Driving Evidence-Based Health Plan Coverage by Recognizing Gaps, Updating Practices

February 13, 2020
Moderator

Jennifer Graff
Vice President, Comparative Effectiveness Research
National Pharmaceutical Council
Employees and Consumers Have Factors to Weigh When Selecting a Health Plan

### Premiums, Deductibles, Estimated Costs, Doctor Networks Quality Ratings

<table>
<thead>
<tr>
<th>Plan</th>
<th>Yearly Cost Estimate</th>
<th>Cost in a Bad Year (7% Chance)</th>
<th>Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td>BlueChoice HMO HSA Standard Bronze $6,200</td>
<td>$7,930</td>
<td>$11,570</td>
<td>Anura, Julian H</td>
</tr>
<tr>
<td>BlueChoice HMO HSA Standard Bronze $7,250</td>
<td>$8,048</td>
<td>$13,218</td>
<td>Anura, Julian H</td>
</tr>
<tr>
<td>KP DC Gold 100/20/Dental</td>
<td>$8,227</td>
<td>$13,497</td>
<td>Anura, Julian H</td>
</tr>
<tr>
<td>KP DC Standard Gold 50/25/Dental</td>
<td>$8,271</td>
<td>$11,531</td>
<td>Anura, Julian H</td>
</tr>
</tbody>
</table>

Sample for Illustrative Purposes Only. DC Health Link.
Trying to Navigate Formularies Adds Another Layer of Complexity

<table>
<thead>
<tr>
<th>KP DC Gold 1000/20/Dental</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Your Prescription Drug Coverage</strong></td>
</tr>
<tr>
<td>Total prescription drugs found in-plan: 3 out of 3</td>
</tr>
</tbody>
</table>

**ATORVASTATIN (Oral Pill) - Oral Tablet - 10 mg**
Category: Cardiovascular Agents Sub-Category: Dyslipidemics, HMG CoA Reductase Inhibitors

- 1 Month In-Network Retail Pharmacy: Copay: $10.00, Copay: Not Applicable
- Prior Authorization Required: NO
- Step Therapy Required: NO

**LISINOPRIL (Oral Pill) - Oral Tablet - 20 mg**
Category: Cardiovascular Agents Sub-Category: Angiotensin-converting Enzyme (ACE) Inhibitors

- 1 Month In-Network Retail Pharmacy: Copay: $10.00, Copay: Not Applicable
- Prior Authorization Required: NO
- Step Therapy Required: NO

**REPATHA (Injectable) - Cartridge - 120 mg/ml**
Category: Cardiovascular Agents Sub-Category: Dyslipidemics, Other

- 1 Month In-Network Retail Pharmacy: Copay: Not Applicable, Copay: 35.00%
- Prior Authorization Required: YES
- Step Therapy Required: NO

**Important Disclaimer:** Although we have attempted to make this prescription search tool as accurate as possible, it may include drugs that are no longer in a plan’s list of covered prescription drugs (called a formulary). In addition, some drugs that do not appear in the prescription search tool results may be covered as medical benefits under a health plan and therefore may not display in the prescription search tool results even though they are a covered benefit.

A plan can change its formulary at any time. To confirm that a particular drug is covered by a plan, always check the plan’s latest formulary on the plan’s own website, or call the insurance carrier to confirm coverage by the plan.
Commercially Insured Patients Encounter Variations and Restrictions in Accessing Specialty Medications

Chambers JD. Specialty Drug coverage varies across commercial health plans in the US. Health Aff 2018;37(7):1041-7.
“Typical” Pharmacy & Therapeutics Committee Process to Develop Formulary Coverage

<table>
<thead>
<tr>
<th>Request for review for one of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>New treatment approval</td>
</tr>
</tbody>
</table>

Research and compilation of clinical information

Preparation of formulary monograph for P&T review meeting

P&T review meeting(s)

<table>
<thead>
<tr>
<th>Safety</th>
<th>Efficacy</th>
<th>± Cost</th>
</tr>
</thead>
</table>

Voting component for formulary status

Provide decision and rationale to relevant stakeholders

Objective Evaluation of Key Characteristics

- Clinical
- Economic
- Humanistic
Assuming there is some evidence to evaluate, it should be possible to get reasonable, open-minded people to agree on the results of this (evidence) step – David Eddy
Today’s Objectives

