WELCOME
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Speaker(s)</th>
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</table>
| 12:30 | Welcome & Introductions                                                     | John Clymer  
John Clymer  
Executive Director  
The National Forum for Heart Disease & Stroke Prevention |
| 12:32 | Value-Based Insurance Design (V-BID) Improving Medication Adherence Without Increase in Total Health Care Spending | A. Mark Fendrick, MD  
A. Mark Fendrick, MD  
Director  
University of Michigan  
Center for Value-Based Insurance Design |
| 12:40 | National Alliance of Healthcare Purchaser Coalitions  
Remedy Partners Collaboration | Michael Thompson  
Michael Thompson  
President & CEO  
National Alliance of Healthcare Purchaser Coalitions |
| 12:48 | Scoping Document for ICER's Review of Canakinumab's ASCVD Indication         | Jennifer Robinson, MD, MPH  
Jennifer Robinson, MD, MPH  
Value & Access Initiative Steering Committee Chair |
Value-Based Insurance Design:

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

www.vbidcenter.org

@um_vbid
#VBID
Three-quarters of Americans feel that our country doesn’t get good value from its healthcare spending.

Policy discussions focus primarily on payment reforms aimed to slow the rate of spending growth.

Moving to value-based system requires a change in how we pay for care and how we engage consumers.

Making patients pay more for all services - “skin in the game” - is the most common approach to change consumer behavior.
Americans are Being Asked to Pay More for ALL Care Regardless of Clinical Value
I can’t believe you had to spend a million dollars to show that if you make people pay more for something, they will buy less of it.

Barbara Fendrick (my mother)
Patient Worry About Out-of-Pocket Healthcare Costs at All-Time High

A report from the Commonwealth Fund noted that patients are not confident they can afford high out-of-pocket healthcare costs.
Americans Do Not Care About Health Care Costs; They Care About What It Costs Them

**Lowering Out-of-Pocket Costs Is Top Health Care Priority**

- Lowering the amount individuals pay for health care
  - Top priority: 67%
  - Important but not a top priority: 26%
  - Not too important: 3%
  - Should not be done: 2%
- Lowering the cost of prescription drugs
  - Top priority: 61%
  - Important but not a top priority: 28%
  - Not too important: 6%
  - Should not be done: 3%
- Dealing with the prescription painkiller addiction epidemic
  - Top priority: 45%
  - Important but not a top priority: 38%
  - Not too important: 9%
  - Should not be done: 5%
- Repealing the 2010 health care law
  - Top priority: 37%
  - Important but not a top priority: 21%
  - Not too important: 7%
  - Should not be done: 31%
- Decreasing how much the federal government spends on health care over time
  - Top priority: 35%
  - Important but not a top priority: 33%
  - Not too important: 9%
  - Should not be done: 18%
One in Four Patients Have Difficulty Affording Their Prescription Medicines

Kaiser Family Foundation Tracker Sept 2016
Potential Solution for Blunt Consumer Cost-sharing: Value-Based Insurance Design (V-BID)

Sets consumer cost-sharing on clinical benefit – not price
• Implemented by hundreds of public and private payers
• ACA preventive care requirement
• Tricare
21 studies found improvement (range: 0.1–14.3 percent) in medication adherence

Increase in adherence was associated with no effect on total health care spending
V-BID: Bipartisan Political and Broad Multi-Stakeholder Support

- HHS
- CBO
- SEIU
- MedPAC
- Brookings Institution
- Commonwealth Fund
- NBCH
- American Fed Teachers
- Families USA
- AHIP
- AARP
- DOD
- BCBSA
- National Governor’s Assoc.
- US Chamber of Commerce
- Bipartisan Policy Center
- Kaiser Family Foundation
- American Benefits Council
- National Coalition on Health Care
- Urban Institute
- RWJF
- IOM
- Smarter Health Care Coalition
- PhRMA
- EBRI
- AMA
2018 Budget Bill Expands MA V-BID Model Test to all 50 States
WASHINGTON — Congress and the Trump administration are revamping Medicare to provide extra benefits to people with multiple chronic illnesses, a significant departure from the program’s traditional focus that aims to create a new model of care for millions of older Americans.
CMS and Congress created two overlapping paths for MA plans to implement VBID

**VBID Model Test**
- CMMI demonstration project with waiver of uniformity rule for participants only.
- Formerly in few states, will be in 25 states in 2019, all states by 2020.
- Has strict participation and application criteria, procedures.
- VBID benefits for Part C and Part D.

