medcomm

Market Access 102

STRATEGIC INSIGHTS FROM LOCAL TO GLOBAL

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Market Access Basics

Market Access Overview

In our Market Access 101 Whitepaper, we discussed how market access allows patients to obtain and benefit from advances in the medical field. Some key components of market access basics that were covered in the whitepaper include:

- Patient Access and Social Determinants of Health
- Shifting from Volume to Value
- US Market Access Stakeholders
- Drug Distribution in the US
- FDAMA 114
- Global Market Access Considerations

Market Access 102 aims to expand on global market access considerations and discuss the impact of current events and emerging therapies on patients.

Market Access Challenges: Focusing on Patient Access

While manufacturers face several market access hurdles with regards to pricing and regulatory concerns, a patient's ability to access quality healthcare is an essential focus. Social Determinants of Health (SDoH) are pivotal in shaping market access, as they heavily influence health outcomes.[3] SDoH includes patients' neighborhoods, workplaces, and systematic policies that impact day-to-day life.[4] Patients without health insurance, for example, will have barriers to accessing quality care, impacting their overall health. In rural areas with limited access to physicians and healthcare facilities, also known as "healthcare deserts," patients' geographic location directly impacts their health - from identifying symptoms to diagnosing conditions, treatment options, and procedures.[5] It is well established that certain racial and ethnic minority groups have higher rates of illness and death in the US from a series of health conditions when compared to their White counterparts.[6] Poor outcomes within distant populations can result in a higher cost burden to payors. To improve population health, many payers have rolled out specific programs to support health equity initiatives. Availability, affordability, and awareness of treatment can significantly impact the success of a product.[7] Patient centricity in market access conversations and strategy can improve the ability of the individual to obtain high-quality care.[7]

Poor outcomes within distant populations can result in a higher cost burden to payers.

Global Market Access Landscape

North America

The United States has a fragmented healthcare system with multiple payors, including private insurers, government programs like Medicare and Medicaid, and managed care organizations.[1] This diversity opens opportunities for companies to tailor their services and secure reimbursement through various avenues, while also driving competition among providers, insurers, and healthcare companies. This competition ultimately fuels innovation and improvements in medical technology, treatments, and healthcare delivery. The emphasis on Health Economics and Outcomes Research (HEOR) allows companies to demonstrate cost-effectiveness, which facilitates the ability to secure favorable pricing and reimbursement. However, the complexity of navigating diverse formularies, state specific regulations, and varying price negotiations poses several challenges. For example, the fragmented system existing within the US creates variability in pricing and access across states and regions, making consistent pricing strategies difficult to implement.[1] Additionally, managing inconsistencies in drug price negotiations with payers and PBMs (Pharmacy Benefit Managers), ensuring compliance with varying state and federal healthcare regulations, and addressing disparities in patient access due to pricing variability add layers of complexity.[2] These challenges are compounded by the barriers in obtaining coverage approvals from different payors and the impact of regional differences in reimbursement policies on market access strategies. The regulatory landscape and high costs associated with market entry further complicate the process for companies seeking to establish a presence in this dynamic and demanding healthcare market access environment.

Canada's primary regulatory authority, Health Canada, oversees food and drug safety, medical device regulation, and national healthcare standards.[3] The Canadian healthcare system operates on Medicare, a decentralized, universal model that can vary based on region and province.[3] All Canadians are eligible for universal healthcare coverage, which provides access to core physicians and hospital services. Despite facing tax burdens up to 51% higher than their US neighbors, Canadians often experience similar out-of-pocket healthcare costs.[4] To offset these expenses, over half of Canadians also have supplemental private insurance, typically obtained through their employer.[3] Private insurance provides reimbursement for certain services not fully covered by public insurance including dental, vision, pharmaceuticals, allied health services, and much more.[5] The Canadian Agency for Drugs and Technologies in Health (CADTH) conducts Health Technology Assessments (HTAs) to evaluate the clinical and economic value of new health technologies, significantly influencing market access and reimbursement decisions.[6] This structured approach strives to balance healthcare costs with the delivery of effective treatments. However, challenges that impact access to care like lengthy wait times for urgent care and staff shortages continue to reflect the ongoing pressures on the Canadian healthcare system.[7]

Europe

The European market access landscape is diverse and complex, reflecting the continent's varied healthcare systems, regulatory environments, and reimbursement processes. Each European country has its own approach to market access, with different criteria for evaluating and approving new health technologies, pharmaceuticals, and medical devices. This diversity necessitates tailored strategies for each market, considering local regulations, HTA processes, and payor requirements.

In the European Union (EU), the European Medicines Agency (EMA) provides centralized regulatory approval for drugs, allowing them to be marketed across all member states.[8] However, after EMA approval, the responsibility for pricing, reimbursement, and market access lies within individual countries. This leads to variations in the time it takes for new products to become available in different markets, as each country conducts its own HTA to assess the clinical and economic value of a product.

