WHAT DO VALUE & ACCESS REALLY MEAN?

A LANDSCAPE REPORT ON STAKEHOLDER PERSPECTIVES
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The National Forum’s Value & Access Initiative is made possible through support from Amgen (Founding Sponsor), Regeneron, and members of the Value & Access Steering Committee.

The opinions stated in this report do not necessarily reflect official opinions or policies of the organizations represented by the Value & Access Initiative sponsors or Steering Committee.

This report summarizes the perspectives expressed by stakeholders during interviews. The National Forum selected the organizations and individuals for interviews based on their participation in the Value & Access Steering Committee or their recognized expertise and knowledge. Their insights and views are important contributions. Because interviewees were not randomly selected and the sample size was small, the views presented in this report cannot be considered as representative of every organization or individual within each stakeholder group or of the National Forum.
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EXECUTIVE SUMMARY

What constitutes value and how easily people should be able to access healthcare are hot issues amid ever-rising healthcare costs and countervailing forces aimed at cost-containment. The COVID-19 pandemic has drawn added attention to these issues and made solving them more urgent. Differences in how stakeholders think about the issues are major obstacles to solving them.

The National Forum for Heart Disease & Stroke Prevention (National Forum) issued a report in 2016 that raised awareness about how the terms value and access mean different things to different stakeholders such as the “6 Ps”: patients, providers*, payers, purchasers, public health, and pharma/biotech. This 2020 edition of What Do Value and Access Really Mean? reveals how the 6 Ps’ perspectives on value and access have evolved and what the terms mean in 2020.

Also, in 2016, the National Forum launched the Value & Access Steering Committee comprised of decision-makers representing the 6 Ps. Its purpose is to jointly identify and advance strategies to improve people’s access to evidence-based care while ensuring future innovation. The Steering Committee used the 2016 report to educate stakeholder groups, change the environment surrounding healthcare value and access issues, and form collaborations across the sectors.

STAKEHOLDERS DEFINITIONS OF VALUE CONTINUE TO DIFFER

This 2020 update, based on interviews and a literature review, reveals how perspectives of value and access have evolved and what the terms mean to the 6 Ps today.

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<tr>
<th>Stakeholder Interviewee Perceptions of Value</th>
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<td><strong>Pharma/Biotech</strong></td>
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<td><strong>Public Health</strong></td>
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*The use of the term “providers,” throughout this paper and initiative, is defined as all licensed healthcare professionals involved in patient care, including clinicians, physicians, nurses, pharmacists, psychologists, social workers, hospital administrators, and others.*
EXECUTIVE SUMMARY

AREAS OF STAKEHOLDER CONVERGENCE

All stakeholders are concerned about the rising cost of healthcare. Patients are caught in the middle of efforts to contain costs, and they are paying a larger portion out-of-pocket. Patients, providers, payers, purchasers, pharma/biotech, and public health share a goal: improve access to high-value treatments for patients who need them.

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<td><strong>Public Health</strong></td>
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STAKEHOLDER VIEWS AND ROLES HAVE EVOLVED

Patients and providers now pay more attention to costs than in 2016. Patients are better organized and more engaged in value and access issues. The pharmaceutical and biotech industries (manufacturers) focus more of their attention on the patient experience than before.
IMPORTANT CHARACTERISTICS OF THE HEALTHCARE LANDSCAPE OVER THE LAST THREE YEARS

Payers, purchasers, and manufacturers are focused on moving from fee-for-service to value-based reimbursement systems, but the amount of focus on value-based care and reimbursement systems varies across stakeholders.

- Value assessment frameworks continue to be refined, though not without challenges.
- While price cuts and coverage changes improved access to cholesterol-lowering PCSK9 inhibitors, the challenges of access to affordable medications remain.
- The number of uninsured individuals increased starting in 2017, after six years of declines. A Commonwealth Fund study found that “Of the 194 million U.S. adults ages 19 to 64 in 2018, an estimated 87 million, or 45 percent, were inadequately insured.”
- Cardiovascular disease remains the leading cause of death in the United States.

IMPORTANT CHALLENGES AND CONSIDERATIONS FOR IMPROVING VALUE AND ACCESS

Stakeholders expect prices will continue to increase. Prescription drugs account for 10-15% of healthcare spending. Larger costs include hospital care (33%) and physician and clinical services (20%).

