VALUE & ACCESS:

INNOVATIVE COLLABORATIONS TO IMPROVE ACCESS TO EVIDENCE-BASED CARDIOVASCULAR CARE
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EXECUTIVE SUMMARY

Through its Value & Access initiative, the National Forum for Heart Disease & Stroke Prevention (National Forum) has answered a need identified by its members in bringing together a steering committee comprised of diverse decision-makers from varied stakeholder groups (patients, providers, payers/purchasers, public health and pharma/biotech) to engage in discussion and solution-oriented activities on value and access issues related to cardiovascular health.

Through convenings and communication facilitated by the National Forum, the steering committee developed a consensus goal statement and action agenda that contribute to educating, progressing and empowering expansive, collaborative action throughout the stakeholder groups, while keeping patient-centered care as the focus. 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
• Supporting the implementation of evidence-based care that aligns incentives for patients, providers, payers, and other stakeholders

Members of the Value & Access Initiative have been engaged in communicating, sharing evidence and best practices, and identifying areas for improvement in four primary areas:
1. Increasing Communication to Enhance Effectiveness & Support of Existing Leverage Points
2. Understanding Best Practices on Payer/Purchaser Coverage Decisions
3. Patient Engagement Strategies:
   • Increasing Adherence
   • Shared Decision Making Tools & Models
4. Framework to Shift Spending from Low- to High-Value Care

To date, the initiative has:
• Built trust and fostered environment-changing dialog
• Influenced pricing on innovative therapies
• Expanded and strengthened stakeholder engagement with value framework assessment developers
• Raised understanding among stakeholders
• Developed tools and programs to communicate evidence-based strategies and strengthen shared decision making and patient engagement
• Increased open communication and exchange of programming, events, tools and resources
Many of the 121.5 million Americans living with cardiovascular disease (CVD) face barriers to receiving evidence-based treatments that will improve their health and well-being. While innovation and patient access to treatments that are safe, effective, affordable and result in better health outcomes and quality of life are valued, our current healthcare system is strained. Improving the prevention and treatment of disease requires innovation. Yet, determining the real value of an innovation is difficult, because stakeholder definitions of “value” vary widely. Furthermore, pricing of new drugs may encourage payers to limit patient access.

The issues of value and access concern all stakeholders, as CVD remains the number one killer of Americans and drives substantial costs and other burdens on U.S. society. Many of these treatments target chronic diseases, so the increasing size of the aging population is shifting the cost burden from private to public payers.

Through its Value & Access Initiative, the National Forum for Heart Disease and Stroke Prevention (National Forum) is engaging diverse stakeholders in a transformative, consensus-building initiative to overcome barriers to access, better define value to fit the needs of all stakeholders, increase understanding of the drug innovation pipeline and distribution chain, and foster awareness of how these elements affect value and access. Together, the Value & Access Initiative participants are accelerating collaboration, overcoming barriers, and improving access to evidence-based care to enhance health and well-being.

This white paper shares experiences, recommendations and the impact to date of the Value & Access Initiative.
BACKGROUND

THE NATIONAL FORUM

The National Forum for Heart Disease & Stroke Prevention (National Forum) is a non-profit organization whose mission is to lead and encourage collaborative action among stakeholders committed to preventing the number one killer of both men and women: heart disease and stroke.

Although cardiovascular disease could potentially be prevented in 4 out of 5 people, progress against the debilitating, deadly and costly disease has been unacceptably slow, even losing ground in recent years.7

The National Forum disrupts this unacceptable status quo by bringing together the most dynamic and diverse organizations in cardiovascular health to:

• Share successful strategies, practices and lessons learned
• Discuss new ideas in a collaborative environment
• Develop, pilot and scale innovative approaches to prevent cardiovascular disease

In 2015, the introduction of new therapies with the potential to substantially reduce the burden of heart disease and stroke were approved. The responses varied. Patients and healthcare providers welcomed the new drugs (PCSK9 inhibitors), which clinical trials showed to reduce cholesterol and prevent heart attacks and strokes. Payers warned that the costs of these medications could bankrupt the healthcare system6.

That year, clinician groups, industry, and patient advocacy members asked the National Forum to create a path to help them join the national debate about the value of and access to new therapies for heart disease and stroke5. Others were concerned about the pressure on economic incentives for innovation. Numerous organizations already were active on these topics, and the National Forum determined it would only enter the value and access arena only if it could make a distinct contribution to progress on the issue.

Most of the existing initiatives came from one or two stakeholders’ perspectives on value and, particularly, access. As a result, perspectives were often conflicting, leading to gridlock in which people were not able to access medications to reduce their risk of cardiovascular disease or slow its progression.10 11 12 13

In consultation with a broad array of its members, the National Forum identified the gaps in the discourse, and developed a plan to spark disruptive collaboration to address these gaps. The plan centered on inclusively convening National Forum members and experts to raise understanding across stakeholder perspectives, build consensus and lead collaboration. It would bring high-level representatives of patients, providers, public health, private and governmental payers and the pharmaceutical/biotechnology industry together in dialogue and collaboration. The National Forum applied for and received funding from Amgen in 2016 to launch the Value & Access initiative. Additional funding was later received from Sanofi-Regeneron. To minimize conflicts of interest, Amgen and Sanofi-Regeneron did not actively participate in the discussions or meetings of the National Forum Value & Access Initiative; however, they are permitted to attend as observers.
As its first step in the role of disruptive convener, the National Forum identified thought leaders representing patients, payers, providers, public health and pharma/biotech (the 5 Ps) and conducted 60-minute structured telephone interviews to gather stakeholders’ definitions and perceptions of value and access.

The interviews, along with peer-reviewed and gray literature, formed the basis of a landscape report, What Do Value and Access Really Mean, that chronicles how the concepts of value and access have evolved over time to reflect changes in the healthcare system and therapy innovation, defines the relevant stakeholder groups, and reports the differences in perspectives and considerations among stakeholder groups.

Key takeaways from the report include:

- The concept of value and access to medications has affected how healthcare is delivered and received. The concept of value has evolved along with the U.S. healthcare system. Understanding how the healthcare system has evolved can provide insight into current issues regarding the value of and access to medications.

- Perspectives on value and access vary widely. In the U.S., innovation of medical therapies is encouraged, and patients seek affordable and timely access to new medications\(^1\). However, different stakeholders have different perspectives on the value of innovation:
  - Patients assign value to therapies based on their personal experiences, health benefits and finances. “Value” may include enhanced quality of life.
  - Manufacturers define value as improved patient outcomes, and they want prices to reward innovation and provide incentives for further development of new therapies.
  - Providers are concerned about improving patient outcomes and want minimal barriers to prescribing new drugs that they consider appropriate for their patients.
  - Payers (private and government) are concerned about maximizing health benefits across all covered patients within constrained budgets, and that manufacturers use the argument of incentivizing innovation to pursue higher profit.
  - Public health stakeholders are concerned about improving the health and well-being of broad populations over the long term.

(cont.)
The majority interviewed believe that the lack of a clear and measurable definition of value can be problematic.

As with the term "value," there is not a uniform definition of "access," and there are varying facets to the term.

Stakeholders are generally more comfortable with "access" as a term compared to "value".

Nearly all stakeholders agree that patients ultimately lose when there is confusion over, or barriers around, value or access.

Different stakeholders had different opinions on which types of cardiovascular patients face the greatest challenges.

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

Nearly all stakeholders agree that patients ultimately lose when there is confusion over, or barriers around, value or access.

### 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:

- **Scope**
  - Broad, society view
  - Individual

- **Focus Area(s)**
  - Balance of clinical with cost; long-term considerations
  - Cost implications across specific populations
  - Clinical outcomes across a range of patients
  - Personal health benefits and personal finances

*Fig. 2: Differing Stakeholder Views*
DISRUPTIVE CONVENING

The National Forum saw open dialogue among all stakeholders as the first step toward unlocking the gridlock that left patients unable to access innovative medications while providers, payers, and manufacturers blamed one another.

Establishing rapport and trust among stakeholders began with face-to-face discussion involving representation from all 5P perspectives. The National Forum identified and recruited 20 senior leaders of organizations representing the 5 Ps to serve as members of the Value & Access Initiative Steering Committee (VASC). In recruiting VASC members, the National Forum sought out individuals both from within and outside of its membership who could speak on behalf of and had decision-making authority within the organization that they were representing. The goal was to have at least two representatives from each sector at the table.

The National Forum convened the first face-to-face meeting of the VASC in December 2016 in Washington, DC. The charge to the committee was audacious – to come to a consensus regarding the meaning of value and how it should influence access to improve and eliminate disparities in cardiovascular health. The aspiration was to identify principles, policies and practices that could apply across disease categories, not just CVD.