In July 2024, German parliament passed the Medical Research Act as a mechanism to increase pharmaceutical Research and Development within Germany.[9] One major change resulting from the act is the introduction of confidential reimbursement pricing. This would allow pharmaceutical companies in Germany to keep reimbursement prices confidential with the hopes that this would prevent German pricing from impacting pricing globally.[9] Additionally, the Medical Research Act incentivizes companies to keep clinical trials within Germany by directly tying reimbursement pricing to the amount of research conducted within Germany.[9]

Brexit has disrupted UK access to EU supply chains and excluded it from EU strategies to address shortages, like joint purchasing. The UK's exit from the EMA left the Medicines and Healthcare products Regulatory Agency (MHRA) solely responsible for drug and med-tech approvals. This shift has slowed down the approval process for both medicines and medical devices, raising concerns that regulatory alignment with the EU could ease the burden on researchers and manufacturers.[10] As of March 2024, Great Britain faces delays in authorizing EU-approved medicines, with 56 drugs approved later than in the EU between December 2022 and December 2023, and eight not approved at all.[10] Brexit has also led to risks undermining patient care, as collaborations with the EU that have sped up access to new treatments have faltered, leaving NHS (National Health Service) patients at serious risk due to limited treatment options.[10] A survey conducted by the European Association of Hospital Pharmacists reflects that a clear majority of hospitals experienced shortages in 2023, including shortages of active ingredients, manufacturing and supply chain issues, poor planning, demand, and medicine pricing.[11] The consequences are urgent, leading to interruptions or delays in care, and less effective clinical substitutions.[10]

Asia

Countries like Japan, China, South Korea, and India, among others, each have unique processes for bringing new pharmaceuticals, medical devices, and health technologies to market.

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) is the lead regulatory agency overseeing the approval of drugs and medical devices.[12] Access to care in Japan is facilitated by a statutory health insurance system (SHIS).[13] The SHIS covers basic medical care along with approved prescription drugs, as determined by the national government.[13] Recent pharmaceutical initiatives in Japan involve utilizing Artificial Intelligence (AI) to assess viable new drug candidates and streamline the approval process.[14] Other countries in Asia, such as South Korea, experience markedly slower times to access globally approved drugs.[15] South Korea's single-payor system often leads to high patient co-pays and non-reimbursed services.[16] India operates under a decentralized, universal health system where individual states are responsible for providing coverage to citizens.[17] It is a hotspot for generic drug development and is often referred to as "the pharmacy of the world," though the FDA found that India had the lowest percentage of acceptable final outcomes in manufacturing.[17-18] However, despite India's rapid economic growth, many rural communities have limited access to care and significant unmet public health needs.[19]