• Describe:
  • Gaps between evidence and coverage policies; variation across health plans in the quantity, breadth and types evidence used to inform coverage policies.
  • The challenges associated with variations in evidence and coverage policies for specialty medicines present to patients, clinicians and the health care system as a whole.
  • The current state of formulary development practices and priority considerations for stakeholders.
Jennifer Graff, PharmD
Vice President, Comparative Effectiveness Research
National Pharmaceutical Council (Moderator)

Scott Thompson
Area President
Gallagher Research & Insights

James Chambers, PhD, MPharm, MSc
Associate Professor of Medicine
The Tufts Medical Center Institute for Clinical Research and Health Policy Studies
How to Ask a Question

To Submit Questions
Submit questions and comments via the Questions section in the Control Panel.

Note: We may not be able to answer all questions in the time allotted.
James Chambers, PhD, MPharm, MSc
Associate Professor of Medicine
The Tufts Medical Center Institute for Clinical Research and Health Policy Studies
Variation in Commercial Health Plan Decision Making

- Covered – No restrictions
- Covered – Restrictions
- Not covered

Why Variation in Plan Decision Making?

1. Tailoring of decisions to specific populations

2. Differences in financial resources

3. Differences in contracting

4. Inconsistency in the evidence used to support decision making
4,811 specialty coverage decisions from 17 of the 20 largest insurance companies reviewed

207 drugs

167 conditions
Data Source

- 200+ specialty drugs
- 150+ diseases
- 100+ biopharma companies
- 4,800+ coverage decisions
- 27,000+ citations
Nusinersen

Table of Contents

Coverage Policy .................................................. 1
FDA Approved Indications ......................................... 2
Recommended Dosing ............................................. 2
General Background .............................................. 3
Coding/ Billing Information ....................................... 7
References .......................................................... 7

Related Coverage Resources

Genetic Testing for Hereditary and Multifactorial Conditions

Coverage Policy

Nusinersen (Spinraza™) is considered medically necessary when ALL of the following criteria are met:

- Documented diagnosis of Type 1, 2, or 3 spinal muscular atrophy (SMA) supported by clinical records
- Onset of clinical signs and symptoms consistent with SMA at age 15 years or younger
- Genetic documentation of SMN1 or 5q SMA homozygous or compound heterozygous pathogenic or likely pathogenic gene variants
- The individual does not require permanent ventilation (defined as tracheostomy or ventilatory support for at least 16 hours per day for more than 21 continuous days in the absence of an acute reversible event)
- Established baseline motor ability, documented by the submission of medical records from ONE of the following exams:
  - Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
  - Hammersmith Infant Neurological Exam Part 2 (HINE-2)
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Revised Upper Limb Module (RULM) Test
  - 6-Minute Walk Test (6MWT)
References

Questions

1. What evidence do payers cite in their coverage policies?

2. Does cited evidence vary by health plan?

3. How consistent is the evidence plans cite in their policies?
Takeaway 1: Little Consistency in Evidence Cited by Commercial Plans

Does Cited Evidence Vary by Health Plan? Quantity of Cited Evidence

Average number of studies cited per document

All Plans (number of coverage policies)

Evidence Payers Cite in Their Coverage Policies (n=27,130)

- Randomized Controlled Trials: 17%
- Guidelines: 15%
- Other: 13%
- FDA Label: 11%
- Health Technology Assessments: 11%
- Editorials & Other Reviews: 11%
- Other Clinical Studies: 10%
- Real World Evidence: 7%
- Evidence Syntheses: 4%
- Economic Evaluations: 1%
- Other: <1%
Does Cited Evidence Vary by Health Plan?

Evidence Types

- Randomized Controlled Trials
- Real World Evidence
- Economic Evaluations
- FDA Label/Package Insert
- Synthesis, HTA, and Guidelines
- Others, Editorial

Little Consistency in Evidence for Health Plan Coverage Policies

- Only 15% of the health plan coverage policies for the same drug and same condition cited the same study
  - Only 38% of all studies were cited by more than one plan
- Volume of evidence cited as the basis for coverage policies varied
  - Ranged from 4 studies per policy at one plan to 64 studies per policy at another
- Types of evidence cited varied
  - Some site RCTs; others do not cite any evidence synthesis

1. Unclear if plans cited all the evidence they reviewed
2. Different plan committees may consider different evidence
3. Our findings might not be generalizable
4. We did not account for the quality of cited studies
Thank you!

jchambers@tuftsmedicalcenter.org
Panelist Questions

• What is most important to employers, patients, providers?