- Stakeholders expect the healthcare system will remain complicated. Patients and providers need to be empowered to navigate the system and make it work better for patients.
- While getting all the stakeholders engaged and at the table simultaneously is not easy, and there are different definitions of value. Success requires identifying a common framework for assessing value.
- Value and access are not just national issues; state differences in healthcare coverage and provider scope of practice must be addressed.

OPPORTUNITIES FOR THE NATIONAL FORUM VALUE & ACCESS INITIATIVE GOING FORWARD

- The Value & Access Steering Committee provides a unique forum for addressing key topics such as payment mechanisms, formulary decision-making, patient/provider shared decision-making, value metrics, non-pharmaceutical healthcare costs, and drug rebates.
- Through the Value & Access Initiative, the National Forum can more fully engage an expanded group of diverse stakeholders to reach solutions with a focus on addressing patient needs and interests.
- To advance solutions to value and access issues, the National Forum can coordinate with additional aligned coalitions and organizations, such as the Smarter Health Care Coalition.
- The Value & Access Initiative can broaden acceptance and support for value-based care and reimbursement systems that align different stakeholders’ interests, thus increasing support for these systems.
The following updates summarize the perspectives expressed by stakeholders during interviews. The National Forum selected the organizations and individuals for interviews based on their participation in the Value & Access Steering Committee or their recognized expertise and knowledge. Their insights and views are important contributions. Because interviewees were not randomly selected and the sample size was small, the views presented in this report cannot be considered as representative of every organization or individual within each stakeholder group or of the National Forum.
PATIENTS

- **Individually who use healthcare products and services for personal health, well-being, and quality of life**

Patients’ perspectives of value and access tend to focus on:

- Their ability to get the treatments and medications their providers prescribed
- Barriers that prevent their access and ability to afford what is prescribed

Patient access has been impacted by the utilization management practices of payers and pharmacy benefit managers (PBMs), such as formulary designations, step therapy, prior approvals, and denials. Additionally, patients are experiencing higher out-of-pocket costs because of increased co-pays and deductibles. Out-of-pocket costs can also limit access (see Figures 1-4). Overall, the landscape for patients has improved in terms of coverage, largely because of the Affordable Care Act (ACA). However, disparities still exist based on geographical location and other socioeconomic factors, and are worsening as the rates of uninsured and under-insured are increasing. Thus, having insurance does not guarantee access to care and treatment.

VALUE

Patients focus on how treatments and medications affect their quality of life and on the required costs (monetary and non-monetary) of the treatment. Additionally, while patients may have their own perceptions of value, their decisions about treatments or medications may also be affected by their providers’ sense of value.

While the definition of value has not changed, how value is assessed, and what is attributed to value has shifted. Quality of life for patients is not limited to their medical condition; it includes additional factors that matter to them, such as their ability to enjoy time with family members and provide for their needs. One of the concerns expressed by patient stakeholders is that value assessment frameworks and cost-effectiveness analyses do not account for these non-monetary, non-medical metrics of quality of life. Therapies that effectively treat their condition and improve their quality of life have value for patients, but they will weigh that against the costs when deciding whether to adhere to a prescription.

ACCESS

To patients, access means the availability of prescribed treatments and medications, which includes insurance coverage and affordability. Insurance, through formularies and cost-sharing, may determine what choices are available to patients. Additionally, access is impacted by having the right provider and influenced by non-medical factors, such as location, time of services, transportation, income, education, and availability of childcare and other caregiving services. Patient stakeholders indicated that not all patients are benefitting from scientific advances and an increase in the number of treatment options. The ACA has improved coverage, especially for preventive care, but having insurance does not always mean having access. Healthcare still costs too much for many patients and utilization management strategies present additional barriers.
AVERAGE OUT-OF-POCKET SPENDING FOR PEOPLE WITH LARGE EMPLOYER COVERAGE

- Deductible
- Copay
- Coinsurance

Figure 1. Source: KFF analysis of IBM MarketScan Commercial Claims and Encounters Database

THREE IN TEN SAY THEY HAVEN’T TAKEN THEIR MEDICINE AS PERSCRIBED DUE TO COSTS

Percent who say they have done the following in the past 12 months instead of getting a prescription filled because of the cost:

- Not filled a prescription for a medicine: 19%
- Taken over-the-counter drug instead: 18%
- Cut pills in half or skipped doses: 12%
- Percent who did not take prescription medicine as directed because of the cost: 29%

Figure 5. Source: Kaiser Family Foundation Health Tracking Poll, February 2019
“Has there been a time in the last 12 months when you or a member of your household had a health problem but you did not seek treatment due to the cost of care?”

