Value & Access
Partner Spotlight Webinar Series

September 11, 2019
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<td>12:30</td>
<td>Welcome &amp; Introductions</td>
<td>Jen Childress&lt;br&gt;Senior Public Health Consultant&lt;br&gt;The National Forum for Heart Disease &amp; Stroke Prevention</td>
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<td>12:32</td>
<td>Federal Policy and Advocacy Efforts</td>
<td>Amy Friedrich-Karnik&lt;br&gt;Vice President&lt;br&gt;Advocacy &amp; Communications&lt;br&gt;WomenHeart</td>
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<td>12:42</td>
<td>Policy and Advocacy Update</td>
<td>Sara van Geertruyden, JD&lt;br&gt;Executive Director&lt;br&gt;Partnership to Improve Patient Care (PIPC)</td>
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Value and Access: Federal Policy and Advocacy Efforts

WomenHeart
September 11, 2019
Federal Policy Agenda

Priorities:

- Access to Coverage and Care
- Equity and Access to Cardiac Rehabilitation
- Increased Representation of Women in Clinical Trials and Medical Research
- Full Funding for Heart and Stroke Research
- Pregnancy and Heart Disease
Access to Cardiac Rehabilitation Bill

New legislation would increase access to cardiac rehab for those with Medicare.

In 2018, Congress passed a law that would authorize advanced practice clinicians to supervise cardiac rehab under Medicare.

New bill (H.R. 3911) would:
- Move up the effective date of the new law to 2020 (currently set for 2024)
- Allow advanced practice clinicians to order cardiac rehab under Medicare
Proposed Rule that would eliminate the general prohibition on discrimination in health care settings based on gender identity.

WomenHeart helped draft comments and engage other patient and consumer organizations to oppose the rule, which would:

- Reduce the number of entities subject to non-discrimination requirements
- Eliminate protections against discrimination for certain populations, including LGBTQI patients
- Remove protections against discriminatory marketing practices and insurance benefit design
- Weaken protections that provide access to interpretation and translation services for individuals with limited English proficiency
Family planning clinics that receive federal Title X funding serve nearly 4 million people each year – and are often women’s only source of health care.

In addition to family planning, Title X providers offer preventive care:

- Height/weight/BMI
- Blood pressure
- Screen for Type 2 diabetes in asymptomatic patients with sustained high blood pressure

New federal rule – went into effect this summer – broadens the scope entities eligible to receive Title X funds, opening the door to those who are not licensed medical providers. Rule is unclear as to whether recipients must follow the program’s clinical recommendations.

WomenHeart submitted comments in opposition (July 2018) and signed amicus briefs in current legal challenges.
Amy Friedrich-Karnik
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Spotlight: The Partnership to Improve Patient Care

Sara van Geertruyden
Executive Director
September 11, 2019
Overview

- PCORI Reauthorization
- Perils of the QALY
- Emerging Efforts to Entrench Use of QALYs
- The Disability and Patient Response
- CMMI and Patient-Centeredness Criteria
- Shared Decision-Making
PCORI Reauthorization
Overcoming the Politics

- The Right:
  - A few Republicans warned that there’s little to stop the federal government from using CER results to average which medications or treatments achieve similar results for less cost.
  - When that happens, according to Sen. Pat Roberts (R-KS), it won’t be long before Medicare starts rationing care.

- The Left:
  - Establish within AHRQ a Center for Comparative Effectiveness (not independent).
  - Allow for cost comparisons.
  - Allow for use of cost effectiveness data to be used for coverage decisions.

- The Outcome:
  - Senator Max Baucus (D-MT) and Senator Kent Conrad (D-ND) introduced the Comparative Effectiveness Research Act in 2008, which evolved into the Patient-Centered Outcomes Research Act of 2009.
  - Passed as part of the Affordable Care Act (ACA) as compromise between right and left.
Friends of PCORI Reauthorization