• How does the inconsistency in evidence used to inform coverage decisions impact you as a stakeholder?

• What incentives would be needed to facilitate greater consistency and transparency in evidence developed and used to guide coverage and reimbursement?
Presenters

Jennifer Graff, PharmD
Vice President, Comparative Effectiveness Research
National Pharmaceutical Council
(Moderator)

Scott Thompson
Area President
Gallagher Research & Insights

James Chambers, PhD, MPharm, MSc
Associate Professor of Medicine
The Tufts Medical Center Institute for Clinical Research and Health Policy Studies
What is most important to employers, patients, providers?
Panelist

Scott Thompson
Area President
Gallagher Research & Insights
Employers continue to navigate familiar challenges while keeping abreast of emerging issues and the implications these new dynamics will have.

Importance of Trends Impacting Pharmacy Benefit Management
(percentage rating highly important)

- Cost of specialty Rx biologics: 73%
- Consumerism (help manage their health and make smarter choices): 67%
- PBM transparency (from the employer perspective): 64%
- Availability of biosimilars: 60%
- Addressing employee compliance and adherence with prescribed medications: 54%

n=107 Employers
Approach to Health Plan Management of Specialty Medications and Biologics that Fall Under Medical Benefit (vs. Pharmacy Benefit)

- **14%** Not aware of health plan approach
- **11%** Aware but have not discussed or taken action
- **38%** Actively discussed
- **26%** Require active management
- **11%** Not applicable - Moved all coverage from the medical to pharmacy benefit

n=117 Employers
As employers grapple with the management of biologics, cost tops the list of worries

**Concerns Pertaining to Biologics**

*(percentage highly concerned)*

<table>
<thead>
<tr>
<th>Concern</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost to employer</td>
<td>87%</td>
</tr>
<tr>
<td>Cost to employee/patients</td>
<td>64%</td>
</tr>
<tr>
<td>&quot;Site-of-care&quot; pricing issues</td>
<td>63%</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>57%</td>
</tr>
<tr>
<td>Patient adherence</td>
<td>50%</td>
</tr>
<tr>
<td>&quot;Buy and bill&quot;</td>
<td>40%</td>
</tr>
<tr>
<td>Savings/copay cards</td>
<td>36%</td>
</tr>
<tr>
<td>Impact of productivity &amp; absenteeism</td>
<td>33%</td>
</tr>
<tr>
<td>Patient adherence 50%</td>
<td>50%</td>
</tr>
<tr>
<td>&quot;Buy and bill&quot; 40%</td>
<td>40%</td>
</tr>
<tr>
<td>Savings/copay cards 36%</td>
<td>36%</td>
</tr>
<tr>
<td>Impact of productivity &amp; absenteeism 33%</td>
<td>33%</td>
</tr>
</tbody>
</table>

n=107 Employers
Employers are largely willing to make a formulary change if presented with compelling evidence, yet just 26% have received this information.

### Employer Perspectives on PBM’s National Formulary and Exclusion Lists

*(percentage strongly agreeing)*

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Percentage Agreeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>If presented with compelling evidence we would be willing to make a formulary change with our PBM to cover a specific Rx</td>
<td>60%</td>
</tr>
<tr>
<td>We call on third party vendors (e.g., benefits advisors/consultants) to help us evaluate PBM drug lists</td>
<td>49%</td>
</tr>
<tr>
<td>We trust our PBM to be experts and largely rely on their drug coverage recommendations</td>
<td>42%</td>
</tr>
<tr>
<td>We want to better understand how formulary decisions are made</td>
<td>37%</td>
</tr>
<tr>
<td>We have been presented with clinical evidence to support making individual Rx decisions and evaluations</td>
<td>26%</td>
</tr>
<tr>
<td>We are reluctant to make formulary/exclusion list changes due to PBM financial penalties</td>
<td>20%</td>
</tr>
</tbody>
</table>

n=100 Employers

Note: Does not include those who were not given an exclusion list or develop and manage their own formulary.
EBCs and PBMs hold greatest influence in Rx decisions, but many also watch employer peers for outcomes of benefit design initiatives.