**General Flexibility**
- CMS reinterpretation of uniformity policy in 2019 final rule & HPMS guidance.
- Applies to all MA Plans. Part C only.
- No “application.” VBID benefits submitted in PBP as part of bid.
- Benefits must relate to clinical condition.
• HSA-HDHP reform – amend IRS guidance to allow pre-deductible coverage of chronic disease services
• Create a V-BID plan template that lowers premiums and provides more generous coverage of high value services
Moving V-BID Forward
Ongoing Policy Initiatives – Low Value Care

• Low Value Care - identification and removal of unnecessary services to create headroom for more spending on high value care

1. Diagnostic Testing and Imaging Prior to Surgery
2. Vitamin D Screening
3. PSA Screening in Men 75+
4. Imaging in First 6 Weeks of Low Back Pain
5. Branded Drugs When Identical Generics Are Available
National Forum for Heart Disease and Stroke Prevention

National Alliance of Healthcare Purchaser Coalitions
Remedy Partners

Discussion Guide
August, 2018
National Alliance Episode-Based Payment Initiative Overview

• Program objectives
  • Strategic alliance between National Alliance, Remedy Partners, coalitions (employers)
  • Build a national platform that would offer an accelerated path towards adoption of episode-based payment (and related value based benefit design)
  • Expand the capacity and capability of Member Coalitions to drive change in their markets
  • Achieve meaningful and financially relevant Payment Reform that can reduce waste and set a new bar for healthcare value across the country.

• By 2020, our collaborative relationship is intended to achieve:
  • Targeted bundles representing 34% of medical spend in the applicable markets
  • Targeted coalition markets represent at least 20% of National Alliance collective plan sponsor members
  • Targeted value-based plan designs adopted by at least 20% of Plan Sponsors participating in coalitions with meaningful lives in applicable markets
  • This is a “down payment” on a national “80% solution” that accelerates Value-based Payment Reform across the country
About the National Alliance

The National Alliance is dedicated to drive innovation, health, and value through the collective action of public and private purchasers. We accelerate the nation’s progress toward safe, efficient, high-quality healthcare and the improved health status of the American population.

Nonprofit network of Healthcare Purchaser coalitions:
• Approximately 50 coalitions with significant presence across the country
• Coalitions represent more than 12,000 purchasers and 45 million Americans
• Coalition member employers spend more than $300 billion on healthcare
• Includes public & private purchasers as well as Taft Hartley organizations

Assets and Capabilities
• Only healthcare purchaser-led organization with national/regional structure
• Distributed “change agents” across country with deep knowledge of issues and markets
• Strong relationships with key national (National Health Leadership Council) and regional stakeholders
• Established structures/processes to educate and influence purchasers and healthcare supply chain
• Trusted advisor to coalitions and purchasers based on objectivity, independence and competence
About Remedy Partners

Remedy Partners is the largest Awardee Convener in the BPCI program with 62% of the market share operating in 45 States with expertise in:

- Provider recruitment in episodes of care models, quickly scaling up across both BPCI and BPCI-A initiatives
- Multi-payer platform support
- Collaborative approach to provider engagement
Healthcare Costs Crushing Purchasers and Average American Family
Spending on healthcare isn’t just crowding out public sector investments.

**Sky High Prices**
Higher prices account for half of the total difference in national healthcare expenditures compared to other developed countries.

**Bloated Administration**
The U.S. also spends considerably more on health benefits administration than any other nation, adding up to $465 billion a year in excess costs.

**Over Utilization**
We also use more services than are needed, including low-value ones identified by Choosing Wisely, and constantly push to put more heads in beds.