The meeting was structured to engage steering committee members in:

• Reviewing and discussing key insights from What Do Value and Access Really Mean? and other landscape information
• Listening to and understanding other stakeholders’ perspectives on challenges to appropriate access
• Identifying common ground
• Identifying existing best practices that multiple stakeholder groups see as effective
• Discussing ways that existing best practices can be expanded or amplified to better serve patients

At the outset, the National Forum created ground rules to establish an environment of trust. To do that, individuals had to take some risks, speaking candidly not only about their patient-oriented goals, but also about their business goals. The expectation was that the VASC would focus on solutions, not blaming or finger-pointing. As a result, VASC members felt they could communicate freely and be heard by each of the stakeholder groups.

Everybody is at this table today, trying to find common ground. In 30 years in this business, primarily cardiology, I’ve never seen that before.

Norm Linsky
then-Executive Director, Mended Hearts
# BARRIERS

The VASC members discussed and identified a variety of value- and access-related barriers:

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<th>Barriers</th>
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<td>• Identifying and sharing data</td>
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<td>• The lack of objective, uniform performance measures</td>
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<tr>
<td>• The time frame for recouping costs</td>
</tr>
<tr>
<td>• Not trusting other players</td>
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<tr>
<td>• Limited sharing of best practices relative to disparities in access</td>
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<tr>
<td>• Nontransparent cost structure</td>
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<tr>
<td>• Legal complexities</td>
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<tr>
<td>• Related to data sharing and transparency</td>
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<tr>
<td>• Limitation on scope of practice by various providers</td>
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<tr>
<td>• Proprietary information/competition</td>
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<tr>
<td>• Medication and treatment adherence challenges</td>
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<td>• Identifying patient populations not likely to benefit</td>
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<td>• Genetics/race/ethnicity/gender</td>
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# THEMES

The VASC identified five primary themes (patient-focused support, data, evidence-driven policy/decision-making, aligned incentives and accountability/transparency) as areas that could be focused on to improve value and access:

**Patient-Focused Support**

- Access to Care – address disparities, insurance/cost/high deductibles, participation in clinical trials
- Adherence – identify responsibility, patterns in care/patient education, support, self-care management, multifactorial social determinants
- Patient preferences/autonomy – honor shared decision-making, knowledge, belief, intentions
- Apply patient-focused team-based approach

**Evidence-Driven Policy/Decision Making**

- Base policy on information and science
- Create consistency across stakeholders
- Identify best/leading practices (and a clearinghouse to share efforts)
- Improve evidence-based performance
- Become aware of and involved in FDA drug-approval & adherence strategies
- Identify treatment guidelines and dosing that are appropriate to specific patient populations

**Data**

- Include both quantitative and qualitative data
- Improve data utilization – e.g., use data that’s already available and build from there

**Accountability/Transparency**

- Increase transparency across stakeholder groups
- Enhance data sharing
- Implement universal performance standards - “level playing field”
- Identify PBMs pros and cons
- Improve communication across and between stakeholders
- Facilitate bi-directional flow of information
- Increase Transparency in policy at all levels
  - Federal
  - State
  - Local
  - Payers
  - Health systems
  - Employers
  - Pharma

**Key Steps**

- [Key Steps]

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**Aligned Incentives**

- Improve patient health & wellbeing and outcomes while managing cost
- Implement value-based benefit design & payment systems
- Support innovation sparked by and between patients, employers, insurers, pharma and healthcare
- Address
  - re-insurance mechanisms - annuities
  - Rare disease/orphan drugs
  - Genetic disease - life course costs
BEST PRACTICES

As the themes were identified, VASC members recognized the vastness and complexity of addressing the myriad issues. They acknowledged that various sectors and organizations had work underway that addressed, in part, many of the issues. Over the course of the meeting, consensus began to develop around best-practice areas that the VASC believed could be expanded upon or repurposed to improve value and access across cardiovascular therapies.

Consensus began to develop around best practice areas that the steering committee believes can be expanded upon, or repurposed to improve patient access. Examples discussed included:

- Bidirectional informational programs to share medication script info, such as those used in APhA Foundation’s Project IMPACT: Immunization and the state of Minnesota use of the NCPDP SCRIPT standard requirement
- Medical synchronization model similar to those utilized in pharmacy programs
- Hurricane Katrina data sharing success that opened up information silos
- New York state Regional Health Information Organization (RHIO)
- Value-based contracting engages payer provider, and manufacturer stakeholders to promote patient care
- Data-based approaches as promoted by WomenHeart Access Now! Education and Advocacy Campaign
- Team-based care similar to APhA Foundation’s Project IMPACT: Diabetes

TO KEEP IN MIND

To further understand the issues of value and access, and to keep the meeting moving toward actions that could be taken, participants identified items of importance and topics to be kept in mind vis-à-vis the respective stakeholder groups.

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<th>Patients</th>
<th>Payers</th>
<th>Providers</th>
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| • Transparency  
• Health literacy  
• Lifestyle  
• Incentives  
• Affordability  
• Effectiveness | • Access  
• Benefit design  
• Consistency of coverage  
• Immediate vs. long-term benefit | • Team-based care  
• Incentives  
• Clinical guidelines |

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<th>Pharma/Biotech</th>
<th>Public Health</th>
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| • Value of product relative to cost  
• Steps to help define appropriate population  
• Regulatory barrier on data sharing  
• Incentives for innovation | • Policies that affect payment modalities, licensing/scope of practice, team-based care, & use of community health workers  
• Evidence-driven policy |
DETERMINING A CONSENSUS GOAL & ACTION AGENDA

CONSENSUS GOAL

The face-to-face VASC meeting successfully established open dialogue across sectors and obtained stakeholders’ buy-in to work together. The next step was to create a consensus goal statement to which collaborative efforts would be aligned. The National Forum presented draft goal statements to the VASC in a February 16, 2017 virtual meeting.

Discussion on how to frame the goal statement centered on the term “cost.” Patients and providers felt cost factors were not in their control and complicated the issue. Payers felt including cost and appropriate care made sense but including the word “optimize” could add confusion or imply throwing the door open to access, causing costs to increase. They felt it was important to strike a balance by incorporating controlling costs and managing appropriate care. All stakeholders acknowledged that if there were no profit in pharma and biotech, invention and development would cease. Therefore, the VASC recognized a need for return on investment in innovation, while ensuring that costs are not barriers to patient access.

VASC members also discussed the challenges posed by pharmaceutical companies determining the pricing of treatments and the effect that pricing has on the need to manage costs.

As representatives from patient and provider groups were not comfortable with the cost terminology, the discussion pivoted to terminology around “high-value therapy.” Use of this term recognizes that certain treatments are expensive, they can improve patient outcomes, and could be argued as being of high value for some patients. Thus, the suggestion for moving forward on consensus was to focus on terminology around optimizing value and efficient resource utilization—centering on a value proposition associated with patient care in which all stakeholders are involved.

In a subsequent virtual meeting, the steering committee ultimately agreed upon the following expanded goal statement:
VALUE & ACCESS INITIATIVE: GOAL STATEMENT

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

• SUPPORTING THE IMPLEMENTATION OF EVIDENCE-BASED CARE THAT ALIGNS INCENTIVES FOR PATIENTS, PROVIDERS, PAYERS, OTHER STAKEHOLDERS
THE ACTION AGENDA

With agreement on the goal, the VASC turned to developing a high impact action agenda. The goal of the Value & Access Initiative is not to duplicate, but rather bring to the attention of others, the collective energy behind best practices and policies, and emphasize that there is consensus to increase patient access to high-value therapies. The VASC focused on PCSK9 monoclonal antibodies as a case study for members to develop frameworks and approaches for addressing value and access issues. Over a series of webinars and a second face-to-face meeting of the VASC in September 2017, consensus emerged regarding the most effective action plan.

Throughout the process, VASC members were highly engaged in setting the meeting agenda and the discussions. Members were individually surveyed off-line as well in order to capture the range of opinions regarding key concepts:

- In your group’s view, what evidence-based criteria can all stakeholders agree upon for determining appropriateness of care?
- What specific evidence-based actions can be taken to align incentives for stakeholders?

A series of virtual and in-person meetings were held to identify four areas of focus most likely to have shorter or nearer-term impact:

1. Increasing Communication to Enhance Effectiveness & Support of Existing Leverage Points
2. Understand Best Practices on Payer/Purchaser Coverage Decisions
3. Patient Engagement Strategies:
   - Increasing Adherence
   - Shared Decision Making Tools & Models
4. Framework for Identifying and Shift Spending from Low- to High-Value Care

VASC members were recruited to participate in workgroups for each of the four focus areas, and the National Forum facilitated ad hoc working group meetings.

The following section outlines the main discussion items and outputs of the VASC workgroups and activities undertaken by National Forum leadership and staff.
INCREASING COMMUNICATION TO ENHANCE EFFECTIVENESS

The VASC identified the need for members to keep up to date on each of the organizations’ activities and to be provided with information and messaging to send to their constituents, as well as to help partner organizations further their resources and get greater value through concerted amplification.