**“YES”**

<table>
<thead>
<tr>
<th>Annual Household Income</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>&lt;$90,000</td>
<td>26%</td>
<td>74%</td>
</tr>
<tr>
<td>$90,000-$120,000</td>
<td>19%</td>
<td>81%</td>
</tr>
<tr>
<td>$120,000-$180,000</td>
<td>19%</td>
<td>81%</td>
</tr>
<tr>
<td>$180,000+</td>
<td>13%</td>
<td>87%</td>
</tr>
</tbody>
</table>

“Has there been a time in the last 12 months when your household has been unable to pay for medicine or drugs that a doctor had prescribed for you because you didn’t have enough money to pay for them?”

**“YES”**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Failed to inform their doctor</td>
<td>26%</td>
<td>74%</td>
</tr>
<tr>
<td>Reported that their condition was “very serious”</td>
<td>19%</td>
<td>81%</td>
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</table>

Figure 3. Source: The U.S. Healthcare Cost Crisis

Figure 4. Source: The U.S. Healthcare Cost Crisis
PROVIDERS

- Healthcare professionals and organizations that provide medical care and treatment to patients, including physicians, nurses, pharmacists, and hospitals

The topics of discussion included:

- Team-based care and communication between providers
- Access to cholesterol lowering therapies (PCSK9 inhibitors)
- Formulary design
- Patient-provider relationships
- How to streamline prior authorization and avoid denials for PCSK9 inhibitors
- Health care affordability
- Social determinants of health
- Improving health equity

For providers, access issues include a combination of patient access to the right clinician and therapy. Access to PCSK9 inhibitors was a challenge over the last three years. It highlighted how manufacturer pricing and payer utilization management strategies affect access to effective treatments. The primary challenges that providers face are related to the additional time and resources needed to process paperwork for prescription coverage approvals and respond to denials. Providers want to empower patients to advocate for themselves in the process.

While providers feel they still have the same access challenges, the approval rate for PCSK9 inhibitor prescriptions is improving. Access might be improving because the price of PCSK9s dropped, yet that has not eliminated the challenges. Providers are concerned that the access difficulties they experienced with PCSK9 inhibitors may be repeated as new therapies come to market. They acknowledge these challenges and are looking for ways to address them. Their sense is that payers are now open to discussions with more transparency than in 2016.

VALUE

The components of value for providers are clinical outcomes, patient goals and experience, and costs and risks.

The ongoing challenge is determining what makes up those components. Another challenge is realizing value through changes in practice. Providers who want to implement team-based care might be limited by a system that does not support that approach. The system might also impose a definition of value that impacts whether they can prescribe a medication because of utilization management limitations or because a patient cannot afford it.

ACCESS

From the provider perspective, access includes patient access to the right clinician and the ability to obtain the right treatment and medications as prescribed. Access barriers can change provider behavior by influencing their decisions on which therapy to prescribe. Utilization management and repeated denials can lead to “prescription fatigue” when providers, weary from the process, stop prescribing medications that patients may value.

Hospitals have been looking at ways to improve access through such initiatives as home care, telehealth, and community-based services. Access has improved, but there is still work to be done. Denials of PCSK9 inhibitors decreased after awareness and education efforts by providers and patient advocacy groups and the manufacturers’ price cuts. However, many patients still cannot access needed medications due to out-of-pocket costs.
Figure 5. Physicians report spending more time on prior authorizations and responding to denials, sometimes leading to “prescription fatigue.”
Source: Medscape Physician Compensation Report 2019™
UPDATES TO STAKEHOLDER PERSPECTIVES

Payers & Purchasers

- Payers are private and public (Medicare and Medicaid) health insurance providers and benefit management organizations.
- Purchasers are employers, unions, and governments that insure patient populations directly (self-insurance) or through health insurance providers.

