Evaluating Patient Access to Type 2 Diabetes and Renal Cell Carcinoma Therapies across G20 Countries

Prepared by: IMS Health

February, 2016

Contents

1. Background 3
2. Objectives and Methodology 3
2.1 Countries of Focus 4
2.2 Medicines for RCC and T2D under Evaluation 5
3. Country Healthcare System Overview 6
3.1 Healthcare Spending by County 6
3.2 Defining National Reimbursement of Medicines across Countries 8
4. Comparing National Reimbursement of Medicines across Countries 13
4.1 Regulatory Approval Status 13
4.2 Public Reimbursement Status 14
5. Conclusion and Discussion 17
6. Appendix 19
6.1 Appendix A: Pricing and Reimbursement System Review 19
6.2 Appendix B. Glossary 34
6.2.1 G20 countries 34
6.2.2 Terminology 34

1. Background

Patient access to medicines is one of the clearest indicators of quality in a healthcare system. Inadequate access to medicines can limit therapy choices, cause great financial burden to patients, and potentially compromise treatment outcomes. As governments around the world are increasingly committed to improving the quality of healthcare for citizens, strategies to improve patient access are more important than ever.

A large body of research has examined patient access to medicines in the developed western world. However, comparative research that extends the study scope to the emerging world remains relatively less common. By nature, this type of research is challenging due to the difficulty in making a fair comparison across unique healthcare systems. This challenge is intensified when comparing developed and emerging markets. Nevertheless, an in-depth analysis of patient access across both developed and emerging healthcare markets is essential, providing a critical perspective, and helping build a truly global understanding of drug access.

Therefore, this study aims to provide a comparison of patient access among the "G20 nations", a group of countries composed of different income levels and stages of economic development. Given the crucial role of governments in providing coverage and making access decisions, the focus of the study is specifically on public access, or patient access provided by governments.

Medicines in two disease areas, Renal Cell Carcinoma (RCC) and Type 2 Diabetes (T2D), are selected as proxies to represent terminal diseases and chronic conditions, respectively. The treatment of RCC, the most common form of kidney cancer, has made significant advances over the past ten years and a global review of newly-approved products provides a comprehensive look at the current status of the most up-to-date RCC therapies across markets. As one of the most prevalent forms of diabetes, T2D imposes a large economic burden on patients due to long-term primary care requirements. Access to T2D medications, therefore, is a significant window into patient access, and its impact on cross-country patient populations.

This cross-country comparison of patient access to medicines intends to contextualize disparities in treatment choices and help policy makers identify the key gaps that must be effectively addressed in order to improve the quality of their healthcare systems.

2. Objectives and Methodology

The objective of this study is to provide a systematic comparison of patient access to medicines of RCC and T2D across the varying healthcare systems of G20 countries.

In order to establish a consistent, and replicable, comparison across such different markets, three critical decisions were made:

1. **A definition of patient access**: For this study, "patient access" refers to the ability of patients to obtain key healthcare treatments in their country. It also refers specifically to *public access*, or access provided by government sponsored or funded reimbursement schemes.

2. **Establish a universal comparison of patient access across markets**: Due to the wide variation of infrastructure, pricing policies and reimbursement systems across the G20 countries, and due to the availability of data, this study focuses primarily on *national, rather than regional,* access decisions.

3. **Focus on representative therapy areas**: Terminal illnesses and chronic diseases are two of the biggest challenges for governments in establishing universal access models for citizens. Renal Cell Carcinoma represents one of the most common, and deadliest, cancers, while Type 2 Diabetes has a massive patient population across all countries that needs to be addressed. In addition, both diseases have a number of traditional and innovative medicines currently available, allowing for a greater volume of comparison.

2.1 Countries of Focus

This study evaluated the "G20" nations, which are considered to be globally representative, geographically, socially and economically. These countries (excluding the European Union) have been further segmented by the World Bank into "high income" and "middle income" cohorts, based on their Gross National Income (GNI) (See Table 1). The result is an excellent cross section of markets that enables comprehensive and inclusive international comparisons.

Table 1: Segmentation of G20 countries by income level

Segment	Country (n = 19*)	
High-income countries	Australia Canada France Germany Japan Italy	Russia Saudi Arabia South Korea United Kingdom United States
Middle-income countries	Argentina Brazil China Indonesia	India Mexico South Africa Turkey

**Only individual countries in G20 are included. The European Union (EU), although is a member of G20, is not included in this study*

2.2 Medicines for RCC and T2D under Evaluation

This study focuses on evaluating commonly used medicines for RCC and T2D, which are chosen as proxies to represent terminal diseases and chronic conditions, respectively. It should be noted that these two conditions differ significantly in patient size, disease severity, treatment duration and treatment purposes. In addition, for the purposes of this study, drugs were selected based on US treatment guidelines; first-line and second-line treatment labels refer to US protocols.

RCC is the most common form of kidney cancer. The treatment of late-stage RCC has undergone significant improvement in recent years, as several innovative targeted therapies have become available. These therapies can prolong survival as well as improve patient experience[1]. Eight drugs in first- and second-line therapies were selected for this study (see Table 2).

Table 2: RCC products covered in this study

Treatment Line (US)	Molecule Name	Brand name (US)
First-line therapy	Sorafenib	Nexavar
	Sunitinib	Sutent
	Temsirolimus	Torisel
	Bevacizumab	Avastin
	Pazopanib	Votrient
	Axitinib	Inlyta
Second-line therapy	Everolimus	Afinitor
	Erlotinib*	Tarceva*

**For use in non-clear RCC (systemic therapy only)*

*** Date refers to the approval date of Tarceva in Non Small Cell Lung Cancer*

Diabetes is highly prevalent across all countries, with a total worldwide patient population reaching 387 million, according to an estimate by the International Diabetes Federation (IDF)[2]. Type 2 Diabetes (T2D) is the most common form of diabetes and causes heavy clinical and financial burden to both patients and the healthcare system at large. However, the rise of innovative therapies such as DPP-4, SGLT-2 inhibitors, and novel insulin-based products has driven significant therapy advancements in the past decade. In comparison to traditional drugs, these innovative therapies are more effective in lowering blood sugar level and provide greater administration convenience for patients[3]. Twenty drugs from multiple drug classes, covering different lines of treatment, were selected for this study (see Table 3).

[1] Namita Chittoria, MD and Brian I. Rini, MD. Renal Cell Carcinoma (August 2013). Available at: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/nephrology/renal-cell-carcinoma/#top.
[2] http://www.idf.org/worlddiabetesday/toolkit/gp/facts-figures?language=fr, Diabetes: facts and figures
[3] Chao. EC. SGLT-2 Inhibitors: A New Mechanism for Glycemic Control Clinical Diabetes January 2014 vol. 32 no. 1 4-11. Available at: http://clinical.diabetesjournals.org/content/32/1/4.full.