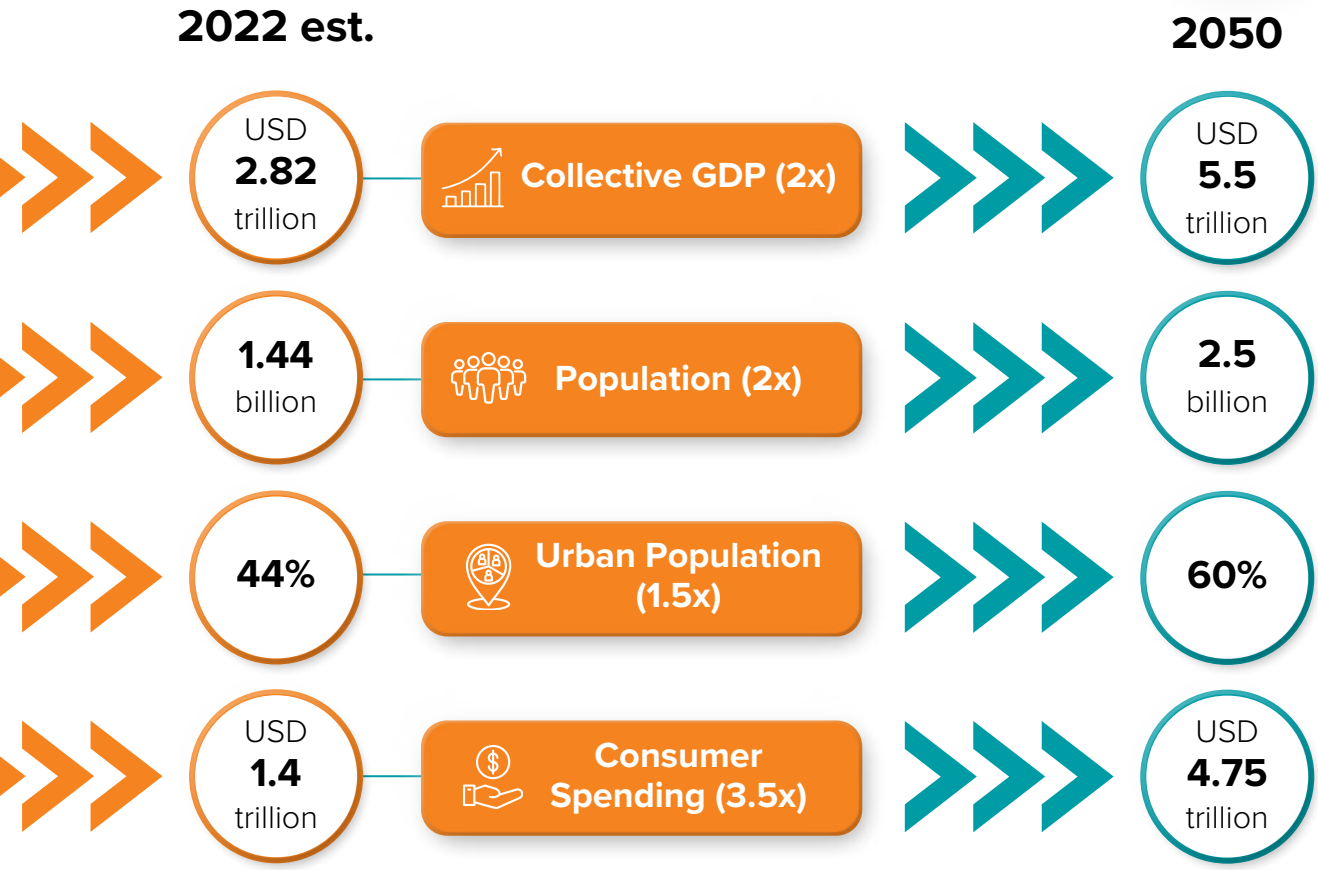
Latin America

Navigating Latin America's healthcare market involves tackling complex reimbursement models and cost-sensitive systems. Pricing and reimbursement policies differ across Latin American countries, with bureaucratic processes influencing the speed and valuation of new product approvals. Budget constraints prioritize cost-effectiveness, shaping pricing strategies and technology adoption. While regional integration efforts like MERCOSUR aim to harmonize regulations and facilitate cross-border trade, they face challenges in aligning diverse frameworks.[20]Additionally, uneven healthcare access between urban and rural areas and across socio-economic groups complicates the landscape, driving ongoing efforts to address these disparities.

Despite these challenges, the pharmaceutical market in Latin America has doubled over the past decade, fueled by population growth, rising healthcare expenditures, and Increasing demand for healthcare services.[21] Regulatory reforms, including streamlined registration processes and faster approval times, have redefined the landscape. For example, Brazil's adoption of online submissions has accelerated approvals, while stronger post-market surveillance ensures drug safety.[21] These advancements position Brazil to become one of the top five pharmaceutical markets globally in the coming years.[22] Mexico has increased pharmacovigilance and post-market surveillance to improve patient safety and ensure ongoing monitoring of pharmaceutical products after they hit the market.[21] Meanwhile, Colombia has introduced reforms to simplify regulatory processes, easing the registration and commercialization of pharmaceutical products for companies.[21] Across Latin America, a shift toward risk-based regulation is prioritizing high-risk products, making the system more efficient and speeding up access to essential treatments.

Africa

Africa is a diverse market with a growing population with rapidly changing public health needs. Pharmaceutical spending across Africa varies widely by region.[23] Most medications used within Africa are imported which can drastically impact access for patients.[23] There is significant genetic diversity within Africa, and research has yet to effectively represent this population within clinical trials.[23] Access to medical care in Africa is limited and coverage differs across the continent. As health spending in the continent continues to rise, universal coverage will be vital to accessing affordable preventive care and chronic care interventions.[23] Additionally, pharmaceutical development and innovation within the region is necessary to properly represent the population in clinical trials.[23]



Of the additional 2.4 billion people projected between 2015 and 2050, 1.3 billion will be born in Africa[23]

Current Events in US Market Access

Inflation Reduction Act (IRA)

The Inflation Reduction Act (IRA), signed into law in 2022, marks a significant federal effort to enhance healthcare affordability by lowering prescription drug costs.[24] Key provisions affecting market access include capping out-of-pocket expenses for Medicare beneficiaries and empowering the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices directly with manufacturers.[25]

Medicare Part B and D, which cover outpatient prescription drugs, are the primary targets of the changes introduced by the IRA. Medicare Part D was created in 2003 and implemented in 2006 as an effort to make prescription drugs more accessible.[26] Medicare beneficiaries typically opt for coverage under Medicare Part A, B, and D to ensure adequate coverage for medical and inpatient drug costs.[27] By emphasizing accountability and fair pricing practices, the act aims to create a more accessible and affordable healthcare system, alleviating the financial strain on individuals and improving overall healthcare affordability.

