit assessment of the new pharmaceutical. IQWiG responds with a statement to G-BA. Except for orphan drugs: in this case, the G-BA evaluates the new pharmaceutical.	
3.	After consultation with the manufacturer, G-BA decides whether the new pharmaceutical provides additional benefit compared with the "state-of-the-art" therapy (corresponding products). In the event of no additional benefit, the price should not exceed the reference price for corresponding products (according to the German "health care standard").	3-6 months

	Process	Time
4.	If the pharmaceutical is considered to provide additional benefit, negotiations on the price between the manufacturer and the GKV-SV are initiated. There is a possible discount on the manufacturer's initial price. However, the manufacturer's price is valid during the first 12 months.	6-12 months
5.	If agreement is not reached, the case will be sent to an arbitration board. In arbitration, the manufacturer, GKV-SV, and outside experts participate. The arbitration board decides on the price. The new price applies retrospectively to the 12-month date.	12-15 months
6.	If the arbitration board's decision is not accepted, the manufacturer may withdraw. Both sides have the option to go to court, which may refer the case back to the arbitration board.	Uncertain

Source: Swedish Dental and Pharmaceutical Benefits Agency.<sup>86</sup>

## SWITZERLAND

Switzerland has a universal market-based health insurance system, in which every Swiss citizen purchases private coverage on the individual market.<sup>87</sup> The insurance benefit package is somewhat standardized by the Federal Office of Public Health (FOPH) and includes the cost of prescription drugs.<sup>88</sup> The individual regions in Switzerland (cantons) have some flexibility in how their insurance markets are structured.<sup>89</sup> Insurers in a given canton can band together to jointly negotiate drug prices with a manufacturer.

The Federal Drug Commission advises the FOPH on the inclusion of prescription drugs in the standard insurance benefits package. The FOPH determines drug reimbursement and drug pricing every three years and posts the maximum prices health insurers will pay for drugs in the List of Pharmaceutical Specialties (SL).<sup>90</sup> Swissmedic is the regulatory agency responsible for authorizing and supervising drug-product market approvals in Switzerland. In order to apply to the FOPH for coverage of a prescription drug, pharmaceutical manufacturers must have already received a positive recommendation from Swissmedic.<sup>91</sup> Conditions for inclusion in the SL include Swissmedic approval of the drug and a determination that the drug is cost-effective. The FOPH cost analysis for a drug incorporates both external reference prices and internal reference pricing (therapeutic price comparison within Switzerland). Since 2017, the FOPH has used the pricing mechanisms of external reference pricing and internal reference pricing in equal shares (each weighted 50 percent) to define new drug prices.<sup>92</sup>

Switzerland uses nine reference countries for its external pricing. The reference countries are: Denmark, the Netherlands, France, Germany, the United Kingdom, Austria, Belgium, Finland, and Sweden. If available, the manufacturer's list price of the drug in these countries is used. Switzerland chose these countries because they are considered similar to Switzerland in terms of economic conditions and treatment traditions. In the absence of data on international reference prices (for example, if the pharmaceutical is not on the market in other countries), only the internal reference price is used. Reference price reviews take place every 36 months.<sup>93</sup>

In order to increase cost savings for generic drugs, in 2017, the price gaps between originator drugs and generic drugs were also adjusted. When included in the SL, generic drugs now have to be between 20 percent (in the case of small-market volumes) and 70 percent (in the case of large-market volumes) less expensive in prices than the originator drug product.<sup>94</sup> If a generic alternative to a prescription drug is available but not selected, the patient pays an approximately 20 percent of the remaining cost of treatment after health insurance coverage is applied.

## DENMARK

Denmark has a comprehensive, single-payer health insurance system financed by general taxation and administered at the regional level.<sup>95</sup> Denmark's five geographical regions each have their respective health authorities and budgets; collectively, they are known as the State. Denmark distributes pharmaceutical products through two channels—the primary (outpatient) health

sector and the hospital sector (inpatient)—with varying reimbursement and access approaches for each. The State, along with individual Danish patients, are the payer stakeholders in the Danish pricing system.<sup>96</sup>

The Danish Medicines Agency, in addition to being responsible for legislation concerning pharmaceuticals, medical devices, and clinical trials, decides which primary (outpatient) medicines the State is to reimburse.<sup>97</sup> Drug manufacturers are free to set their own prices in the outpatient sector after they notify the Danish Medicines Agency of the pharmacy purchasing price. The Danish national health service reimburses for any drug at the lowest price offered by a drug manufacturer for a given active pharmaceutical substance.<sup>98</sup> Consumers who choose a high-priced version of the drug must pay the difference out of pocket.