The topics of discussion around value and access included:
- Define value and access
- Avoid excessive care
- Provide the same or better outcomes for less cost
- Move from fee-for-service to value-based approaches

Payers want patients to receive the right treatments and medications at the right time in the most effective and efficient way. Payers and purchasers are concerned when plans pay for low-value drugs without restrictions, yet some high-value drugs are not covered as effectively as they could be. An additional concern for purchasers is that value assessment frameworks do not look at some of the broad impacts that drugs have on areas of interest to employers, such as return to work and medication adherence.

The challenges for payers and purchasers include the following:
- Determining which services really provide value based on the evidence and ensuring all patients have appropriate access to those high-value services.
- Getting the information needed to make decisions on whether certain services can be provided.
- Making care affordable and continuing to provide coverage for employees as costs go up.
- Addressing over-utilization incentivized by a fee-for-service system and rebates for lower-value drugs.
- Limiting access to therapies is a primary means for payers to lower their costs. They hope the pharmaceutical industry will respond by lowering prices.

Payers and purchasers perceive that the challenges have not changed much over the past three years. They existed before, but now they are more visible, and there is more interest in addressing them. However, because of the polarized political environment, Congress has been unable to pass reforms for health plan design and using value-based measurements. One opportunity for addressing these challenges is to increase the involvement of purchasers in formulary decisions made by payers and Pharmacy Benefit Managers (PBMs).

Value

Value for payers and purchasers is a combination of quality, results, experience, and cost. Value is realized when they can spend less and obtain the same or, ideally, better patient outcomes and quality of life. A challenge for commercial payers and purchasers is determining the monetary value of prevention efforts for heart disease risk factors. It is difficult for purchasers to know what the actual costs of medications are because rebates are not transparent (see Figure 6).

Access

Payers are focused on patient access to coverage, providers, and services. One way of providing access is by providing on-site clinics at workplaces. Payers also see access as including the opportunity to get information, feedback, and questions answered. This might include the use of team-based care and telemedicine. Concerning medications, the goal is to do a more effective job of getting the right drugs to the right patients.
Figure 6. Prescription drugs pass through distributors and pharmacies between manufacturers and consumers. Related dollars pass through many more hands, in multiple directions, making it difficult for purchasers, patients, providers, and public health to determine real costs and who benefits and in what amounts from the current drug rebate system.

Source: American Patients First, U.S. Department of Health and Human Services, 2018
PHARMA/BIOTECH

- Research, develop, manufacture, and market medicines for various populations

Conversations of value and access include:

- Ensuring that there is a comprehensive definition of value that includes what is valuable to the patient as an integral component of care.
- Ensuring that value is accurately measured and assessed and includes the value that patients experience over time from biopharmaceuticals.
- Navigating the reimbursement environment.
- Looking for innovative payment and delivery models that can incentivize high-value care and access.
- Ensuring that payments and delivery models recognize patient differences so that patients can access the medicines they value.
- Addressing the rising financial burden that is being placed on patients and the healthcare system to ensure that patients have meaningful access to appropriate medications. This includes promoting positive formulary and benefit designs.

The challenges for manufacturers include benefit designs that limit patients’ ability to access treatments and that do not recognize patient heterogeneity. Recently, manufacturers have been tasked with fitting new innovative therapies into existing reimbursement systems, which is a slow process. They are also challenged by how PBMs define value to determine coverage limits for drugs. With the movement toward using value assessment frameworks, manufacturers are concerned that the limitations of those tools will result in more restrictions on access. While these challenges probably have not changed over the last three years, addressing them has become more urgent.

VALUE

Pharmaceutical and biotechnology companies consider what is valuable to patients. Incentives play an important role so they can market their medications and develop additional drugs, including those for specific conditions. They are producing products that have value to patients and society, but in order to do that well, they need good measures of what that value is. A tool that can help manufacturers and payers is value-based agreements, which help to get valuable treatments to patients.

ACCESS

For manufacturers, access involves working with payers (especially Medicare) to ensure that high-value medications get to patients. That means that a patient can obtain and use a drug to improve their health without an onerous financial burden. The Affordable Care Act and changes in CMS, along with value-based care and value-based insurance design, have made medications more accessible. However, while the healthcare system seems to work for most people, manufacturers recognize there is a population with expensive conditions and high out-of-pocket costs who have limited access to medications. The issue of access then puts pressure on manufacturers to demonstrate the value of their products so that patients can get meaningful access.