Specific provisions of interest include the following:

Vaccine Provision: Vaccines covered under Part D often have cost sharing requirements which vary based on the vaccine administered. Under the IRA's vaccine provision, recommended immunizations will be free for beneficiaries covered by Part D.[25]

Out-Of-Pocket Cap: The IRA set forth a $2,000 annual cap on out-of-pocket expenses and will reduce coinsurance for beneficiaries who exceed their catastrophic coverage.[28-29]

Maximum Fair Price Negotiation: Center for Medicare and Medicaid Services (CMS) can now negotiate the maximum fair price of a drug with the manufacturer. When negotiating the maximum fair price, CMS will consider the manufacturer's R&D costs, unit cost of production, and revenue data. In return, drug manufacturers undergoing negotiation must submit information regarding the drug's comparative effectiveness and target population to CMS.[25]

Penalties and Rebates: The IRA will enact penalties for pharmaceutical companies that fail to comply with the new pricing regulations.[30] These penalties are designed to act as a deterrent and encourage adherence to fair pricing practices. Along with penalties, CMS can collect rebates from drug companies whose drug prices increase faster than the rate of inflation.[29]

PBM Federal Trade Commission (FTC) Investigations

PBMs (Pharmacy Benefit Managers) are responsible for negotiating with drug manufacturers and managing drug benefits for health plans.[31] In negotiations, PBMs have a significant impact on the price patients will pay for the drugs offered under their health plan.[31] Drug manufacturers will pay PBMs via rebates and cite this as a reason for the growing prices of drugs.[32] The skyrocketing of drug prices has made it difficult for people to afford their medication, with nearly one-third of Americans rationing or skipping doses due to medication costs.[32]

In 2022, the FTC (Federal Trade Commission) launched an investigation of PBMs in 2022 in efforts to understand the role PBMs play increased drug prices and released a report in 2024 compiling their grievances with PBMs, emphasizing their role in high drug costs.[33] The FTC report notes that 95% of prescriptions filled are controlled by six PBMs.[33] Additionally, independent pharmacies are closing at rapid rates. The FTC claims that the level of power held by top PBMs are limiting patient's ability to access affordable medication.[33]

The FTC report notes that **95% of prescriptions filled** are controlled by six PBMs.[33]

These concerns are rooted in several practices that PBMs use to drive up drug prices:

Rebate and Fee Negotiations: PBMs negotiate rebates from drug manufacturers in exchange for placing certain drugs on their formularies.[34] However, these rebates often don't lead to lower consumer prices. Instead, manufacturers may raise the list prices of drugs to cover the cost of the rebates, causing overall prices to surge.

Spread Pricing: PBMs sometimes use a practice called spread pricing, where they charge health plans and insurers more for a drug than they reimburse the pharmacy that dispenses it, keeping the difference as profit.[31] This practice can drive up the overall cost of medications.

Formulary Management: PBMs control which drugs are included on a health plan's formulary (the list of covered medications). They may prioritize drugs with higher rebates over lower-cost alternatives, leading to higher prices for patients.[35]

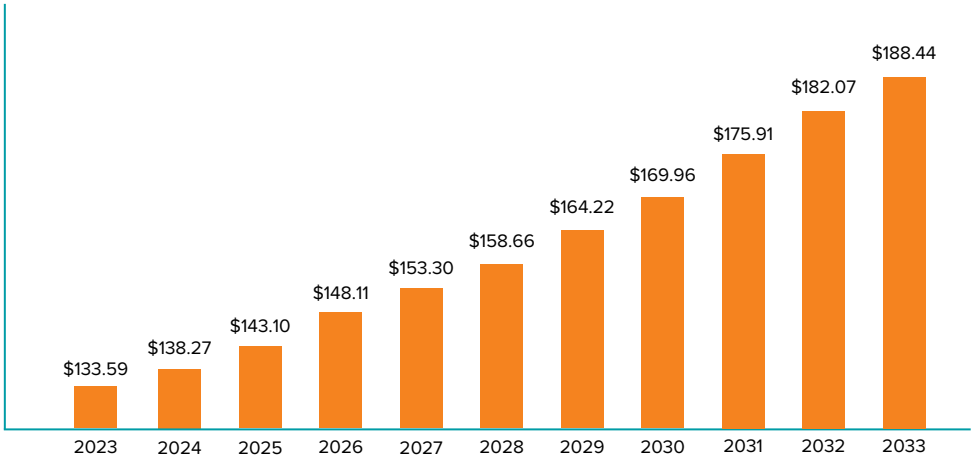
Clawbacks: Some PBMs engage in clawback practices, charging patients a co-pay that exceeds the actual cost of the drug, pocketing the difference. This not only increases out-of-pocket costs for patients but also contributes to higher overall drug spending.[36]

Vertical Integration: Many PBMs are now part of larger healthcare conglomerates that include insurers and pharmacies. This consolidation gives them significant market power, allowing them to influence prices across the supply chain, often leading to higher costs.[33]

Generic Drugs

The generic drug market is rapidly transforming, driven by the urgent need for more affordable treatments. While streamlined approval processes have made it easier for new generics to enter the market, companies still face tough regulations and tight competition. The competitive landscape is instrumental for expanding medication access and slashing costs, making treatments more affordable for millions. Today, generics fill around 91% of prescriptions and, with over 32,000 FDA-approved options, they are crucial in boosting healthcare access and stabilizing supply.[37]

