WHAT DO VALUE & ACCESS REALLY MEAN

Differing stakeholder views lead to confusion in today’s environment
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Background on the National Forum Value & Access Initiative

Goal
To support the 84 million Americans who live with cardiovascular disease\(^1\) by identifying ways to improve their access to prevention and treatment.

Specifically:

- Understand the history of, impact of and meaning of value and access to various stakeholder groups.
- Convene diverse stakeholders to better understand challenges and existing best practices.
- Develop collaborative solutions that can reduce the burden of cardiovascular disease by improving patient access to appropriate treatment.

\(^1\)http://www.hopkinsmedicine.org/healthlibrary/conditions/cardiovascular_diseases/cardiovascular_disease_statistics_85.P00243/
### About This Report

This research product is designed to fill an information gap by providing a comprehensive overview of value and access and the meaning of these concepts to all relevant stakeholder groups – patients, providers, payers, manufacturers, and public health.

<table>
<thead>
<tr>
<th>The information presented here:</th>
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<tbody>
<tr>
<td>- Chronicles how the concepts of value and access have evolved over time to reflect changes in the healthcare system and therapy innovation</td>
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<tr>
<td>- Defines the relevant stakeholder groups</td>
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<td>- Reports perspectives and considerations that stakeholder groups are expressing around the concepts of value and access</td>
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Methodology

- Primary and Secondary Research Included:
  
  - Informal telephone discussions were conducted with leaders of key stakeholder organizations Aug. 8-Sept. 25 to develop a more nuanced understanding of how value and access are perceived among this audience.

  - A team of MS/PhD public health researchers identified, collected and synthesized information related to value and access (peer-reviewed & gray literature).
INTRODUCTION
Why are value & access important in CVD treatment, prevention?

• The U.S. healthcare landscape raises issues about the value of and access to medical therapies:
  – Aging population is shifting cost burden from private to public payers.¹
  – Pricing of new drugs encourages payers to limit patient access.²
  – Definitions of value vary among stakeholders.

• These issues concern all stakeholders, as CVD remains the No. 1 killer of Americans³ and drives substantial costs and other burdens on US society.⁴

• The National Forum believes this creates important needs and opportunities to:
  – Better define value to fit the needs of all stakeholders.
  – Elevate understanding of the drug innovation pipeline and distribution chain, how they affect value and access, and vice versa.

² Edlin BR. Access to treatment for hepatitis C virus infection: time to put patients first. The Lancet Infectious Diseases. 2016; 16(9):e196 - e201.2
The cost burden of cardiovascular disease

<table>
<thead>
<tr>
<th>The most recent US-based estimate of CVD costs is staggering.(^1)</th>
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<tr>
<td>• The 2010 <strong>direct-cost</strong> burden from CVD was <strong>$273 billion</strong> and is projected to rise to <strong>$818 billion</strong> by 2030.</td>
</tr>
<tr>
<td>• 2010 <strong>indirect costs</strong> related to lost productivity/work/etc. were <strong>$172 billion</strong> and are projected to <strong>more than double to $276 billion</strong> by 2030.</td>
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<table>
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<tr>
<th>This creates growing economic challenges.(^2)</th>
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<tr>
<td>• 17% of private-payer medical costs and 30% of public-payer costs are due to 4 CVD conditions (coronary heart disease, stroke, hypertension, heart failure) and other cardiovascular diseases.</td>
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<tr>
<td>• The CVD category has a high payer impact; e.g., hypertension medications are the single-greatest prescription burden for all payers.</td>
</tr>
<tr>
<td>• The increasing aging population will soon qualify for Medicare/Medicaid, moving more cost burden to the broader society via government and taxpayers.</td>
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HISTORICAL OVERVIEW
Understanding the historical context for CVD value & access

Several historical events are pivotal to understanding today’s CVD therapy landscape:

- **1973**: Nixon signs Health Maintenance Organization Act to manage exponential rise in healthcare costs.
- **1983**: Medicare begins to move away from fee-for-service to prospective payment system based on diagnosis.
- **1996**: First of numerous biologic agents approved, setting the stage for discussions of cost-effectiveness and access to new therapies.
- **2010**: ACA is enacted to address overall issues of health insurance access, but underinsurance challenges persist.
- **2014**: Hepatitis C therapies that offer a cure raise issues around value and access, sparking conversations among multiple stakeholders about how to define these constructs.
- **2014**: In the face of growing costs, ICER and other private organizations begin devising value scales to help stakeholders make decisions that affect access.
- **2015**: The PCSK9s and Entresto (sacubitril/valsartan) bring the issue of medication cost to the cardiovascular field.

The topics of value and access and their effects on how healthcare is delivered and received have evolved as the US healthcare system has changed.
Historical evolution of value and access

- **Early 1900s**
  - Patients paid doctors directly
  - AMA is created as a lobby to help physicians maintain control of practice

- **1930**
  - Social Security Act

- **1950**
  - Medicare signed into law. Medicaid coverage made available, and new health insurance companies boom

- **1970**
  - Health Maintenance Organization Act
  - Medicare moves away from fee-for-services

- **1990**
  - Resource-Based Relative Value Scale created

- **2000**
  - Push for universal health coverage

- **2010**
  - Both new HHS value-based programs (ACOs, IQR, etc.) and value frameworks (ICER, NCCN) emerge
  - Patient Protection and Affordable Care Act signed into law

**Access**
- Significant increase in access to medications, treatments and procedures
- Decrease in insurance access
- Decrease in healthcare access
- Increase in access to insurance

**Key healthcare-related events**
- Early 1900s: Patients paid doctors directly
- 1930: Social Security Act
- 1950: Medicare signed into law. Medicaid coverage made available, and new health insurance companies boom
- 1970: Health Maintenance Organization Act, Medicare moves away from fee-for-services
- 1990: Resource-Based Relative Value Scale created
- 2000: Push for universal health coverage
- 2010: Both new HHS value-based programs (ACOs, IQR, etc.) and value frameworks (ICER, NCCN) emerge

**Costs**
- Cost of medical care increases
- Employers begin offering health insurance to offset pay cuts
- Health Maintenance Organization Act
- Resource-Based Relative Value Scale created
- Possible stabilization of medical care costs

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Early 1900s: A diffuse system

Understanding how the healthcare system has evolved over the decades may provide insight into current issues.