VALUE-BASED AGREEMENT

A written contractual agreement in which the payment terms for medication(s) or other healthcare technologies are tied to agreed upon circumstances, patient outcomes, or measures.
UPDATES TO STAKEHOLDER PERSPECTIVES

PUBLIC HEALTH

- Federal and state governments that create legislation and provide services that impact patients, providers, manufacturers, employers, etc.
- Organizations that advocate for protecting and improving the health of communities and populations.

The conversations for public health have been focused on:

- The population-level impact of affordability on medication adherence
- Prioritizing high-value therapies and interventions for the country as a whole
- Access to opportunities to be healthy at the individual and community levels (e.g., access to quality food, places for physical activity, etc.)
- Policies and interventions, such as those that affect access to Medicaid and the services it covers

A concern for public health is that the rising out-of-pocket costs of cardiovascular care will have a negative effect on cardiovascular risk factors in the population, such as diabetes and high cholesterol. Addressing this and the social determinants of health that impact cardiovascular health are major challenges. Another concern is that medication adherence declines when out-of-pocket costs put drugs out-of-reach, and socioeconomic factors present barriers to access. Educating patients and the public to empower them to address these challenges needs to improve.

The Affordable Care Act has opened access to basic primary care to more people, which should help to improve risk factors. Additional policy wins have included the Medicare Advantage Value-Based Insurance Design Demonstration Project and allowing high-deductible health plans to remove financial barriers to evidence-based services. However, affordability of care, specifically out-of-pocket costs of pharmaceuticals, has not improved.

VALUE

For public health, value includes the benefits of prevention, as well as the benefits of therapy. The focus is on population interventions that have measurable benefits. The value of medications is enhanced when drugs are affordable (thus accessible) so that the effect on public health is a decrease in morbidity and mortality. However, focusing solely on costs can be problematic if the therapy or drug does not improve outcomes.

ACCESS

The public health perspective focuses on access to high quality, evidence-based health care, and prevention. Access overall has improved due to changes put in place by the Affordable Care Act that allowed Medicaid expansion in some states, though access to some evidence-based therapies may not have improved.

WHY ADHERENCE MATTERS

Medication nonadherence—not taking medications as prescribed or at all—contributes to approximately 125,000 premature deaths yearly.14
All stakeholders deem value and access issues as important and reported addressing them over the past three years.

Stakeholders noted that events of the last three years have highlighted the intersection of value and access. They also emphasized the need to educate patients and providers about medication costs and how the health care system works for pricing, coverage, approval, payment, and reimbursement. Doing so will empower patients and providers to navigate the current system better and advocate for changes that will improve value and access.

A fundamental goal across stakeholder groups is to improve access to high-value treatments for patients who need them. Manufacturers are now more aware of the need to demonstrate the value of their products in order to justify giving patients access to them.

Stakeholder definitions of value continue to differ, and how they assess value and what they attribute to value has shifted.

For example, as deductibles and co-pays have increased, providers and patients increasingly consider the out-of-pocket costs in their assessment of value and whether to prescribe a therapy or fill a prescription. Manufacturers’ emphasis is now less on cost savings and more on what is valuable to the patient.

The ways in which stakeholders respond to access challenges have evolved over the last three years.

Payers and purchasers are putting more emphasis on limiting access in order to control costs. In response, providers are paying more attention to barriers that can impede their patients from getting prescribed treatments. Those barriers sometimes lead to prescription fatigue. And manufacturers are focused even more than before on benefit design and coverage determinations that define value, which can determine access.

A concern for public health is that the rising out-of-pocket costs of cardiovascular care will have a negative effect on cardiovascular risk factors in the population.
THE EVOLUTION OF STAKEHOLDER PERSPECTIVES

CONTRASTS AND AGREEMENTS BETWEEN STAKEHOLDERS

The cost of healthcare is a universal concern.

Each stakeholder has unmet needs; and all stakeholders recognize those of patients. Some see patients caught in the middle between other stakeholders’ efforts to contain costs. All stakeholders are interested in maximizing the use of what they each consider high-value care to achieve optimal outcomes.

Differences in perspectives may not be as great as stakeholders perceive them to be. However, stakeholders believe the differences can be obstacles to progress, especially when value and access are defined differently. Following is a summary of the nuanced differences of each stakeholder’s perspective.