U.S. Generic Drugs Market Size 2023 to 2033 (USD Billion)[38]



The global generic drugs market size was estimated at USD 465.19 billion in 2023 and is projected to hit around USD 779.68 billion by 2033, growing at a compound annual growth rate (CAGR) of 5.3% during the forecast period from 2024 to 2033.[38]

2024 Election

The outcome of the 2024 US election will likely have a significant impact on the healthcare landscape. Health care policy is a substantial issue discussed in politics, and the executive branch plays a role in the affordability and accessibility of healthcare. For example, the rollout of the Affordable Care Act (also known as Obamacare) decreased the number of uninsured Americans over ten years.[39] A major component of the Democratic platform involves lowering the cost of pharmaceuticals, reducing healthcare costs, and improving healthcare quality.[40] This may involve increased government regulation of healthcare and increased negotiation power for government programs.[41] Republicans' main platform regarding healthcare involves protecting Medicare, especially for senior citizens.[42] Depending on the election's outcome, market access for U.S. citizens could shift dramatically, with potential changes in drug pricing, insurance coverage, and regulatory landscapes. A Democratic victory might expand access through stricter price controls and broader insurance coverage, while a Republican win could prioritize preserving existing structures like Medicare, potentially limiting broader access but stabilizing costs for current beneficiaries.

Innovative Programs Improving Market Access

Cost Plus Drugs | Cuban's Prescription for Affordable Medicine

Mark Cuban's Cost Plus Drugs has disrupted the healthcare market by offering generic medications at a fraction of traditional prices, significantly improving access for patients. The platform's success lies in its transparent pricing model and direct-to-consumer approach, which bypasses middlemen like PBMs, resulting in reduced costs.[43] However, challenges remain in scaling the model to include a broader range of medications and navigating regulatory hurdles, underscoring the importance of continuous innovation and strategic partnerships.

MARK CUBAN CostPlus DRUG COMPANY

Prime Diagnostics | Amazon Dx Future for At-Home Health

Amazon Dx is revolutionizing healthcare market access with its on-demand diagnostic lab, initially offering COVID-19 tests for home use and planning to expand into sexually transmitted infections, fertility, and hormone testing.[44] By championing Amazon Web Services (AWS) for data analysis and cloud computing, the company is driving innovation through diagnostic testing and research, enhancing efficiency and accuracy. Amazon's exploration into next-gen digital therapeutics further disrupts traditional care models by providing software-driven solutions for disease management and prevention, highlighting the need for ongoing adaptation and technological integration in healthcare.

Market Access Strategies for Emerging Therapies

Access to Innovative Therapies and Orphan Drugs

Treatments for rare diseases and conditions are often “orphaned” or discontinued due to limited financial incentive.[45] The FDA incentivizes the development of treatments for rare diseases through the Orphan Drug Act.[45] The program provides tax credits, 7-year market exclusivity, and waived Prescription Drug User Fees to drug developers. [45]

While the Orphan Drug Act has encouraged the development of rare disease treatments, exorbitant costs associated with these orphan drugs have become a challenge for patients facing such rare and often life-threatening conditions.[46] Despite the invaluable benefits these medications offer to individuals with rare diseases, the financial burden placed on patients is staggering.[47] Orphan drugs often come with limited market competition, enabling pharmaceutical companies to set prices at unprecedented levels. Aside from treatment costs, absenteeism, and forced retirement are also key factors in rare disease’s financial burden.[47]

The excessive cost of orphan drugs and treatment underscores the need for a more sustainable approach to ensure that those in need of these specialized medications can access them without compromising their financial stability or sacrificing other essential aspects of their well-being.[47] Securing adequate payor coverage for orphan drugs and rare disease treatment is often a barrier to accessible care. The prohibitive costs associated with the development and production of these specialized medications place a strain on healthcare payors, as well.[48] Additionally, the scarcity of treatment options for rare diseases can leave patients with few alternatives, intensifying the need for coverage.[49-50] The intricate nature of the diseases themselves complicates drug efficacy data and further influences payor decisions. Balancing the need for affordability and accessibility with the economic realities of developing orphan drugs presents a dilemma that requires collaborative efforts among pharmaceutical companies, healthcare providers, and payors.

Patient-Centric Approaches

Engaging patients in their medical care and creating personalized interventions are critical to effective patient-centered care. These approaches improve health outcomes and increase patient satisfaction.[51] Patient-centered care prioritizes patient goals, values, and communication. Transparency between physicians and patients allows patients to make informed decisions about their medical treatment and often improves adherence.[52] Pharmaceutical companies have a strong interest in emphasizing patient-centricity in research and development processes to ensure relevance in the evolving market.[53] One aspect of patient-centered care in research is properly representing targeted populations within clinical trials.[54] Additionally, patient support services are becoming increasingly in demand as a method of engaging patients, especially those with rare diseases.[54]

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Case Studies of Effective Access Strategies

The FDA has utilized patient input as a method of assessing new drugs or medical devices. For example, the FDA's Center for Devices and Radiological Health (CDRH) utilized a benefit-risk preference survey to determine how much risk patients would be willing to undergo to lose weight.[55] In June 2018, patients shared their experiences and feedback at a CDRH listening session, and this insight was used to shape future directions of weight loss devices.[56] In 2023, the FDA released draft guidance as frameworks for the development of medical devices.[56] Methods such as listening sessions and surveys showcase the benefit of patient-centric care within market access. By actively involving patients, the FDA ensures that the perspectives and real-world experiences of those who will ultimately use these treatments are factored into regulatory decisions.