Table 3: T2D products covered in this study

Treatment Line (US)	Drug Class	Molecule Name	Brand name (US)
First-line therapy	Metformin	Metformin	Glucophage
Alternative first-line therapy & second-line therapy (add-on to metformin)	Sulfonylurea	Glimepiride	Amaryl
		Glibenclamide	Micronase
Alternative first-line therapy & alternative second-line therapy	α-glucosidase inhibitor	Acarbose	Precose
Alternative second-line therapy	Thiazolidinedione (TZD)	Pioglitazone	Actos
	Dipeptidyl peptidase-4 inhibitor (DPP4)	Sitagliptin	Januvia
		Saxagliptin	Onglyza
		Linagliptin	Tradjenta
		Alogliptin	Nesina
Alternative second-line therapy (US Only)	SGLT-2 inhibitor	Canagliflozin	Invokana
		Dapagliflozin	Farxiga
		Empagliflozin	Jardiance
Third-line therapy (used alone or in combination with metformin)	Human Insulin NPH	Human Insulin Isophane	Humulin N
		Human Insulin Isophane	Novolin N
	Long-acting Insulin	Glargine Insulin	Lantus
		Detemir Insulin	Levemir
	Biphasic Insulin (pre-mix)	Recombinant Human Insulin Lispro Injection	Humalog Mix 50
		Insulin Aspart 30	Novomix 30
Alternative third-line therapy	GLP-1	liraglutide	Victoza
		Exenatide (once per day)	Byetta

3. Country Healthcare System Overview

3.1 Healthcare Spending by County

Healthcare spending, as a percentage of GDP, varies greatly across the G20 countries; while the US spent ~17% of its GDP on healthcare, India spent only ~3% in 2012 (see Figure 1). On average, high-income countries spend a noticeably higher portion of their GDP on healthcare than middle-income countries do. In the studied countries, high-income countries spent 9.6% of their GDP on healthcare in contrast to middle-income countries' 5.7%[4]. This variation is driven by multiple factors,

[4] WHO. World Health Statistics. Published in 2015. Available at http://www.who.int/gho/publications/world_health_statistics/en/

including a country's economic strength, healthcare infrastructure and government commitment.

Patient contribution to healthcare expenditure also varies significantly across the G20 countries, ranging from 7% to 61% (see Figure 2). Patients in high-income countries tend to bear less financial burden, contributing approximately 18% of total costs out of pocket. In these markets, governments play a vital role in funding healthcare. For example, government contribution is recorded to be 84% in the UK, 82% in Japan and 77% in France. In contrast, patients in middle-income countries contribute around 36% of healthcare costs out of pocket. India, Indonesia, Russia and Mexico have the highest contribution rates by patients, ranging from 44% (Mexico) to 61% (Indonesia).

Figure 1: Total Spending on Healthcare as % of GDP in 2012[5]

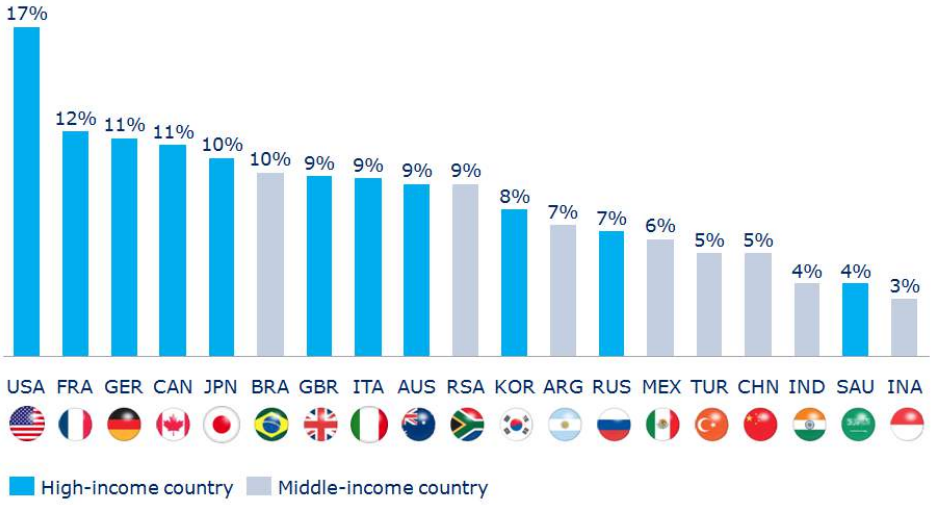
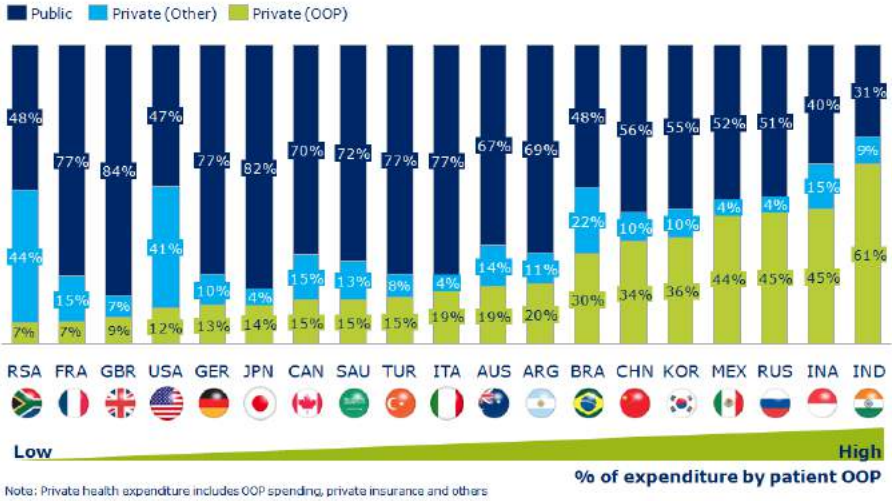


Figure 2: Proportion of total health expenditure by funding source[6]



[5] WHO. World Health Statistics. Published in 2015. Available at http://www.who.int/gho/publications/world_health_statistics/en/

[6] WHO. World Health Statistics. Published in 2015. Available at http://www.who.int/gho/publications/world_health_statistics/en/

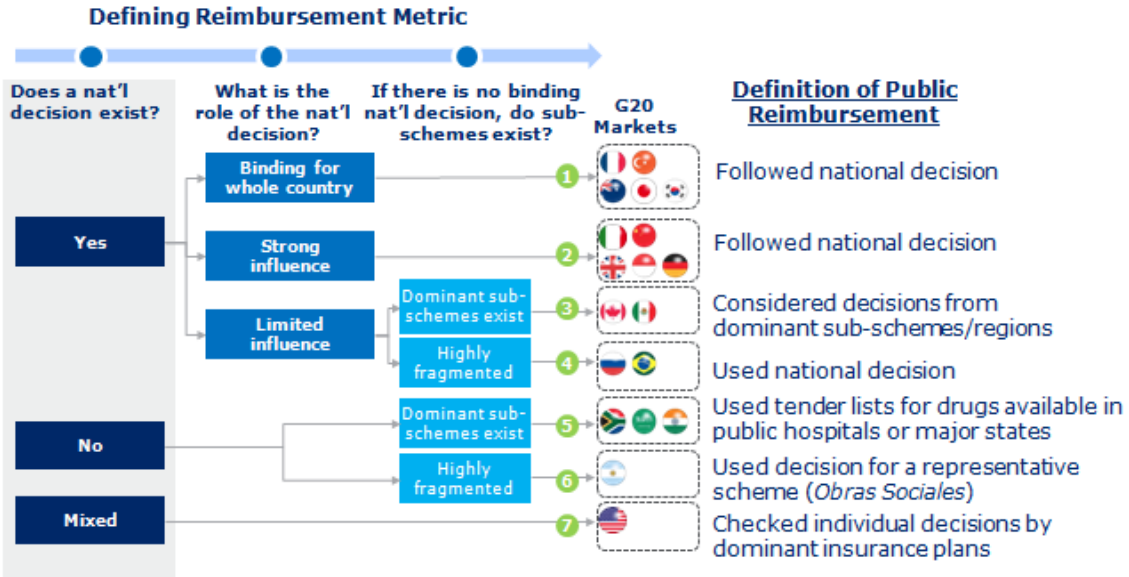
3.2 Defining National Reimbursement of Medicines across Countries

Public access to medicines is typically provided through government reimbursement channels, primarily in the form of a reimbursed drug list or formulary authorized by payers. However, reimbursement provisions can differ greatly depending on the variation and complexity of healthcare systems, including infrastructure, size of patient pool, geographic coverage, and funding sources. These variations create significant challenges for cross market comparisons.