**PATIENTS**

Patients define the terms “value” and “access” from a personal perspective centered on how a treatment or medication will address their specific needs and improve their quality of life. While their focus is individual, patient interests are broader than their medical condition, extending to family, work, and overall well-being. Any therapy that improves their overall condition has value. Their access concerns are focused on affordability and availability. Affordability is determined by their out-of-pocket costs, and availability is determined by insurance and socioeconomic (life) factors. Thus, patients can still have difficulty accessing lower-priced drugs if their out-of-pocket costs remain unaffordable.

**PROVIDERS**

The provider perspective is centered on treating the patient. Thus, they view value in terms of what will result in better patient outcomes. Their focus on access is ensuring that patients get the treatments and medications determined to be effective. Patient out-of-pocket costs and limitations on access have increasingly become factors in treatment decisions.

**PAYERS & PURCHASERS**

Because the cost of treatments and medications directly impact payers and purchasers, they focus on those costs in determining value. Payers and purchasers view access as a means to maximize outcomes and as a primary mechanism to control costs. Smaller health plans may align with public health in viewing community health interventions as means to improve health and thus contain costs. Purchasers, primarily employers, are looking for a return on their investment via healthier employees who produce more and cost less to insure.

**PHARMA/BIO TECH**

Value for manufacturers is determined by what patients value and need, what effectively meets their needs, and what the market can afford. In contrast to payers and purchasers, manufacturers want to maximize access so that their products can reach the broadest spectrum of patients who need and value them.

**PUBLIC HEALTH**

For public health, value is determined by the impact on the population as a whole. Access is focused primarily on basic care and prevention at the community level. While payers and purchasers are concerned about costs today, public health recognizes the long-term value of prevention and the costs saved over longer periods of time.
PROGRESS MADE

The Value & Access Initiative brought together a diverse array of stakeholders and created an understanding that collaboration was necessary to improve value and access. The discussions facilitated by the initiative were effective at increasing understanding of the different perspectives and agendas held by different stakeholders, as well as at finding some common ground. As a result of these and other efforts over the past three years, stakeholders are more likely to recognize the need to collectively address value and access issues.

Another area of progress is that patients’ perspectives are being considered via efforts such as Value & Access Initiative, PCORI, and FDA’s patient-focused drug development. Patients are getting better organized and more engaged.

CHALLENGES – REMAINING AND EMERGING

The stakeholders interviewed recognized that the complicated U.S. healthcare system is an ongoing challenge. They expect prices will continue to increase. While much of the focus is on costs associated with pharmaceuticals, there continue to be challenges with other costs rising as fast or faster, such as for administration and hospital-based services (see Figure 7). Thus, the need still exists to reconcile the different stakeholder perspectives and frames of reference in order to determine value in a way that allows decision-making with a common framework.

Developing a common framework that bridges the different goals that stakeholders have for defining value will not be easy. Payers, purchasers, and patients are not always represented in efforts to do so, yet meaningful and effective progress cannot be made without them. Getting all the stakeholders at the table at the same time and engaged in developing solutions continues to be a challenge.

Additional ongoing challenges include addressing the state to state differences in coverage and empowering providers and patients to make the system work better.

DIFFERENT TYPES OF HEALTHCARE EXPENDITURES ARE EXPECTED TO OUTPACE THEIR RECENT GROWTH RATES

As a result of these and other efforts over the past three years, stakeholders are more likely to recognize the need to collectively address value and access issues.

While much of the focus is on costs associated with pharmaceuticals, there continue to be challenges with other costs rising as fast or faster.

Figure 7. Source: Peter G. Peterson Foundation

Figure 7. Source: Peter G. Peterson Foundation
THE FUTURE OF VALUE AND ACCESS

Stakeholders are cautiously optimistic about the future. They foresee patients becoming more sophisticated in making healthcare decisions. Strengthening shared-decision making is a Value & Access Initiative Steering Committee consensus strategy to improve patients’ access to the care they need. At the same time, stakeholders expect that prices will continue to rise, and the healthcare system will remain complex.

The Federal government is advancing value-based payment models for Medicaid and Medicare. While much of the future will depend on political and policy developments, some expect inertia at the Federal level and that more decisions will be made on state levels.

The hope is that value-based care will lower costs and improve access to high-value therapies. However, there is also a shared concern that if the current systems of payments and pricing do not change, then new therapies might present the same challenges as experienced with PCSK9 inhibitors.

