Payer Use of Evidence

March 15, 2012

Comparative Effectiveness: A Real-World User’s Guide
Avalere Health LLC
Comparative Evidence and the Commercial Payer

- How do payers apply comparative evidence to formulary decision making?
- What are payer requirements for real-world comparative evidence?
- Are there specific situations where comparative evidence is critical to decision making?
- Guidance for industry partners in developing comparative evidence?
  - Selecting the comparator
  - Evidence standards
- How can the biases toward industry research be addressed?
Know Your Customer – What are their main motivations

- Responsibility for a large group of members
- Focus on most good most people
- Generalizability very important
- Digestible/applicable data
- Who are decision maker(s)
- Assume the best
Commercial Payer Decision-Making Process

**Evidence Review**
- Literature search conducted by dedicated internal staff
- Search may be supplemented by AMCP dossier
- Evidence may be graded or scored
- Recommendations are submitted to the P&T Committee

**Coverage Determination**
- Based on recommendations provided by internal expert staff, P&T Committee determines whether to add a drug to the formulary

**Value Assessment**
- In the final stage, a ‘value assessment committee’ will make decisions on formulary placement and benefit design, such as cost-sharing and utilization management
- A separate review of outcomes and financial data may be conducted to inform benefit design decisions

AMCP – Academy of Managed Care Pharmacy; P&T – Pharmacy and Therapeutics Committee
Inside View Of Pharmacy And Therapeutics (P&T) Committee

The P&T Committee is charged with policy development, communication and education, and formulary management.

Who Is Typically Involved

- Physicians
- Pharmacists
- Nurses
- Administrators
- Quality-improvement managers
- Other healthcare professionals and staff
- Medical staff and administration approve P&T committee appointments

Responsibilities

- Formulary system management
  - Reviews evidence to evaluate product value and recommend coverage decisions
  - Appraises, evaluates and selects medications for formulary on an ongoing basis
- Evaluates, educates and advises in all matters pertaining to medication use

Inside View Of Value Assessment

The Value Assessment Committee is responsible for making final formulary, tier placement and benefit design decisions for all products.

Who Is Typically Involved

- Physicians
- Pharmacists
- Administrators
- Economists
- Financial analysts
- Quality-improvement managers
- Other healthcare professionals and staff

Responsibilities

- Finalize formulary decisions
  - Reviews P&T Committee decisions and recommendations to make final determinations
- Benefit design management
  - Reviews clinical, outcomes and financial data and makes final cost-sharing and utilization management decisions

P&T Committee Assesses Clinical Evidence to Inform Recommendations for Coverage and Formulary Management

- Pharmacoeconomic studies re: appropriate, safe & cost effective therapy
- Peer reviewed medical literature
- Scientific evidence & standards of practice
- Well-established clinical practice guidelines

Clinical Justification for P&T Decisions

Coverage
Binding on Plan

*Use of prior authorization, step therapy, quantity limits or generic substitution.
Key Trends in Payer Decision-Making
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<th>Current</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>Payers are becoming more sophisticated in the evidence they use</td>
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<td>2</td>
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<td>Payers are requiring a broader range of evidentiary sources</td>
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<tr>
<th>Emerging</th>
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<tr>
<td>3</td>
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<td>Payers are increasing transparency on their evidence appraisal</td>
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<td>processes</td>
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<td>4</td>
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<td>Payers are using evidence as the foundation for value-based</td>
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<td>payment and delivery initiatives</td>
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<td>5</td>
<td></td>
<td>Payers are being engaged in translation and dissemination of</td>
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<td>evidence and research</td>
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Healthcare Trends Are Leading Payers to Become More Sophisticated in the Evidence They Use

| Limitations of RCT Evidence | Demand for evidence of effectiveness in real-world setting
|                            | Growing interest to use new study designs and data sources

| Increased Federal Investment in CER | ARRA allocated $1.1 billion toward CER
|                                  | ACA established the Patient Centered Outcomes Research Institute (PCORI)

| Emerging Data Sources | 46% of ARRA CER awards are for infrastructure¹
|                       | Private sector developing data infrastructure

Source: Avalere Analysis of EBM Navigator.
This has led to a greater demand for new types of evidence to supplement traditional data.

