WELCOME

We convene. We spark conversation. We accelerate collaboration.
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:00</td>
<td>Welcome &amp; Introductions</td>
<td>John Clymer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Executive Director, The National Forum for Heart Disease &amp; Stroke Prevention</td>
</tr>
<tr>
<td>3:02</td>
<td>Results from the ABC and ACC Survey: Eliminating Access Disparities</td>
<td>Keith C. Ferdinand, MD, FACC, FAHA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Professor of Medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tulane Heart and Vascular Institute, Tulane University School of Medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair, ABC Access Initiative</td>
</tr>
<tr>
<td>3:10</td>
<td>Guide to ASPC’s Mobile App</td>
<td>Seth Baum, MD, FASPC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>President</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The American Society for Preventive Cardiology (ASPC)</td>
</tr>
<tr>
<td>3:18</td>
<td>Access to Innovative Medicines Tool</td>
<td>Sue Koob, MPA</td>
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<td></td>
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<td>Chief Executive Officer</td>
</tr>
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<td></td>
<td></td>
<td>Preventive Cardiovascular Nurses Association (PCNA)</td>
</tr>
<tr>
<td>3:26</td>
<td>Q &amp; A</td>
<td></td>
</tr>
</tbody>
</table>

Results from the ABC and ACC Survey: Eliminating Access Disparities

Keith C. Ferdinand, MD, FACC, FAHA, FNLA, FASH
Professor of Medicine
Tulane University School of Medicine
Association of Black Cardiologists

National Forum for Heart Disease and Stroke Prevention
June 6, 2018
Why Focus on Access?

The issue:

Despite advanced therapies and new treatment options for patients with, or at risk for CVD, access remains a challenge, particularly for underserved minority patient populations.
Convened CV opinion leaders and advocacy experts from different areas to understand and address issues related to patient access.

Meeting held: November 11, 2016

ABC/ACC Survey to Address Information Gaps

- **Online survey:**
  - Sample of ABC and ACC active physicians
  - ABC cardiologists randomly selected
  - ACC cardiologists randomly selected from areas with higher proportion of households below poverty level
- **Invitation to participate through email communication**
- **Field period:** Jan. 23 – Feb. 16, 2018
- **N=159**

**Survey Objectives**

- Assess disparities in patient care
- Understand impact of prior authorization (PA) on care of underserved and minority patients
# Demographics

## Physician Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/African American</td>
<td>37%</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>36%</td>
</tr>
<tr>
<td>Asian</td>
<td>20%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>3%</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>6%</td>
</tr>
<tr>
<td>Refused</td>
<td>3%</td>
</tr>
</tbody>
</table>

## Practice setting

<table>
<thead>
<tr>
<th>Practice Setting</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Group</td>
<td>36%</td>
</tr>
<tr>
<td>Medical School/University</td>
<td>35%</td>
</tr>
<tr>
<td>Hospital</td>
<td>12%</td>
</tr>
<tr>
<td>Multispecialty Group</td>
<td>8%</td>
</tr>
<tr>
<td>Solo Practice</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>4%</td>
</tr>
<tr>
<td>None/Not in practice</td>
<td>1%</td>
</tr>
<tr>
<td>No answer</td>
<td>1%</td>
</tr>
</tbody>
</table>

N=159

Overall, physicians indicate an average of about 41% of the patients served by their practice are minority patients.
Ease or Difficulty Accessing New Therapies

Ability to access new pharmacologic therapies, such as:
- Angiotensin receptor-neprilysin inhibitors (ARNi)
- Novel oral anticoagulants (NOAC)
- Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i)

How easy or difficult is it for you to get access to new pharmacologic therapies (e.g., ARNI/PCSK9i/NOACs) for your patients from health plans/pharmacy benefit managers (PBMs)?

N=159
Access to CVD Therapies Limited

Prescriptions “Always” or “Often” delayed or denied\textsuperscript{1,2}

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|}
\hline
 & 2016 & (N=151) \\
\hline
NOACs (afib) & 36\% & 8\% & 44\% \\
ARNIs (heart failure) & 34\% & 17\% & 51\% \\
PCSK9is (hyper-lipidemia) & 25\% & 39\% & 64\% \\
\hline
\end{tabular}
\begin{tabular}{|l|c|c|}
\hline
 & 2018 & (N=157) \\
\hline
NOACs (afib) & 25\% & 3\% & 28\% \\
ARNIs (heart failure) & 26\% & 10\% & 36\% \\
PCSK9is (hyper-lipidemia) & 28\% & 26\% & 34\% \\
\hline
\end{tabular}
\end{table}


\textsuperscript{2}American College of Cardiology. Eliminating Barriers and Reducing Disparities. January - February 2018 Survey.
Do you have sufficient employee resources in place to properly manage prior authorization (PA) documentation, submissions, and appeals?