The greatest challenge in evaluating public reimbursement across different countries – especially developed and emerging markets – is the variation in where and how coverage is defined. Many countries provide coverage at the national level through a universal drug list, while some countries, such as Canada, provide coverage at the regional level. The US is even more unique in that it mainly provides coverage to select populations and the decisions are made by different insurance schemes and health plans. For the purposes of this study, national level public reimbursement was given priority in analysis, as it represents the most universal level of coverage. For countries such as Canada and the US, where no clear national level coverage exists in many cases, the dominant regional/health plan formulary or drug lists were evaluated as representative of public coverage.

To ensure a fair comparison of the patient access to drugs across the G20 nations, we categorized the nations into eight distinct groups based on how national reimbursement was defined and applied across. These groups demonstrate the complexity and difficulty in evaluating access across such wide variations in process and structure (see Figure 3).

Figure 3: Decision tree for defining public reimbursement across G20 countries



- **<u>Country Group 1</u>: National reimbursement list is the only list applied to the whole country**
  These countries develop a single national reimbursement list and use it as the only reference for reimbursing drugs for the whole nation. In this environment, citizens enjoy universal access to the listed medicines. Therefore, patient access is clearly defined by the listing status of a drug on the national list. France, Turkey, Australia, Japan and South Korea follow this practice and regularly publish and update the national drug list (see Table 4).

Table 4: Definition of Public Reimbursement for Country Group 1

Country	National Reimbursement	
	List Used	Definition
France	National decision on a drug's actual benefit level (Service Médical Rendu, SMR, rating)	Considered as "Reimbursed" if the drug's SMR rating is above "Insufficient"
Turkey	Positive reimbursement list for Social Security Institution (Sosyal Güvenlik Kurumu, SGK)	Considered as "Reimbursed" if included in the list
Australia	PBS List	Considered as "Reimbursed" if included in the list
Japan	NHI Drug List	Considered as "Reimbursed" if included in the list
South Korea	National Reimbursement Drug List	Considered as "Reimbursed" if included in the list

- **<u>Country Group 2</u>: National reimbursement list has a dominant influence on local reimbursement decisions**
  In some countries, although regions or individual insurance schemes have the flexibility to develop their own reimbursement lists, their decisions typically conform to a national reimbursement standard. For this group, the national listing status of a drug was considered as the determinant of patient access status. Germany, UK, Italy, China and Indonesia generally follow this practice (see Table 5). In China, for example, the national public insurance body publishes a national reimbursement drug list (NRDL) and each province makes minor adjustments to define their own provincial drug list. Similarly, Italy's national reimbursement decisions, made by AIFA, have a strong influence on each sub-region's practices.

Table 5: Definition of Public Reimbursement for Country Group 2

Country	National Reimbursement	
	List Used	Definition
U.K.	NICE recommendation; Cancer Fund Listing (for RCC drugs only)	Considered as "Reimbursed" if recommended by NICE or Cancer Fund
Germany	EMA approval; G-BA/AMNOG decision	Considered as "Reimbursed" if approved by EMA (prior to AMNOG) and passed AMNOG assessment (post AMNOG)
Italy	AIFA decision	Considered as "Reimbursed" if it is recommended by AIFA
China	National Reimbursement Drug List (NRDL)	Considered as "Reimbursed" if included in the list
Indonesia	National Formulary	Considered as "Reimbursed" if included in the formulary

- **Country Group 3: National reimbursement list has limited impact on regional decisions; a few dominant sub-national lists exist**

  Although there is some form of national guidance on drug reimbursement, regions or individual insurance schemes do not closely follow the national list. In this scenario, patient access to medicines is largely determined at the sub-national level. As a result, to build an accurate picture of national patient access, these individual sub-national lists must be analyzed. For each nation falling within this system, a number of dominant sub-national lists were selected to act as a proxy in evaluating national patient access (see Table 6). For example, in Canada, provinces typically make their own reimbursement decisions, which often override national recommendations by the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Pan-Canadian Oncology Drug Review (pCODR). This study analyzed the decisions by four major provinces (Ontario, Quebec, British Columbia) since they cover ~87% of the total population of Canada. In Mexico, decisions by two institutions, the Mexican Social Security Institute (IMSS) and the State's Employees' Social Security and Social Services Institute (ISSSTE), were analyzed, as they collectively cover around half of the population.

Table 6: Definition of Public Reimbursement for Country Group 3

Country	National Reimbursement	
	List Used	Definition
Canada	Provincial lists from Ontario, Quebec, British Columbia and Alberta	Considered as "reimbursed" if covered drugs listed in regions that have more than 50% of total Canadian pop.

Mexico	IMSS and ISSSTE formulary	Considered as "reimbursed" if included in both IMSS formulary and ISSSTE formulary

- **Country Group 4: Reimbursement decisions are regionalized and highly fragmented**
  Nations in this group exhibit similar characteristics to *Country Group 3*; the national list is often overridden by regional/individual reimbursement lists. However, there is a need to separate nations with a large number of regions, as their reimbursement decisions become inevitably fragmented. To address the practical difficulty in collecting data for all regions, this study utilized the national list to evaluate the reimbursement status in the countries (see Table 7). Russia and Brazil belong to this category as both countries are geographically large and have numerous provinces making individual drug reimbursement decisions. And while their national drug list does not perfectly represent patient access across the whole country, it does serve as a general guidance and enables a quick and simplified comparison of these two countries to others.

Table 7: Definition of Public Reimbursement for Country Group 4

Country	National Reimbursement	
	List Used	Definition
Russia	National Essential Drug List (EDL)	Considered as "Reimbursed" if included in the list
Brazil	RENAME (National list of essential drugs) CEAF (Componente Especializado da Assitencia Farmaceutica)	Considered as "Reimbursed" if included in either of these 2 lists

- **Country Group 5: No national list exists and regional decisions are highly fragmented**
  Some countries do not have a dominant national reimbursement list thus the decisions are highly variable. Defining national reimbursement is most challenging for this cohort. Argentina falls into this category as public reimbursement is offered through 300 different social funds (Obras Sociales), a PAMI scheme for retirees and the disabled and public insurance for the under-covered population. This study uses the PMO list to present an overall picture for T2D drugs whilst the SSS list for *Obras Sociales* is used as a proxy to determine patient access to specialty drugs in RCC, since it has a strong influence in shaping individual social funds' reimbursement lists (see Table 8).

Table 8: Definition of Public Reimbursement for Country Group 5

Country	National Reimbursement	
	List Used	Definition
Argentina	National PMO list Obras Sociales system coverage	For RCC, it is considered "reimbursed" if it is on the SSS list for Obras Sociales; For T2D, it is considered "reimbursed" if it is on PMO list

- **Country Group 6: No obvious reimbursement lists exist at national or sub-national levels**
  Some countries lack well-defined and widely adopted reimbursement lists at both national and sub-national levels. Medicines here are purchased by, and stocked in, public hospitals and are reimbursed for patients receiving care in the public sector. For South Africa and Saudi Arabia, we evaluated the national procurement records of public hospitals as a proxy for reimbursement status. For India, we evaluated the tender lists or essential drug lists in the major of states, which are used by public hospitals to stock drugs and provide free drugs to patients (see Table 9).