Creating a calendar of events, posting links to initiatives, and providing sample messaging and communications were all strategies that the VASC felt would be useful.

The VASC recognized that, while certain organizations have limitations on what they can do regarding messaging or activities such as lobbying, having the opportunity to review and share messages, or sign on to appropriate activities, would be beneficial, and that an online clearinghouse would facilitate this process.

In 2017, the National Forum created an online clearinghouse for disseminating Value & Access related materials, and to serve as a hub for information sharing.

SUPPORT OF EXISTING LEVERAGE POINTS

The VASC acknowledged the variety of efforts related to value and access and felt that part of the Value & Access Initiative’s charge would be to provide input and feedback, and where appropriate, support and amplify work that helped advance the consensus goal. Three areas in which the initiative fulfills this is through: advancing value-based care and value-based insurance design; providing input into value frameworks and exchanging information through the clearinghouse & communications.

ADVANCING VALUE-BASED CARE AND VALUE-BASED INSURANCE DESIGN (VBID)

To carry out the strategy of supporting the implementation of evidence-based care that aligns incentives for patients, providers, payers, and other stakeholders, per the recommendation of VASC members, the National Forum has become an active participant in both the Smarter Health Care Coalition and the National Alliance of Healthcare Coalitions. These organizations carry out complementary work, including policy and engagement of purchasers, related to advancing both value-based care and value-based insurance design (VBID) to improve access. The National Forum provides input to these organizations on cardiovascular issues and social determinants of health.

PROVIDE INPUT INTO VALUE FRAMEWORKS (ICER)

The National Forum opened communications with the Institute for Clinical and Economic Review (ICER), which describes itself as an independent and nonpartisan research organization that objectively evaluates the clinical and economic value of prescription drugs, medical tests, and other health care and health care delivery innovations. The National Forum has convened the VASC multiple times to obtain, discuss and agree on input to ICER.

ICER invited and responded to the Value & Access steering committee’s and partners’ feedback on its 2017 PCSK9 new evidence update, ICER incorporated some of these recommendations in its PCSK9 Evidence Update, and ICER has sought additional, direct input from groups recommended by the National Forum.

ICER invited Value & Access Initiative Chair, Jennifer Robinson, and the National Forum Executive Director, John Clymer, to meet with ICER’s Chief Scientific Officer, Chief Medical Officer and Program Manager regarding the VASC’s and partners’ recommendations to improve ICER’s modeling, as well as ODYSSEY data presented at ACC. The meeting took place in March 2018.

The relationship has extended beyond PCSK9s, and the VASC responded to ICER’s request for input by stakeholders to ICER’s draft scope on canakinumab. Dr. Robinson participated in follow-up calls with ICER for additional discussion of feedback submitted and ICER’s draft scoping document for additive cardiovascular therapies. In August 2019, the VASC submitted public comments on ICER’s draft evidence report on additive cardiovascular disease therapies.

Through the facilitation of webinars to discuss technical aspects of the evidence updates and soliciting member feedback, the Value & Access Initiative has provided an opportunity for members and partners to become engaged in the value assessment framework process and share their voices as a collective unit representing various stakeholder perspectives.

CLEARINGHOUSE & COMMUNICATIONS

The National Forum facilitates monthly calls among the steering committee and partners and added monthly partner spotlight calls, where two to three partners share more in-depth information about current initiatives.

Through these monthly gatherings, the National Forum has increased open communication and sharing of programming, events and updates among stakeholder groups. These meetings help partners amplify their efforts through broader dissemination and encouragement to support one another’s efforts (as appropriate) through sharing across networks, participation in events, and providing input and feedback.
ENHANCING COMMUNICATION

Throughout the course of this initiative, a key theme has been enhancing communication and understanding among stakeholders. One area identified by VASC members as unclear was that of health plans’ Pharmaceutical and Therapeutics (P & T) Committee’s processes and their relationship to prior authorization. Prior authorization (PA) is any process by which physicians and other health care providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage. Health plans often use PA to restrict access to costly services and therapies—particularly newer treatments. Health plans may also use PA to ensure that a therapy is appropriate and safe for a specific patient.

Payer representatives noted the challenge with PAs is that each health plan and payer have a discrete group of physicians, pharmacists, and administrators that establish coverage criteria (P&T Committees).

Prior to and independent of the establishment of the VASC, provider (American Society for Preventive Cardiology and National Lipid Association) and patient (FH Foundation) representatives within the VASC published a paper, PCSK9 Inhibitor Access Barriers—Issues and Recommendations: Improving the Access Process for Patients, Clinicians, and Payers including a proposed universal PA form for PCSK9 Inhibitors to be completed by the prescriber with the intent to streamline the process and reduce the likelihood of payer rejection. To raise awareness and further work done by partner organizations, this paper was circulated among the VASC and relevant stakeholder contacts, as well as placed in the Value & Access Clearinghouse.

PA processes are complex and systematic changes will be necessary for change to occur. As stakeholders were raising awareness regarding the recommendations referenced above, several patient and provider members cited report cards highlighting high percentages of health plan rejection rates of PCSK9 inhibitors as barriers to access to these treatments. Payer representatives within the group felt that the report cards did not paint the full picture (e.g., reasons for rejection were not included in the data) and felt that the communications regarding the rejection rates were therefore misleading.

To open lines of communication, in March 2018, the National Forum facilitated a presentation by VASC member, Independent Health, along with Baylor Scott & White Health, and the Alliance of Community Health Plans (ACHP). The goal was to provide insight on the P & T Committee processes and PA for innovative therapies. The presenters provided information and case studies on what their organizations were doing specifically related to PCSK9 inhibitors. In addition, Independent Health agreed to answer questions and continue dialogue on coverage criteria and rejection rates, which helped to foster clarification and more open communication between stakeholders. Independent Health reported that with its online PA form submission process, approval rates for PAs on PCSK9 inhibitors was 79%, which was above the national rate (62% per the report cards).

In August of 2019, the FH Foundation published its research – Effect of Access to PCSK9 inhibitors on Cardiovascular Outcomes – demonstrating that patients with FH, ASCVD, or both who were prescribed PCSK9 inhibitors were at high risk for cardiovascular events, and had a higher risk for cardiovascular events when those prescriptions were denied or went unfilled.

BEST PRACTICES

Health plans have a critical role in closing existing, significant quality gaps in control of heart disease and stroke risk factors. Well-structured and staffed P&T committees can help them do so. The Best Practices for Pharmacy & Therapeutics (P&T) Committees checklist (see appendix), incorporating the principles of the Value & Access Initiative Goal Statement, is a model process for P&T committees to make equitable coverage decisions in their formularies.

The work behind this piece of the initiative is grounded in the recognition that every participant in the healthcare system must balance multiple factors when treating individual patients and caring for populations of patients, including:

- Safety
- Effectiveness
- Efficiency

Main tenets of conversation throughout the initiative which made their way onto the checklist, included:

- Transparency – Including the makeup of the committee (e.g., the types of representatives serving on the committee, or key opinion leaders), evidence used in decision-making, and processes for decision making and accessing medication.
- “Ease of use” (for participating providers and members) – Assuring timely access to medications, including special cases where first order treatments have failed to achieve desired results and patients’ risk factors are still not controlled. Such as, making PA or step therapy criteria readily available, easy to understand, and implementing a user-friendly submission process.
- Timeliness – As a key metric to ensure minimum delays in getting members needed treatment.
- Collaboration – Between both providers and payers to avoid denials based on incomplete information.
Patient Engagement: Increasing Adherence & Shared Decision Making Tools & Models

INCREASING PATIENT ADHERENCE

The VASC identified medication adherence as an opportunity to work with patient groups to improve patient outcomes. VASC members expressed that medication and lifestyle adherence is important, and that patient-clinician communication about the disease process and the importance of medication is vital. They stressed the importance of trying to help people understand their disease risks and potential benefits and harms of available treatment options. Committee members noted that there are existing materials and programs, and that those materials could deliver the most impact if the committee could identify the most effective ones and the optimal methods of delivery.

The U.S. Food and Drug Administration (FDA) established the Enhanced Medication Adherence Strategies Initiative (EASI) to improve cardiovascular medication adherence. FDA signed a first-of-its-kind memorandum of understanding with the National Forum to engage public-private collaborators in support of EASI. This collaboration published a state of the art review of adherence and an article about disparities in adherence.

To continue and build on the EASI collaboration, the FDA is represented on the VASC and their work informed the foundation of the survey outlined below.

This workgroup’s action plan includes identifying and endorsing or highlighting models, research, tools and resources and disseminating information and resources among stakeholders.