- **Sufficient employee resources to handle PA documentation, submissions and appeals**: 45%
- **Do not have sufficient employee resources to handle PA documentation, submissions and appeals**: 43%
- **Don’t know**: 11%
- **N/A**: 1%

N = 159
How Formulary Restrictions Impact Patients

In your opinion, how do medication formulary restrictions impact patients? N=159; multiple responses allowed

- Disparities in care: 75%
- Patient confusion and lack of understanding: 53%
- Increased medication discontinuation: 53%
- Reduction in patient adherence and persistency to medications: 46%
- Lower costs to system/insurer: 32%
- Worse patient outcomes: 31%
- Lower costs to patient: 11%
### Attitudes Toward Minority Health Care

<table>
<thead>
<tr>
<th>Statement</th>
<th>Top 2 box - total agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am in a position to make a difference in the quality of health care that minority patients receive</td>
<td>79%</td>
</tr>
<tr>
<td>Whites with heart disease are more likely than some minorities with heart disease to get the newest medicines and treatments</td>
<td>73%</td>
</tr>
<tr>
<td>Across the US, minority patients generally receive lower quality care than white patients</td>
<td>71%</td>
</tr>
<tr>
<td>Some minorities with heart disease are less likely than whites with heart disease to get specialized medical procedures and surgery</td>
<td>70%</td>
</tr>
</tbody>
</table>
### Attitudes Toward Minority Health Care

**N=159**

<table>
<thead>
<tr>
<th>Statement</th>
<th>Top 2 box - total agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I often think about what I can do to interact more effectively with my minority patients</td>
<td>67%</td>
</tr>
<tr>
<td>It is important for physicians to devote extra time to the health needs of their minority patients</td>
<td>66%</td>
</tr>
<tr>
<td>In health care, in general, clinically similar patients receive different care on the basis of race/ethnicity</td>
<td>58%</td>
</tr>
<tr>
<td>In my hospital or clinic, clinically similar patients receive different care on the basis of race/ethnicity</td>
<td>24%</td>
</tr>
</tbody>
</table>

*Please rate your level of agreement with the following statements*
## Being Part of the Access Solution

What role would you like to see the ABC/ACC have in helping to ease your burden of providing medication PA’s/documentation and overcoming insurance denials?

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take leadership in helping providers and patients reduce administrative burden of access to innovative new evidence-based therapies</td>
<td>65%</td>
</tr>
<tr>
<td>Develop standardized PA forms</td>
<td>61%</td>
</tr>
<tr>
<td>Create centralized repository to access formulary coverage information and patient assistance programs</td>
<td>48%</td>
</tr>
<tr>
<td>Communicate/disseminate guidelines and expert consensus pathways to better inform guideline directed care and medical necessity to satisfy requirements for PA</td>
<td>47%</td>
</tr>
<tr>
<td>Create more resources that help overcome barriers</td>
<td>45%</td>
</tr>
</tbody>
</table>

N=159
# ABC Commitment to Access

## Multi-sector Access Workgroups:
- PA Resource Kit
- Physician/Payer Meeting
- Medication Therapy Management (MTM) Pharmacy Program

## National Programs and Communication
- ABC/ACC Roundtable
- National Black Nurses Association (NBNA)
- National Medical Association (NMA)
- American Heart Association (AHA)

## Community/Grass Roots Programming
- Spirit of the Heart
  - Birmingham, AL
  - Houston, TX
  - Charlotte, NC
  - Macon, GA
  - Richmond, VA
  - Gary, IN
Thank you!
Gaining Access to PCSK9 Inhibitors: Unveiling of a New Mobile App

A Town Hall Series
ASCVD Is Not Going Away

• Approximately 15% of the U.S. adult population has either ASCVD or diabetes

• Only 55% of this population was treated with LLT with a subset attaining LDL-C targets, suggesting undertreatment of this high-risk population

Incidence of CV Events in the General Population Over the Past Two Decades

Elevated Lipids Have the Greatest Impact on MI Risk

INTERHEART Study: Population Attributable Risk from Various Risk Factors on Acute MI (Overall Population)

PAR = population attributable risk, which indicates the number or proportion of cases that would not occur in a population if the risk factor were eliminated.²

PARs from individual risk factors are reported. Note that the sum of individual PARs is greater than 100% because ‘cases’ can simultaneously be attributed to more than one risk factor and be counted twice. PAR percentages reflected here do not indicate the amount of risk that would decrease by addressing the identified risk factors.