Table 9: Definition of Public Reimbursement for Country Group 6

Country	National Reimbursement	
	List Used	Definition
South Africa	Master Procurement Catalogue from Ministry of Health (MoH)	Considered as "Reimbursed" if included in Master Procurement Catalogue from MoH
India	State-level tender drug lists from 17 major states	Considered as "Reimbursed" if its population coverage of reimbursement is more than 50% of the total population of all 17 states that were evaluated in this research
Saudi Arabia	SGH (Secretariat General of Health) tender list	Considered as "Reimbursed" if included in SGH tender list (MoH hospitals use this list)

- **Country Group 7: National list exists only for some drug types while sub-national lists exist for other drug types**
  In the US, reimbursement lists vary by drug type and by insurance scheme. This study analyzed drug reimbursement for Medicare, which covers the

elderly and disabled, as it is the most dominant public insurance scheme in the US. Relevant drug lists for RCC and T2D were selected for the assessment, since non-oral drugs are typically reimbursed through Medicare Part B while oral drugs are reimbursed through Medicare Part D, which are managed by individual private plans (see Table 10).

Table 10: Definition of Public Reimbursement for Country Group 7

Country	National Reimbursement	
	List Used	Definition
United States	Medicare Part B (CMS) and Part D (United, Humana, CVS Caremark, ESI, Aetna, Cigna)	For injectibles: Considered "Reimbursed" if a product is reimbursed by Medicare Part B. For oral drugs: Although Medicare is the actual funding source, formulary decisions for oral products are managed by individual private insurance plans. Patients have the freedom to pick the plan of choice. Six largest Part D plans were sampled to understand the reimb. status. Considered "Reimbursed" if a product is included by any of the Part D plans since patients have the freedom to choose a plan that covers the medicine in need

*Please see appendix for the sources of lists above

4. Comparing National Reimbursement of Medicines across Countries

For the selected RCC and T2D drugs, we compared both approval and reimbursement status using the below methodology.

4.1 Regulatory Approval Status

In each country, drugs need to be registered and approved by local regulatory authorities (e.g. FDA in the US and EMA in Europe) before they can be marketed. Therefore, any delay in access will undoubtedly include a lag in approval.

For RCC, most of the eight innovative target therapies this study focused on have been given market authorization in all G20 countries. Exceptions are Axitinib, which

is not approved in Indonesia, Brazil, South Africa Saudi Arabia; and Pazopanib, which is not approved in China (See Figure 4).

In contrast to RCC drugs, T2D drugs show more variation in approval status, especially among middle-income countries. Out of the 20 T2D drugs reviewed, only an average of 16 drugs have currently been approved in Turkey, China, India, Argentina, Saudi Arabia, South Africa and Indonesia (See Figure 5). The delayed approval is most evident for innovative therapies used in 2nd line treatment, such as DPP4 and SGLT-2.

Figure 4: Availability of RCC products in G20 (n=8 molecules)

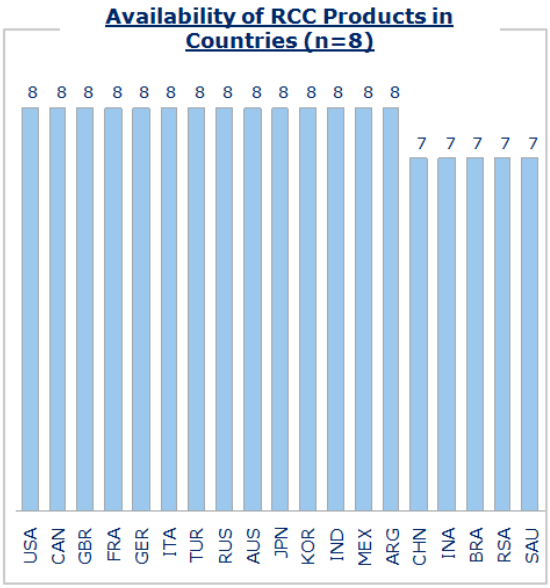
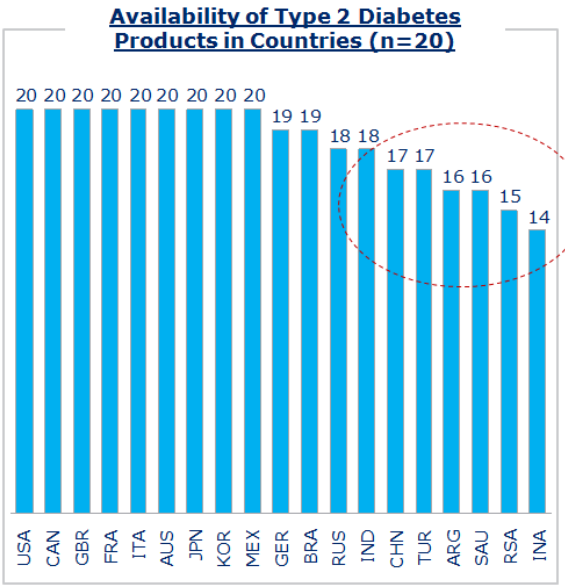


Figure 5: Availability of Type 2 Diabetes Products in G20 (n=20)



4.2 Public Reimbursement Status

Reimbursement status is evaluated for the selected RCC and T2D drugs that have been approved by local authorities in each country.

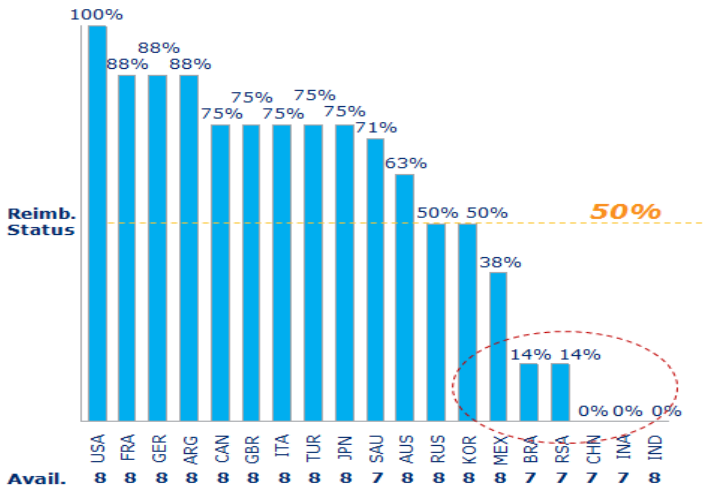
Reimbursement Status of RCC Products

There is significant variation in the reimbursement status for RCC drugs across the G20 countries (See Figure 6). On average, high-income countries have noticeably better coverage for these medicines than middle-income countries. This is due, in large part, to the significant barriers to access for specialty drugs in countries such as China, India and Indonesia.

The US is the only country that reimburses all studied RCC drugs. Other high-income countries, including France, Germany, Canada, UK, Italy, Japan and Saudi Arabia, reimburse 71%-88% of RCC drugs. On the other hand, a number of middle income countries have severely limited reimbursement; analysis revealed that Brazil, Russia,

China, Indonesia and India reimburse less than 14% of the studied RCC drugs. As a result, patients in these countries are forced to either give up effective therapies, or bear the financial burden by themselves. For example, India's total lack of public reimbursement typically results in patients having to pay 100% of treatment costs out of pocket to treat RCC. Similarly in Indonesia, although the government is establishing a unified insurance system under the umbrella of National Health Insurance (NHI), the current national reimbursement drug list does not include any of the studied innovative RCC therapies. Therefore, while these RCC drugs have been endorsed by major treatment guidelines and are prescribed regularly to patients in high-income countries, patients in middle-income countries are forced to adopt sub-optimal treatment approach.