Future Trends in Market Access and Emerging Trends

Digital Health

Digital therapeutics (DTx) are transforming healthcare by leveraging technology to enhance the delivery of medical services, improve patient outcomes, and streamline the healthcare experience.[57] It encompasses a wide range of innovations, including telemedicine, wearable devices, mobile health apps, and artificial intelligence-based diagnostics.[57] These technologies empower patients to take a more active role in managing their health, enable real-time monitoring of chronic conditions, and facilitate remote consultations with healthcare providers.[57] As digital health continues to evolve, it holds the potential to make healthcare more accessible, personalized, and efficient, ultimately leading to better health outcomes and reduced costs. Within digital health, digital therapeutics are software meant to treat health conditions.[58] The potential uses for DTx span a wide range of health conditions, including mental illnesses, chronic diseases, and pain disorders.[59-60] These conditions can be treated by DTx through mobile apps, artificial intelligence (AI), wearables, and sensors.[58] The continuous symptom monitoring offered by DTx can produce valuable insights for patients and providers, as real-time data analytics of patient symptoms can lead to improved treatment plans. Additionally, patients can utilize DTx to remotely communicate with provider teams and receive updated advice.

As digital health continues to evolve, it holds the potential to make healthcare more accessible, personalized, and efficient, ultimately leading to better health outcomes and reduced costs.

Cross-Border Collaborations

Cross-border collaborations are vital to sharing knowledge, resources, and expertise across countries. This allows countries to streamline processes and brainstorm solutions to common challenges. Many countries find that drug pricing negotiations are smoother when acting as a joint force.[61] Cross-border collaborations also allow pharmaceutical companies to navigate different and complex market access landscapes.[61] Global health initiatives serve as valuable tools to address health concerns that impact the global population.[62]

Artificial Intelligence & Machine Learning

AI is revolutionizing patient care, bringing unprecedented precision and personalization to treatments.[63] With AI-driven insights, healthcare companies can now build compelling cases for reimbursement and highlight the cost-effectiveness of groundbreaking therapies.

Explore the ways AI is revolutionizing the industry:

- **Medical Imaging:** AI is being increasingly used in the medical field as a method of analyzing medical imaging. AI has the ability to supplement the analysis of computed tomography (CT), magnetic resonance imaging (MRI)< and positron emission tomography (PET).[64] AI algorithms can analyze medical images with remarkable accuracy, assisting radiologists in detecting anomalies such as tumors or fractures more quickly and accurately.

- **Natural Language Processing (NLP):** AI-powered NLP tools can sift through unstructured data in EHRs to extract valuable clinical information, aiding in clinical decision-making. NLP offers significant benefits in market access by streamlining data analysis, improving regulatory compliance, and enhancing stakeholder communication.[65] NLP can efficiently process vast amounts of unstructured data, such as clinical trial reports, patient feedback, and healthcare regulations, which can provide actionable insights for market access strategies.[65] It also aids in monitoring and interpreting evolving regulatory requirements, ensuring timely compliance.[65] NLP facilitates clearer communication with healthcare providers, payers, and patients, helping companies tailor their messaging and align products with market needs more effectively.[65]

- **Personalized Medicine:** AI can analyze large data sets quickly, allowing medical professionals to gather relevant information about patients efficiently.[66] AI can also analyze genetic information to predict how individual patients will respond to different treatments, enabling truly personalized care plans. Utilizing AI in this manner can also prevent mistakes during data assessments caused by human error, such as fatigue.[66]

Real World Data Analytics

Real-world data (RWD) refers to data collected at the patient-level through real-world applications.[67] This includes data collected from electronic medical records (EMR), wearable devices, or disease registries.[68] Collecting health data outside of a controlled clinical trial environment can provide valuable insights into the true impact of a disease or intervention on patients. This allows for a comprehensive understanding of a disease or comorbidities which can inform potential treatment options. RWD also allows for increased diversity within research. Understanding demographic differences in clinical trial participants is vital for gathering accurate data and bridging gaps in medicine. The demographics of the targeted treatment population should be reflected in the research population, but this is often not the case.

Health Equity

According to the World Health Organization (WHO), “health equity is achieved when everyone can attain their full potential for health and well-being".[69] Reaching health equity requires addressing health disparities. Health disparities are preventable differences in health experienced by diverse populations.[70] These health disparities stem from inequitable distribution of resources stemming from individual and community Social Determinants of Health (SDoH).[70] Pressing health disparities include:[71-72]

Black women are 3x more likely to die from pregnancy-related issues than White women[73]

Almost half of LGBTQ+ students have considered attempting suicide[71]

Black and American Indian and Alaska Natives infants were at least 2x as likely to die as White infants[72]

Key factors in reducing health disparities include improving access to safety net programs, health coverage, and other necessary public health resources.

