Comparative Effectiveness Research

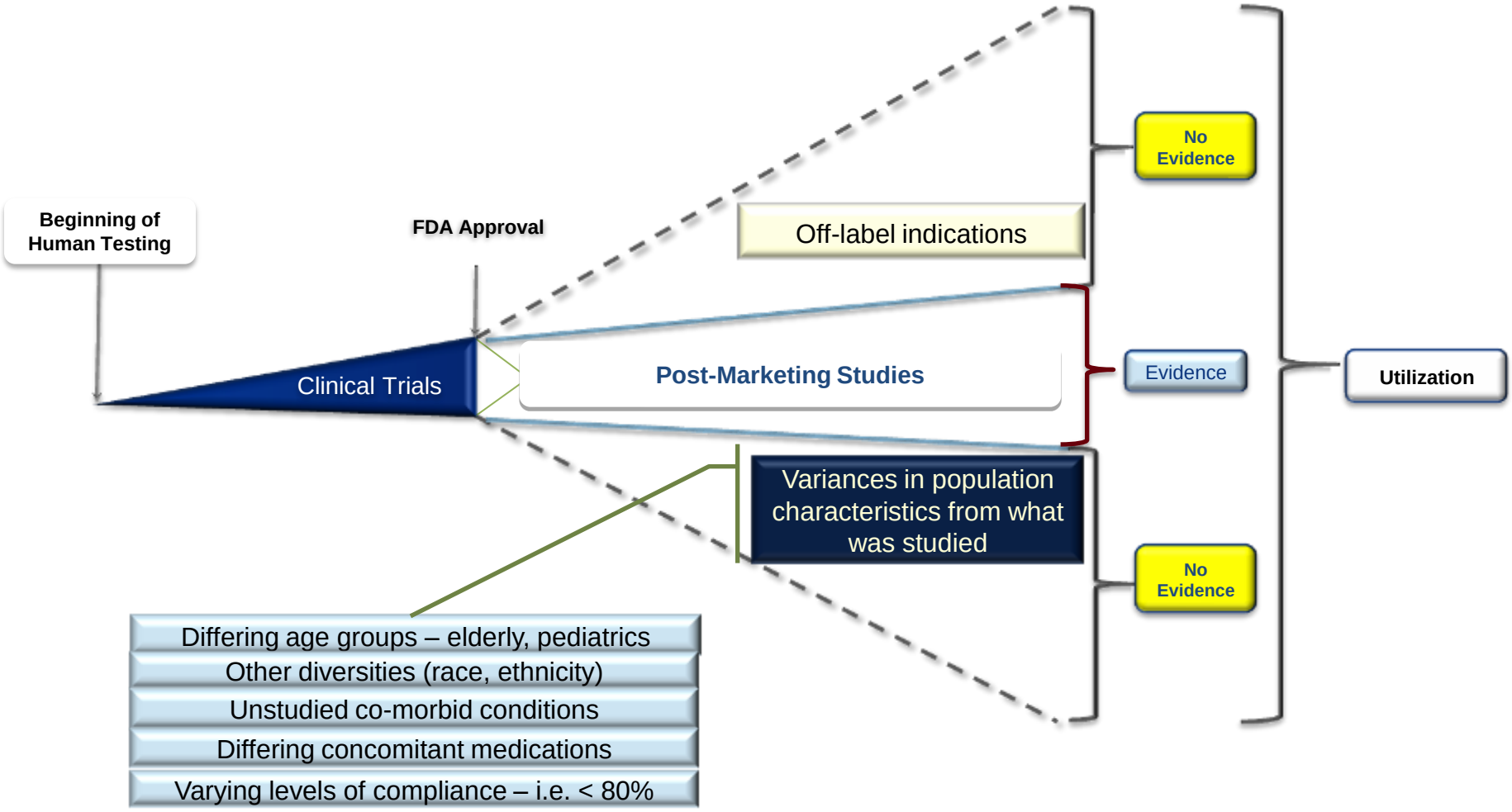
Informing Public and Private Payer Decision-Making

Brian Sweet, Chief Pharmacy Officer

June 24, 2010

WELLPOINT
Health. Care. Value.