- Co-chaired by PIPC Chairman Tony Coelho (D) and former Congressman Dr. Phil Gingrey (R)
- Purpose to convene a bipartisan, large and growing group of patient/family caregiver, provider, employers/payers, industry, and research stakeholders that have an interest in supporting reauthorization of PCORI in 2019
- 177 Member Organizations
- Letter signed by nearly 170 organizations to House and Senate leaders supporting PCORI reauthorization
  - Reauthorize PCORI and its current funding mechanism for at least an additional 10 years.
  - Ensure PCORI stays true to its mission of patient-centered research by maintaining its mandate to conduct comparative clinical effectiveness research.
- Resources available online for advocates
- Learn more and join at www.reauthorizePCORI.org!
PCORI Reauthorization 2019

- Expected to be part of a “health extenders” package including other programs that also require reauthorization
- Senators Cassidy (R-LA), Capito (R-WV), Warner (D-VA) and Van Hollen (D-MD) are leading PCORI reauthorization efforts in Senate
  - Discussion Draft expected soon
- On July 17, Congresswoman Degette (D-CO) led committee mark-up of House E&C bill H.R. 2328, the “Community Health Investment, Modernization, and Excellence Act”
  - 3 year reauthorization
  - 7 year reauthorization;
  - minor changes to PCORI’s national research priorities to include substance use, mental health, and maternal morbidity and mortality.
Key Issues

- Representation on Board of Governors
- **Length of reauthorization**
- Funding Sources
- Comparative clinical effectiveness research versus cost effectiveness analysis
- Prioritization of high cost treatments
- Dissemination and use of evidence
The Perils of QALYs
QALYs Have Historically Been Rejected by Policymakers

- The ACA explicitly prohibits PCORI from using the cost-per-QALY to determine effectiveness, and further restricts use in Medicare to determine coverage, reimbursement, or incentive programs.

- In 1992, HHS rejected Oregon’s prioritized list of covered services for Medicaid citing the potential for violating the ADA due to use of QALYs and cost effectiveness.
Oregon Health Plan

“Oregon's plan in substantial part values the life of a person with a disability less than the life of a person without a disability. This premise is discriminatory and inconsistent with the Americans with Disabilities Act.

Given the outpouring of comments received by this department and the White House on this issue, I am confident in saying Oregon would have been sued if we had approved the waiver, preventing Oregon from implementing the plan for years. Accordingly, we requested revision of the proposal to remove factors impermissible under the Americans with Disabilities Act.”


QALYs discriminate against people with disabilities by placing a lower value on their lives.

What’s the value of your life?

Person with Cancer

Person with Rheumatoid Arthritis

Person with Diabetes

Perfect Health

Death
Challenges with QALY Model

- Under population survey models, the non-disabled population may systematically overestimate the burden of life with disability.
  - Research suggests a majority of American public says they would rather have HIV than be blind (Scott, 2016).

- Common QALY measure (EuroQol-5D) rates inflammatory arthritis as “worse than death” (Harrison, 2009).
  - Significant variation between TTO and VAS quality of life assessments reported under EuroQol-5D

- Under models where PWD self-report QoL, well supported people with disabilities who report relatively high levels of quality of life due to access to adequate support may find it very hard to demonstrate sufficient gains in QoL due to treatment efficacy.
Why the evLYG Doesn’t Fix the Problem

• The evLYG **partially** mitigates the life-extension problem – if insurers use it.
• But it still offers payers a means of refusing access to an effective and beneficial drug
• The evLYG doesn’t address the undervaluing of quality of life improvements or ignoring clinical knowledge.
  – People don’t think of health in mild, moderate, severe terms
• QALY-based systems are less effective than condition-specific means of assessment
Lack of *Meaningful* Patient Engagement in Development of ICER Studies

Despite ICER acknowledging a majority of comments, only 27 percent were incorporated into final reports.

Comments from patient advocates were half as likely to be incorporated compared to other stakeholder groups.