The Danish Ministry of Health has the latitude to choose not to reimburse for drugs in therapeutic areas with a monopoly supplier, though consumers are free to pay for these drugs out of pocket. Denmark fixes the prices of medicines for 14-day periods.<sup>99</sup> Pharmaceutical manufacturers submit price changes to the Danish Medicines Agency. The agency then publicly posts these updated drug prices every two weeks.<sup>100</sup> This infrastructure makes it possible to successfully ensure strong competition and thus low outpatient drug prices in Denmark. Overall, analyses have shown that Denmark has some of the lowest pharmaceutical prices in Europe.<sup>101</sup> Since pharmaceutical companies might lose market share if their prices are too high, they have an incentive to price their products competitively.<sup>102</sup>

The Danish State's hospital budget fully pays for the drugs used in the hospital sector (inpatient). A pharmaceutical procurement service collectively owned by the Danish regional governments, Amgros, centralizes hospital drug purchasing. Amgros assesses the cost-effectiveness of a drug and negotiates hospital drugs' prices with their respective drug manufacturers.<sup>103</sup> After the negotiations with a drug's manufacturer, Amgros submits a report to the Danish Medicines Agency that contains the result of the negotiation, a report on added clinical value, as well as an assessment of the additional costs of the drug. After this, the Danish Medicines Agency decides finally whether it will recommend the pharmaceutical as a standard treatment at public hospitals.<sup>104</sup>

In the past few years (2016-2019), the Danish Association of the Pharmaceutical Industry and Danish governmental bodies both agreed to use a negotiated formula (capping price growth) for hospital-sector drugs. Prior to capping price growth, the Danish system had used external reference pricing during price negotiations between Amgros and manufacturers to reduce list prices for new drugs in the hospital sector.<sup>105</sup> These price negotiations were not legislatively mandated.<sup>106</sup> Denmark uses nine reference countries for its external pricing negotiations: Austria, Belgium, Germany, Finland, Ireland, the Netherlands, Norway, Sweden, and the United Kingdom.<sup>107</sup>

In an attempt to contend with continued high drug prices, the Danish government recently proposed applying external reference pricing to those hospital drugs that are not already covered by the voluntary price-cap agreement.<sup>108</sup> Pharmaceutical companies that haven't already entered into voluntary price-cap agreements by early 2019 would have to report their prices on medicinal products in Denmark's nine external reference pricing countries.<sup>109</sup> If adopted, the external reference pricing proposal will be implemented in 2020. As of this report, adoption of this measure has not yet taken place.

## U.S. EXPERIENCE WITH REFERENCE PRICING

The United States does not currently use external reference pricing. However, as mentioned earlier, the administration as well as members on both sides of the aisle in Congress have proposed using external reference pricing in the context of paying for certain drugs. The section below summarizes the public- and private-sector experiences of implementing internal reference pricing in the United States.

### Public Sector

A variant of internal reference pricing, CMS has previously used the least costly alternative (LCA) approach in both Part B and Part D. In addition, CMS has used the "functional equivalence standard" as part of the hospital outpatient prospective payment system.<sup>110</sup>

With respect to Part B, starting in 1995, Medicare contractors began using LCA policies to control the cost of a specific class of prostate cancer drugs called luteinizing hormone-releasing (LHRH) agonists. Initially, CMS deemed two LHRH agonists as clinically comparable, though both had vastly different costs. The LCA policy set the payment amount for the group of clinically similar drugs at the reimbursement level for the least costly drug. Beneficiaries could still receive the more costly drug if the provider or beneficiary covered the difference in costs.<sup>111</sup>

In 2008, Medicare contractors proposed instituting LCA policies for two drugs used to treat chronic obstructive pulmonary disease and other lung diseases. However, a lawsuit ensued prior to implementation that resulted in the withdrawal of the proposal. The courts decreed that Part B-covered drugs must be reimbursed based on the ASP and CMS did not have legal authority to establish LCA policies. Thereafter, CMS eliminated these policies for Part B drugs.<sup>112</sup> A subsequent study by HHS Office of the Inspector General found that if LCA policies for LHRH agonists had not been discontinued, Medicare expenditures would have been reduced by \$33.3 million over one year.<sup>113</sup>