*Irregular consumption of fruits and vegetables; †ApoB/ApoA1 ratio; INTERHEART Study. n=15,152 patients and 14,820 controls in 52 countries

Lower LDL-C is Better: Over 25 Years of Lipid Lowering Trials Consistently Demonstrate\textsuperscript{1,2}

Adapted from Raymond, et al.\textsuperscript{2}
Even Among Those Treated With High-Intensity Statins, Many US Adults With Cardiovascular Disease Are Not Achieving Recommended LDL-C Levels\textsuperscript{1,*,†}

Multiple etiologies may exist for failure to achieve desired LDL-C, including nonadherence, very high baseline LDL-C, and hyporesponsiveness to therapy.\textsuperscript{3-5}

\*Data obtained from the Truven Health MarketScan\textsuperscript{®} Research databases claims data. Cardiovascular disease was defined according to the ACC/AHA criteria.

High intensity statin was defined as >30 mg/day atorvastatin, >15 mg/day rosuvastatin, >60 mg/day simvastatin. Patients with a valid LDL-C assessment in 2013 were included if they were continuously enrolled in the dataset for 24 months prior to their LDL-C assessment; 2,707 patients met the ASCVD criteria; \textsuperscript{†}2011-2012 NHANES: A data analysis examined 131 established CVD patients taking statin therapy, representing 5.87 million individuals with established CVD in the US. Patients with established CVD were defined as those who reported being told by an HCP they had CHD, angina, MI, or stroke in the past (PAD and TIA were not captured in the survey) Statin use was self-reported and confirmed at the patient's NHANES visit.


Even on high-intensity statins ~60% of established CVD patients do not achieve LDL-C <70 mg/dL\textsuperscript{1}

80\% of established CVD patients on statin therapy do not achieve LDL-C threshold of <70 mg/dL\textsuperscript{2,†}

---

**Diagram:**
- X-axis: LDL-C, mg/dL
- Y-axis: Number of Patients
- Red shaded area: LDL-C <70 mg/dL
- 80\% of patients do not achieve LDL-C <70 mg/dL.
Unprecedented Barriers to Medication Access

A Growing Body of Evidence
Baum, et al. Showed Unprecedented Rejection Rates for PCSK9i

PCSK9i’s FDA approved for use in patients with ASCVD and FH

**BUT…**

- 83% claims rejected on first attempt
  - Flawed initial review process

- Higher approval rates with Medicare (57%) versus commercially insured (30%)
FH Foundation’s Findings: High Rejection Rates

All patients with at least one adjudicated claim for a PCSK9i or Ezetimibe prescription
N=1,112,876

Presumptive FH† in claims adjudication data
N=5,795

- Prescribed PCSK9i
  N=515
  LDL-C>190 mg/dL while on LLT‡
  N=237
  Claims Adjudication:
  Rejected: 150 (63.3%)
  Paid: 53 (22.4%)
  Abandoned*: 34 (14.3%)

- Prescribed Ezetimibe
  N=5,442
  LDL-C>190 mg/dL while on LLT‡
  N=2,573
  Claims Adjudication:
  Rejected: 232 (9.0%)
  Paid: 1,651 (64.2%)
  Abandoned: 690 (26.8%)

Diagnosed ASCVD§ in claims adjudication data
N=415,133

- Prescribed PCSK9i
  N=25,349
  LDL-C>100 mg/dL while on LLT†
  N=1,622
  Claims Adjudication:
  Rejected: 933 (57.5%)
  Paid: 426 (26.3%)
  Abandoned: 263 (16.2%)

- Prescribed Ezetimibe
  N=399,603
  LDL-C>100 mg/dL while on LLT†
  N=27,246
  Claims Adjudication:
  Rejected: 2,244 (8.2%)
  Paid: 1,651 (64.2%)
  Abandoned: 690 (26.8%)