- Mid-1800s-early 1900s
  - As health insurance begins to be offered by some employers, the American Medical Association is formed by a group of physicians in attempt to protect their freedom to practice medicine as they felt was necessary for optimal patient outcomes.¹

- 1920s²
  - Most people do not have health insurance and billing patients directly is still standard practice. However, the cost of medical care starts to increase at a rate that is not affordable to the American middle class. As the Great Depression approaches, the cost of care remains an important political concern.

1930s-40s: Building blocks of current system

- **1930s**
  - Social Security Act is passed; it does not include healthcare.\(^1\)
  - AMA exerts its influence to limit legislation on health insurance programs, in fear that medical care will become politicized and limit physician freedom.\(^2\)

- **1940s**
  - WWII - With federal wage controls in place, some employers offer health insurance to supplement pay. This marks the start of the system offered by employers today.\(^3\)
  - Truman proposes a nationalized healthcare system, which is defeated partially by AMA lobbying efforts that labeled it “socialized medicine.”\(^2\)

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1950s: Therapies become more widely available

- 1950s
  - New, significant advances in making medications and medical treatments/procedures more widely available.
  - Although vaccinations & antibiotics had been discovered decades (or more) prior, companies are able to make them widely available.
  - With therapies/procedures being more available, hospital costs double compared to previous decades.
  - Efforts to move to nationalized healthcare are “compromised” with tax incentives for employers that provide healthcare coverage.

1960s: The access boom

- **1960s**
  - Medicare is signed into law.
  - Medicaid coverage is made available to poor and disabled.
  - The number of new health insurance companies increases dramatically.
  - The payer system motivates physicians to move from generalists to specialists.
  - Patients go to the doctor in droves; access to medical care is virtually unlimited.
  - The nation's health-care bill increases from $39 billion in 1965 to $75 billion in 1971.
  - Being a physician is an elite, high-paying job, and physicians have unquestioned control.\(^2\)\(^3\)
  - Without a plan to control healthcare costs, government programs such as Medicare and Medicaid become unsustainable.

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1970s: Beginning to manage rising costs

- **1970s**
  - Nixon signs the Health Maintenance Organization Act to manage exponential rise in healthcare costs.¹-²,
    - Provides grants for HMOs to develop to control medical inflation.
    - HMOs offer “prepaid programs” that ideally, will be equally available to all Americans.
  - HMOs dramatically change how patients access care, moving from unlimited care to treatment restrictions and drug formularies.
  - Medicare and Medicaid can now capitate how much they pay per person, regardless of whether that money is used.³

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1980s-90s: Changes in health care management & payment

• 1980s1-3
  – Medicare begins to shift from fee-for-service (rewarding volume) to prospective payment system (PPS) based on diagnosis (capping Medicare payments to hospitals and rewarding value).
  – Approximately 87% of the US population now has health insurance.

• 1990s2,3
  – Access to care policies begins to shift as PCPs become gate-kn eepers to specialists and therapies, leading to decreased access for patients and decreased costs for payers.
  – 1992 - Resource-Based Relative Value Scale is created by AMA and used to determine physician reimbursement by specialty; used by Medicare and HMOs.

2000s-10s: Affordable care

• 2000s\(^1-3\)
  – Push for universal health coverage and passage of ACA opens conversation about balancing between unlimited access and providing the best value.
  – ACA is enacted in 2010 to address overall issues of health insurance access, but *under*insurance challenges persist.

• 2010s
  – High-cost therapies, such as hepatitis C cures, trigger new access and value concerns.
  – In face of growing costs, ICER and other private organizations begin devising value scales to inform stakeholders’ access decisions.\(^4\)

CURRENT STAKEHOLDER PERSPECTIVES
Perspectives on value and access vary widely

Our culture values innovation for life-saving therapies and seeks widespread patient access.\textsuperscript{1-3} But determining the true value of an innovation is difficult, because stakeholder definitions of “value” vary widely:

- **Patients** assign value to therapies based on their personal experience, and “value” may include intangibles such as enhanced quality of life.

- **Manufacturers** define value as improved patient outcomes, but also want incentives built into their product costs to acknowledge current/support future innovation.

- **Providers and payers** (private and government) are concerned that the cost of incentivizing innovation has turned into manufacturers’ pursuit of higher profits.

In response to this division, institutes such as ICER have sought to define value in terms that take into consideration both manufacturer profits and patient/payer cost-sharing.

### Defining value by stakeholder

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Definition of value</th>
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<tbody>
<tr>
<td>Economic Viewpoint</td>
<td>“The aggregate impact on society as a whole.”</td>
</tr>
<tr>
<td>Patient</td>
<td>&quot;...Obtain optimal health in order to meet personal goals. Yet it was also mentioned that patients do not necessarily believe they need more care to achieve better health provided that transparency of information, evidence, and treatment options exists.&quot;</td>
</tr>
<tr>
<td>Employer</td>
<td>“Not only maintaining healthy and productive workers and families at the lowest cost possible, but also focusing on enhancing community health.”</td>
</tr>
<tr>
<td>Provider</td>
<td>“Evidence-based, effective diagnostic interventions and treatments that are delivered efficiently. They also considered value in terms of focusing principally on appropriateness of care discussions that fully engage providers and consumers together, rather than conversations about controlling costs.&quot;</td>
</tr>
<tr>
<td>Payer</td>
<td>“Evidence-based medical interventions that are highly effective and around structuring incentives to encourage the use of these interventions.&quot;</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>“...Maintaining incentives for product innovation while simultaneously considering the impact of their products on individual patients’ health in terms of costs and benefits over time.”</td>
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Defining Value and Access

PATIENT PERSPECTIVE
General patient/consumer perspective

Who are patients?
Individuals who are sick and/or who must make use of healthcare products or services.