Patient Support Programs

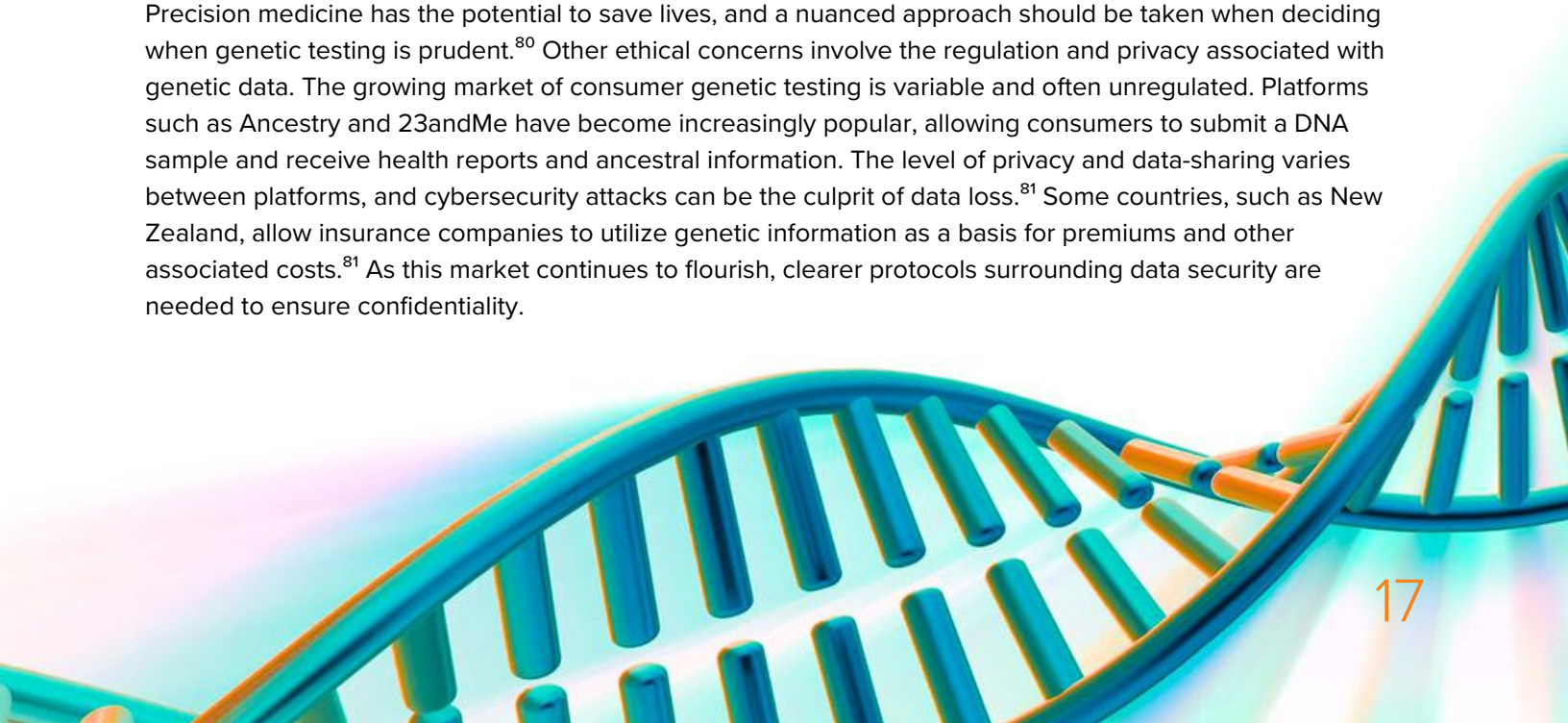
Patient support programs are initiatives, often led by pharmaceutical companies, meant to improve access and adherence to a prescription drug regimen.[74] Types of patient support programs include patient assistance programs and patient education programs. Patient assistance programs are used to help patients navigate complex insurance problems and understand their coverage options.[74] Some patient assistance programs offer logistical support such as transportation to clinics.[74] Financial patient support programs have certain eligibility requirements that can provide patients with free or low-cost prescriptions.[74] Education programs provide patients with educational resources for their condition or treatment regimen. This is especially helpful for complex treatment plans. Each of these programs can benefit patient access and adherence which can improve health outcomes.