Figure 6: Proportion of products reimbursed over available RCC products

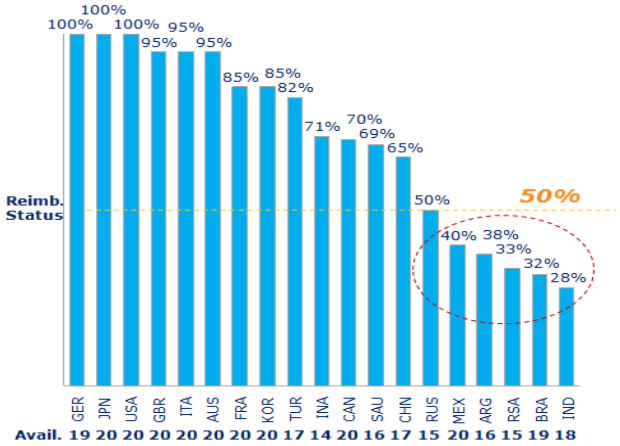


Reimbursement Status of T2D Products

Similar to RCC products, the reimbursement status of T2D products also varies significantly across G20 countries, with high-income countries reporting better reimbursement status than middle-income countries. There is also variation across treatment lines, especially SGLT-2 inhibitor and DPP-4, which often face more reimbursement hurdles than older generation products.

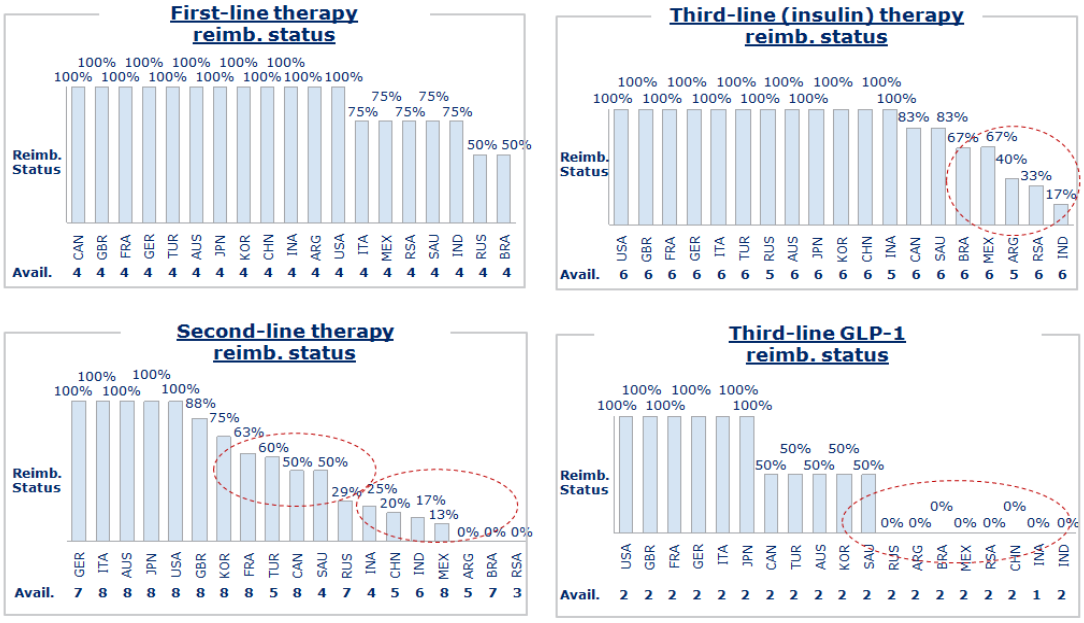
High-income countries such as Germany, Japan, England, Italy, Australia, France, South Korea, Turkey and the US have widespread reimbursement coverage for T2D medicines, ranging from 80%-100% of the analyzed drugs. Middle-income countries, however, face more reimbursement hurdles, and only reimburse 28%~71% of the studied drugs (see Figure 7).

Figure 7: Proportion of drugs reimbursed per country over available drugs (T2D)



If the reimbursement status is broken down by treatment line, first-line and third-line insulin therapies report better reimbursement across G20 countries (see Figure 8), averaging 88% and 84%, respectively. For second- and third-line GLP-1 therapies, reimbursement is averaged at 52% and 45%, respectively. Newly launched innovative drugs in second- and third-line treatment face more reimbursement hurdles, as payers face higher price burdens and challenge the lack of tangible health economic outcomes. This trend is not only limited to middle-income countries, but also observed in a number of high-income countries. For example, second line SGLT-2 inhibitor and DPP-4 are not fully reimbursed in US, Canada or France. Granted, the access situation worsens dramatically in middle-income countries.

Figure 8: Proportion of drugs reimbursed over available T2D drugs by treatment line



5. Conclusion and Discussion

As governments around the globe are increasingly committed to improving patient access to quality care, this study provides important evidence on the disparity in public access to medicines among G20 nations and identifies potential areas for improvement. In particular, this deep-dive analysis establishes a practical approach to defining patient access to medicines despite unique healthcare systems across countries. In addition, it reveals significant variations in patient access for RCC and T2D, diseases which are representative for terminal illnesses and chronic conditions, respectively. As our study focused on access to medicines provided by governments, these results establish a common understanding of patient access across major countries and call for greater actions by policy makers around the global to further improve access to medicines and the overall quality of healthcare.

Highly diversified reimbursement systems across the G20 nations present a major challenge in ensuring a fair global comparison of patient access to medicines. While acknowledging the significant difference in system set-up, funding sources and decision making processes, we established a universal framework that can be practically applied across the G20 nations. Our framework incorporated the most critical elements in defining public access for each country, including the availability of national policies for reimbursement, the level of impact, and decisions made by dominant regions or insurance schemes. This framework not only provides a practical definition of patient access to ensure a fair comparison, but also pinpoints the key gate-keepers of access, whether at the national or regional level.

This comparative study on public access to medicines in RCC and T2D revealed a range of access characteristics across the G20 group. First, regardless of reimbursement levels in each country, it is clear that the basic level of drug availability varies. While RCC drugs are generally available across all G20 nations, T2D drugs are less available in middle-income countries, largely due to the lack of approval of 2nd line drugs (e.g. DPP4, SGLT-2 inhibitors). Second, major gaps in reimbursement for both RCC and T2D are observed. For RCC, although the US and a number of high-income countries offer reimbursement for the majority of the studied drugs, there are still gaps in several high-income countries, such as Australia, Korea and Russia. Additionally, several middle-income countries do not have any meaningful public coverage for the studied RCC products, which increases financial burden of patients with this terminal disease and significantly compromises physicians' treatment options. For T2D, although 1st line and 3rd line insulins are reimbursed across most countries (except for India), inadequate coverage in 2nd line and 3rd line GLP-1 class is common in middle-income countries, again limiting treatment options and potentially comprising the treatment outcomes. Interestingly, despite the variation in infrastructure as it relates to patient access, it is clear that there are successful models in each system. Therefore, improved patient access can indeed be achieved, regardless of the level of decision making and the organization of insurance schemes.

Without a doubt, this study has reinforced the complexity and variation in patient access around the world. Although it establishes a comprehensive picture of reimbursement status of medicines in a range of markets, it does not review many other aspects that can compromise the quality of patient access, including patients' cost burden for reimbursed drugs and regional practices that do not follow a national reimbursement decision. For example, there is a significant difference in the level of patient financial burden for medicines, even with reimbursement systems in place; middle-income countries, for example, tend to require greater co-pay levels than high-income countries. Although not studied in great depth in this analysis, these metrics are as important as the reimbursement status of medicines and should be further evaluated to help policy makers make informed decisions on improving the overall access to quality care.