**Traditional**
- Efficacy
- Clinical
- Experimental
- Placebo

**Emerging**
- Efficacy + Effectiveness
- Clinical + Economic
- Experimental + Real-World
- Placebo + Comparative

**Evolving Trend**
- Increased generalizability
- Cost per value gained
- Real-world care setting
- Patient-relevant treatment choices

Which means...
Payers Require a Broader Range of Evidentiary Sources

Broad range of potential evidentiary sources, including:

- **Most**
  - Real-World Evidence (*Includes payer-generated CER*)
  - Third party reviews (*e.g., AHRQ, BCBS TEC, DERP*)
  - Clinical trial data from manufacturer (*AMCP dossier*)
  - Peer-reviewed literature

- **Least**
  - Prescribing Information (*FDA label, may be sole source of evidence*)
## Increased Transparency In How Payers Use Evidence: WellPoint’s Public Evaluation Criteria

- Payers are becoming more transparent regarding their internal decision-making processes

<table>
<thead>
<tr>
<th>Organization</th>
<th>WellPoint</th>
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<tbody>
<tr>
<td>Objective</td>
<td>WellPoint released comparative effectiveness guidelines in May 2010 to increase transparency regarding their formulary decision-making process</td>
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<tr>
<td>Key Points</td>
<td>Well-conducted CER or observational studies may complement RCT data</td>
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<td>WellPoint will evaluate:</td>
</tr>
<tr>
<td></td>
<td>» 1) Scientific credibility and rigor of the study</td>
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<td></td>
<td>» 2) Relevance of the study and generalizability to the WellPoint population</td>
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<td>WellPoint has tested their new guidelines on previously evaluated CER studies</td>
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<td>Guidelines</td>
<td>2010 comparative effectiveness guidelines rank CER studies on level of usefulness based on 23 different criteria regarding credibility, methodology, relevance, and other technical specifications</td>
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Evidence Is Driving Value-Based Purchasing Decisions: UnitedHealth’s Oncology Episode-of-Care Payment Model

- Payers are looking to realign payments and/or delivery to incentivize the provision of high-value care

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<tr>
<th>Organization</th>
<th>UnitedHealth Group</th>
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<td><strong>Design</strong></td>
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<tr>
<td>Focused on breast, lung, and colon cancer</td>
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<td>Physicians are paid flat rate for each regimen chosen</td>
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<td>- Any drugs prescribed outside of regimen will be reimbursed at cost</td>
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<tr>
<td><strong>Use of Evidence</strong></td>
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<tr>
<td>Various treatment regimens will be compared and evaluated to determine best practices</td>
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<td>- Cost will be considered in the analysis</td>
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<td>Physician groups will present performance data annually</td>
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<td><strong>Participants</strong></td>
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<tr>
<td>The Center for Cancer and Blood Disorders, Fort Worth, TX</td>
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<tr>
<td>Dayton Physicians, LLC, Dayton, OH</td>
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<tr>
<td>Kansas City Cancer Center, Kansas City, MO</td>
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<tr>
<td>Northwest Georgia Oncology, Marietta, GA</td>
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<td>West Clinic, Memphis, TN</td>
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Improving Provider Education: ARRA Funding Addresses Lack Of CER Training Among P&T Committees

- Payers and others are engaging with providers in order to translate and disseminate the most recent and relevant evidence

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<th>Title</th>
<th>Innovative Diffusion of Comparative Effectiveness Research</th>
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<td>Awardee</td>
<td>University of Arizona</td>
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| Objective | - Investigate awareness of CER guides by pharmacists and physicians  
- Identify critical skills needed to use these reviews in the P&T process  
- Provide CER-specific training to pharmacists and physicians involved in the P&T process |
| Participants | - Academy of Managed Care Pharmacy  
- American Society for Health-System Pharmacy  
- The P&T Society  
- Indian Health Service  
- National Association of State Medicaid Directors |

Questions?

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- Avalere Health LLC
- fwilmot@avalerehealth.net
Fiona Wilmot, MD, MPH
Vice President
Avalere Health

Fiona Wilmot MD MPH is a Vice President in the Evidence-based Medicine and Reimbursement Practices. Dr. Wilmot has over 20 years of experience in managed care with a focus on technology assessment, comparative effectiveness and formulary design.

For over 6 years, Dr. Wilmot served as the Medical Director of Policy, Pharmacy and Therapeutics for Blue Shield of California where she established medical and pharmaceutical coverage policies for 2.7 million covered lives. Additionally, she managed the Transplant Center of Excellence Program and served as liaison with California state regulators around the use of evidence in decision making as well as beneficiary appeals and grievances. Dr. Wilmot has served as Medical Director at Aetna and at a Northern California IPA. Her clinical experience includes working as a hospitalist as well as caring for patients a busy Internal Medicine practice. She has taught Medicine at the University of California San Francisco and is a frequent speaker and facilitator on healthcare business and policy issues. Prior to joining Avalere, Dr. Wilmot was an independent consultant assisting life science clients with navigating market access in commercial health plans.

Dr. Wilmot graduated from Stanford University with distinction in English Literature, and earned her medical degree from the Boston University School of Medicine. She received an MPH from the University of California Berkeley and completed her Internal Medicine training at Mt Zion/UCSF in San Francisco. Dr Wilmot is Board Certified in Internal Medicine.