How do they think about value?
Value centers on satisfaction with their provider, desirable outcomes regardless of the economic cost of the therapy (since much of the cost is covered by insurance), and perceptions of best treatment.

How do they think about access?
Patients consider structural barriers to access to therapy, e.g., high co-payments, premiums and deductibles, pre-authorizations, and formularies; as well as personal choice, e.g., between receiving treatment and paying bills. They recognize such choices can have serious implications, such as suboptimal outcomes or medical bankruptcy.

Citations available on following slides
Overall patient perspective on value\textsuperscript{1-3}

The patient perspective on healthcare value seems to be a relatively recent consideration. Changes in the healthcare model, such as the advent of health insurance in the early 20\textsuperscript{th} century, CMS quality measures and recent events such as the implementation of the Affordable Care Act have contributed to the current patient definition of value.

Patients largely define value in terms of intangibles (such as personalized care), rather than tangibles (such as monetary cost). As a result, when asked about value, patients generally cite their patient-provider relationship, as well as treatments that are brand-name (vs. generics) and the best available for their condition, without direct regard to cost.

Patient value considerations: Provider relationships

Patients say good value care occurs when:¹⁻²

- They have easy access to their doctor with short appointment wait times, as well as fast access over the phone.
- Their providers take the time to listen, are supportive, are partners in decision making and appear knowledgeable.
- Their providers have a good personality.
- Their provider is competent at advocating for them, selecting the correct diagnostic tests and treatments and following up with them.
- Their providers ensure there is continuity of care by sharing their medical records with other providers and specialists, and following up on that care.
- The office has a nice aesthetic and support staff are friendly.

Patient value considerations: Impact of therapy

While patients largely define value in terms of the patient-provider relationship, those who do think about costs or value of specific therapies and procedures may consider factors such as:

- **Quality of life**: How much will my quality of life deteriorate during and after a treatment or procedure?
- **Length of life**: How much longer will I live with the treatment?
- **Financial toxicity**: Will the financial burden of the treatment cause me so much stress that it ultimately undermines the treatment?
- **Impact on loved ones**: Will the treatment cause undue burden to my caregivers (by requiring physical and/or financial support)?

Factors Affecting Patient Access

- Patient access to medication and care can be limited by high copays, insurance premiums, and deductibles.
- Access considerations also include procedural obstacles, such as pre-authorizations, off-label approvals and formulary placement.

Patient access to care (therapies & providers) can impact both clinical and non-clinical outcomes such as, quality of life, duration of life, satisfaction & adherence.

Accessing care can also have consequences on patients from a financial perspective, and may send some patients into medical bankruptcy.

Timeliness and affordability of care impact patient value (defined by health outcomes, patient-provider relationships as compared to cost.)

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Patient access: Barriers to therapies

Barriers to patient access to therapies can vary by payer type (Medicare, Medicaid, commercial), but largely focuses on affordability of co-pays. Many non-financial barriers are barriers from both the patient and provider perspective, such as pre-authorizations and off-label use.

Top 6 barriers to medication access:
1) Affording the co-payment
2) Getting payer pre-authorization
3) Not approved for off-label use
4) Patient underinsured
5) Drug not on formulary
6) Medicare part D coverage issues

Patients generally accept the idea of cost-saving therapies such as generics in the abstract, but prefer name-brand therapies when it comes to their own use.¹

Patient access: Financial burden

From the patient perspective, high co-pays and insurance deductibles not only represent barriers to access, but also can have drastic effects on patients’ financial burden. To access appropriate care, some patients are forced to take on debt. The degree of this financial burden can vary by payer type, but has become a significant concern for many patients, as illustrated by the growing incidence of medical bankruptcy.

Patient value and access perspectives: A look ahead

Rising drug co-pays, premiums and deductibles can be expected to reduce access.

- “Between 2014 and 2015, consumers saw a 13 percent increase in their average deductible and out-of-pocket maximum costs.”

Growing concern around patient cost sharing has given rise to concepts such as financial toxicity and medical bankruptcy, especially in cancer care.

- Financial toxicity leads to lower QOL and poorer outcomes – components of the patient definition of value.
- 77% of patients owe more than $500 in medical bills even while access to credit drops.

Cost will likely continue to be a driving factor for patients who “want to talk about cost, but don’t want their physicians making treatment decisions based on cost.”

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Defining Value and Access

PROVIDER PERSPECTIVE
General provider perspective

Who are providers?
Providers are defined as those who provide medical care to patients, including mainly physicians, but also nurses, psychologists and other medical professionals that receive payment for services provided.

How do providers think about value?
Defining value generally involves considering primary vs. secondary prevention, innovative/novel therapies vs. inexpensive generics, as well as the patient-physician relationship.

How do providers think about access?
Providers are most concerned with the ability to decide which medical tests and treatments a patient should receive to optimize outcomes. They would also like to monitor patients’ illnesses and risk factors based on evidence that suggests that more frequent follow-ups are best for patient outcomes.

References:
Providers value flexibility in prescribing treatments

With primary prevention, providers prefer to individually select medications for risk-factor management (high bp, high lipids etc.), even though systematic reviews do not strongly favor one medication over another.¹

Some providers believe it may be better to use cheaper or generic statins, anti-hypertensives and blood thinners for optimizing value in primary prevention, while allowing providers to tailor secondary prevention by considering more novel approaches to care.²

For high-risk patients (such as those with diagnosed ASCVD or FH), it is recognized that preventive efforts should be more intensive.³

Provider value and access perspectives: A look ahead

Providers may be torn between favoring patient or payer needs.