**Percentage of Stakeholder Comments Incorporated Into ICER Final Evidence Reports**

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<th>Percentage</th>
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<td>Industry</td>
<td>33.2%</td>
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<td>Patient advocates</td>
<td>15.9%</td>
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<tr>
<td>Professional/provider societies</td>
<td>32.6%</td>
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<tr>
<td>Overall</td>
<td>27.2%</td>
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*All comments:* Industry, N=208; patient advocates, N=157; professional/provider societies, N=95

Research supported by Xcenda
Different People Respond Differently to the Same Drugs
For many conditions, such disparities are reflected in clinical knowledge – but not yet in research literature
Emerging Threats
State Use of QALYs

- The President’s budget proposed a 5-state demonstration inviting states to “make drug coverage decisions that meet state needs.”
- CMS opened door to restricted coverage in their response to MA proposed waiver:
  - “Adopting a closed formulary with at least a single drug per therapeutic class would enable MassHealth to negotiate more favorable rebate agreements with manufacturers... the majority of commercial pharmacy benefit managers (PBMs) have adopted such closed formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations.”
- MA considering the New York model
  - Massachusetts Disability Policy Consortium is leading efforts to ban QALYs
- Other state Drug Utilization Review Boards referencing ICER:
  - Oklahoma Example: ICER’s QALY-based studies were used as part of deliberations to impose prior authorization requirements on Takhzyro, medication for Hereditary Angioedema, and Zolgensma, medication for spinal muscular atrophy.
New York State Medicaid Drug Cap

Drug cap process:
- If projected spending exceeds the "drug cap" then the state can look for additional rebates
- The Dept of Health identifies drugs for review by the Drug Utilization Review Board (DURB)
  - At this time the DURB has only 1 of 3 consumer seats filled, themselves a small minority of the 23-seat board
- The DURB has used ICER as the benchmark for value in the past
  - This year's budget gave more explicit authority to use a third party like ICER to determine that “target” price despite letter signed by over 40 groups opposing provision in budget
- For a manufacturer that did not agree to target supplemental rebates, the commissioner can impose utilization management on all of the manufacturer’s drugs, not just the one targeted for supplemental rebates.
  - Utilization management tools include requiring prior authorization, directing managed care plans to stop covering the drugs, and promoting “cost effective” and clinically appropriate drugs in place of them, such as indicated by ICER.
• 59% of payers indicated that they used ICER reports (likely more so today as ICER is conducting more studies)  
  – May 2016 Survey conducted by Dymaxium

• Payers report using ICER reports to guide their drug information process and frequently using ICER reports to inform prior authorization and step therapy requirements.  
  – One payer specifically commented that ICER reports are reviewed in nearly every relevant clinical and value subcommittee.  
  – Study by ICON
A significant number of patients in five disease areas would lose access to treatments they are currently on, which their doctors deemed best for them, if Medicaid began utilizing an ICER-based formulary.

- Between 42% and 99% of patients across five disease areas would be required to switch treatments if Medicaid used ICER’s judgement to determine patient access.

- Essentially all Medicaid patients with MS would be forced to switch treatments, since ICER has deemed only one medication “high value” for MS, and it accounts for only .04% of prescriptions.

- 87% of Rheumatoid Arthritis prescriptions would change if Medicaid used an ICER-based formulary.
More than half of Medicare Part B beneficiaries in the selected disease areas would lose access to needed care if ICER’s judgments were used as a government value standard.

- Between 55% and 62% of patients across four disease areas would be required to switch treatments if Medicare used ICER’s judgement to determine patient access in Medicare Part B.

- The switch would most impact MS patients most significantly – nearly 93% of patients would lose access to the treatment their physician prescribed.
Implications for Veterans

• In 2017, ICER announced a partnership with the VA “to integrate ICER reports into the VA formulary management process of evaluating the comparative clinical effectiveness and value of drugs.”
  – Over 40 organizations signed a letter expressing concern to the VA

• In a recent review, PIPC found that ICER evaluated 54 drugs at low-intermediate value and 42 of them are not covered on the national VA formulary
Experience in Other Countries

**Worse Outcomes**
For breast, colon, lung and prostate cancers, 5-year survival rates are higher in U.S. than those in Canada, France, Germany, Italy, Japan and the U.K.

**Fewer Options**
Almost 80% of cancer medicines reviewed by U.K. health officials between 2007 and 2014 had some form of access restriction.

**Slower Access**
U.S. patients have access to cancer medicines on average 2 years earlier than patients in other developed countries.