The cost implications of foregoing LCA policies have been examined for other treatments as well. For example, a 2011 study by the Office of the Inspector General focused on two clinically comparable antibody treatments for age-related macular degeneration and found that if CMS paid for the more expensive drug at the level of the less expensive off-patent drug, Medicare would have saved approximately \$1.1 billion and beneficiaries would have saved approximately \$275 million in copayments.<sup>114</sup> Similarly, in 2008, the CBO estimated the impact of clinical comparable viscosupplements for the treatment of osteoarthritis and found that with an LCA approach, Medicare would have saved approximately \$200 million from 2010 to 2014 and almost \$500 million from 2010 to 2019.<sup>115</sup>

With respect to Part D, while the HHS secretary has the authority to allow Part D plans to use internal reference pricing, CMS prohibited the use of reference pricing in 2009. At the time, it was reported that approximately 30 insurers, mostly local or regional drug-plan providers, employed reference-based pricing in 63 drug plans.<sup>116</sup> However, beneficiary advocates argued that plan enrollees could not accurately or easily determine their incremental cost-sharing amounts if they chose the more expensive medication.<sup>117</sup> Within Medicare's outpatient prospective payment system, the "functional equivalence standard," similar to LCA, was briefly used between 2003 and 2005 for treatment of specific types of anemia. However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 limited use of this standard, and CMS ultimately reverted to reimbursement based on ASP.<sup>118</sup>

## Private Sector

The most well-studied application of internal reference pricing in the private sector has been that of the RETA Trust, a national association of 55 Catholic organizations that purchases health insurance for clergy, schoolteachers, and other lay and religious employees. In 2013, the RETA Trust switched its pharmacy benefit management of non-specialty drugs from a standard tiered formulary to one where it categorized 1,302 outpatient drugs into 78 therapeutic classes. Classes were included if there was significant price variation among clinically comparable products. Payments for drugs were made based on the least costly drug in each therapeutic category. Patients whose physicians submitted clinical justification for the more expensive drug were granted one; otherwise, patients preferring a more costly drug were required to pay the price difference between the drug and the least costly one themselves.<sup>119</sup>

Results demonstrated that implementation of reference pricing was associated with a higher percentage of prescriptions filled for the reference drug within its therapeutic class, a lower average price paid per prescription, and a higher rate of copayment by patients than a comparison group. During the first 18 months after implementation, employer spending decreased by \$1.34 million while employee copayments increased by \$0.12 million relative to the comparison group.<sup>120</sup>

MedPAC, in its *Report to the Congress: Medicare and the Health Care Delivery System, June 2019*, also cited a study from an Arkansas state employee health plan demonstrating the use of internal reference pricing for proton pump inhibitors that reduced both member copayments and net cost per member per month.<sup>121</sup>