Precision Medicine & Genomics

Precision medicine is an emerging field that utilizes patient gene profiles to predict risk, inform diagnosis, and determine the most effective treatment.[75] By sequencing a patient's genome, clinicians can learn more about their susceptibility for certain diseases as well as their probable response to different types of drugs, a concept known as pharmacogenetics.[76] Genetic profiling can be performed using blood, tissue, or saliva.[77] The BRCA 1 and BRCA 2 gene are valuable examples of the importance of genetic screening. The presence of these genes can inform women of their breast cancer risk and provide insight into the best course of action.[78]

A significant barrier in market access for precision medicine is the lack of diversity in genomic research. In more than 6,000 studies evaluating population genomes, 90% of all people analyzed were of European descent.[78] The limited diversity in these studies can lead to less effective genomic tests for people of color.[78] Other ethical concerns exist within genomics, specifically regarding widespread genetic testing of newborns. Some experts worry about the implications of the public having access to genetic testing reports.[79] The presence of certain genes does not guarantee the individual will develop a disease, nor are there treatment options for all diseases tested.[81] The presence of certain genes could potentially lead to depression or anxiety in individuals, even if they do not end up developing the associated condition.[80]

Precision medicine has the potential to save lives, and a nuanced approach should be taken when deciding when genetic testing is prudent.[80] Other ethical concerns involve the regulation and privacy associated with genetic data. The growing market of consumer genetic testing is variable and often unregulated. Platforms such as Ancestry and 23andMe have become increasingly popular, allowing consumers to submit a DNA sample and receive health reports and ancestral information. The level of privacy and data-sharing varies between platforms, and cybersecurity attacks can be the culprit of data loss.[81] Some countries, such as New Zealand, allow insurance companies to utilize genetic information as a basis for premiums and other associated costs.[81] As this market continues to flourish, clearer protocols surrounding data security are needed to ensure confidentiality.



About PFG MedComm

A Strategic Market Access Agency

PFG MedComm is a woman and minority owned strategic communications agency - we specialize in achieving health access goals through medical and value communications strategy. Having transformed the traditional agency model, our approach takes a holistic 360° view that considers the research and clinical development continuum.

We are experts in developing end-to-end communication strategies and tactics for all healthcare stakeholders, from clinical to the general public. We are specialists in the areas of clinical and medical information, population health, health economics, patient outcomes, social determinants of health, racial and other health disparities, and more.

As a full-service strategic market access agency, we focus on leveraging value communication to achieve market access priorities.

60+	33+	50+	20+	10+
BRANDS	US & GLOBAL LAUNCHES	INDICATIONS	THERAPEUTIC CATEGORIES	YEARS IN BUSINESS

Certifications

Professional Organizations

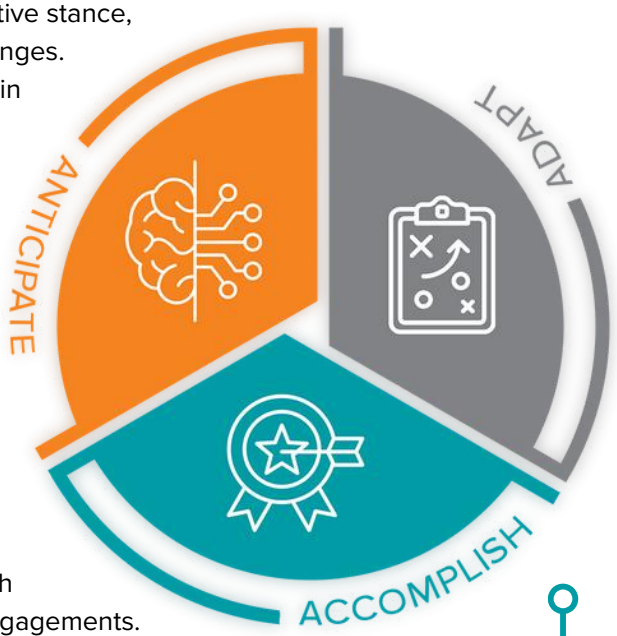
Awards

Our 360° Approach to Access®

Tranforming the Traditional

We have reimagined the traditional approach by applying a market access lens across the entire product development lifecycle - from clinical to commercialization, launch through post-launch. Our unique approach to access fits into any phase of development, while navigating the medical, legal and regulatory requirements at each.

In an ever-changing market access landscape, we take a proactive stance, anticipating future opportunities and identifying potential challenges. Our distinctive process integrates the market access lens early in development and extends throughout the launch strategy, utilizing landscape analyses and strategic scenario planning to craft a dynamic market access plan.



We specialize in adapting market access plans, tailoring stakeholder-specific messaging to enhance the value proposition based on access opportunities and challenges. Our customized tactical plans, combined with strategic workshops, simplify the value story, creating compelling customer selling propositions.

As a comprehensive agency, we go beyond creating tools and tactics. We equip field teams with adapted tactical plans through a series of strategic workshops, ensuring effective customer engagements. Our proprietary training methodology goes a step further, simulating real-world customer interactions and empowering teams to communicate unique value stories.

This complete view ensures comprehensive, tailored strategies across market access stakeholders.

Our 360° Approach to Access® involves anticipating challenges, adapting strategic plans, and accomplishing access through wraparound engagement.

Contact PFG MedComm to learn more: hello@pfgmed.com

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