The PSCK9 inhibitor experience highlighted the need for collaboration among stakeholders to address both value and access so that similar issues do not occur again with new drugs coming on the market. Specific opportunities to improve value and access mentioned by stakeholders include the following.

- Ensure that patient-centered outcomes are measured earlier in the process.
- Fully engage all stakeholder groups, especially patients. Misperceptions can create barriers, so it is important to understand different stakeholders’ perspectives.
- For new medications, start discussions before a drug is released, to ensure that pricing by manufacturers and coverage by payers is determined in ways that prevent repeating the PCSK9 inhibitor experience.
- Collaborate with openness and transparency regarding stakeholder perspectives and goals for addressing value and access.

The following are topics which might be addressed by the Value and Access Initiative in a collaborative effort based on stakeholder interviews:

- Shifting payment mechanisms toward value-based contracting
- Engaging employers in formulary decisions
- Strengthening patient involvement in shared decision-making
- Value metrics for decision-making
- Value and access of non-pharmaceutical drivers of healthcare costs (i.e., hospitals and specialty care)
- Drug rebates and their impact on value and access
- Determining effective coverage of high-value therapies
LITERATURE-BASED UPDATE TO THE LANDSCAPE OF VALUE AND ACCESS

A review of the literature identified the following key developments over the last three years in the value and access landscape.

VALUE: THE EVOLUTION OF VALUE-BASED CARE AND VALUE ASSESSMENTS

The definition of “value” continued to vary among stakeholders. Even when stakeholders agree on the components of value, they may disagree on the importance of each factor. For example, the Value in Health Care Survey found patients and providers agreed that the cost of care was important, but only 5% of providers ranked it as most important, while 26% of patients ranked it as most important.

To help determine value and inform healthcare decision making, stakeholders are using value assessment frameworks such as those developed by the Institute for Clinical and Economic Review (ICER) and Avalere and FasterCures (Patient-Perspective Value Framework). While useful, value assessment frameworks also present limitations, including:

- Lack of transparency that impedes replication and validation
- Outdated assessments that do not keep up with the dynamics of value
- Inability to assess all areas of healthcare
- Assessments that do not adequately incorporate the patient perspective

A transition from fee-for-service reimbursement to value-based reimbursement has been underway for ten years. A value-based system pays providers based on patient health outcomes rather than services provided. Despite the decade-long transition, 40% of respondents to a Health Care Executive Group survey believe that a market in which the majority of value-based relationships might include both upside and downside shared-risk remains three-to-five years away.

Many purchasers (employers) are interested in alternative payment and delivery models including accountable care organizations (ACOs) and high-performance networks (HPNs). Nearly a third (31%) plan to implement (directly or through their health plan) one or both strategies in 2020. That percentage could nearly double to 60% by 2022.

In 2018, for the first time, the American Heart Association/American College of Cardiology Guideline on the Management of Blood Cholesterol included a Value Statement. This underscores the need for clinicians and patients to factor in the cost of drugs in determining appropriate treatments.

ACCESS: CHANGES IN THE UNINSURED POPULATION

From 2010 to 2016, the population of uninsured nonelderly individuals in the United States declined from over 46 million to below 27 million. The numbers of uninsured then increased for two years in a row (See Figure 8). The numbers of underinsured also increased. Being uninsured or underinsured is a barrier to access.

Figure 8. Source: KFF Analysis of 2008-2018 American Community Survey, 1-Year Estimates
OUT-OF-POCKET COSTS ARE STILL A CONCERN

In 2015, the FDA approved the use of PCSK9 inhibitor drugs along with diet and statins as an innovative therapy for lowering low-density lipoprotein (LDL) cholesterol in high-risk cardiovascular patients. High initial list prices limited patients’ access to these medications. (For more information on how prices for cholesterol-lowering drugs have changed in recent years, see Figure 9.)

During the past three years, additional studies found that PCSK9 inhibitors can provide value for high-risk and very high-risk patients. In an effort to improve access, manufacturers decreased the list prices of PCSK9 inhibitors by 60%. However, access to these treatments remains a challenge. More than half of Medicare Part D patients without low-income subsidies will have to pay $100 per month or more out-of-pocket for PCSK9 inhibitors in 2020.