The Patient Adherence workgroup sought to determine perceptions on patient adherence factors directly from the patient perspective. They used the article, “Improving Medication Adherence in Cardiometabolic Disease: Practical and Regulatory Implications” as the framework for a survey that was distributed to participants at the Mended Hearts’ (a United States-based charity which functions as a support group for individuals suffering from heart disease) 2018 Annual Meeting. The purpose of the survey was to gain insight on medication adherence and what techniques and approaches patients found helpful.

SURVEY RESULTS SUMMARY

146 participants took the survey. The participants were predominantly heart patients, female and white. The average age of participants was 65, with ages ranging from 27 to 88. Of those who completed the survey, 117 were Mended Hearts members and 35 were Mended Little Hearts (a subsidiary of Mended Hearts, focused on patients and families of children with congenital heart disease) members.

Given that many respondents did not fill out all the questions, it was not possible to compute advanced statistical analyses. However, knowledge was gained about which patient adherence technique was most commonly employed and most helpful. The survey also provided insight into which kind of healthcare provider patients most often had conversations about medications with, and which they found most helpful.

**Fig 3. Survey Responses Patient Perspective on Helpful Medication Adherence Techniques & Approaches**

This figure depicts which patient adherence technique was most commonly offered and most useful. The survey also provided insight into which kind of healthcare provider patients most often had conversations about medications with, and which they found most helpful.

Additional information regarding where patients receive health information and reasons for not starting, missing and stopping medication, was also obtained.

In line with identifying and endorsing models and amplifying efforts underway, the workgroup developed a template for soliciting information from and is engaging patient advocacy members of the Value & Access Initiative and others in identifying and highlighting resources for inclusion in the clearinghouse. The resources and information will be regularly disseminated among stakeholders.
Patient Engagement: Increasing Adherence & Shared Decision Making Tools & Models (cont.)

**SHARED DECISION MAKING TOOLS & MODELS**

This workgroup’s action agenda strategy is to identify effective shared decision making tools and models and develop recommendations on how successful models can be scaled.

Recognizing that there is already extensive research and work in the area of adherence, this workgroup conducted a literature evaluation on shared decision-making (SDM) tools and models, searching Medline and EMBASE from January 2015 forward for relevant articles.

The articles were organized by outcomes (clinical, humanistic and economic). To make the work more actionable, the workgroup used a model found in its literature evaluation and built upon it by adding a new component to enhance the likelihood of the SDM model achieving optimized clinical, humanistic and economic outcomes. This enhanced, evidence-based, structural framework is referred to herein as the SHARED approach.

The workgroup is translating the SHARED framework into infographics designed to be used by patients and providers modeling patient-physician conversations. The worksheets focus on treatment and management of LDL-C for patients with FH (familial hypercholesterolemia), statin-related side effects, and atherosclerotic cardiovascular disease (ASCVD).

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**Fig 4: SHARED decision making worksheets**

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The VASC recognizes that there are limits to health care spending, and spending on low-value care crowds out spending on high-value care.

The Shift Spending from Low- to High-Value workgroup comprises purchaser, payer and provider organizations. The purpose of this workgroup is to generate potential solutions to shift spending from low-value to high-value care. Below is a summary of its activities.

In its initial meetings, the workgroup came to a consensus that there was a need to:

• Work in good faith to identify and understand each stakeholder group’s realities, challenges and barriers.
• Map out what each stakeholder would need to give up and what others would gain.

The group agreed to:

• Go beyond sharing best practices and information, to model a solution (or solutions).
• Focus on the basics (closing gaps where solutions are known).
• Stop talking in generalities; instead, talk about specific tradeoffs in terms of procedures, volume, pricing, discounting, etc.

The workgroup acknowledged the difficulty in visualizing the procedures that should be stopped and started, and how that would shift in terms of capacity and ensuring that stakeholder incentives (salaries and revenues) are not negatively affected.

• They acknowledged that many providers are not willing to move into actuarial risk, and that there is no clear sense of what stakeholders should do and what the tradeoffs are.
• They agreed that the primary driver is economic and that it was unrealistic to expect any of the stakeholders involved in healthcare to start doing something that they would not get paid for.
• They also expressed that it is unrealistic to expect clinicians to have a concept of what is happening at the population level or to make differential decisions.
• They acknowledged that payment reform is being addressed and underway, and that the group’s efforts would best be directed in building upon work that is already being done, and in not trying to take on every facet of the issue.

The group felt that the best approach for addressing a topic this complex is to narrow the scope, be specific, not be afraid of openly communicating and laying the factors out on the table for discussion and be direct in conversation with one another—as well as acknowledging that there will be winners and losers in tradeoffs that occur. Ultimately, the group concluded, there is a higher collective obligation to make sure that the patient benefits.

The group decided that one way to address the issue of better managing resources would be to focus on upstream interventions that affect the base, or largest population of the health triangle, and work toward preventive efforts related to cholesterol and blood pressure risk. (See figures 3 & 4 on page 22).

They felt that higher value could best be achieved by focusing on the largest area of potential impact, the base of the triangles, and those that have not been diagnosed, which would enable value benefits to flow up the triangle where innovative treatments could be provided to the right patients. Challenges with this approach include:

• The interventions being discussed are not the focus of cardiologists; rather, they are the focus of primary care doctors.
• Many groups are focused on preventive efforts. There is the desire to not be duplicative or compete with these efforts.

(Cont.)
Despite there being many efforts geared toward high blood pressure and high cholesterol awareness, prevention and treatment, there is still a low level of awareness regarding the proven high-value care that is offered through blood pressure and cholesterol control. In addition to low awareness, there are other reasons that people do not access these types of care.

Preventing and treating blood pressure and cholesterol (screening paired with standard treatment and management to guidelines) are cost-effective, and in the case of statins, cost-saving. And the benefit, or value, of these types of low-cost intervention comes from more consistent application, which then obviates the need for lower value care down the line.

With this approach, the workgroup agreed that unless stakeholders are invested in the outcome, fee-for-service or for-profits are not going to engage in shifting from low- to high-value care. However, if the model is changed so that they are the parties at risk, then they will engage.

The workgroup agreed that the problem will not be solved by using standard tactics; creative thinking needs to be applied. The workgroup’s reasoning aligns with research conducted by OptumLabs analyzing low-value care and accelerating value in healthcare. The research found that:

- It is more difficult to curtail some low-value services than others.
- Awareness alone is not always enough for change.
- There are some additional tactics that can help push change, including:
  - reducing barriers to patient-provider conversations,
  - rewarding a de-implementation culture of low-value services and
  - encouraging bundles of related services for common patient situations.

**NEXT STEPS**

As next steps, the workgroup outlined the following as proposed actions:

- Define goals for what the country should be able to achieve for controlling rates for heart disease and stroke-related risk factors, likely to align with Healthy People and Million Hearts®.
- Adopt a framework that has worked and help stakeholders figure out what role they play.
- Identify a simple way to stratify and describe drivers and talk about gaps in performance as they relate to those drivers and specific implications of those gaps.
- Look at how the workgroup can link with existing initiatives (e.g., Million Hearts, CDC’s 6|18 and the Network for Regional Healthcare Improvement (cost drivers)).

Workgroup members feel that in general, there are fewer constructive conversations with any organization considered a payer, such as pharmacy benefit managers, health plans, employers, etc. They attribute the decrease in conversation to the massive consolidation of insurance companies. The workgroup felt that it was important to find a way for collective action to create and maintain connection among organizations within the Value & Access group with big payers to talk about these issues. Defining low- and high-value is challenging. Instead of operating in a vacuum, members prefer to listen to and talk with payers.

The more you can get traditionally adversarial stakeholders in dialogue, the better the chances of progress being made.

Brendan Mullen, Executive Vice President, American College of Cardiology

Each stakeholder group is using the term “value” and trying to motivate discussion on value. As What Do Value and Access Really Mean? documented, there are challenges defining and measuring it. Additionally, there are several value frameworks used to assess the value of medical services and biopharmaceutical products designed to help stakeholders with healthcare decision making. Yet, there remain highly variable determinations of value for the same treatment therapy. The lack of a universal definition for value means stakeholders do not have a common language for what is considered valuable. At least some of the stakeholders see the Value & Access Initiative helping to resolve this issue.

Observers of the Value & Access Initiative pointed out that bringing the siloed stakeholders together and engaging them in dialogue has helped change the environment, enabling pharmaceutical manufacturers to sit down with payers to negotiate simplification of utilization management criteria and substantial cost reductions to move toward improving access. While credit for that progress goes to the manufacturers and payers, and is inherently difficult to quantify, their progress points to the value of having more constructive conversations.
4 Framework to Shift Spending from Low- to High-Value Care (cont.)