**Influence of External Stakeholders on Pharmacy Benefit Decisions**

- **Benefits Advisor/Consultant (pharmacy advisor if applicable)**: 58% very influential, 32% moderately influential, 90% total.
- **Pharmacy Benefits Managers (PBM)**: 35% very influential, 56% moderately influential, 91% total.
- **Specialty Pharmacy Provider (SPP)**: 26% very influential, 53% moderately influential, 79% total.
- **Health Plan/TPA**: 22% very influential, 62% moderately influential, 84% total.
- **Employer Peers**: 21% very influential, 65% moderately influential, 86% total.

n=107 Employers
Panel Discussion

Jennifer Graff, PharmD
Vice President, Comparative Effectiveness Research
National Pharmaceutical Council
(Moderator)

Scott Thompson
Area President
Gallagher Research & Insights

James Chambers, PhD, MPharm, MSc
Associate Professor of Medicine
The Tufts Medical Center Institute for Clinical Research and Health Policy Studies
How does the inconsistency in evidence used to inform coverage decisions impact you as a stakeholder?
What incentives would be needed to facilitate greater consistency and transparency?
Consistency in Evidence Evaluation is Not Unique to Plan Coverage

% of shared references across clinical practice guidelines for care

- Agence Nationale d'Accreditation et d'Evaluation en Sante'
- Canadian Medical Association
- Dutch College of General Practitioners
- American Diabetes Association
- Italian Society for Diabetology
- Catalan Society of Primary Care
- Scottish Intercollegiate Guidelines Network
- Institute for Clinical System Improvement
- New South Wales
- New Zealand Guidelines Group
- East London Guidelines for General Practice

Create Carrots and Sticks for More Consistent Use of Evidence

- P&T Model Practices (e.g., RWE expert, >1 trained member)
- More Complete Reporting (e.g., Core Template for Submission)
- Update Good P&T Processes (1999)
- Payer Research Prioritization (C-suite vs. contracting vs. medical)
- Enhance Processes
- Develop Better Evidence
21st Century Formulary Development Practices

Principles of a Sound Drug Formulary System

(2000)

- Principles of a Sound Drug Formulary System


- As a concise and robust set of principles for sound drug formulary system development and management. This document provides a framework for the development and implementation of sound drug formulary systems that are consistent with the needs of the patients and the healthcare system.

AMCP Principles for Sound P&T Practices (2020)


ABSTRACT

A 25-year history of sound drug formulary system development and management has led to the development of a robust set of principles that guide the development and implementation of sound drug formulary systems. These principles provide a framework for the development and implementation of sound drug formulary systems that are consistent with the needs of the patients and the healthcare system. This document provides a framework for the development and implementation of sound drug formulary systems that are consistent with the needs of the patients and the healthcare system.

The 21st Century Formulary Development Practices

- Principles of a Sound Drug Formulary System

- AMCP Principles for Sound P&T Practices

- ASHP Principles of a Sound Drug Formulary System
AMCP 2020: Principles and Best Practices

Evidentiary Considerations

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy.

Consider or include the following types of evidence in reviews:

- Randomized clinical trials, making sure to assess the study design and results objectively
- Real-world data, to provide additional context in coverage decision reassessments and formulary updates
- Cost-effectiveness research and modeling, to assess the value of a therapy
- Patient perspectives, to provide insight into the practical use of therapies and impact on quality of life outcomes.
- Expert opinions and reports from external organizations are helpful for reevaluations, new indications, and instances where limited data are available.
AMCP 2020: Principles and Best Practices

Training and Education

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities. Consider building educational programs to support the competencies of new stakeholders.

Provide training to all committee members and staff on the following:

- How to develop and present fair and relevant information in an accessible manner
- Methods, benefits, and limitations of various types of research approaches like health technology assessments, cost-effectiveness research, and economic evaluations
- Clinical data interpretation skills
- Value and cost-benefit assessments
Questions

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How to Ask a Question

Submit questions and comments via the Questions section in the Control Panel.

Note: We may not be able to answer all questions in the time allotted.
Key Takeaways

- Evidence A Key Part of Coverage Decisions. Not the Only Component.
- Incentives AND Infrastructure Required to Encourage Greater Transparency

Key Takeaways

More Transparent Evidence Evaluation

Assuming there is some evidence to evaluate, it should be possible to get reasonable, open-minded people to agree on the results of this (evidence) step - David Eddy

Better Informed Consumers Plan Selection and Appropriate Use
Thank you!

Your feedback is appreciated. Please complete the forthcoming evaluation survey.