Personalized medicine is driving a push for individualized care\(^1\) yet ACOs and other pay-for-performance reimbursement methods are pushing clinical pathways-based care.\(^1\)

Consideration is given to the concept of net benefit, which is based on the potential for disease reduction and adverse effects.\(^2\)

As the healthcare landscape continues to evolve, with cost shifting and higher costs of care, providers will need to be able to improve patient-provider communication about financial toxicity and treatment affordability\(^3\) to help better educate their patients regarding treatment decisions.


\(^3\)
Defining Value and Access

PAYER PERSPECTIVE
### General payer perspective

<table>
<thead>
<tr>
<th>Who are payers?</th>
<th>Private and public (Medicare and Medicaid) health insurance providers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do payers think about value?</td>
<td>Value is tied to performance, where providers help patients achieve desirable health outcomes with cost-effective use of resources. Some payers will consider paying for non-medical services, such as acceptable housing and transportation, as part of reimbursable needs. But defining “desirable outcomes” has been a big challenge across stakeholder groups.</td>
</tr>
<tr>
<td>How do payers think about access?</td>
<td>Access is affected by patients’ out-of-pocket costs, and payers’ net costs. Payers largely control which services, treatments and procedures a patient receives, but there is inconsistency among plans in how this is determined.</td>
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Payer value perspectives

Payers are largely moving away from the fee-for-service model to alternative reimbursement approaches that stress fee-for-value. There are many different payment models, including fee-for-performance, where new, innovative but costly treatments are reimbursed if the treatment works.

Other models, such as the Medicare model of Accountable Care Organizations, put the risk of providing highly effective, high-value care on the provider by offering the provider a percentage of the savings relative to historical costs of treating certain conditions or populations.

With subsidies expanded through ACA, the government is picking up a greater healthcare burden, resulting in many valuation decisions being made by legislatures. In addition, Medicare is being administered by private companies in many states. As a result, government officials and administrators are becoming more and more responsible for formulary decisions.

## Multiple payer models exist

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Fee-for-Service</strong></td>
<td>The most traditional model; requires patients or payers to reimburse the healthcare provider for each service performed. Results in no incentive to provide preventive care strategies, prevent hospitalization or take other cost-saving measures.</td>
</tr>
<tr>
<td><strong>Pay-for-Coordination</strong></td>
<td>Goes beyond fee-for-service by coordinating care among the primary-care provider and specialists. Coordinating care among multiple providers can help patients and their families manage to a unified care plan and can help reduce redundancy in expensive tests and procedures.</td>
</tr>
<tr>
<td><strong>Pay-for-Performance</strong></td>
<td>Also known as value-based reimbursement. Providers are only compensated if they meet certain metrics for quality and efficiency, which ties physician reimbursement directly to the quality of care they provide.</td>
</tr>
<tr>
<td><strong>Bundled Payment or Episode-of-Care Payment</strong></td>
<td>Reimburses providers for specific episodes of care, such as an inpatient hospital stay. This payment model encourages efficiency and quality of care because there is only a set amount of money to pay for the entire episode of care.</td>
</tr>
<tr>
<td><strong>Upside Shared Savings Programs (CMS or Commercial)</strong></td>
<td>Provide incentives for providers with respect to specific patient populations. A percentage of any net savings realized is given to the provider. Upside-only shared savings is most common with Medicare Shared Savings Program (MSSP) Accountable Care Organizations, but all MSSP participants must move to a downside model after three years.</td>
</tr>
<tr>
<td><strong>Downside Shared Savings Programs (CMS or Commercial)</strong></td>
<td>Include the gain-share potential of an upside model, but also the downside risk of sharing the excess costs of healthcare delivery between provider and payer. Because providers are taking on greater risk with this model, the upside opportunity potential is larger, in most cases, than in an all-upside program.</td>
</tr>
<tr>
<td><strong>Partial or Full Capitation</strong></td>
<td>Patients are assigned a per-member per-month (PMPM) payment based on their age, race, sex, lifestyle, medical history and benefit design. Payment rates are tied to expected usage regardless of whether the patient visits more or less. Like bundled payment models, healthcare providers have an incentive to help patients avoid high-cost procedures and tests to maximize their compensation. Only certain types or categories of services are paid on a basis of capitation.</td>
</tr>
<tr>
<td><strong>Global Budget</strong></td>
<td>A fixed total dollar amount paid annually for all care delivered. Participating providers can determine how dollars are spent. Global budgets limit the level and the rate of increase of healthcare costs, and typically include a quality component.</td>
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A newer concept: Value-based insurance design

Value-Based Insurance Design (V-BID) is built on the principle of lowering or removing financial barriers to essential, high-value clinical services.¹

A central tenet of V-BID plans is the concept of “clinical nuance,” which recognizes that:

- Medical services differ in the amount of health produced.
- The clinical benefit of a medical service depends on who is using it, who is delivering the service and where it is being delivered.

Clinically nuanced insurance designs seek to shape incentives to minimize the impact of⁶:

- Moral hazard: Individuals over-consuming when they are not responsible for the cost of their behavior.
- Behavioral hazard: Sub-optimal choices made by individuals based on their own behavioral biases.

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⁴Choudhry NK, Fischer MA, Smith BF, Brill G, Girdish C, Matlin OS, Brennan TA, Avorn J, Shrank WH. Five features of value-based insurance design plans were associated with higher rates of medication adherence. Health affairs. 2014 Feb 12:10-377.
⁵Maciejewski ML, Wansink D, Lindquist JH, Parker JC, Farley JF. Value-based insurance design program in North Carolina increased medication adherence but was not cost neutral. Health Affairs. 2014 Feb 13;33(2):300-8.
CMS has influenced the private sector

CMS has made multiple changes to reimbursement rates and structure, delineated in this table.