Fig. 4: Population Health Triangle: Cholesterol

- 10 million w/ uncontrolled cholesterol despite treatment
- 41 million Have been treated
- 66 million Have been diagnosed
- 108 million Americans with high cholesterol

Fig. 5: Population Health Triangle: Blood Pressure

- 37 million with uncontrolled blood pressure
- 58.3 million Under Current Treatment
- 63.5 million Aware They Have It
- 77.9 million Americans with high blood pressure
From the outset, the National Forum created an environment of trust, enabling stakeholder groups to convene and communicate with one another. The National Forum sought to expand the circle of stakeholders – especially payers – and members involved in the Value & Access Initiative to promote diverse voices and perspectives. In 2018, leaders within Optum/UnitedHealth Care and Blue Cross Blue Shield South Carolina joined the VASC. Throughout the initiative, VASC members expressed surprise at the candor and quality of dialogue among the group, as well as the achievement of consensus on goals and strategies.

Stakeholders have credited the National Forum with bringing players together to collaboratively define the vocabulary, problems and potential solutions, including influencing pricing and negotiations. At the beginning of this initiative, and up to the release of the 2018 ACC/AHA Guideline on the Management of Blood Cholesterol, the average wholesale list price for PCSK9 inhibitors was about $14,000 a year. The majority of cost effectiveness analyses, including those performed by the manufacturers, showed that PCSK9 inhibitors in almost all, except for FH

36 populations were of low value without substantial discounting37. As a result of efforts focused on enhancing the value of these treatments (including this initiative) in 2018, both manufacturers of PCSK9 inhibitors reduced pricing of the therapies by 60% to $5,850 per year. Most recently, the National Lipid Association released a statement paper38 providing clinicians with updated guidance for enhanced value of PCSK9 use in select patient populations showing reasonable cost-effectiveness in many patient groups at the new pricing level. Given the price reductions and new guidance, the goal is to continue to improve people’s access to evidence-based care that is appropriate for them.

Stakeholders have additionally credited the Value & Access Initiative and its process as breaking new ground, ultimately influencing pricing on other specialty drugs beyond the cardiovascular space.

IMPACT

Over the past three years, the Value & Access Initiative has made progress in opening discussion and bringing together a multi-stakeholder group to focus on issues of value and access related to cardiovascular therapies.

BUILDING TRUST AND FOSTERING ENVIRONMENT-CHANGING DIALOG

EXPANDING AND STRENGTHENING STAKEHOLDER ENGAGEMENT WITH ICER

INFLUENCING PRICING ON INNOVATIVE THERAPIES

RAISING UNDERSTANDING AMONG STAKEHOLDERS THROUGH REPORTS AND CONVENINGS

INCREASING OPEN COMMUNICATION AND EXCHANGE OF PROGRAMMING, EVENTS, TOOLS AND RESOURCES

Impact

What the National Forum has done with the Value & Access Initiative has been a very positive force. Getting different groups on the same page is difficult to do and it doesn’t happen very often. The National Forum did it and broke new ground, as manufacturers were hearing open discussion among the stakeholders. This approach may have played a role in reducing costs of PCSK9s, and ultimately, could influence pricing decisions on other specialty drugs.”

Jim Ballenger, RPh, MBA - Principal, BallengeRx Consulting

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Jim Ballenger, RPh, MBA - Principal, BallengeRx Consulting

On behalf of the VASC, the National Forum has advocated with ICER to include more stakeholder voices and data in its value analysis process. As a result of the National Forum opening communications and building rapport, ICER sought feedback and incorporated some of the recommendations submitted by a set of VASC members into its PCSK9 New Evidence Update. Additionally, ICER has sought direct input from VASC members as recommended by the National Forum and has engaged in follow-up meetings with the Value & Access Chair to help further inform issues.

With its landscape summary report outlining different stakeholder perspectives on value and access, the National Forum set the stage for the Value & Access Initiative. Through regular convenings, the National Forum provides opportunities for VASC members and partners to engage with one another to continue to build and strengthen relationships and knowledge. And, via the Shared Decision Making Workgroup, VASC members including the American Pharmacists Association Foundation, FH Foundation, and National Lipid Association have collaborated in developing tools modeling patient-provider conversations and goal setting related to FH treatment options, statin-related side effects, and atherosclerotic cardiovascular disease.

As an extension of the monthly communication calls and virtual meetings, the National Forum established and continually expands the Value & Access Clearinghouse hosted on the National Forum’s website. The purpose of the clearinghouse is to increase partners’ awareness of relevant literature and one another’s reports, tools and other resources, and increase their accessibility to strengthen collective advocacy efforts, dissemination of partner information, events and resources.
The National Forum produced a landscape report on stakeholder definitions of “value” and “access”; established the Value & Access Initiative steering committee (VASC); established open, productive dialogue among stakeholders; and facilitated development of a consensus goal statement and strategies.

The VASC identified the need and desire for regular, frequent communication among the groups to better know what each of the stakeholders was doing related to value and access, share insights into the challenges and approaches being taken by the respective groups, and allow for coordination of programs and events. The VASC charged the National Forum with serving as a:

- **Clearinghouse**
  - Inventory, share and promote evidence and best practices
- **Communicator**
  - Compile and develop messaging that supports best practices
  - Promote use of messaging by National Forum stakeholders and other advocates/influencers
- **Catalyst**
  - Encourage promotion, adoption and implementation of best practices across public, private and nonprofit sectors

To help carry out its roles of clearinghouse and communicator, the National Forum instituted monthly partner information-sharing calls. These 30-minute calls provide a consistent forum for partners to exchange information and promote initiatives, events and programs being implemented by VASC and partner organizations. The virtual gatherings also serve to maintain open communication across the stakeholder groups.

The National Forum serves as a catalyst by assembling the VASC to advance the VASC’s action agenda. The National Forum facilitates a process for stakeholders to discuss, promote, adopt and implement best practices. The National Forum added a monthly, 30-minute segment in which two organizations give presentations on pertinent programs and tools.

The National Forum produced a landscape report on stakeholder definitions of “value” and “access”; established the Value & Access Initiative steering committee (VASC); established open, productive dialogue among stakeholders; and facilitated development of a consensus goal statement and strategies.

The VASC identified the need and desire for regular, frequent communication among the groups to better know what each of the stakeholders was doing related to value and access, share insights into the challenges and approaches being taken by the respective groups, and allow for coordination of programs and events. The VASC charged the National Forum with serving as a:

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CONCLUSION

The Value & Access Initiative has provided a forum for stakeholders representing all facets of the cardiovascular care continuum to engage with one another, in a patient-centric, solution-focused environment based on trust and open communication.

Through involvement in this initiative, stakeholders have had the opportunity to hear perspectives from other stakeholders with whom they previously had limited engagement, to better understand the challenges and barriers faced, and to work together to define terminology and potential solutions to increasing access to the right patient, for the right treatment, at the right time. Working together, the VASC and partners have helped change the landscape by accelerating collaboration, breaking the stalemate and improving access to evidence-based care.

The National Forum will continue to engage the VASC in advancing the consensus action agenda and adapting it to take advantage of timely issues, for example; changes to the medication cost structure, barriers to interventions proven to improve adherence, and social determinants affecting access.
APPENDIX

VALUE & ACCESS STEERING COMMITTEE ROSTER

SHARED DECISION MAKING WORKSHEETS
What is FH?...And What Do I Do About It?
What are Statin-Related Side Effects?...And What Do I Do About Them?
What is Atherosclerotic Cardiovascular Disease (ASCVD)?...And What Do I Do About It?

BEST PRACTICES FOR PHARMACY & THERAPEUTICS COMMITTEES CHECKLIST

ENDNOTES
## VALUE & ACCESS INITIATIVE
### 2018-19 STEERING COMMITTEE MEMBERS

### CHAIR
**Jennifer G. Robinson, MD, MPH**
- Professor
- Departments of Epidemiology & Medicine
- Director
- Prevention Intervention Center
- University of Iowa

### PATIENTS
**Cat Davis Ahmed, MBA**
- Vice President
- Policy and Outreach
- FH Foundation

**Madeleine Konig, MPH**
- Director
- Value in Healthcare Initiative
- American Heart Association

**Norm Linsky**
(Member from 2016 – August 2019)
- then–Executive Director
- Mended Hearts

**Sara Traigle van Geertruyden**
- Executive Director
- Partnership to Improve Patient Care

**Amy Friedrich-Karnik**
- Vice President
- Advocacy and Communications
- WomenHeart

### PROVIDERS
**Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA, FASPC**
- Immediate Past President
- American Society for Preventive Cardiology

**Benjamin M. Bluml, RPh**
- Senior Vice President
- Research and Innovation
- American Pharmacists Association Foundation