6. Appendix

6.1 Appendix A: Pricing and Reimbursement System Review

Reimbursement systems, focusing on medication access in this research, vary significantly between different countries. This variation is due to different healthcare provisions, reimbursement management systems and different levels of agencies.

The tables below clarify the role of public access and the reimbursement decision process in each country.

USA

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Residents of the US are able to access healthcare via both public and private providers. However, a significant portion of the population, which cannot afford private care but which is not eligible for public coverage, remains uninsured	Private and public payers use a variety of methods and criteria to determine whether a product should be reimbursed. **Medicare** The Centers for Medicare and Medicaid Services (CMS) is responsible for deciding whether coverage of a drug is "reasonable and necessary" under the Medicare Part A and Part B schemes. **Private payers for Part D benefit** Private health plans may offer Medicare Part D benefit for oral drugs for beneficiaries. Individual plans determine the level of reimbursement	Medicare B (CMS)	CMS database of Part B reimb. product list	Medicare provides public funding for aged and disabled beneficiaries (~16.5% of total population, 2013) Part B covers inject able oncology products
		Part D (United): 22% of lives	United Healthcare Comprehensive Formulary	Although Medicare is the actual funding source, formulary decisions for oral products are managed by individual private insurance plans; Patients have the freedom to pick the plan of choice; Considered as "reimbursed" if a product is included by any of the 6 sampled Part D plans (because beneficiaries have the freedom to choose and switch plans)
		Part D (Humana): 16% of lives	Humana Formulary List of covered drugs	
		Part D (CVS Caremark): 12% of lives	Caremark formulary drug list	
		Part D (ESI): 7% of lives	Express Scripts Medicare 2015 Formulary (List of Covered Drugs)	
		Part D (Aetna): 6% of lives	Comprehensive Formulary, Aetna Medicare (List of Covered Drugs)	
		Part D (Cigna): 5% of lives	Formulary (List of Covered Drugs)	

Canada

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Under Canada's universal healthcare system (known as Medicare), residents are guaranteed access to medically necessary primary and secondary care through 13 interlinked provincial and territorial healthcare plans. Responsibility for the implementation of Medicare is shared between the federal government and the provinces/territories. To secure full federal funding under the Canada Health Transfer (CHT), provinces'/territories' respective health programmes must meet certain standards of care for in- and outpatient	Individual public and private drug plans decide which drugs should be accepted for out-patient reimbursement. No single reimbursement procedure exists. **Public Sector** Responsibility for deciding on a drug's reimbursement status lies primarily with individual provincial/ territorial drug plans.	CADTH decisions	https://www.cadth.ca/node/88649	Canadian Agency for Drugs and Technologies in Health (CADTH) publishes reimbursement "recommendation " for primary care prescription drug at national level. This list was referenced in this study
		pCODR reports	https://www.cadth.ca/pcodr/find-a-review	Pan-Canadian Oncology Drug Review (pCODR) publish reimbursement "recommendation " for oncology drugs at national level. This list was referenced in this study
		BC – PharmaCare formulary and BC cancer drug benefit list: 13% of lives	1) PharmaCare Formulary Search 2) BCCA Benefit Drug List	Provinces are not required to follow national recommendations and have the authority to negotiate price and make reimbursement decisions. Most provinces have provincial drug formularies, or lists, covering primary prescription drugs, such as diabetes and insulin, and additional cancer or other funding programs' drug list covering oncology products. Quebec is one exception where there is a comprehensive
		Alberta – Alberta drug benefit list and Alberta outpatient cancer drug benefit list: 12% of lives	1) Alberta Drug Benefit List 2) http://www.albertahealthservices.ca/assets/programs/ps-1025651-drug-benefit-list.pdf	
		Ontario – Ontario drug benefit list, exceptional access program and new drug	1) http://www.health.gov.on.ca/en/pro/programs/drugs/formulary42/edition_42.pdf 2)	

hospital treatment (including coverage for prescription drugs used in hospitals). These standards are outlined in the 1984 Canada Health Act (CHA).		funding program list: 39% of lives	http://www.health.gov.on.ca/en/pro/programs/drugs/formulary42/edition_42.pdf	list covering all range of products. BC, Alberta, Ontario and Quebec's formulary covers up to ~86% of lives in Canada in 2014.
		Quebec – RAMQ list of medications : 23% of lives	1) http://www.ramq.gouv.qc.ca/en/regie/press-room/news/2015/Pages/updated-list-of-medications-june-2015.aspx 2) http://www.ramq.gouv.qc.ca/en/regie/press-room/news/2015/Pages/updated-list-of-medications-june-2015.aspx	

U.K.

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
All UK residents are able to access universal healthcare via the National Health Service (NHS). The NHS is funded by the central UK government, via general taxation and income-dependent National Insurance contributions by UK residents.	All new medicines are theoretically reimbursed once they have received marketing authorization from the European Medicines Agency (EMA), unless they are included on the negative list or grey list. In practice, however, products that have been deemed not to be cost-effective are unlikely to be funded	NICE	http://www.nice.org.uk/guidance/cg87/chapter/1-recommendations#oral-glucose-control-therapies-1-metformin-insulin-secretagogues-and-acarbose	NICE assesses cost-effectiveness of new products and provides guidance as to whether these drugs should be made available
		Cancer Fund	http://www.england.nhs.uk/wp-content/uploads/2015/03/ncdf-list-mar-15.pdf	The Cancer Drugs Fund enables patients to access oncology medicines that have not received a positive NICE appraisal and which are not funded by their local CCG

France

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
A statutory health insurance scheme provides all residents with access to comprehensive healthcare services (including physician consultations, pharmaceuticals, and in- and out-patient hospital care). Founded on the principles of social solidarity, equal access and quality care, the scheme forms one of the three branches of the social security system (the other two being family and pensions).	The High Authority for Health (HAS)'s Transparency Commission (CT) is responsible for assessing all drugs seeking access to reimbursement. The results of this assessment are critical for subsequent pricing negotiations between the manufacturer and the Pricing Committee (CEPS). Based on the information supplied by the manufacturer, the CT assesses, for each indication, the product's perceived medical benefit (SMR) rating and improvement in medical benefit (ASMR) rating.	Actual benefit (SMR)	http://www.has-sante.fr/	The product's medical benefit or therapeutic value is assessed by assigning an SMR rating to determine reimbursement status and rate. Possible SMR ratings are: Major/important/ moderate/weak/ insufficient Taken into account by CEPS during price setting
		Improvement in actual benefit (ASMR)		Possible ratings under ASMR are: I: major therapeutic progress II, III, IV: important, moderate, minor progress V: none

Germany

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Health insurance is compulsory (since 1 January 2009), but patients are free to choose their health insurance fund. The majority of the population is insured via one of the statutory health insurance funds, while a minority are eligible to opt for a private insurer.	Drugs are automatically granted reimbursed status following marketing authorization. However, nonprescription drugs (with some exceptions – see below) and drugs for the treatment of lifestyle conditions are not eligible for reimbursement. Moreover, drugs with a more economic alternative on the market, with comparable therapeutic benefit, may also be excluded from reimbursement or subject to prescribing restrictions. The regulations governing reimbursement exclusions and prescribing restrictions are detailed in the mandatory physician drug prescribing guidelines (Arzneimittel-Richtlinien, AM-RL) issued by the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA).	Approval status by EMA	http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fmedicines%2Flanding%2Fepar_search.jsp&mid	Drugs are automatically granted reimbursed status following marketing authorization, which after getting approval status by EMA
		G-BA/AMNOG decision	www.g-ba.de	Since Arzneimittelmarkt-Neuordnungsgesetz (Pharmaceuticals Market Reorganisation Act, AMNOG), benefit assessments for new drugs were conducted for reimbursement decisions