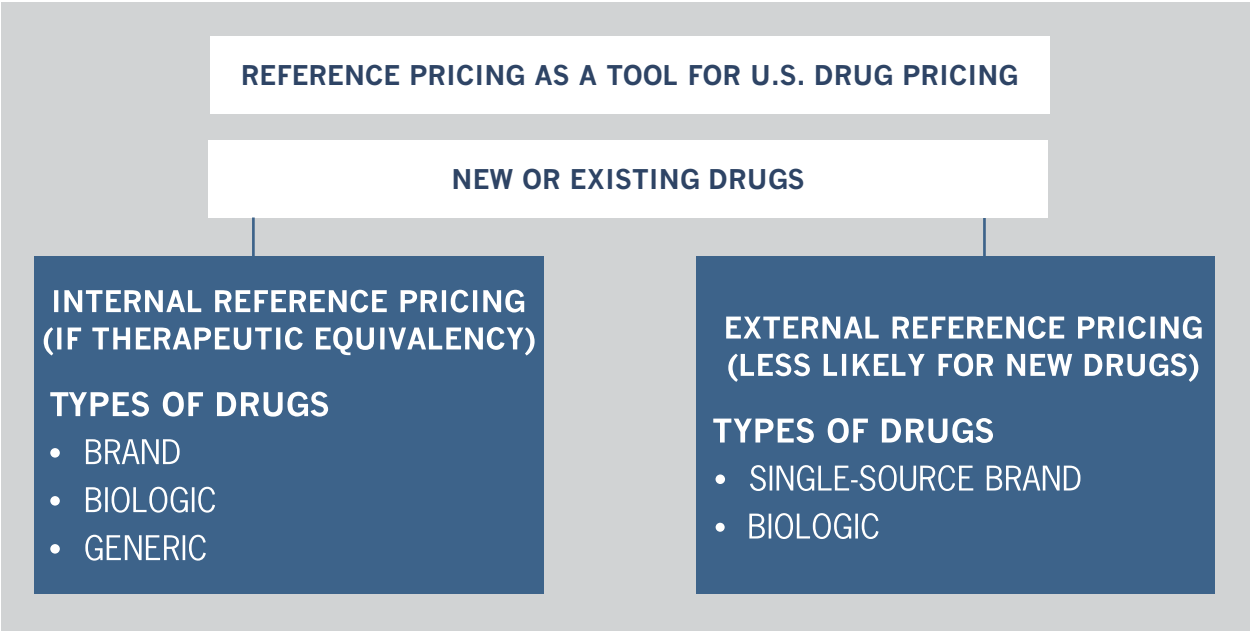
Finally, the foundation of internal reference pricing is based on the ability to determine the therapeutic equivalence of drugs. That evaluation occurs informally throughout the country in a proprietary fashion by industry stakeholders as well as by provider and payer pharmacies and therapeutics committees. Independent entities, such as the Institute for Clinical and Economic Review (ICER), also conduct and take these evaluations into account in their assessment of the value of prescription drugs and other health care delivery innovations. ICER's analyses can support higher prices corresponding to the added clinical value of a drug, a method that can augment traditional internal reference pricing based on the requirement of therapeutic equivalence. Also, of note, ICER recently proposed to identify how each of its comparative clinical-effectiveness assessments translate into the rating system used by Germany's IQWiG to describe a treatment's added clinical benefit. ICER anticipates this may help decision-makers consider different ways to assess the strength of evidence behind new interventions and spur further dialogue and alignment of evidence assessments across pharmaceutical markets.<sup>122</sup>

# Policy Discussion and Considerations

The following policy considerations focus on how the public and private sectors might use pharmaceutical reference pricing to increase the affordability of medicines. It should be emphasized that reference pricing is a tool that could be used in conjunction with many other pricing and reimbursement strategies, including value-based pricing, negotiation, and cost-plus pricing. Reference pricing alone is not a panacea and will not address all the affordability and accessibility challenges in the pharmaceutical sector. However, in the right setting, focused on the most appropriate drugs, and in combination with additional approaches, this tool could be impactful.

In general, evidence suggests that external reference pricing is most impactful for determining the maximum price of drugs without generic or therapeutic competition.<sup>123</sup> Thus, single-source brand-name drugs or biologics that are relatively expensive and face limited to no competition are prime candidates. Internal reference pricing may be used in several different situations. Scenarios include the following four examples: (1) two therapeutically equivalent brand-name drugs with significantly different price points; (2) a biologic drug with a significantly higher price point than a biosimilar; (3) a brand-name drug with a significantly higher price point than a generic; and (4) a generic with a significantly higher price point than another generic or another low-cost brand-name drug. Figure 1 provides a summary of how the United States might use pharmaceutical reference pricing as a tool. Finally, while studies from abroad point to the potential for reference pricing to reduce pharmaceutical prices, additional research looking at broader outcomes of interest—namely total costs of care, health care utilization, and most importantly, health outcomes—would be extremely helpful to policymakers.

**Figure 1**



## External Reference Pricing

1. The use of external reference pricing for new drugs in the United States may be possible in cases when a drug first reaches market in a foreign country. In a more likely scenario, external reference pricing could be used for existing drugs that have already been marketed in other countries. Various policymakers and experts have proposed the application of external reference pricing as tool to lower drug prices in several instances: the administration for select Medicare Part B drugs, academic experts for Medicare Part D brand-name drugs,<sup>124</sup> and members of Congress on both sides of the aisle for all brand-name drugs.



Policymakers looking to establish external reference pricing in the United States for select drugs should consider principles from the *Euripid Guidance Document on External Reference Pricing* as well as recommendations from the WHO's Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. For example, empiric evidence suggests that smaller, carefully chosen, country baskets result in similar or lower average prices while limiting administrating efforts and potential spillover effects to additional countries.<sup>125</sup> In addition, price monitoring at regular intervals with subsequent price revisions may lead to greater reductions in price. This is thought to occur because lower-priced reference countries included in the market basket may not have been considered in the initial price setting due to the likely nonavailability of medicines in these markets.<sup>126</sup> With respect to the selection of price type, while the use of list prices is most feasible, there is empirical evidence to suggest that if policymakers are able to obtain discounted prices (a better estimate of the true costs of drugs), this may result in lower prices.<sup>127</sup>