- Prescribed Ezetimibe
  N=25,349
  LDL-C>100 mg/dL while on LLT†
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  Claims Adjudication:
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  N=27,246
  Claims Adjudication:
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  Paid: 1,651 (64.2%)
  Abandoned: 690 (26.8%)

†Patients presumed to have FH as defined by patients with (1) LDL-C levels that meet Make Early Diagnosis Prevent Early Death (MEDPED) criteria for FH who are not on lipid-lowering therapy (LLT) or (2) LDL-C levels above a threshold defined by adjusting MEDPED criteria by factoring a 30% reduction in LDL-C for patients adherent to LLT meeting AHA guidelines for moderate or high intensity statins
§Atherosclerotic Cardiovascular Disease as defined by diagnosis and procedure codes
‡Lipid-lowering therapy defined as high intensity statin +/- ezetimibe or moderate intensity statin + ezetimibe
¶Lipid-lowering therapy defined as high intensity or moderate intensity statin
*Patients whose final disposition was abandoned although prescription was approved
Knowles, et al. 10.1161/CIRCULATIONAHA.117.027705
Navar, et al. Showed in the First Year of Availability, Less than Half of Patients Prescribed a PCSK9i Received Approval

Of the approvals, less than one-third of patients prescribed PSCK9 inhibitors therapy never received therapy owing to lack of cost sharing.
Hess et al showed that what really matters for approval is your insurance, not your LDL!

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: 65+ vs 18.64</td>
<td>1.20 (1.05, 1.38)</td>
</tr>
<tr>
<td>Female vs Male</td>
<td>0.93 (0.84, 1.03)</td>
</tr>
<tr>
<td>Cardiologist vs PCP (FM, IM)</td>
<td>1.61 (1.42, 1.81)</td>
</tr>
<tr>
<td>Endocrinologist vs PCP (FM, IM)</td>
<td>1.23 (0.93, 1.61)</td>
</tr>
<tr>
<td>Other vs PCP (FM, IM)</td>
<td>1.40 (1.15, 1.70)</td>
</tr>
<tr>
<td>ASCV: Yes vs No</td>
<td>1.22 (1.10, 1.36)</td>
</tr>
<tr>
<td>LDL-C Value (Continuous)</td>
<td>1.000 (0.999, 1.001)</td>
</tr>
<tr>
<td>Ezetimibe Use (Within 12 Months of the Index Date)</td>
<td>1.5 (1.09, 1.42)</td>
</tr>
<tr>
<td>High Statin Intensity vs Not High Intensity</td>
<td>0.94 (0.81, 1.11)</td>
</tr>
<tr>
<td>Statin Use Prior 12 Months: 2 Statins</td>
<td>0.90 (0.74, 1.11)</td>
</tr>
<tr>
<td>Statin Use Prior 12 Months: 3 Statins</td>
<td>0.84 (0.47, 1.49)</td>
</tr>
<tr>
<td>Statin Use Prior 12 Months &gt;3 Statins</td>
<td>1.31 (0.25, 6.87)</td>
</tr>
<tr>
<td>Statin Duration (91-180 Days) vs (up to 90 Days)</td>
<td>1.01 (0.80, 1.28)</td>
</tr>
<tr>
<td>Statin Duration (181+ Days) vs (up to 90 Days)</td>
<td>1.20 (1.01, 1.42)</td>
</tr>
<tr>
<td>Statin Intolerant</td>
<td>0.86 (0.77, 0.96)</td>
</tr>
<tr>
<td>Payer: All Other vs Commercial</td>
<td>OR=12 (7.21)</td>
</tr>
<tr>
<td>Payer: Cash vs Commercial</td>
<td>OR=245 (63,953)</td>
</tr>
<tr>
<td>Payer: Medicaid vs Commercial</td>
<td>1.31 (0.85, 2.00)</td>
</tr>
<tr>
<td>Payer Medicare vs Commercial</td>
<td>5.37 (4.23, 6.80)</td>
</tr>
</tbody>
</table>
Very Few patients diagnosed with FH are prescribed a PCSK9i

109,224 Individuals were Prescribed a PCSK9i Through April 2017

110,577 Diagnosed FH Individuals

1,188 Diagnosed FH Individuals were Prescribed a PCSK9i

Underuse of PCSK9i’s When Finally Approved

Unpublished data, The FH Foundation
Why Do We Face This Perilous Problem?
Poor Utilization Review, Adjudication, and Oversight