**Brian Hart, JD**
- Executive Director
- National Lipid Association

**Sue Koob, MPA**
- CEO
- Preventive Cardiovascular Nurses Association

**Karyn Lockshine, CAE**
- Executive Director
- American Association of Heart Failure Nurses

**Cassandra McCullough, MBA**
- CEO/Executive Director
- Association of Black Cardiologists

**J. Brendan Mullen**
- Executive Vice President
- American College of Cardiology

**Joyce Ross, MSN, CRNP, CS, CLS, FNLA**
- President 2016-2017
- National Lipid Association

### Payers/Purchasers
**Jim Ballenger, RPh, MBA**
- Principal
- BallengeRx Consulting

**Michael Cropp, MD, MBA**
- President and CEO
- Independent Health

**Michael Thompson, FSA**
- President and CEO
- National Alliance of Healthcare Purchaser Coalitions

### PUBLIC HEALTH
**A. Mark Fendrick, MD**
- Director
- Center for Value-Based Insurance Design (V-BID)
- University of Michigan

**Miriam Patanian, MPH**
- Lead Consultant
- Cardiovascular Health Team
- National Association of Chronic Disease Directors

**Marcus Plescia, MD, MPH**
- Chief Medical Officer
- Association of State and Territorial Health Officials

**Fortunato “Fred” Senatore, MD, PhD, FACC**
- Medical Officer, Division of Cardiovascular and Renal Products
- Center for Drug Evaluation and Research
- U.S. Food and Drug Administration
**What is FH?**

Shared Decision Making (SDM) is a collaborative process enabling both patients and providers to make healthcare decisions together. It takes into account both medical information and patient preferences.

The SHARED approach was created to help facilitate the SDM process, which can help improve patient outcomes, rates of self-management, satisfaction with care, and lower healthcare costs.*

---

**S**
Seek Your Patient’s Participation

What do I need to do? How does this impact my family?

FH is different. It’s genetic. It’s not your fault. Treatment can lower risk.

---

**H**
Help Your Patient Explore and Compare Treatment Options

Can you tell me about my treatment options, do I have to take medication?

The goal of treatment is to lower LDL cholesterol and therefore, lower your risk for heart disease. Often, a combination of treatments are needed, including medication.

---

**A**
Assess Your Patient’s Values and Preferences

Are there side effects? Will these treatments work for me?

There are several statins available. Usually, you can find one that works for you without side effects. Some people experience muscle aches from statins, but most muscle symptoms are not related to statin therapy.

---

**R**
Reach a Decision With Your Patient

What would treatment look like for me?

Let’s take a look at your goals for the next month. We want to focus on healthy eating, exercise, and sticking to your medication.

---

**E**
Evaluate Your Patient’s Decision

What if I have challenges in sticking to my goals?

By sticking to these goals, we hope to see a decrease in your LDL cholesterol. Don’t be discouraged as challenges arise.

---

**D**
Decide Which Local Resources Will Effectively Support the Patient and How To Connect

Are there any other resources available to help me? Is there an advocacy group for FH?

Your FH Care Team includes me, a nurse practitioner, registered dietician, and a pharmacist. We can help.

---


National Forum’s Value & Access Initiative is made possible through support from Amgen (Founding Sponsor), Sanofi/Regeneron, Mended Hearts, National Lipid Association, Partnership to Improve Patient Care, and Preventive Cardiovascular Nurses Association.
Seek Your Patient’s Participation

Why Does FH Diagnosis and Management Matter?

• FH is different. It’s genetic and it’s not your fault. Having FH means a lifelong exposure to high LDL cholesterol (LDL-C).

• FH is high risk, meaning that it increases your risk for the following: early heart attack, the need for stents or bypass, peripheral artery disease, and even sudden cardiac death.

• The good news is that FH treatment can lower risk.

• Protect your family. If you have FH, each of your children has a 50% chance of also having it. Get them screened to find out.

What can you do to lower your LDL-C? FH Management

Because people with FH start with such high LDL cholesterol, a combination of more than one treatment might be needed to lower LDL-C enough.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Approximate LDL-C Lowering Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Healthy Diet and Regular Exercise</td>
<td>↓10-15%</td>
</tr>
<tr>
<td>Statins: First line treatment. Safe and effective.</td>
<td>↓35-55%</td>
</tr>
<tr>
<td>Non-statins:</td>
<td></td>
</tr>
<tr>
<td>• Ezetimibe</td>
<td>↓18-25%</td>
</tr>
<tr>
<td>• PCSK9 inhibitors</td>
<td>↓40-65%</td>
</tr>
<tr>
<td>• Bile acid sequestrants</td>
<td>↓18-25%</td>
</tr>
<tr>
<td>Other options:</td>
<td></td>
</tr>
<tr>
<td>• LDL apheresis</td>
<td>↓20-40%</td>
</tr>
<tr>
<td>• Lomitapide for HoFH only</td>
<td>↓35-50%</td>
</tr>
<tr>
<td>Control other risk factors (manage blood pressure &amp; diabetes, maintain a healthy weight, don’t smoke).</td>
<td></td>
</tr>
</tbody>
</table>


Help Your Patient Explore and Compare Treatment Options

Help Your Patient Explore and Compare Treatment Options

Let’s take a look at the treatment options that are best for you

Assess Your Patient’s Values and Preferences

Questions to Ask about Treatment:

Will these treatments work for me?

• Statins have been studied in clinical trials in 200,000+ people over 30 years and have been shown to be safe and effective in preventing cardiovascular disease.

• Large reductions in LDL-C result in large reductions in CV risk.

• All of these treatments have shown a benefit for both men and women.

• Women who are pregnant or breastfeeding should not take statins.

Are there side effects to the medications?

• Some people who take statins will experience muscle aches but most muscle symptoms are not related to statin therapy. Stopping and retrying statins can help determine if symptoms are related to treatment. If you experience rhabdomyolysis symptoms (muscle pain or weakness, or dark/decreased urination), a very rare side effect, stop your statin and call me right away.

• There are seven statins available. Usually you can find one that works for you without side effects.

• There is a small increased risk for diabetes with statins in people who have other risk factors for diabetes. The benefit of statins for reducing heart attack and stroke risk outweighs the small increase in risk of diabetes. Regular physical activity and weight control also reduce the risk of diabetes.
Reach a Decision With Your Patient

My Treatment Plan
Date: _______________ For the next _____ months
Diet goals: __________________________________  Exercise goals: __________________________________
_____________________________________________________________________________________
Other risk factor goals: ___________________________________________________________________
_____________________________________________________________________________________
Medication: ______________  Medication: ______________  Medication: ______________
Dose Frequency  Dose Frequency  Dose Frequency
Lab test:_____ months  Next appointment: _____ months

Evaluate Your Patient’s Decision

What do we hope to see?
• ______________________________________________________________________________________

What might get in the way of achieving your goals and what can we do about that?
• ______________________________________________________________________________________

Start small – each change you make adds up.

Decide Which Local Resources Will Effectively Support the Patient and How To Connect

Connect the FH Care Team
• Primary Care Physician: __________________________
• Nurse Practitioner: ______________________________
• Registered Dietician: _____________________________
• Genetic Counselor: _______________________________
• Pharmacist: _____________________________________
• Other Specialist Referrals: Pediatric Specialist, Cardiologist___________________________
• Health Insurance Plan: __________________________________

This is how I connect with my FH Care Team

Connect with the FH Foundation for Support and Education
www.theFHFoundation.org
What are Statin-Related Side Effects

**...AND WHAT DO I DO ABOUT THEM?**

Shared Decision Making (SDM) is a collaborative process enabling both patients and providers to make healthcare decisions together. It takes into account both medical information and patient preferences.

The SHARED approach was created to help facilitate the SDM process, which can help improve patient outcomes, rates of self-management, satisfaction with care, and lower healthcare costs.

**S**
Seek Your Patient's Participation

- Why do I need to take a statin?
- I've heard that statins might not be the best option.
- Statins are the most widely prescribed class of medications in the United States. Statins reduce the risk of heart attack, stroke and death in a wide range of patients.

**H**
Help Your Patient Explore and Compare Treatment Options

- What are the side effects of statins?
- How would I know if I can’t tolerate taking them?
- Although many patients have symptoms during statin therapy, serious side effects related to statins are very uncommon in clinical trials. Most patients with symptoms during statin therapy can switch to a lower dose or a different statin.

**A**
Assess Your Patient’s Values and Preferences

- What are some of my other treatment options?
- You can benefit from statin therapy to lower your risk. Do you want to retry a low dose of the statin you have? Or, try another statin at a low dose once or twice a week: There are seven statins we can try.

**R**
Reach a Decision With Your Patient

- How long do we try this out?
- Take the statin until our next visit. Call me if you have problems before then and we can decide what to try next.

**E**
Evaluate Your Patient’s Decision

- What resources are available to help me?
- Your Care Team includes me, a nurse practitioner, registered dietician, and a pharmacist. We can help.