In addition, American policymakers could provide closer scrutiny to the specific countries in the market basket used to determine a reference price. For example, with respect to the administration's Medicare Part B IPI proposal, some experts have recommended that the basket be modified such that countries with market-oriented health care systems similar to the United States (for example, Netherlands, Switzerland, and Denmark) are selected.<sup>128</sup> Alternatively, several experts have proposed a competitive private sector for Part B drugs in which vendors would negotiate with manufacturers and be paid no more than the ASP for the cost of drugs.<sup>129,130</sup> While the ASP methodology is based on domestic market data, some experts recommend adding market-based prices in other developed countries, such as Germany and the Netherlands, to the methodology. The thought is that a broader index that includes external prices might help lower Part B prices while maintaining incentives for research.<sup>131</sup>

Implementing any external reference pricing scheme would require building an infrastructure and developing the capacity to collect and update comparable data from various countries. Experts caution that external reference pricing is not necessarily an easy-to-implement policy but rather requires careful planning to maximize effectiveness and reduce administrative burden.<sup>132</sup>

Overall, there should be continued bipartisan interest in HHS implementing a pilot program using external reference pricing for a subset of Medicare Part B or D single-source brand-name drugs or biologics that are relatively expensive and face limited to no competition. Applying lessons learned from other countries and adhering to best practices can potentially increase the affordability of drugs in the United States while minimizing unintended consequences.

## Internal Reference Pricing

The next three considerations focus on building an infrastructure in the United States to support internal reference pricing. Specifically, systems and processes that allow for the assessment of therapeutic equivalency are necessary for any internal reference pricing scheme.

2. The current investment in comparative-effectiveness research in the United States is less than adequate. Despite public- and private-sector efforts, clinicians and patients still lack the information needed to determine whether one health care intervention is better than another for that individual. To this point, the reauthorization of the Patient-Centered Outcomes Research Institute (PCORI) is critical and should garner bipartisan support.

Building on existing investments and infrastructure, there are several policy options to specifically increase the comparative therapeutic assessment of different drugs. One policy option is to build the assessment of *comparability* into the regulatory apparatus for the approval of drugs. While some have proposed that the FDA add a comparability standard

to its assessment of safety and efficacy, other experts have cautioned that this would either substantially increase the burden and costs of clinical trials or it would lead to methodologically poor studies that would not provide the information desired.<sup>133</sup>

Another option is for CMS to take on an assessment of comparability in its coverage determination process. Some experts have proposed that upon making a new coverage decision, Medicare could assess the clinical comparative effectiveness and determine reimbursement accordingly (usual pricing with evidence of superior effectiveness; reference pricing to an equally effective alternative with comparable evidence; dynamic pricing if there is insufficient evidence and reassessment within three years). This type of *evidence-based reimbursement* could steer drug innovation toward new products that have significantly greater enhanced effectiveness.<sup>134</sup>

3. Over the last 40 years, there have been multiple federal efforts to establish health technology assessments. Their failure resulted largely from organized opposition from industry and the medical establishment as well as a perception that these efforts would threaten access to the latest innovations for patients.<sup>135</sup> If a new effort were proposed, one option would be to limit its scope to assess only the clinical effectiveness of an intervention, without any assessment of cost. In concept, this is similar to the function of Germany's IQWiG, a national-level institute that evaluates the additional therapeutic benefit of new pharmaceuticals. Limiting scope in this way would also demonstrate sensitivity to the long-standing uneasiness in the United States about government intervention in determining the cost-effectiveness of a given medical intervention.

Specifically, HHS could establish an advisory group or task an existing office to look at the comparative effectiveness of any new brand-name drug or biologic approved versus the standard of care. For drugs that have a potential existing therapeutic equivalent, comparative-effectiveness research could be undertaken; whereas, for drugs without an existing comparable treatment course, a clinical assessment of the drug's benefit to patient health could be undertaken compared with the standard of care. Experts recently recommended a similar process for new drugs covered under Medicare Part B without a comparable treatment.<sup>136</sup> To inform HHS's efforts, federal funding could be provided to multiple private-sector research organizations to undertake these studies, which would include both data from randomized controlled trials as well as real-world evidence. The office or advisory group could review the data received these from various sources, including information from manufacturers and from other countries, and publish an expert assessment. Ultimately, this information could help inform private-sector price negotiation of drugs.