PCSK9 Inhibitors: Florida

- PCSK9 Inhibitors
  - Patients with low density lipoprotein (LDL) cholesterol levels ≥150 mg/dL are eligible for PCSK9 inhibitors
- Analysis of Health Plan Coverage & Access
  - 45% of Health Plans approved
  - 22% of Health Plans rejected
  - 19% of Health Plans pending

- Favors Approval of PCSK9 Inhibitors
  - Factors: Cost, Evidence, Safety, Compliance, FEES
- Favors Rejection of PCSK9 Inhibitors
  - Factors: Effectiveness, Cost, Evidence, Compliance, FEES

- Factors: Cost, Evidence, Safety, Compliance, FEES

- Favors Approval of PCSK9 Inhibitors

- Favors Rejection of PCSK9 Inhibitors
Continued and Tireless Progress for Improvement

2016 to Present
We Are Making Headway

- Town Hall Meetings
- Developed Consortium of Associations
- Publication on Insights and Recommendations

- Town Hall Meetings at Major Association Conferences
- Clinical Cardiology Consensus Paper

- Unveil Innovative Mobile App
- Initiate Collaborative Action Group
- Convene Town Hall Meetings at Major Conferences
- Debate Health Economics at Health Care Conferences
- Educate Healthcare Professionals
Download App and Improve Patient Care

Go to the App Store on your phone and search for:

ASPC App

DOWNLOAD ASPC APP
Download App and Improve Patient Care

Once Downloaded –
Click on ASPC App to
Begin Improving Patient Care
When App opens

Register for 2018 Congress

Get PCSK9i access for your patients
“PCSK9i Access Made Easy” App Interface

Click on one of the easy to follow tabs for any situation.
Approval Made Easy: Step-by-Step

10 Simple Steps
- ASPC PCSK9 Paper
- Tools if Denied
- Insurance Plans
- St. Ins. Comiss.
- OHSU Method
- Partner Orgs.
- Other Resources
- Drug Valuation

Facilitating Patient Access To PCSK9 Inhibitors
10 Actions That Optimize the Approval Process

Developed by Seth J. Sauter, MD, FACC, FACP, FAHA, FNA, FASPC

"I consider the PCSK9 inhibitors to be the greatest advance in lipid-lowering therapy in the past 30 years. I've had to fight to obtain these medications for my patients, and these are the techniques I've used."

— Seth J. Sauter, MD

1. Satisfy Indications for Use
2. Start the Patient on Samples
3. If Denied, Appeal, Use the Single-Page Appeal Form
4. Engage the Patient
PCSK9 inhibitor access barriers—issues and recommendations: Improving the access process for patients, clinicians and payers

Seth J. Baum1 | Peter P. Tobin2 | James A. Underberg2 | Paul Jelling3 | Joyce Ross5 | Katherine Wilkerson

1Department of Integrated Medical Services, Kaiser Permanente Southern California, Downey, California, USA
2Department of Pharmacy Services, Kaiser Permanente Southern California, Downey, California, USA
3Department of Pharmacy Services, Kaiser Permanente Southern California, Downey, California, USA
4Department of Pharmacy Services, Kaiser Permanente Southern California, Downey, California, USA
5Department of Pharmacy Services, Kaiser Permanente Southern California, Downey, California, USA

Abstract
The prevalence of cardiovascular disease (CVD) and its related complications are a major health concern in the United States. The emergence of PCSK9 inhibitors has revolutionized the treatment of hypercholesterolemia, offering a new approach to lowering LDL-C levels in patients with heterozygous familial hypercholesterolemia (HeFH) and other high risk individuals. However, the high cost of these medications has raised concerns about access and affordability, particularly for low- and middle-income countries. This review discusses the challenges of accessing PCSK9 inhibitors, including barriers to treatment, and provides recommendations for improving access to these life-saving medications. The discussion highlights the need for a comprehensive approach that involves stakeholders from various sectors, including healthcare providers, patients, payers, and pharmaceutical companies, to ensure equitable access to these life-saving therapies.
Insurance Plans