**D**
Decide Which Local Resources Will Effectively Support the Patient and How To Connect

- What are Statin-Related Side Effects
- Taking a statin is one of the most effective ways to lower your risk of cholesterol build up in your arteries (atherosclerosis). It’s a silent disease that usually develops without any symptoms; and could lead to a heart attack or stroke.

- Why do I need to take a statin?
- I’ve heard that statins might not be the best option.
- Statins are the most widely prescribed class of medications in the United States. Statins reduce the risk of heart attack, stroke and death in a wide range of patients.

- What are the side effects of statins?
- How would I know if I can’t tolerate taking them?
- Although many patients have symptoms during statin therapy, serious side effects related to statins are very uncommon in clinical trials. Most patients with symptoms during statin therapy can switch to a lower dose or a different statin.

- What are some of my other treatment options?
- You can benefit from statin therapy to lower your risk. Do you want to retry a low dose of the statin you have? Or, try another statin at a low dose once or twice a week: There are seven statins we can try.

- How long do we try this out?
- Take the statin until our next visit. Call me if you have problems before then and we can decide what to try next.

- What resources are available to help me?
- Your Care Team includes me, a nurse practitioner, registered dietician, and a pharmacist. We can help.

### Seek Your Patient’s Participation

**Why Is Taking A Statin Important?**

- Taking a statin is one of the most effective ways to lower your risk of atherosclerosis (cholesterol build up in your arteries).
- Atherosclerosis is a silent disease that usually develops without any symptoms, until there is a blood clot, causing a heart attack or stroke.
- At least 1 in 3 people over their lifetime will experience a heart attack or stroke that will cause death or damage to the heart or brain.
- Statins are generally well-tolerated; and reduce all-cause mortality by 10% per 39 mg/dL reduction in LDL "bad" Cholesterol (LDL-C).
- The potential benefits of taking statins outweigh the potential risks for most people.

### Help Your Patient Explore and Compare Treatment Options

**What do you need to know about taking statins?**

- Statins have been studied in clinical trials in 200,000+ people over 30 years and have been shown to be safe and effective in preventing cardiovascular disease.
- Statins are recommended if you have:
  - Atherosclerotic cardiovascular disease (ASCVD)
  - LDL levels of ≥ 190 mg/dL
  - Type 2 diabetes
  - An estimated 10-year risk of ASCVD ≥ 7.5% and are between 40-75 years old
- Rates of muscle, liver and cognitive adverse events are similar in statin and placebo groups, and in high-versus moderate-intensity statins.
- Rates of serious myopathy/rhabdomyolysis, or hemorrhagic stroke are about 1/10,000 patients per year in randomized controlled trials (RCTs).
- In RCTs, the majority of patients reporting intolerance to two or more statins can tolerate 20 mg of atorvastatin.
- There are other treatment options that we can discuss, including: bile acid sequestrants, ezetimibe, PCSK9 inhibitors, fibrates, and viscous fiber (found in oat bran, legumes, & psyllium).
- Also, swapping mono- or polyunsaturated fats for trans fats or saturated fats could be beneficial.
- While they help and are important factors for your cardiovascular disease, diet and lifestyle changes alone don’t result in as much LDL-C lowering as they do in combination with a statin.
- There are seven statins available. Usually you can find one that provides the best results for you.

**Let’s take a look at the treatment options that are best for you.**

### Assess Your Patient’s Values and Preferences

**Statin-Related Side Effects are real, but uncommon.**

Below are some side effects that you might feel:

- Muscle aches in the legs, trunk, or shoulders and upper arms
- Muscle weakness
- And uncommonly, other symptoms

Stopping and retrying statins, under medical supervision, can help determine if symptoms are related to treatment. If you experience rhabdomyolysis symptoms (severe muscle pain or weakness, or dark/decreased urination), a very rare side effect, stop your statin and call me right away.

There is a small increased risk for diabetes with statins in people who have other risk factors for diabetes. The benefit of statins for reducing atherosclerosis, heart attack and stroke risk outweighs the small increase in risk of diabetes. Regular physical activity and weight control also reduce the risk of diabetes.

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Reach a Decision With Your Patient

It is recommended that you aim to maintain statin treatment in some form. However, the decision of whether to continue taking the statin is up to the patient.

The symptoms that I’m experiencing while taking my statin(s) include:

- Muscle aches in my legs, trunk, shoulders, or upper arms
- Muscle weakness
- Other: __________________________

Date: _______________ For the next _____ months

Heart-Healthy Diet goals: _______________________________________________________________________________

Exercise goals: __________________________________________________________________________________________

Other risk factor goals: ____________________________________________________________________________________

_________________________________________________________________________________________________________

Medication: _______________  Medication: ______________  Medication: ______________

Dose Frequency  Dose Frequency  Dose Frequency

Lab test: _____ months  Next appointment: _____ months

Evaluate Your Patient’s Decision

What are the benefits of taking a statin for you?

• _______________________________________________________________________________________________________

What might get in the way of achieving your goals and what can we do about that?

• _______________________________________________________________________________________________________

Decide Which Local Resources Will Effectively Support Your Patient and How To Connect

Connect with the Cardiovascular Care Team

- Primary Care Physician: __________________________________________
- Nurse Practitioner: _______________________________________________
- Registered Dietician: ______________________________________________
- Genetic Counselor: ________________________________________________
- Pharmacist: ______________________________________________________
- Other Specialist Referrals: Pediatric Specialist, Cardiologist_________
- Health Insurance Plan: ____________________________________________

This is how I connect with my Cardiovascular Care Team.


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**Shared Decision Making (SDM)** is a collaborative process enabling both patients and providers to make healthcare decisions together. It takes into account both medical information and patient preferences.

The **SHARED** approach was created to help facilitate the SDM process, which can help improve patient outcomes, rates of self-management, satisfaction with care, and lower health care costs.

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**S**  
Seek Your Patient’s Participation

- **What is ASCVD?**

- **How do I know if I have ASCVD or am at risk for ASCVD?**

- **Atherosclerotic Cardiovascular Disease (ASCVD) develops due to a buildup of sticky, cholesterol-rich plaque. Over time, plaque can harden and narrow your arteries. ASCVD causes heart attacks, strokes, symptoms from blocked arteries, and death.**

**H**  
Help Your Patient Explore and Compare Treatment Options

- **If I have ASCVD or am at risk for ASCVD, what can I do about it? Are there any side effects?**

- **Healthy lifestyle habits are the foundation for preventing risk factors and ASCVD events. With increasing age or higher risk factor levels, medications such as statins are often need to be added to reduce the risk of an ASCVD event and death.**

**A**  
Assess Your Patient’s Values and Preferences

- **What would treatment look like for me?**

- **Statins are recommended for all people with an ASCVD event and people at high risk of an ASCVD event. Although some people have symptoms during statin therapy, most can find a statin and dose that works for them.**

**R**  
Reach a Decision With Your Patient

- **How long do we try? How will I know if what I am doing is making a difference?**

- **Let’s set some goals for the next 1-3 months. We want to focus on healthy eating, exercise and taking your medication. After that time, we will check your LDL-C levels again.**

**E**  
Evaluate Your Patient’s Decision

- **What if I have challenges sticking to my goals? What resources are available to help me?**

- **Your Care Team includes me, a nurse practitioner, registered dietician, and a pharmacist. We can help.**

**D**  
Decide Which Local Resources Will Effectively Support the Patient and How To Connect

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Shared Decision Making for Atherosclerotic Cardiovascular Disease (ASCVD)

Seek Your Patient’s Participation

Why Is A Heart-Healthy Lifestyle Important?

- At least 1 in 3 people will experience a heart attack or stroke that will cause death or damage to their heart or brain.
- Eating a healthy diet, filled with vegetables, fruit, whole grains, and limiting sweets and red meats; exercising; maintaining a healthy weight; and not smoking, help reduce your risk for heart attack, stroke, and death and other health conditions.
- Knowing your ASCVD risk, LDL-C and blood pressure numbers is important; and can help your care team best assess whether the therapy is working for you.

Help Your Patient Explore and Compare Treatment Options

Why is taking medication important?

- In addition to a heart-healthy lifestyle, medications to lower your LDL-C level will reduce your ASCVD risk.
- Taking a higher intensity (dose) of statin will lower LDL-C more, and prevent more ASCVD events, than a lower dose. Most patients can tolerate higher intensities (doses) of statin.
- Once statin therapy is maximized, some high risk patients may benefit from further lowering their LDL-C with a nonstatin medication such as ezetimibe, a PCSK9 inhibitor or a bile acid sequestrant. High risk patients include those who have had more than one heart attack, stroke or other ASCVD event, those with ASCVD and multiple risk factors, or those with familial hypercholesterolemia with ASCVD or other risk factors.
- The more LDL-C is reduced the greater the ASCVD risk reduction, so it is important to lower LDL-C as much as possible from a statin before adding a nonstatin to further lower LDL-C.