Because of its sheer number of beneficiaries, CMS effectively forces these changes onto providers and other payers.

### Shifting Paradigms in the Medicare Framework

<table>
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<tr>
<th>Area</th>
<th>Past</th>
<th>Future</th>
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<td>Insurance Market Opportunities</td>
<td>Administrative Services</td>
<td>At Risk</td>
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<td>Medicare Supplementary Policies</td>
<td>Health Plans</td>
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<td>Insurance Technology/Infrastructure</td>
<td>Fee-for-Service, Cost</td>
<td>Premiums</td>
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<td>Reimbursement</td>
<td>Outcomes and Satisfaction</td>
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<td>Provider Credentialing</td>
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<td>Provider Culture and Expectations of Insurance</td>
<td>Cut Unreimbursed Costs</td>
<td>Shift Costs</td>
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<td>Pay Costs</td>
<td>Competitive Bids</td>
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<td>Procedure Code Culture</td>
<td>Provider at Risk</td>
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<td>Too Many Services</td>
<td>Too Few Services</td>
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<td>Advocate of Patient</td>
<td>Partner of Plan</td>
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<td>Buyer Culture and Expectations of Insurance</td>
<td>Choice of Providers</td>
<td>Choice of Plans</td>
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<td>Standard Benefits and Premiums</td>
<td>Varying Benefits and Premiums</td>
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<td></td>
<td>Beneficiaries</td>
<td>Subsidized Buyers</td>
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<td></td>
<td>Entitled to Coverage</td>
<td>Choice</td>
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How CMS is being influenced

- The anti-discrimination language in the original 1965 Medicare legislation makes it impossible to tailor Medicare benefits for specific patient populations in the way that personalized medicine and “clinically nuanced” benefit design advocate.

- A goal of groups working with V-BID is to create a clinically nuanced benefit design that will encourage Medicare beneficiaries to increasingly use services that improve patient-centered outcomes, and this goal has progressed:
  - In June 2016, the U.S. House of Representatives passed a bill to allow more precise, clinically nuanced benefit design in the Medicare Advantage Program.¹
  - CMS will begin testing a Value-Based Insurance Design demonstration program in 2017 to assess whether clinically nuanced insurance design improves care while containing costs.

How do payers balance personalized care with population health?

• “For population-based care, you can really implement value-based insurance design because the treatments are not expensive and you can remove some of those barriers without hurting anyone’s bottom line.”¹

Provider performance data that payers share with patients may have the effect of limiting access to various treatment options.

• Major payers provide “value” scores for providers directly to the patients (so they can see how cost-effective they are), which may impact the provider/patient relationship.

Payers’ willingness to pay for treatment is linked to evidence from actual practice.

Payer considerations – Use of technology

Many new payer requirements force providers to become more IT-savvy, so that they can capture billing, track their own progress and participate in population health discussions, but also to participate in CMS incentive programs, which give providers financial rewards for meeting/exceeding value goals.

As private payers move to consider value-based fees and contracts, they have begun to partner with IT companies who sell analytics software that assesses treatment patterns of providers and hospital systems. This means these entities are now stakeholders, as well.¹⁻³

Payer value and access perspectives: A look ahead

CMS is experimenting with new methods for increasing patient-centered, value-based care by moving the burden from itself to the provider.¹

- Continue to offer incentive programs.
- Reimburse for nontraditional care that ultimately reduces illness.

Payers may continue to push for legislation that establishes limits to manufacturer profitability.²

Many private payers are also beginning to experiment with alternative reimbursement plans even while others continue with fee-for-service – but effects from these decisions have yet to be seen.

Defining Value and Access

MANUFACTURER PERSPECTIVE
General manufacturer perspective

Who are manufacturers?

Manufacturers are engaged in researching, developing, manufacturing and marketing therapies for use in medicine.

How do they think about value?

They define value as the total cost savings an innovative drug can provide relative to the “costly complications of chronic disease.” Therapy valuation is determined by more than the direct cost of prevention or treatment; it also is driven by the total savings from avoided care such as visits to the ER, hospital admissions and stays, major medical complications and surgeries and caregiving burden. These savings are projected outward for several generations.¹

How do they think about access?

Access to therapies means that patients can receive cutting-edge treatments when their providers recommend them. With most patients covered by health insurance, manufacturers are increasingly lobbying for newer drugs to be available on formularies and reimbursed by payers.

Drug development costs and value

The cost to develop a new drug is about $2.6 billion; manufacturers believe this should factor into a therapy’s “value.”

- Out-of-pocket costs average $1.4 billion
- Time costs (expected returns that investors forego while a drug is in development) average $1.2 billion

Factors included in this estimate are:
- Increasing trial complexity
- Requirements on trial size
- Costs for contracting medical experts
- Increased use of technology in studies
- Costs associated with targeting chronic vs infectious disease
- Requirements for additional studies
- Higher failure rates for drugs tested in human subjects

From 1983-94, the adjusted cost of drug development increased by 145%, potentially limiting who has the financial capacity to innovate.

Cancer Moonshot, an effort led by former Vice President Joe Biden to find a cure for cancer, has direct implications on researchers and drug developers. The program aims to:

- Streamline the drug development process by reducing “paperwork pushing” — IRB approval, contract negotiations, study start-ups, etc. This applies to all drugs, not just cancer drugs.
- Ensure transparent data are available to all researchers immediately after they’re collected.
- Require interdisciplinary partnerships (no more working in silos). Suggests that this work should be more philanthropic than profit-driven and considers discussing how to handle “too high” profits.

As with the real moonshot, this is an opportunity to create goodwill and collaboration that captures public imagination and literally changes the future, i.e. an opportunity for manufacturers to be “good guys.”