“People don’t care about the cost of healthcare. They care about how much healthcare costs them.”

- A. Mark Fendrick, MD, Director, University of Michigan Value-Based Insurance Design Center

New, potentially lower-priced treatments are on the horizon. However, drug costs remain a burden for patients, even among high-income households and individuals with insurance. Remedies such as the recently reintroduced Chronic Disease Management Act, allowing insurers to cover certain services for chronic conditions pre-deductible aim to reduce patient costs. As heart disease is the leading cause of death in the U.S., preventing, treating, and managing related risk factors will remain top issues for healthcare spending.
METHODS

STAKEHOLDER INTERVIEWS
Interviews were conducted in January 2020 with Value & Access Steering Committee members and other leaders from organizations representing the views of patients, providers, payers, purchasers, public health, and pharma/biotech. The purpose was to assess convergence in understanding terminology across stakeholder groups and changes in how people understand value and access.

The 20 interviewees included:
- 4 representatives of patients
- 6 representatives of providers
- 5 representatives of payers and purchasers
- 2 representatives of pharmaceutical and biotechnology
- 3 representatives of public health

Length of interviews: 30 – 60 minutes
The topical guide for interviews covered the following areas:
- Stakeholder conversations about value and access
- Defining value
- Defining access
- Stakeholder experiences with value and access
- Stakeholder challenges in addressing value and access
- Differences in stakeholder perspectives
- Changes in the landscape of value and access (past, present, and future)

Interviews were recorded and transcribed for analysis. The National Forum thanks the following organizations for their participation in the interviews.

- American College of Cardiology
- American Hospital Association
- American Pharmacists Association Foundation
- American Society for Preventive Cardiology
- Association of State and Territorial Health Officials
- BallengerRx Consulting
- Biotechnology Innovation Organization
- Cigna Healthcare
- FH Foundation
- Independent Health
- Mended Hearts
- National Alliance of Healthcare Purchaser Coalitions
- National Lipid Association
- National Pharmaceutical Council
- Partnership to Improve Patient Care
- Preventive Cardiovascular Nurses Association
- U.S. Food & Drug Administration
- University of Michigan Center for Value-Based Insurance Design
- WomenHeart

LITERATURE REVIEW
The literature review was conducted December 2019 – January 2020 to update the landscape of value and access in the healthcare marketplace since the release of the original report. Literature was identified that focused on cardiovascular disease using the following search strategy:
- Search period: 2017 – 2019
- Search terms: related to trends, access, value, and major news events in healthcare
- Search engines:
  - Peer-reviewed literature: Pubmed, Web of Science, Google Scholar
  - Grey Literature: Google, Google Trends
- Updates to reports cited in the original 2016 report
The National Forum for Heart Disease & Stroke Prevention (National Forum) established the Value & Access Initiative to bring together decision-makers from various stakeholder groups in discussions and solution-oriented collaboration on value and access issues related to cardiovascular health. These decision-makers formed the Value & Access Steering Committee and represent patients, providers, payers, purchasers, public health and pharma/biotech (manufacturers). The goal of the initiative is to:

Enhance health and well-being by supporting people’s access to evidence-based care that is appropriate for them by:

- Identifying evidence-based strategies for determining appropriateness of care, and
- Supporting the implementation of evidence-based care that aligns incentives for patients, providers, payers, and other stakeholders.

The Value & Access Steering Committee identified four primary areas for improvement:

1. Increasing Communication to Enhance Effectiveness & Support of Existing Leverage Points
2. Understanding Best Practices on Payer/Purchaser Coverage Decisions
3. Patient Engagement Strategies:
   a. Increase Adherence
4. Framework to Shift Spending from Low- to High-Value Care

**ACHIEVEMENTS OVER THE PAST THREE YEARS**

- Built trust and fostered environment-changing dialogue among diverse stakeholders.
- Influenced pricing on innovative therapies.
- Developed tools which Mayo Clinic testing found increased patient engagement and strengthened shared decision-making.
- United multiple stakeholder sectors to provide unique, collective input to the Institute for Clinical and Economic Review (ICER).
- Increased exchange of programming, events, tools, and resources among stakeholders.
- Expanded and strengthened stakeholder engagement with value framework assessment developers.
VALUE & ACCESS INITIATIVE STEERING COMMITTEE MEMBERS 2020

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ENDNOTES


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