Accredo
Aetna
Alliance Rx Walgreens Prime
Amber Pharmacy
Avella Specialty Pharmacy
BriovaRx Specialty Pharmacy
Cigna Specialty Pharmacy
CVS Specialty Pharmacy
Diplomat
Humana Specialty Pharmacy
Kroger Specialty Pharmacy
Senderra Rx Specialty Pharmacy
State Insurance Commissioners
Application of PCSK9 Inhibitors in Practice
Challenges and Opportunities
Tina M. Kofinas, P. Barton Ewell, Jonathan O. Paulson, Corney Wijck, Sergio Farias, Michael D. Shapiro

Atherosclerotic cardiovascular disease is a major contributor to global mortality and morbidity. The assessment and management of patients with cardiovascular disease requires a multidisciplinary approach that includes pharmacological therapy and lifestyle modifications. For patients who are not adequately controlled with maximally tolerated doses of high-intensity statins, PCSK9 inhibitors have emerged as a novel class of cholesterol-lowering agents. The approval of the first PCSK9 inhibitor, alirocumab, by the U.S. Food and Drug Administration (FDA) in 2015 marked a significant advancement in the management of hypercholesterolemia. This approval was based on robust clinical trial data demonstrating the efficacy and safety of PCSK9 inhibitors in reducing low-density lipoprotein cholesterol (LDL-C) levels, resulting in significant improvements in cardiovascular outcomes.

However, the use of PCSK9 inhibitors in clinical practice is complex and challenging. Healthcare providers must consider the patient's baseline lipid profile, comorbidities, and other risk factors when determining the appropriate use of PCSK9 inhibitors. Additionally, the cost of these medications is high, and insurance coverage is variable, which can impact patient access. The following viewpoints highlight some of the key challenges and opportunities associated with the use of PCSK9 inhibitors in clinical practice:

1. **Challenges**
   - **Cost:** The high cost of PCSK9 inhibitors can significantly impact patient access, especially in the absence of insurance coverage or in cases where the medications are not approved by the patient’s insurance plan.
   - **Coverage:** Variability in insurance coverage for PCSK9 inhibitors can lead to inconsistent access to these therapies, impacting patient outcomes.
   - **Monitoring:** Regular monitoring of patients taking PCSK9 inhibitors is necessary to assess for potential side effects and adjust treatment as needed.
   - **Lifestyle Modifications:** While PCSK9 inhibitors can lower LDL-C levels, they do not replace the need for lifestyle modifications, such as dietary changes and regular exercise, to maintain optimal cardiovascular health.

2. **Opportunities**
   - **Advanced Therapy:** PCSK9 inhibitors offer an advanced therapeutic option for patients with cardiovascular disease who are not adequately controlled with maximal statin therapy. They provide an additional layer of cholesterol reduction, potentially reversing atheromatous plaque and improving cardiovascular outcomes.
   - **Research:** Ongoing research into the long-term safety and efficacy of PCSK9 inhibitors is necessary to fully understand their impact on cardiovascular health.
   - **Policy and Advocacy:** Advocacy efforts are crucial to ensure that policymakers recognize the value of PCSK9 inhibitors and support their widespread adoption.

In summary, the use of PCSK9 inhibitors in clinical practice is a complex issue that requires careful consideration of patient needs, cost-effectiveness, and the integration of these therapies into broader cardiovascular management strategies.
Link to Partner Organizations

- Association of Black Cardiologists
- American College of Cardiology
- American Association of Clinical Endocrinologists
  [https://www.aace.com/](https://www.aace.com/)
- FH Foundation
  [https://thefhfoundation.org/](https://thefhfoundation.org/)
Link to Other Resources
Drug Valuation
Let's All Download the App to Improve Patient Care
Preventive Cardiovascular Nurses Association

ACCESS TO INNOVATIVE MEDICINES

Sue Koob, CEO
Implementing Effective Treatments: Beyond the Prescription Pad

While national guidelines may indicate which medications should be prescribed in particular situations, how do you make sure that these medications get into the hands of your patients?

Preauthorizations (PA):
Many new cardiovascular medications require a preauthorization—a process that can be complex and time-consuming for health care providers (HCPs).
Common Steps In PA Process (may repeat annually or when insurance changes)

Discuss process with patients and support people to ensure they meet initial criteria and are on board with necessary steps

Know the correct form or process for particular payer

Know the insurance plan-specific criteria

Does the therapy require an order from a cardiologist or other specialist?