Italy

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
The National Health Service (Servizio Sanitario Nazionale, SSN) is based on the principles of universal and equal access to healthcare. The central government is responsible for healthcare policy and for determining which healthcare services must be made available to all patients across the country: the Livelli Essenziali di Assistenza (LEA) [essential levels of care]. The provision of healthcare is decentralized to the regions via the local health authorities (Aziende Sanitarie Locali, ASLs) in the 20 regions and autonomous provinces. The regions are permitted to provide additional healthcare services to those included in the LEA.	Since June 2013, all drugs which have received marketing authorization are initially included in a special sub-section of the 'Class C non-reimbursed' reimbursement category, pending a decision on their future reimbursed status. Decisions over admission to the reimbursement system are taken by the Italian Medicines Agency (AIFA).	AIFA decision	http://www.gazzettaufficiale.it/ricerca/atto/serie_generale/originario?reset=true&normativi=false	National reimbursement list by AIFA operates as a guide for all regions (e.g Class A: Essential drugs for serious and chronic diseases; Class H: Drugs for use in the hospital sector; Class C: Non-essential non-reimbursed prescription drugs)

Turkey

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
The Universal Health Insurance Scheme (UHIS) provides access to healthcare services for residents of Turkey. It was estimated that the scheme covered 98% of the population(including green card members – see below) at the end of 2012 (latest available data). The UHIS was established under legislation approved in 2006, in line with the government's 10-year Health Transformation Programme (HTP, Sağlıkta Dönüşüm Programı), and combines a number of formerly separate health insurance schemes.	Manufacturers may apply for reimbursement provided they have been granted marketing authorization and an approved maximum ex-factory price. The Reimbursement Commission (Ödeme Komisyonu) – an entity within the Social Security Institution (SGK) – makes decisions on reimbursement, subject to final approval by the President of the SGK.	Positive reimbursement list (for Social Security Institution (Sosyal Güvenlik Kurumu, SGK))	SGK positive list	The Universal Health Insurance Scheme (UHIS) provides access to healthcare services for residents of Turkey, which covers ~98% of the population

Russia

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Infrastructure problems have affected the Russian healthcare system for many years. The system remains fragmented, complex and inefficient, despite the government's commitment to the principle of the free provision of healthcare services to all citizens. The Ministry of Health is responsible for overall healthcare policy, as well as for overseeing federal programmes, including a compulsory health insurance scheme, the Federal Fund for Mandatory Medical Insurance (FFOMS).	Reimbursement for out-patient drugs currently is limited to beneficiaries of the federal Dopolnitel'noe Lekarstvennoe Obespechenie (DLO) scheme, and those covered by established regional schemes that offer inconsistent levels of drug provision for some patients. A range of other federal and regional schemes also provides pharmaceutical coverage. Federal programmes provide free in-patient treatment for patients suffering from cancer, diabetes, hepatitis, HIV and tuberculosis. In addition, out-patient coverage for people with such conditions is provided under some regional schemes.	EDL inclusion	EDL list, updated 2014	EDL is the base for several insurance schemes or regional lists (Federal: ONLS(reimbursement for specific patient population, e.g Military personnel)), regional hospital lists (vary by 85 regions)

Australia

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Australia's universal healthcare system (Medicare – established in 1984) allows beneficiaries access to free/subsidized out-patient care and free in-patient treatment in public hospitals. The Pharmaceutical Benefits Scheme (PBS) provides Medicare beneficiaries with subsidized access to prescription medicines. Both Medicare and the PBS are administered by Medicare Australia. However, strategic and managerial control belongs to the Department of Health.	The Pharmaceutical Benefits Advisory Committee (PBAC) considers applications for reimbursement, then advises the Minister for Health on which products should be subsidized under the Pharmaceutical Benefits Scheme (PBS) and listed on the Schedule of Pharmaceutical Benefits.	PBS listing decision	http://www.pbs.gov.au/pbs/search	Universal healthcare (Public Insurance ("Medicare")) is provided for all citizens. Drug reimbursement is indicated under the Pharmaceutical Benefits Scheme (PBS)

Japan

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Residents of Japan have access to comprehensive and universal health care via compulsory membership in one of two insurance schemes. Employee Health Insurance (EHI) covers the majority of working-age citizens and eligible residents aged 18-64, with the remainder of the population (including children, the self-employed and the unemployed) covered by the National Health Insurance (NHI) scheme.	Manufacturers seeking reimbursement for a new active ingredient must submit a combined pricing and reimbursement application to the Ministry of Health, Labor and Welfare (Korosho).	NHI Drug List	NHI Drug List	Applicable to 100% public, different schemes share the same NHI Drug List. Different schemes include: NHL (National Health Insurance), EHI (Employee Health Insurance)

South Korea

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
The National Health Insurance (NHI) system is funded largely by mandatory social insurance contributions and provides healthcare coverage for 97% of the population. The other 3% (those in poverty) are covered by the Medical Aid Programme (MAP), which is financed by the government.	South Korea has operated a positive reimbursement list system since the beginning of 2007. A manufacturer seeking to have a drug included on the positive list is required to file an application with the Ministry of Health and Welfare (MOHW), which is forwarded to the Health Insurance Review & Assessment Service (HIRA) for consideration by its Drug Benefit Evaluation Committee (DBEC).	Positive Reimbursement List	http://www.kimsonline.co.kr/drugcenter/search/totalSearch/Humulin%20N	Apply to 100% public, different schemes share the same Positive Reimbursement List. Different schemes include: NHI (National Health Insurance) & Medical Aid

China

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Basic medical care is provided to eligible citizens via three health insurance schemes: 1) Basic Medical Insurance (BMI) for Urban Employees 2) BMI for (non-working) Urban Residents 3) NRCMS (New Rural Co-operative Medical Scheme) In 2014, over 95% of the population was covered by the three schemes.	The reimbursement system is the responsibility of the Ministry of Human Resources and Social Security (MoHRSS) and its local agencies. The National Health and Family Planning Commission (NHFPC) and the Ministry of Finance are also involved in defining the scope of coverage and in the provision of funding.	NRDL (National Reimbursement Drug List)	NRDL, updated in 2009	Applicable to urban population, including urban employees and urban residents (elderly, unemployed)

Indonesia

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Jaminan Kesehatan Nasional (JKN, National Health Insurance Programme) started on January 1, 2014 as an attempt to integrate various government insurance schemes into one (under the umbrella of NHI). Currently in its first phase, it covers about 145 Mn people, (~60% of total population). The MoH develops a national formulary as a base for this integrated insurance. Despite its ambitious goal, the progress is not as fast as planned		National Formulary	National Formulary, updated in 2013	It is the base for integrated insurance under reform

India

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
India has no national reimbursement mechanism existing that covers the general population; however, for many states/provinces in India, there are tender lists/formularies for hospital procurement, which include only some essential drugs, to be provided to patients free-of-charge.		In this research, tender lists/formularies of 17 major states are used, covering about 88% of all Indian residents.	Tender lists/formularies of 13 out of the 17 states are obtained from the government websites of the states. For the other 4 states, hard copies were obtained from India OPPI.	Drugs included in the tender lists/formularies are provided to Indian patients, free-of-charge. We obtained the reimbursement status of each drug in each of the 17 states, and then considered a drug as nationally reimbursed if it is reimbursed for a population over 50% of the total population of the 17 sampled states.
Note: the following 17 states were evaluated Uttar Pradesh Maharashtra SHS Bihar West Bengal Madhya Pradesh Tamil Nadu Rajasthan Karnataka Gujarat			Andhra Pradesh Odisha Telangana Kerala Jharkhand Assam Punjab Chhattisgarh	