See [www.pipcpatients.org/access](http://www.pipcpatients.org/access) to learn more about other countries.
Looming Federal Policy Threats

• The Administration proposing an International Price Index
• The House of Representatives may consider a model that would reference ICER studies and international prices (all based on QALYs/averages)
• States are considering reference to ICER studies under Medicaid
• DOD is now implementing Section 702 of the FY 2018 NDAA which seeks to “pay for value” by allowing drugs to be excluded from the formulary that “provides very little or no clinical effectiveness to covered beneficiaries and the Department under the program.”
  – It is not clear who defines “clinical effectiveness” and “value” for DOD
The Disability and Patient Response
Consortium of People with Disabilities

• CCD Developed principles for drug pricing:
  – Oppose the use of Quality Adjusted Life Years
  – Support Limits on Cost Sharing
  – Oppose Discriminatory Benefit Design
  – Don’t Use Access to Care as Leverage in Negotiations
  – Support and Strengthen Programs that Provide Access for People with Disabilities
  – Support Access to Generics, but not at Expense of Those who Need Brand Name Medications

  • See http://www.c-c-d.org/fichiers/CCD-Positions-on-Access-to-Prescription-Drugs.pdf
Support for CCD Principles

Allies for Independence
American Association of People with Disabilities
American Association on Health and Disability
American Association on Intellectual and Developmental Disabilities
American Medical Rehabilitation Providers Association
American Physical Therapy Association
American Therapeutic Recreation Association
Autism Society of America
Autistic Self Advocacy Network
Brain Injury Association of America
Center for Public Representation
Disability Rights Education & Defense Fund

Easterseals
Epilepsy Foundation
Justice in Aging
Lutheran Services in America-Disability Network
National Alliance on Mental Illness
National Association of Councils on Developmental Disabilities
National Council for Behavioral Health
National Down Syndrome Congress
National Health Law Program
The Arc of the United States
United Spinal Association
• Acknowledge diversity and differences among patients and people with disabilities
• Should not be misused by payers and policymakers to limit patient access
• Developed using transparent processes and methods
• Meaningfully engage with patient and provider organizations
• Rely on a range of sound, patient-centered sources of evidence
• Address costs and benefits that matter to the patient
• Produce evidence on the value of treatments based on patient-centered outcomes
A Better Way Forward: Partner with Patients

- Use patient-centered and transparent methods when utilizing evidence in making coverage decisions that impact patients’ access to medicines
  - National Health Council’s Value Initiative: Value Rubric, Get Ready Checklist, Educational Program
    - See [http://www.nationalhealthcouncil.org/value-initiative](http://www.nationalhealthcouncil.org/value-initiative)
- Do not depend on a single measure of value to determine coverage and care decisions and instead rely on a range of evidence developed using patient-centered methods
  - Center for Patient-Driven Value Assessment (PAVE)
  - Innovation and Value Initiative (IVI)
  - Multi-Criteria Decision Analysis (MCDA)
- Commit to full transparency around decision making that impacts patient access
  - Advance value-based benefit design that encourages clinically-appropriate treatment and adequately considers patient needs as recommended by clinicians.
CMMI and Patient-Centeredness Criteria
What do patients want?

• Establish, via rulemaking or legislation, the “patient-centeredness criteria” called for under Section 1115A of the Affordable Care Act, which requires evaluation of alternative payment models (APMs) against patient-centeredness criteria
• Convene patient and consumer advisory panels for each of the Innovation Center models under development as well as those currently being implemented, to help ensure each demonstration is meaningfully evaluated against appropriate measures of patient-centeredness
• Define “informed decision-making” as a core criterion of patient-centeredness and a goal of each alternative payment model
  – Advance shared decision-making aligned with National Quality Partners Playbook on Shared Decision-Making
  – Implement appropriate measures
  – Reimburse for care planning
Shared Decision-Making

• The National Quality Partners Playbook on Shared Decision-Making was a multi-stakeholder effort to advance SDM
• Patients and other stakeholders have reached out to CMS and CMMI asking for a focus on:
  – Advancing communication skills training for clinicians
  – Advancing a strategy for certification of decision aids
  – STOP mandates with unintended consequences
• Next Steps: Further education of CMS leaders about the Playbook and development of a patient-led effort to advance SDM including guidelines for high quality SDM.

Recordings Available

• Slides and audio from previous spotlights available at https://www.nationalforum.org/value-access-member-spotlight-webinars