- **YES** Make referral
  - Approval

  - Review appeal process (often needs patient/ family involvement) Sample Appeals Letter
  - Discuss with patient/ family
  - Complete reauthorization process—appeals letter

- **NO** Approval

  - Data from EMR, historical records, previous or concurrent providers, health information management (medical records)

  - Sample PCSK9 PA Form

  - Approval

  - Need more information/correction of information

  - Denial

Complete, submit and document in patient record

Response via email or phone

- Approval

- Need more information/correction of information

- Denial
# Data Frequently Requested by Payers for PAs

<table>
<thead>
<tr>
<th>Diagnosis/ICD-10 code <a href="http://www.icd10data.com/">http://www.icd10data.com/</a></th>
<th>PCSK9</th>
<th>NOACs</th>
<th>New HF therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FH</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>HoFH, HeFH</strong></td>
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<tr>
<td><strong>ASCVD</strong></td>
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<tr>
<td><strong>Statin intolerance</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication history (List brand and generic names; dose; duration for each)</th>
<th>PCSK9</th>
<th>NOACs</th>
<th>New HF therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statin intolerance</strong></td>
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<tr>
<td><strong>Maximally-tolerated statin</strong></td>
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<tr>
<td><strong>Ezetimibe</strong></td>
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<tr>
<td><strong>Bile Acid Sequestrant</strong></td>
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<tr>
<td><strong>Other lipid-lowering therapies</strong></td>
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<tr>
<td><strong>Apheresis</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab data</th>
<th>PCSK9</th>
<th>NOACs</th>
<th>New HF therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lipid panels, especially LDL-C</strong></td>
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<tr>
<td><strong>baseline</strong></td>
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<tr>
<td><strong>current (&lt;30 days)</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Information</th>
<th>PCSK9</th>
<th>NOACs</th>
<th>New HF therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASCVD</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>ACS/MI/Angina</strong></td>
<td></td>
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<tr>
<td><strong>Coronary/Other arterial revascularization</strong></td>
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<tr>
<td><strong>Stroke/TIA</strong></td>
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<tr>
<td><strong>PAD</strong></td>
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<tr>
<td><strong>Subclinical atherosclerosis</strong></td>
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<tr>
<td><strong>Pregnancy or plans for pregnancy</strong></td>
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<tr>
<td><strong>Renal disease</strong></td>
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</tr>
</tbody>
</table>

*PCNA Cardiology*
Glossary

ACE: Angiotensin converting enzyme inhibitor
ACS: Acute coronary syndrome  AHA: American Heart Association
ARB: Angiotensin-receptor blockers
ASCVD: Atherosclerotic cardiovascular disease
CrCl: Creatinine clearance
DVT: Deep vein thrombosis
eGFR: Estimated glomerular filtration rate
FH: Familial hypercholesterolemia
HeFH: Heterozygous familial hypercholesterolemia
HF: Heart failure
HF-PEF: Heart failure with preserved ejection fraction
HF-REF: Heart failure with reduced ejection fraction
HoFH: Homozygous familial hypercholesterolemia
INR: International normalized ratio
LDL-C: Low-density lipoprotein cholesterol
LFT: Liver function test
LVEF: Left ventricular ejection fraction
MI: Myocardial infarction
NOAC: Novel oral anticoagulant
NVAF: Nonvalvular atrial fibrillation
NYHA: New York Heart Association
PA: Prior authorization
PAD: Peripheral artery disease
PE: Pulmonary embolism
TIA: Transient ischemic attack
VTE: Venous thromboembolism
Best Practice Tips for Clinicians to Help Patients Access Medications

• Initial Conversation with Patients
• Office Procedures
• Communicating with Other HCPs
• Cost Considerations
• Patient Follow-up
• Patients as Their Own Advocates and Champions
Helpful Resources to Access Medicines

- Alliance for Patient Access (AfPA)
- The Coupon and Co-Pay Resource
- FH Foundation
- GoodRX
- Needy Meds
- Partnership to Advance Cardiovascular Health (PACH)
- Partnership for Prescription Assistance
- Patient Access Network (PAN)
- RxAssist
### Medication Adherence

Now that you’ve invested the time to get your patients the medication they need, how do you make certain they take it as prescribed?