How Evidence Begins

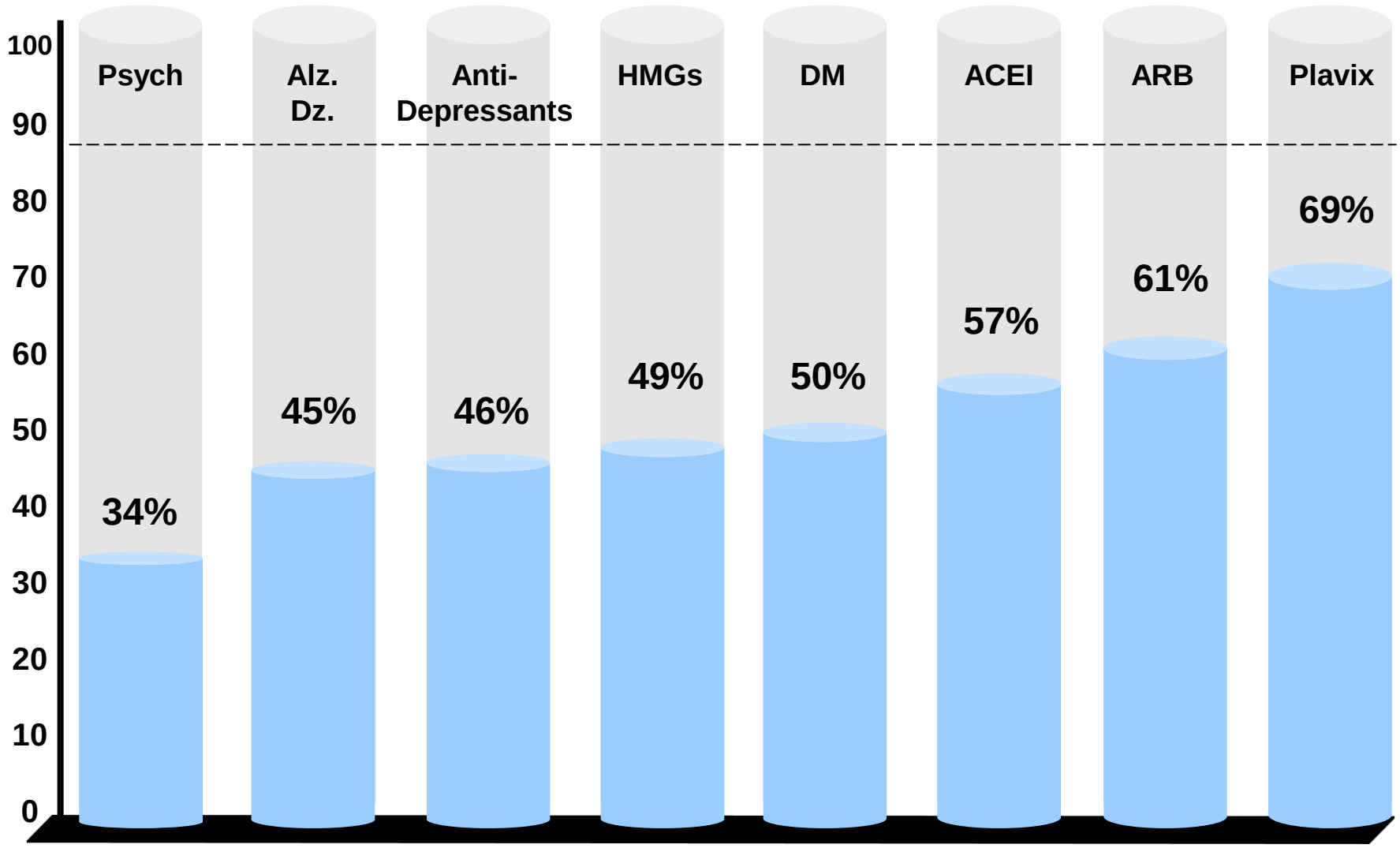


WELLPOINT
Health. Care. Value.

The Evidence Gap
Real-World Effectiveness

	Efficacy (Clinical Trial Data)	Effectiveness (Real-World Data)
Objective	Does it work under ideal circumstances	Does it work under usual circumstances
Setting / Design	Controlled clinical trial	Real-world clinical practice
Purpose	Regulatory approval (FDA)	Drug performance in real-world
Intervention or treatment	Fixed regimen	Flexible regimen
Comparator	Placebo	Active comparator/usual care
Subjects	Homogenous/highly selective (stringent inclusion/exclusion criteria)	Heterogeneous / any subjects
Compliance	High	Low to High
Outcomes	Clinical endpoints (e.g. BP, HbA1c, LDL)	Example: Cardiovascular events, hospitalizations
Internal Validity	High	Low
External Validity (generalize to other populations)	Low to medium	Medium to high

Real-World Adherence is Much Lower than Clinical Trial Adherence



WellPoint's Position on Comparative Effectiveness Research

Enables Physician-Patient Dialogue

Helps enable better informed decision-making

- Compare risks, benefits, and effectiveness of available treatment options
- What is best for a patient's health and financial situation?

Create true health care choices

Translate clinical evidence into action

- Disseminate clear information to public
- Provide decision-support to physicians

Why Should We Care About Comparative Effectiveness Research?