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In discussions about value, both the price and cost of drugs and/or services may be considered. However, price and cost are often not the same thing.

Once a drug is launched, costs at multiple levels can affect what a patient pays for a specific prescription drug.

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Expenditures on prescription drugs are rising

• Spending on prescription drugs is projected to continue to rise faster than overall health spending; it’s currently 16.7% of overall personal healthcare services
  – That’s about $457 billion in 2015
  – $328 billion [71.9 percent] for retail drugs and $128 billion [28.1 percent] for non-retail drugs
• Factors driving the rise in prescription drug spending from 2010 to 2014 can be roughly categorized as:
  – Population growth: 10%
  – Increase in prescriptions per person: 30%
  – Economy-wide inflation: 30%
  – Increase in higher-priced drug prescriptions/overall drug price increases beyond general inflation: 30%

Controversies exist in defining manufacturer role in overall healthcare system

- As concern over rising healthcare costs mounts, new questions are being asked of manufacturers and other healthcare stakeholders that generate high profits, including:\(^1,^2\)
  - What constitutes fair profit?
  - How do profits and formulary placement drive innovation decisions?
  - How should we think about ultimate cost?
  - How should we think about transparency?

- These questions are still evolving, are often controversial and may have implications for how we think about the role of - and focus of - innovation going forward.


Manufacturer considerations: Determining cost

Manufacturers want to consider prevention for determining drug “value” and ultimate cost

- Manufacturers advocate considering more than the short-term benefit of the drug, but also how much future spending is saved in preventive effect.
- In CVD, this leads to the following considerations: whether the drug improves survivorship from a heart attack and whether using it prevents future episodes. This “cost savings” should then be incorporated into the calculation of acceptable cost for the drug.
- Measuring prevention remains difficult and therefore controversial.

Government is demanding increased manufacturer transparency to justify cost of drugs

- Vermont’s governor signed a bill in 2016 to force manufacturers to defend the cost of medications.
- Former Vice President Biden has demanded investigation into why some drug costs increase exponentially from one year to the next.
- As a result of rising drug costs, there is activity in the political arena as well as among PBMs to limit the increase in drug costs, either annually or by contract term.


Successful drugs may produce hundreds of billions of dollars in profit. After recouping the cost of development and making a “fair” profit, the industry is being blamed for price gouging.¹

Politicians and others are asking, “Who defines “fair”?”

There is political debate over whether government should curtail costs.

Companies making the largest profits often do not develop their own drugs.

International companies can sidestep US patent laws, produce low-cost drugs without shouldering development costs.²

Manufacturers do not get paid average wholesale price (AWP) because of the numerous system costs.³

Some have expressed concern that innovation may move to focus only on where Medicare is willing to pay more for a drug.

In contrast to the CVD category, Medicare payments for cancer drugs are more extensive because brand names typically go on the formulary automatically.

Many private payers follow Medicare’s lead.

Manufacturers are developing new and expensive therapies for rare diseases, rather than innovating to provide new treatments for more common disorders that have plentiful available treatments, including CVD.

Defining Value and Access

PUBLIC HEALTH PERSPECTIVE
Public Health perspective

Who is public health?
Groups such as public health organizations, advocacy groups and medical societies, who provide an impartial perspective on protecting and improving the health of communities and families.

How do they think about value?
Public health organizations include both economic and social impact in their definition of value. Public health often looks at value as the health outcome achieved per dollar spent, for example, using QALY (quality-adjusted-life-year) data. Organizations have calculated economic benefit using aggregate QALY data (per population for each QALY gained vs. per person) and do show cost effectiveness and even savings using the QALY measure. This valuation is mirrored in the approach of independent medical economic outcome groups and societies to define value by incorporating qualitative measures of value, such as increased quality of life and decreased side-effect burden.

How do they think about access?
Access to care starts with primary and secondary prevention, which includes lifestyle as well as medication considerations. Therefore, access to prevention measures to address risk factors may drive part of the definition of value.
Private organizations are moving to define value and access to medicine, to increase impartiality in drug valuation and to help address the fact that no definitive value model exists.

Several prominent value models are being developed by independent research or public health organizations:

- Some use quantitative measurements only, while others incorporate qualitative measurements
- QALY is a major component in many of these models
- Some models are specific to therapeutic areas, e.g. cancer, CVD
- The intended audience or users of the models vary, e.g. payer, patients, providers

Four organizations producing the models are:

- American Heart Association (ACC/AHA)
- Institute of Medicine (IOM)
- Institute for Clinical and Economic Review (ICER)
- National Comprehensive Care Network (NCCN)

# Drug value frameworks

<table>
<thead>
<tr>
<th>Organization</th>
<th>Attributes</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Heart Association</td>
<td>Clinical benefit vs risks, cost effectiveness</td>
<td>AHA focuses primarily on the value of specific interventions vs. their risk and costs: “Given accelerating healthcare costs and the desire to achieve the best value, the time has come to include cost-effectiveness/value assessments and recommendations in practice guidelines and performance measures.”¹</td>
</tr>
<tr>
<td><strong>Primary focus: Intervention effectiveness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institute of Medicine</td>
<td>Safety, effectiveness, patient-centeredness, timeliness, efficiency, equity</td>
<td>Value is not addressed in IOM’s search glossary. Instead, it jumps to “quality and safety:” “Patients must rely on healthcare professionals and institutions for their safety and well-being. The IOM focuses on patient safety in order to promote policies and best practices that create safe and high-quality healthcare environments.”²</td>
</tr>
<tr>
<td><strong>Primary focus: System performance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institute for Clinical &amp; Economic Review</td>
<td>Incremental cost, effectiveness + care, value components, budget impact</td>
<td>ICER attempts to balance costs and outcomes for drug therapies in the context of budget caps: the ICER methodology attempts to rationalize caps on global budgeting for healthcare at GDP+1% and uses a Quality Adjusted Life Year (QALY) to assess the value of interventions.³</td>
</tr>
<tr>
<td><strong>Primary focus: Therapeutic value</strong></td>
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<tr>
<td>National Comprehensive Care Network</td>
<td>Efficacy, safety, evidence quality, evidence consistency, affordability</td>
<td>The therapeutic value of interventions is the focus: each factor is scored 1 to 5 for a given intervention, but it is left to the organization to actualize impact.⁴</td>
</tr>
<tr>
<td><strong>Primary focus: Therapeutic value</strong></td>
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Quality-adjusted life years (QALYs)