**Unmitigated Cost Growth**
Employers are picking up ever-increasing share of healthcare sector’s costs. Employees have also paid a price with lower wage increases.

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1 Healthcare Spending In The U.S. And Other Countries, JAMA, 03/18.
Lessons from NHLC Value Discussion

Lessons from Purchaser Value Network Capstone

Success measures need to include:

- A large number of employers adopt best practices in payment reform
- Medicare payment policy aligned with employers and purchasers sending a consistent signal to health plans and providers
- Adopted changes in payments resulting in innovations in care delivery, leading to improved affordability and quality
- A healthy competitive marketplace which drives continuous innovation and improved value
- Broad implementation across markets to support national employer adoption

Lessons from Choosing Wisely & Waste Discussion

Physician Advisory Feedback:

- High interest in addressing low-value care (big opportunity)
- Many clinicians are unaware of Choosing Wisely and are challenged to keep up with current guidelines
- Risk-bearing entities are looking for profit opportunities, medical groups are able to do well by doing better
- Begin with an educational, collaborative “get with the guidelines” approach to physicians with aligned community and employer outreach to patients/public

Lessons from Hospital Pricing Equity Discussion

Observations from MedPAC:

- Hospitals’ all-payer operating margins reached a record high in 2015; slightly lower in 2016 but still near 30 year high.
- All-payer margins remain strong “because the growth of private-payer rates continues to rise faster than costs.”
- “When providers receive high payment rates from insurers, they face no particular need to keep their costs low, and so, all other things being equal, Medicare margins are low because [hospital] costs are high.”
The Essential Ingredients of a Functional Healthcare Market

What it will take to get it done:

Transparency

- Pricing transparency as a percent of Medicare
- Episode of care prices to understand the “all-in” costs
- State APCDs to publish benchmarks and averages that consumers can use to compare with health plan information
- Quality transparency on physicians and facilities that actually differentiates performance

Alternative Payment Models (APMs)

- APMs that reinforce providers' intrinsic motivation of doing well while doing good
- Double-sided risk with appropriate guardrails to reinforce financial accountability for use of resources
- APMs that include line of sight responsibility as well as some attachment to overall costs of care

Alternative Benefits Designs

- Benefit designs that don’t punish patients for taking care of themselves
- Double-sided risk with appropriate guardrails to reinforce financial accountability for use of resources
- Designs that intricately link price and quality transparency with daily decisions about care
- Benefits that drive patients to the highest value providers

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National Alliance Episode-Based Payment - A three way partnership

- National Alliance
- Regional Coalitions
- Remedy Partners
National Alliance Episode-Based Payment - Principles

- Strive To Align With Medicare
- Establish Fixed Cost, High Value Bundle Payments For Each Episode of Care in Every Target Market
- Prioritize Areas Most Financially Significant To Employers Where Known Opportunities Exist
- Develop A Sustainable Approach That Rewards Improved Value Over Time
- Strive for Parallel Execution

“If we build it they will come, if they come we will build it”
• Initial Fixed Fee Bundles
  Targeted at 10-30% off market averages (20% typical)

  • Offset by plan design buy-ups

• Developed off of industry-wide commercial data
  (estimated at 200% - 600% of Medicare)

• Growth targeted at CPI

Initial Commercial Bundle Categories
(Estimated at 34% of Total Health Spend)

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<thead>
<tr>
<th>Cardiology</th>
<th>OB/GYN</th>
<th>Orthopedics</th>
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<tbody>
<tr>
<td>Acute Myocardial Infarction</td>
<td>C-Section</td>
<td>Hip Replacement &amp; Hip Revision</td>
</tr>
<tr>
<td>Arrhythmia/Heart Block</td>
<td>Hysterectomy</td>
<td>Hip/Pelvic Fracture</td>
</tr>
<tr>
<td>CABG and/or Valve Procedures</td>
<td>Pregnancy</td>
<td>Knee Arthroscopy</td>
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<tr>
<td>Coronary Angioplasty</td>
<td>Well Baby Care</td>
<td>Knee Replacement &amp; Knee Revision</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>Vaginal Delivery</td>
<td>Low Back Pain</td>
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<tr>
<td>Heart Failure</td>
<td></td>
<td>Lumbar Laminectomy</td>
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<tr>
<td>Hypertension</td>
<td></td>
<td>Lumbar Spine Fusion</td>
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<tr>
<td>Pacemaker/Defibrillator</td>
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<td>Shoulder Replacement</td>
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Discussion