Brazil

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
The Single Health System (Sistema Único de Saúde, SUS) aims to provide universal and comprehensive healthcare to the Brazilian population free-of-charge. Budgetary and resource limitations (e.g. a lack of facilities, a fragmented care network, and insufficient numbers of healthcare professionals) mean that coverage is not comprehensive. Moreover, while 75% of the population rely on the SUS (and have no alternative coverage), the remaining 25% hold supplementary private healthcare coverage.	Patients covered by the public healthcare system (SUS) are required to pay out-of-pocket for the majority of out-patient pharmaceuticals. However, the Ministry of Health maintains a National List of Essential Drugs (RENAME), covering a range of medicines which can be accessed by patients in the out-of-hospital setting, via SUS clinics and primary care facilities. It is noteworthy, however, that the RENAME does not cover many high-cost out-patient treatments, including cancer drugs. Instead, these are reimbursed through hospitals via defined ambulatory care tariffs.	RENAME (Relação Nacional de Medicamentos Essenciai, meaning National list of essential drugs)	RENAME 9th edition	The system covers all population who meet PCDTs creteria. It is a list that covers range of medicines which can be accessed by patients in the out-of-hospital setting, via SUS clinics and primary care facilities (regions may customize the list for own formulary)
		CEAF (COMPONENTE ESPECIALIZADO DA ASSISTÊNCIA FARMACÊUTICA)	Latest CEAF list	CEAF list contains some high-cost drugs, which can be provided to patients, free-of-charge.

Mexico

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Universal healthcare coverage in Mexico is provided by a mix of public and private sector health insurers. There has been 100% coverage since April 2012. Mexico has made great strides in healthcare provision over the last decade. As recently as 2010, only 3.7% of the population had no form of health insurance. However, although the situation has improved, the Mexican government still faces challenges with ensuring access to care.	For a product to be reimbursed in the public sector, it must be included on the Basic Formulary (Cuadro Básico, covering primary care drugs) or the Catalogue of Supplies (Catálogo de Insumos, covering hospital drugs and medical and diagnostic equipment). Decisions on which new products to include on both lists are made by the Interinstitutional Commission for the Basic Formulary and Ingredients for the Health Sector (CICBISS), within the General Health Council (CSG). The Commission consists of representatives from: 1) the Mexican Social Security Institute (IMSS) 2) the Social Security and Services Institute for Government Workers (ISSSTE) 3) the Ministry of Health.	IMSS formulary	http://www.imss.gob.mx/sites/all/statics/pdf/cuadros-basicos/CBM.pdf	Mexican Social Security Institute, the largest social security provider, covering employers, their dependents and retirees (~40% of pop).
		ISSSTE formulary	http://issseapache.isssste.gob.mx/transparenciaproactiva/Fichero.php	Social Security and Services Institute for Government Workers (~10% of pop).

Argentina

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Healthcare in Argentina is provided via three different sectors: the social insurance sector, the private sector, and the public sector. Social insurance coverage (including through Comprehensive Medical Attention Program (PAMI)) was held by 61% of the population in 2012 (latest data). **Social Insurance Sector** The social insurance sector is administered and organized through 280 national funds and 24 smaller provincial social insurance funds, as well as those specifically for the armed forces. **Private Sector** Private insurance is held by around 7% of the population (for the most part through employer-based schemes). A proportion of these beneficiaries are also affiliated to an Obra. **Public Sector** State-funded healthcare for individuals without either social or private insurance is the responsibility of each of the provincial governments.	Legislation stipulates that all private and social health insurers must reimburse all retail and hospital drugs covered by the minimum package of healthcare services and medicines (PMOE). The PMOE drug formulary is drawn up by the Ministry of Health, on the advice of a special commission under its remit.	Public insurance	Formulary SUR	Public sector only provides meds for the uninsured in public hospitals. Entirely funded by the government and covers ~35% of the population
		PAMI	Manual farmacéutico Kairos (http://ar.kairosweb.com/laboratorios/producto-insulina-lantus-14310)	Provides generous coverage to only covers ~10% of pop (retirees & disabled)
		Obras Sociales system coverage	PMO (Plan Médico Obligatorio - http://www.sssalud.gov.ar/normativas/consulta/000595.pdf)	Covers ~44% of the population via ~300 individual social funds. Coverage is granted to the drugs included in the PMO (Plan Médico Obligatorio). The SSS through the SUR provides funding to Obras Sociales to cover high-cost drugs

South Africa

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Public Public hospitals provide in-patient care free of charge to the uninsured population. Hospitals may procure drugs depending on the needs and budget. The Department of Health runs national procurement on key medicines and makes them available in public hospitals. The majority of the population does not have insurance, but the government provides some basic access for drugs on the WHO essential drug list. 30% of the population is on social grant provided by government. **Private** 20% of the population has private insurance (mostly sponsored by employers) and PMB (Prescribed Minimal Benefits) operates as a guide for private insurance.		Master Procurement Catalogue from MoH		Public hospitals provide in-patient care free of charge to the uninsured population. Hospitals may procure drugs depending on the needs and budget. The Department of Health runs national procurement on key meds and make them available in public hospitals

Saudi Arabia

Role of public access	Reimbursement decision	List used in this research		
		List Used	Source	Methodology
Public 50% public, National Healthcare (state/MoH funded). Coverage is limited usually to basic care and hospital's formulary, under Saudi Nationals Health Insurance (SNHI). 16% public, Army/Guards (state funded) **Private** 27% private health insurance (patient/ employer funded). Covers mostly expatriates and small % of Saudis who choose to work in the private sector		SGH (Secretariat General of Health) tender list		Serves MOH hospitals (Saudi and gulf, where Saudi is 65-70% of the tender)
		MODA (ministry of defense and aviation) tender list		Used for military hospitals
		NUPCO (national unified Procurement company) tender list		
		NG (National Guard) tender list		Serves national guard hospitals and satellite clinics

6.2 Appendix B. Glossary

6.2.1 G20 countries

Continent	Country	Abbreviation
Asia-Pacific	Australia	AUS
	China	CHN
	India	IND
	Indonesia	INA
	Japan	JPN
	Korea	KOR
Europe	France	FRA
	Germany	GER
	Italy	ITA
	Russia	RUS
	Turkey	TUR
	UK	GBR
Americas	Argentina	ARG
	Brazil	BRA
	Canada	CAN
	Mexico	MEX
	United States	USA
Africa and Middle East	Saudi Arabia	SAU
	South Africa	RSA

6.2.2 Terminology

Abbreviation	Terms
ASMR	Improvement of Medical Benefit
BMI	Basic Medical Insurance
EMA	European Medicines Agency
FDA	US Food and Drug Administration
G-BA	The Federal Joint Committee

GSK	Statutory health insurance system
IMSS	Mexican Social Security Institute
ISSSTE	The State's Employees' Social Security and Social Services Institute
NHI	National Health Insurance
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRCMS	New Rural Co-operative Medical Scheme
NRDL	National Reimbursement Drug List
OOP	Out of pocket
P&R	Pricing & Reimbursement
PBS	Pharmaceutical Benefits Scheme
RCC	Renal Cell Carcinoma
SMR	Actual benefit
SUS	The Single Health System
T2D	Type 2 Diabetes