Helps us understand…

Sub-populations

Real-world experiences

Outcomes that matter most to patients

- Which drugs prevent me from having a bone fracture?
- Which blood pressure drugs reduce my risk of heart attack?
- Which cholesterol drugs reduce my risk of a heart attack?

Goal of Outcomes-Based Formulary

The goals of our Outcomes-based Formulary are to provide our members with drugs and therapies that will help:

- **Improve** clinical health outcomes
- **Improve** quality of life
- **Improve** productivity at work, school, and leisure activities
- **Reduce** total cost of care (pharmacy and medical)

A more expensive medication can be less expensive if the member's health is improved, resulting in use of less healthcare resources

- **Improved** health outcomes
- **Reduced** emergency room visits
- **Reduced** hospitalizations

WELLPOINT
Health. Care. Value.

Process of Outcomes-Based Formulary

Promote Evidence-Based Medicine (Critical Review of the Clinical Trial Data)

- We critically review the clinical trial data to determine if the study is of sufficient quality to be used for decision-making. Poor quality studies may have misleading results, and therefore are not used for decision-making.

Evaluation of the Clinical Value of a Drug

- High quality evidence is used to determine if a drug is favorable, comparable, or unfavorable to another drug. We provide drugs that will help result in better outcomes for our members.

Determine Real-World Outcomes and Total Cost of Care

- We conduct analyses using integrated pharmacy, medical, and lab data from one of the largest claims databases in the world. We are able to determine which drugs are most likely to result in favorable outcomes in a “real-world” setting.

Advance Health Care Quality and Improve Outcomes

- We combine high-quality clinical trial data and real-world outcomes data to provide our members with drugs that will result in optimal outcomes (i.e. clinical, quality of life, productivity, and total cost of care).

Outcomes-Based Formulary
Committee Overview

Integrated Pharmacy and Medical Analysis

Critical review of the literature, Assigns a clinical designation based on the evidence. Recommendations sent to the VAC

OUTCOMES ADVISORY COMMITTEE
Outcomes / Pharmacoeconomic Review

ACTUARIAL SUBCOMMITTEE TO VAC (ASVAC)
Analyzes Financial and Pharmacoeconomic Results

Reviews the clinical, outcome, and financial data and makes final tier placement decisions

Clinical appropriateness
FIRST

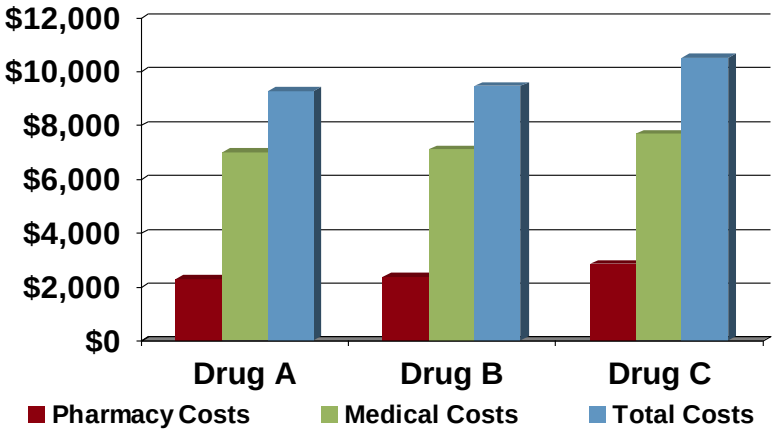
Financial considerations
SECOND

Outcomes-Based Formulary
Osteoporosis

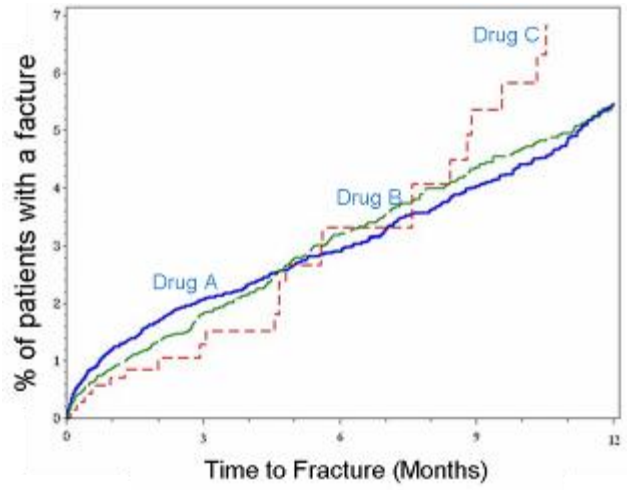
Compared to Drug A and Drug B:

- Compliance lowest for Drug C
- Drug C had higher fracture rates
- Total cost of care (pharmacy plus medical) higher for Drug C