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mthompson@nationalalliancehealth.org
Steering Committee & Partner Feedback:
ICER Draft Scoping Document on Canakinumab for Atherosclerosis

August 8, 2018
The Institute for Clinical and Economic Review (ICER) has posted a Draft Scoping Document outlining a planned review of the comparative clinical effectiveness and value of canakinumab (Novartis) for cardiovascular risk reduction in people with atherosclerosis.

All interested stakeholders are encouraged to submit comments and suggested refinements to the scope to ensure all perspectives are adequately considered.

Also welcomes submissions on examples of low-value care practices within this clinical area. These submissions will inform a report section focused on strategies to reduce waste and preserve resources for high-value, potentially higher cost treatments.
What ICER is Looking For

Stakeholders are encouraged to submit commentary, citations, and guidance relevant to the topic of the upcoming review, especially for:

- Important patient-relevant and patient-centered outcomes, especially those not adequately captured in the clinical trial data
- Other benefits and disadvantages
- Key research needs
- Contextual considerations
- Any other input deemed relevant and critical to a comprehensive understanding of the evidence base
Background

- Patients with ASCVD remain at high risk for additional ASCVD events despite optimal treatment with high-intensity statin therapy and antiplatelet agents.

- Recently, PCSK9 inhibitors have been shown to reduce events in patients with ASCVD, but patients still remain at high risk.

- The Canakinumab Anti-Inflammatory Thrombosis Outcomes Study (CANTOS) 2017, found that canakinumab
  - reduces inflammation & ASCVD events in patients with a prior MI and a hsCRP ≥ 2 mg/L
  - Increased mortality from infectious causes

- Canakinumab initially approved as an orphan drug for several rare periodic fever syndromes and is very expensive. An FDA decision on an expanded indication for canakinumab that includes ASCVD is expected towards the end of 2018.
Key Stakeholder Organizations Identified by ICER

- Aetna, Inc.
- America’s Health Insurance Plans
- American College of Cardiology
- Anthem, Inc.
- Cigna, Inc.
- The FH Foundation
- International Atherosclerosis Society
- Mended Hearts
- National Forum for Heart Disease and Stroke Prevention
- Novartis AG
- Premera Blue Cross
- Society for Heart Attack Prevention and Eradication
- Society for Vascular Medicine
- UnitedHealthcare Services, Inc.
- Women Heart
Stakeholder Events

• ICER is seeking comments to refine their understanding of the clinical effectiveness and value of preventive treatments.

• The patients ICER spoke with were hopeful that canakinumab would provide an option for patients who are intolerant of statin therapy.
  – They did not think that need to give the drug by subcutaneous injection would be a major burden to patients.
  – They did express concerns about barriers to access for the drug including cost and insurance restrictions.
  – Outcomes that mattered to patients included energy level and an improvement in the number of days that patients could be active.
Scope of Clinical Evidence Review

• Evidence will be abstracted from randomized controlled trials as well as high-quality systematic reviews; high quality comparative cohort studies will be considered, particularly for long-term outcomes and uncommon adverse events.