<table>
<thead>
<tr>
<th>Factors that place patients at risk for non-adherence:</th>
<th>Assess patients for medication non-adherence; Questions to ask</th>
<th>Provide education to enhance medication adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cost of medicine</td>
<td>• Do you ever forget to take your medicine?</td>
<td>• Assess patient need for verbal and/or written information</td>
</tr>
<tr>
<td>• Concern over adverse effects</td>
<td>• How many times a week do you forget to take your medicine?</td>
<td>• Stress the benefits of therapies and reasons for prescribing</td>
</tr>
<tr>
<td>• Complexity of medication regimen</td>
<td>• Are you careless at times about taking your medicine?</td>
<td>• Use visuals such as risk communication tools</td>
</tr>
<tr>
<td>• Taking multiple medications</td>
<td>• What is the main reason you might miss your medicine?</td>
<td>• Highlight importance of lifestyle change along with medication to treat problem</td>
</tr>
<tr>
<td>• “Silent” conditions (medicines don’t make them feel better)</td>
<td>• Do you ever cut pills in half or skip medicines to save money?</td>
<td>• Use teach back to ensure patient understanding</td>
</tr>
<tr>
<td>• Forgetfulness</td>
<td>• Sometimes if you feel worse when you take the medicine, do you stop taking it?</td>
<td>• Create a collaborative environment to encourage questions</td>
</tr>
<tr>
<td>• Lack of prioritization of the importance of medication</td>
<td>• Do you feel better, do you sometimes stop taking your medicine?</td>
<td>• Explain how to take medication—frequency, time of day, with or without food, timing with other medications</td>
</tr>
<tr>
<td>• Low health literacy</td>
<td>• When you feel better, do you sometimes stop taking your medicine?</td>
<td>• Include patient support people in the conversation (family member, friend, etc.)</td>
</tr>
<tr>
<td>• Depression</td>
<td></td>
<td>• Can assist with information, questions and help with reminders</td>
</tr>
<tr>
<td>• Cognitive impairment</td>
<td></td>
<td>• Discuss tracking methods and reminder systems</td>
</tr>
<tr>
<td>• Medication as a reminder of the patient’s condition</td>
<td></td>
<td>• Pill boxes</td>
</tr>
<tr>
<td>• Don’t want to be perceived as “sick”</td>
<td></td>
<td>• Smart phone apps</td>
</tr>
<tr>
<td>• Makes patient feel “old” or “bad” about themselves for having to take a “pill” perceived “failure”</td>
<td></td>
<td>• Daily medication schedules</td>
</tr>
<tr>
<td>• Negative previous experience with drug therapies</td>
<td></td>
<td>• Calendar notifications when to request refills to avoid gaps in therapy</td>
</tr>
<tr>
<td>• Sometimes if you feel worse when you take the medicine, do you stop taking it?</td>
<td></td>
<td>• Discuss potential adverse effects</td>
</tr>
<tr>
<td>• Do you ever cut pills in half or skip medicines to save money?</td>
<td></td>
<td>• Tell patient you want to be called if they believe they are experiencing any adverse effect</td>
</tr>
<tr>
<td>• Sometimes if you feel worse when you take the medicine, do you stop taking it?</td>
<td></td>
<td>• Emphasize risks of stopping therapy or not taking therapy as directed</td>
</tr>
<tr>
<td>• When you feel better, do you sometimes stop taking your medicine?</td>
<td></td>
<td>• Schedule follow-up calls or visits to assess patient’s response to therapy</td>
</tr>
</tbody>
</table>

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PCNA PREVENTIVE CARDIOVASCULAR NURSES ASSOCIATION
Specialty Pharmaceuticals and Pharmacies

The fastest growing segment of the prescription drug market, specialty pharmaceuticals and pharmacies, may be new to cardiovascular clinicians. Typically, the products are used to treat chronic and/or rare diseases; they are often high-cost, and may be administered by injection or infusion. Many are biologics—drugs that are derived from living cells—including PCSK9 Inhibitor therapies. They typically require close patient supervision and monitoring, special handling, temperature control, and administrative processes resulting in the delivery of these medications by specialty pharmacies.

Cardiovascular clinicians will need to become familiar with the specialty pharmacies serving their area. Larger health care systems often have them within their institution while other specialty pharmacies are aligned with health plans, managed care organizations, or retail chains. Several independent specialty pharmacies also exist throughout the country.
Q & A
Thank You

• Next Partner Sharing Call – June 13th at 1:00 pm ET

• July Spotlight: Shared Decision-Making – date to be sent early next week

• To be spotlighted or share events and news for posting on the Value & Access Clearinghouse, please contact Jen Childress jen.childress@nationalforum.org