Treatment: Approximate LDL-C Lowering Effect*:

- Heart Healthy Diet and Regular Exercise: ↓10-15%
- Statins: First line treatment. Safe and effective. ↓35-55%
- Non-statins:
  - Ezetimibe: ↓18-25%
  - PCSK9 inhibitors: ↓40-65%
  - Bile acid sequestrants: ↓18-25%

Assess Your Patient’s Values and Preferences

Questions to Ask About Treatment:

Will these treatments work for me?

- Statins have been studied in clinical trials in 200,000+ people over 30 years and have been shown to be safe and effective in preventing cardiovascular (CV)disease.
- Large reductions in LDL-C result in large reductions in CV risk.
- If you do not already have an ASCVD diagnosis, and are not sure about taking a statin, a Coronary Artery Calcium (CAC) score may better guide your decision.

Are there side effects to the medications or anything else I should know?

- Some people who take statins will experience muscle aches; but most muscle symptoms are not related to statin therapy. Stopping and retrying statins, under medical supervision, can help determine if symptoms are related to treatment.
- If you experience rhabdomyolysis symptoms (severe muscle pain or weakness, or dark/decreased urination), a very rare side effect, stop your statin and call me right away.
- There are seven statins available. Usually you can find one that works for you with no or minimal side effects.
- The benefit of statins for reducing heart attack and stroke risk outweighs the small excess risk of diabetes associated with taking them.
- We can also take a look at the potential out-of-pocket costs of therapies.

Reach a Decision With Your Patient

My Treatment Plan
Date: _______________ For the next _____ months
Heart-Healthy Diet goals: _________________________________________________________________________________
Exercise goals: __________________________________________________________________________________________
Other risk factor goals: ____________________________________________________________________________________
___________________________________________________________________________________________________________
Medication: _______________ Medication: _______________ Medication: _______________
Dose Frequency _______________ Dose Frequency _______________ Dose Frequency _______________
Lab test: _____ months Next appointment: _____ months

It is recommended that you aim to maintain statin treatment in some form. However, the decision of whether to continue taking the statin is up to the patient.

The symptoms that I’m experiencing while taking my statin(s) include:
- Muscle aches in my legs, trunk, shoulders, or upper arms
- Muscle weakness
- Other: ___________________________

On a scale from 1 to 10, with 1 being hardly noticeable, to 10 entirely negatively impacting my daily routine, I rate my symptoms as a __________.

Are these symptoms tolerable?  Y  |  N
Is my ability to exercise limited by these symptoms:  Y  |  N

Evaluate Your Patient’s Decision

What are the benefits of sticking with my treatment plan?
- _______________________________________________________________________________________________________

What might get in the way of achieving my goals and what can we do about that?
- _______________________________________________________________________________________________________

Decide Which Local Resources Will Effectively Support Your Patient and How To Connect

Connect with the Cardiovascular Care Team
- Primary Care Physician: __________________________________________
- Nurse Practitioner: _____________________________________________
- Registered Dietician: ____________________________________________
- Genetic Counselor: _____________________________________________
- Pharmacist: ___________________________________________________
- Other Specialist Referrals: Pediatric Specialist, Cardiologist_________
- Health Insurance Plan: _________________________________________

*References

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Best Practices for Pharmacy & Therapeutics (P&T) Committees

Health plans have a fixed amount of money each year to serve their entire population and must weigh the costs of treatment against the entire budget.

The P&T Committee is managed by the health plan and:

- Serves as expert knowledge area consultants
- Manages the formulary system (the list of medications and related information in the diagnosis, prophylaxis, or treatment of disease & promotion of health)\(^1\).
- Works in conjunction with the health plan’s medical and pharmacy departments

While plans that administer Medicare Part D or Medicare Advantage are mandated to have a P&T Committee made up of practitioners, there is not a set process.

The following checklist is presented as a model process for P & T Committees to consider when managing the formulary system in making equitable coverage decisions, focusing on evidence-based processes to select and promote treatments offering the best therapeutic outcomes, while minimizing potential risks and costs to patients.

Responsibilities of the medical leadership (health plan) in creating/managing a P&T Committee

- Ensure that the right people are on the P&T Committee and kept current on upcoming treatments
  - Actively practicing primary care physicians (particularly those focused on high-risk areas)
  - Actively practicing pharmacists and other health care professionals
  - Specialists covering the clinical needs of the majority of enrollees
  - Require full disclosure of conflicts of interest from health plan and pharmaceutical manufacturers (and recusal where there are known conflicts of interest)

- Provide guidelines on the authoring and reviewing of P&T Committee documents\(^2\)
  - This is the most highly ranked factor that could have a perceived beneficial effect on P&T Committee functions.

- Implement standardization across all sites
  - There is a higher likelihood of evidence-based practice with contribution by multiple party decision-making vs. single subject matter expert experience/opinion.\(^3\)

Responsibilities of the P&T Committee

- Gather unbiased, evidence-based information on the following factors to make a recommendation to medical leadership on whether the agent should be covered:
  - Safety
  - Clinical Efficacy
  - Patient convenience, adherence & satisfaction\(^4\)
  - Economic
    - Pricing – Can only come into consideration when there are multiple agents to choose from. With all else being equal, and the physician feeling that either/any of the agents could be prescribed, it is up to the health plans to negotiate pricing with the manufacturer.
If the medical staff leadership accepts a “yes” recommendation, determine how the agent should be made available
  - Agent should be made widely available without prior authorization form
  - Prior authorization required

If prior authorization is required, outline the criteria that must be met, and the process that patients must go through to ensure that safety and efficacy standards are being met, including:
  - Testing
  - Treatment
  - Other considerations

If prior authorization is required, outline the drug utilization management process
  - Medical Director reviews and respond to requests within 14 calendar days (expedited requests within 24 hours).
  - If prior authorization criteria are met, enter authorization into pharmacy billing system for filing, within a sufficient time period to ensure continued therapy under enrollee’s appropriate benefit tier.
  - If prior authorization is denied because criteria is not met, notify both the requesting provider and enrollee in writing, or if the enrollee has agreed to receive information in this manner, electronically, including the reason for denial and the process for appealing the decision.

If step therapy is required, outline the drug utilization management process
  - List specific step therapy criteria on formulary.
  - If claim for required medication is currently in health plan’s system, process the step therapy medication without approval from plan’s pharmacy customer service.
  - If a record of the required medication is not available, the prior authorization process should be followed (submit a request form to pharmacy services).

Non-formulary medications
  - Base reviews on diagnosis, formulary product(s) previously tried, evidence of efficacy, and medical necessity.
  - Generally, approve requests if enrollees have tried and failed formulary products due to either an inadequate response or a medical contraindication to their use, and for enrollees who are previously stable on certain medications that have been determined to be medically necessary.
  - Review and respond to requests in compliance with applicable regulations, not to exceed 14 calendar days. Review expedited requests within applicable regulation, (typically 24 hours)
  - If request does not meet criteria (diagnosis and results of previous therapy), medical director will review.
  - If prior authorization criteria are met, enter authorization into pharmacy billing system for filing, within a sufficient time period to ensure continued therapy under enrollee’s appropriate benefit tier. Notify requesting individual of approval. Notify member following regulatory protocol.
  - If prior authorization is denied because criteria is not met, notify both the requesting provider and enrollee in writing, or if the enrollee has agreed to receive information in this manner, electronically, including the reason for denial and the process for appealing the decision.
- Make available prior authorization forms and information easily available to physicians, so that they can make an immediate decision and start the process
  - Load form on physician desktop
  - Make available on portal

- Appeals Process
  - Communicate decisions on Medicare Part D enrollee appeals according to CMS policy and procedures
    - Standard redetermination involving requests for covered drug benefits = 7 calendar days.
    - Expedited redetermination = 72 hours within receiving request.
    - Health plan will forward the enrollee's request to an appropriate reviewing entity within 24 hours of the expiration of the appropriate adjudication timeframe if a decision is not made.
  - Communicate decisions on Non-Part D enrollee appeals pursuant to regulatory rules
    - Standard appeals involving requests for covered drug benefits = 30 calendar days.
    - Expedited appeals = within 72 hours of receiving request.
  - Make the opportunity available for enrollees to review the status or discuss the request with a decision maker and provide contact information.
  - Grant a temporary override to new enrollees processing through a grievance and appeal.
  - Make the opportunity available (outside of a prior authorization form) for the introduction of additional evidence related to prior authorization criteria, wherein appeals can be taken to an objective & independent third party regulatory committee whose decisions are binding.

- Review formulary on a quarterly basis

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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.


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ENDNOTES


28 What is ASCVD...And What Do I Do About It? 2019. https://www.nationalforum.org/collaborations/value-access-adherence/patient-resources/


38 Ibid.