• The evidence review will include input from patients and patient advocacy organizations, data from regulatory documents, information submitted by manufacturers, and other grey literature when the evidence meets ICER standards.
Atherosclerosis: Draft Scoping Document – Analytic Framework

Figure 1.1. Analytic Framework: Canakinumab for Atherosclerotic Cardiovascular Disease

Interventions:
- Long-term prophylaxis with:
  - Canakinumab

Population:
- Individuals with a history of MI and hsCRP ≥ 2 mg/L

Intermediate Outcomes:
- Lower hsCRP

Adverse Events:
- AEs
- Severe infections
- SAEs

Key Measures of Clinical Benefit:
- Mortality
- ASCVD Mortality
- Non-fatal MI
- Non-fatal stroke
- Unstable angina requiring hospitalization

AE: adverse event, SAE: serious adverse event, ASCVD: Atherosclerotic Cardiovascular Disease, MI: myocardial infarction, hsCRP: high-sensitivity C-reactive protein
Atherosclerosis: ICER Draft Scoping Document

**Populations**
- The population of focus for the review is patients with a prior MI and a high sensitivity hsCRP ≥ 2 mg/L despite use of aggressive secondary prevention strategies. Interventions.

**Intervention**
- Canakinumab 150 mg SC every three months

**Comparators**
- Intention to compare canakinumab to standard of care, which includes high intensity statin therapy and aspirin in patients able to tolerate those therapies.

- Do not expect to be able to assess the efficacy of canakinumab in patients who are receiving a PCSK9 inhibitor in addition to statin therapy.
### Table 1.1. Potential Other Benefits and Contextual Considerations

<table>
<thead>
<tr>
<th>Potential Other Benefits</th>
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<tbody>
<tr>
<td>This intervention offers reduced complexity that will significantly improve patient outcomes.</td>
<td></td>
</tr>
<tr>
<td>This intervention will reduce important health disparities across racial, ethnic, gender, socio-economic, or regional categories.</td>
<td></td>
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<tr>
<td>This intervention will significantly reduce caregiver or broader family burden.</td>
<td></td>
</tr>
<tr>
<td>This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.</td>
<td></td>
</tr>
<tr>
<td>This intervention will have a significant impact on improving return to work and/or overall productivity.</td>
<td></td>
</tr>
<tr>
<td>Other important benefits or disadvantages that should have an important role in judgments of the value of this intervention.</td>
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<table>
<thead>
<tr>
<th>Potential Other Contextual Considerations</th>
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<tbody>
<tr>
<td>This intervention is intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.</td>
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<tr>
<td>This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.</td>
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<tr>
<td>This intervention is the first to offer any improvement for patients with this condition.</td>
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</tr>
<tr>
<td>Compared to “the comparator,” there is significant uncertainty about the long-term risk of serious side effects of this intervention.</td>
<td></td>
</tr>
<tr>
<td>Compared to “the comparator,” there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.</td>
<td></td>
</tr>
<tr>
<td>There are additional contextual considerations that should have an important role in judgments of the value of this intervention.</td>
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Scope of Comparative Value Analyses

• As a complement to the evidence review, ICER will develop a simulation model to assess the lifetime cost-effectiveness of canakinumab compared to aspirin and a high-intensity statin.

• The drug currently has a price for its indications as an orphan anti-inflammatory drug for rare conditions; however, the pricing structure could differ for the cardiovascular indication.
Identification of Low-Value Services (Advances V&A Strategy)

• ICER will include in its reports information on wasteful or lower-value services in the same clinical area that could be reduced or eliminated to create additional resources in health care budgets for higher-value innovative services.

• These services are ones that would not be directly affected by canakinumab (e.g., and will allow assessment of any need for managing the cost of such interventions. revascularization, hospitalization for MI) as these services will be captured in the economic model.

• Rather, ICER is seeking services used in the current management of ASCVD beyond the potential offsets that arise from a new intervention.

• ICER encourages all stakeholders to suggest services (including treatments and mechanisms of care) that could be reduced, eliminated, or made more efficient (e.g., overuse of screening for CHD in asymptomatic individuals).
Timeline

• 8/13 – Deadline for partners to submit input to Jen (jen.childress@nationalforum.org)

• 8/14 – NF synthesizes partners' input

• 8/15 – NF sends out updated document to partners for review/sign off

• 8/20 – Deadline for partners’ final input and opt-out

• 8/22 – NF submits final document on behalf of V&A partners
Partner Spotlight presentations are available at

https://www.nationalforum.org/value-access-member-spotlight-webinars/