### The conventional QALY

- From a scale of 0 (death) to 1 (optimal health), a score is designated to represent desired living state. The goal doesn’t have to be perfect health, but must reflect how much better someone would like to be relative to the treatment.
- Once weights are obtained for each living state, they are multiplied by the time spent in the state; these products are summed to obtain the QALYs.

### The conventional QALY is used by CDC, NIH & international equivalents. But QALYs have not been accepted for reimbursement in the US for a variety of reasons:\(^{1,2}\)

| QALYs can be used as part of healthcare decisions, but are neither the only nor major consideration when allowing therapy access. | ACA prohibits the use of QALYs in determining patient access to therapies. | A major argument against use of QALYs is that US health expenditures do not seem to correlate well with health outcomes. In other words, it’s possible to spend little and see significant results (e.g., use of generic statin drugs), while at other times, it can cost more than $1 million to provide life-saving therapies in cases such as micro-premature infants. | If the US used the UK standard cut point of $30k per QALY, it would take 45 years before QALY value is fulfilled. |

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QALYs allow measurement across disease (rather than # of strokes avoided or decreased perception of pain)

“Why QALYs
An Illustration Of QALYs Gained From An Intervention

EXHIBIT 1
An Illustration Of QALYs Gained From An Intervention

Health-related quality-of-life weights

1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0

Death
Year 1 Year 2 Year 3 Year 4 Year 5

A gain in QALYs resulting from an intervention can be derived from an improvement in a patient’s survival, an improvement in quality of life or both. As illustrated in Exhibit 1, without an intervention (represented by the gray areas), a patient can expect to obtain 1.8 QALYs (0.6 in year 1 + 0.5 in year 2 + 0.4 in year 3 + 0.3 in year 4). With the intervention (represented by the gray plus white areas), this patient can expect to gain 1.3 additional QALYs for a total of 3.1 QALYs, reflecting an increase in both survival and health-related quality of life. QALYs can also be used in cost-effectiveness analyses of interventions to inform resource allocation decisions. The cost-to-QALY ratio is compared across interventions to determine the most efficient ways to furnish health benefits.”

How QALYs are valued

Europe defines value of a QALY at no more than ~$30k-$50k

US is less defined

- Some diseases are so cost prohibitive, a QALY would have to be worth well over $100k to justify the cost of treatment (e.g., cancer).\textsuperscript{1,2}
- There is a distinction between the cost of rare/genetic diseases vs. common diseases.
- Some are reluctant to put a value on life after age 65 (should we be less willing to spend more money to treat older people? A year of life at 75 is less valuable than a year of life at 45).
- Ethical dilemmas exist in making these valuations.

Public health responses to controlling drug costs

Price drugs based on value to individual patients

Broaden the perspective on vital drugs: price drugs based on value to the population

Federal government to support payer coalition to obtain lower prices as part of public health campaign

Federal government to negotiate prices and purchase large quantities of drugs

Federal government to disregard patent and commission alternative entity to produce drugs

Options

Alternative

Public health value and access perspectives: A look ahead

*Considerations for how this perspective may evolve going forward*¹,²

1. Understanding value and access largely from patient perspective

2. More patients may begin to consider whether it is possible to define when it is worth it to treat a person so they can live an extra year (month, week, day?). They may look to get involved in questions such as, “What is the value of time regardless of age?”

3. Patient advocacy groups often see issues differently from groups like ICER.

Current value and access example: PCSK9 inhibitors

- In 2015, the FDA approved two agents in a new cholesterol-lowering drug class indicated for patients with familial hypercholesterolemia (FH) or clinical atherosclerotic cardiovascular disease (ASCVD).
  - These drugs reduce levels of LDL-C by 50% to 70% when added to statins.
  - Evidence suggests that the use of these agents may reduce the risk of CVD mortality by 50% and all-cause mortality by 55%.\(^1\)
- No efficacy data on cardiovascular outcomes or long-term safety data are currently available for these expensive agents;\(^2,3\) they are considered to have “largely unknown benefits and harms.”\(^4\)
- In light of this, the value provided by these agents and patients’ ability to access these agents has been controversial.

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\(^3\)The Medical Letter on Drugs and Therapeutics, August 17, 2015. 57;1475:113-5.
\(^4\)Gutierrez RR, Shah ND, Montori VM. Predicting the overuse of PCSK-9 inhibitors. JAMA, 2015 314:18;1909-10.
Current value and access example: PCSK9 inhibitors

• Some clinical and payer stakeholders believe that adoption of these agents may be premature.
  – This is particularly the case for patients who could benefit from appropriate use of statins.¹
  – PCSK9 use could substantially increase US healthcare costs when used for populations other than FH, such as ASCVD or those who are statin intolerant.²

• Others believe that:
  – Providing access to evidence-based pharmacotherapy could improve health outcomes and save money from a societal perspective over the long term.³
  – These agents can be used in a way that would enable plaque stabilization and not require expensive lifetime treatment.⁴

¹Gutierrez RR, Shah ND, Montori VM. Predicting the overuse of PCSK-9 inhibitors. JAMA. 2015 314:18;1909-10.
Current value and access example: PCSK9 inhibitors

The range of opinion regarding PCSK9 inhibitors is reflected in the agents’ uptake and utilization, showing that payer rejections far outweigh approved scripts:

- Total rejections = rejection count / approved + reversed + rejected
- Total approvals = approval count / approved + reversed + rejected
- Total patient reversal = reversal count / approved + reversed + rejected

1Source: Symphony Health Solutions, (PCSK-9 inhibitor claims analysis). (for the period: 7/30/2015-7/21/2016). Commercial, managed Medicaid, Medicaid, cash-paying, and assistance claims are all included in analysis.
INSIGHTS FROM INFORMAL STAKEHOLDER DISCUSSIONS
Methodology recap

• A series of informal 45- to 60-minute telephone discussions were conducted with leadership from key stakeholder organizations from Aug. 8 to Sep. 27, 2016, to better understand how concepts of value and access are perceived by different stakeholder groups:
  – Patients or Patient Advocates
  – Providers
  – Payers
  – Researchers
  – Manufacturers
  – Public health

• Primary topic areas included:
  – Familiarity with the topics of value and access
  – Stakeholder definition(s) of the concepts of value and access
  – How perspectives of value and access may differ from other stakeholder groups
  – How the landscape of value and access may change in the future
Methodology recap

- National Forum appreciates the participation of the following member and other organizations who represented the various stakeholder groups:
  - Academy of Managed Care Pharmacy
  - FH Foundation
  - National Association of Chronic Disease Directors
  - National Association of County and City Health Officials
  - National Lipid Association
  - National Pharmaceutical Council
  - Preventive Cardiovascular Nurses Association
  - Value Based Insurance Design Center
  - WomenHeart: The National Coalition for Women with Heart Disease

- The National Forum also conducted a number of informal conversations with similar stakeholders and some insights from these discussions have been provided on the following pages.
Key findings

Overall, stakeholder discussions reinforced earlier findings that multiple definitions of both “value” and “access” exist in today’s healthcare environment.

• For the topic of “value,” the majority interviewed believe that the lack of a clear and measurable definition can be problematic.
  – Distinctions were frequently made between value for an individual patient and value at a societal or overall population level.
  – Some groups, including payers, believe “value” has recently become a buzzword, but that the buzzword lacks a clear definition.
  – Some stakeholders report frustration that although there is a growing focus on value in the transition away from fee-for-service, there is not yet a truly actionable way to measure it.

• Stakeholders generally are more comfortable with "access" as a term; however, there does not appear to be a uniform definition, and different facets of access were described as being most important, including:
  – Access to accurate information or a timely diagnosis
  – Access to affordable care and treatments
  – Access to healthy foods
Key findings

• Nearly all stakeholders agreed that patients ultimately lose out when there is confusion over or barriers around value and/or access. Specific types of CV patients were seen as facing the greatest challenges, depending on which stakeholder was weighing in:
  • Heart-failure patients
  • Younger patients with heart issues
  • Patients managing cholesterol/lipids
  • Elderly patients with multiple conditions
  • Patients at lower socioeconomic levels
  • Patients with genetic disorders, such as FH

• Generally, stakeholders believe that more value-based care and reimbursement models will be developed over the next few years, but caution that access challenges may still exist.
Different perspectives in focus

Differences in the way stakeholders think about scope and costs are generally related to their own role in the healthcare environment; this is a central challenge in forming a cohesive view of the “value” issue:

- **Public Health**: Balance of clinical with cost; long-term considerations
- **Payers & Manufacturers**: Cost implications across specific populations
- **Providers**: Clinical outcomes across a range of patients
- **Patients**: Personal health benefits and personal finances

Broad, society view

Scope

Individual
Specific perspectives in focus

• **Patients or patient advocates**
  – There is a belief that some treatments are more “valuable” to individual patients based on their own unique profiles, and that many value calculations do not take this into account.
  – Opinions differ on whether CVD patients face significant access challenges and if so, who experiences them.
  – Some organizations believe that proper diagnosis of relevant CV diseases is the most critical access challenge today.
  – Groups express awareness that in today’s system, every patient will not be able to get precisely the care or treatment he/she wants every time.

• **Providers (including physicians, nurses, and others)**
  – They interpret “access” as patients being able to obtain and afford the therapies that are appropriate for them; they see themselves on “front line” of this issue.
  – Some groups wonder if larger practices allow providers to better respond to barriers.
  – They are not as experienced with topic of “value,” but some do report the perspective that valuation methods (vs. “value”) have changed over time.
    • Also report seeing a difference in how patients and those responsible for healthcare systems view value.
Specific perspectives in focus

• **Payers**
  - Generally believe that “access” to healthcare is the most important type of access for patients.
  - Report seeing value as the combination of: 1) a medication 2) the services surrounding it and 3) the outcome achieved.
  - Tend to associate “value” with risk-based contracts with providers or manufacturers.
  - In separate conversations, some groups indicated that they strongly support side-by-side drug comparisons for the sake of transparency.
  - Believe that the American healthcare system is not sustainable, and issues of cost, value and access will need to be addressed.

• **Manufacturers or Research Organizations**
  - Are experiencing far more dialogue around “value” and “access” than during the fee-for-service era.
  - See rising interest and activity in value-based reimbursement models and insurance design.
    - Incentives for both consumers and providers are considered important.
  - Some believe that the U.S. healthcare discussion should focus on how well dollars are spent, not how many dollars are spent.
  - Believe that employer groups should be included in ongoing discussions.
Specific perspectives in focus

• **Public Health**
  – Report some uncertainty as to where public health can best engage in debates around value and access, especially where they are filling a safety-net-payer role.
  – Perceive “access” to optimally include consideration of healthy food and exercise, as well as providers and therapies.
  – Conscious of the difference in how public health thinks about value in terms of long-term ROI, and how other stakeholders are focused on more immediate or individual determinations.
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83. The Medical Letter on Drugs and Therapeutics, August 17, 2015, 57(1475):113-115.


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