In such a scenario, current regulatory agencies and private-sector organizations would continue with their current responsibilities. The FDA would assess safety and efficacy for the approval of new drugs (in some cases, comparability data is included in new drug applications to the FDA). CMS would continue to base coverage decisions on what is reasonable and necessary. PCORI would continue to focus on its mission, which is much broader than solely supporting comparative trials of pharmaceuticals. The new entity envisioned would simply be filling a gap so that therapeutic equivalency for drugs could be evaluated to a far greater degree than in the status quo.

4. The European Union is looking to strengthen cooperation on health technology assessments to ascertain the added value of new medicines and medical devices. This would involve clinical assessments (benefits compared with existing treatments) jointly done by EU member states. The process would lead to common assessment methods across the European Union and facilitate shared data and expertise. A current proposal before the European Council would leave consideration of other domains, such as the economic impact of a pharmaceutical, to national authorities.<sup>137</sup> If the council moves forward with this plan, the United States could consider requesting permission to join such an effort. This would help spur information exchange and lead to more transparency about the added value of new drugs used in this country.

The next three considerations focus on instituting internal reference pricing for pharmaceuticals by both public and private payers. It is critical that the implementation of any internal reference pricing scheme use a transparent process involving multi-sector stakeholders to accurately identify therapeutic classes and determine therapeutic equivalency. In addition, given that patient responses to drugs may vary, there should always be a process allowing physicians to provide clinical justification in instances when prescribing the therapeutically equivalent higher-priced drug is warranted.

5. Congress could provide CMS authority to implement LCA policies for Medicare Part B and the functional equivalence standard in the hospital outpatient prospective payment system. Currently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that biologics and single-source brand-name drugs be paid based on their ASP and not averaged with or based on other drugs.<sup>138</sup> The HHS Office of the Inspector General has recommended that CMS seek legislative authority to implement LCA policies for Part B drugs.<sup>139</sup> The limited historical experience with this strategy, as summarized in this report, demonstrates significant cost-savings potential without evidence of patient harm. CMS would need to develop a transparent process with public input for determining classes of drugs in which therapeutic equivalency might exist and how policies would be implemented.<sup>140</sup>

In addition, MedPAC has recommended that biologics and their respective biosimilars be grouped into a common billing code to maximize price competition. Based on their observations, while there have been decreases in ASP for biosimilars over time, there have not been corresponding ASP decreases in the originator biosimilar. A consolidated billing code would be another way to use internal reference pricing based on therapeutic equivalency to reduce prices. Congress would need to provide the HHS secretary authority to implement this policy.<sup>141</sup>

6. CMS could update the Medicare Plan Finder tool with real-time information on patient cost-sharing for drugs so that Part D plans can institute internal reference pricing. This would allow patients to better understand how much more they may need to pay for more expensive, but therapeutically equivalent, drugs. The HHS secretary has the authority to allow Part D plans to use internal reference pricing, and there has been past interest by plans to use this tool for brand-name drugs with a generic equivalent.<sup>142</sup>
7. Health care purchasers are increasingly interested in tools that reduce the price variation within individual formulary tiers. While typical plans and PBMs incentivize patients to select drugs from a low copayment tier, there is often little incentive to select a low-price drug from within a tier or to switch the selection after the price of a drug increases.<sup>143</sup> By limiting payment to the price of the least expensive drug in a therapeutic class (internal reference pricing), purchasers incentivize patients to switch to the recommended therapeutic equivalent medication. This switch is usually from a generic with a significantly higher price point to a lower-cost generic, but in some cases, it may be to a low-cost brand-name drug.

Business strategies for PBMs should evolve to steer patients on high-cost medications to low-cost therapeutic equivalents when they exist. While rebates make this a challenge in certain cases, the use of internal reference pricing can successfully be added on to the traditional efforts of PBMs to reduce individual prescription costs for members and total prescription drug spending.<sup>144</sup> CMS should encourage Part D plans to use internal reference pricing to supplement the efforts of PBMs in reducing prescription drug costs.

# Conclusion

External and internal reference pricing are tools that policymakers could use, in conjunction with other pricing and reimbursement strategies, to reduce drug prices in the United States. Their implementation requires careful planning, transparent processes with opportunities for multi-stakeholder input, and a robust data and research infrastructure to support international comparisons and therapeutic equivalency assessments. In the right setting, focused on the most appropriate drugs, and in combination with additional approaches, these tools could increase the accessibility and affordability of drugs in this country.

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