Bisphosphonate Drugs: Total Costs One Year

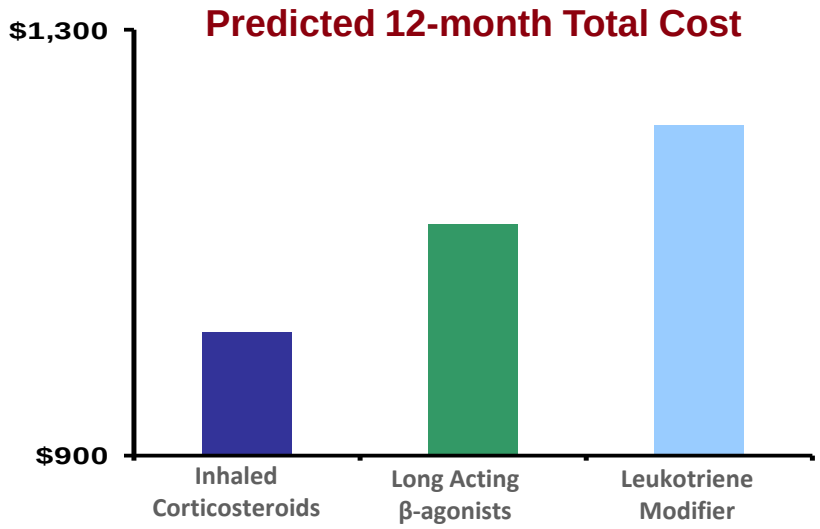


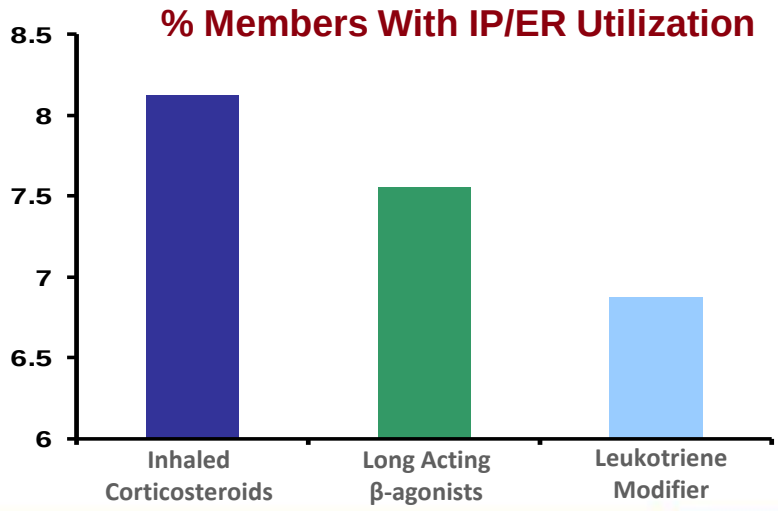
By analyzing pharmacy/medical costs, fracture risk and compliance, we determined **clients could save up to $1,000 per member per year – for each member with osteoporosis using Drug A or Drug B** instead of Drug C which remains a Tier 3 drug.



Comparative Effectiveness:
Asthma Controller Medication

- **Clinical trials established inhaled steroids as most effective treatment**
- **Convened national experts to study "real world" member experience**
- **HealthCore findings on oral meds**
  - Higher compliance
  - Reduced asthma-related emergency room visits and hospitalizations
  - Higher overall cost due to cost of drugs
- **Singulair® to remain in tier 2; remove prior authorization**
- **Best outcomes from members compliant on therapy**





Comparative Effectiveness Research
Expected Results

Improved decision-making by payers and providers

- Improve clinical, economic, and member outcomes
- Increase utilization and market share of “better” performing drugs

Improved population-based outcomes

- Improved quality of care
- Improved quality of life (member perspective)
- Improved productivity (employer/societal perspective)
- Lower total cost of care (pharmacy and medical)

Improved patient targeting for select therapies

Overview of Comparative Effectiveness Research Guidelines

First health plan to publish Comparative Effectiveness Research guidelines

- Create consistency in evaluation of Comparative Effectiveness Research
- Provide guidance to pharmaceutical companies

Guidelines include criteria for Comparative Effectiveness Research and observational studies (OBS)

Comparative Effectiveness Research and OBS may provide data from "real-world" setting

OBS data may be used when randomized, controlled trial data is unavailable

WellPoint Comparative Effectiveness Research Guidelines

Study Evaluation and Study Rating

Data will be reviewed and evaluated to answer the following:

- Does the study have scientific credibility?
  - Bias elimination
- Is the study relevant to WellPoint population?
  - Demographics, co-morbidities, current clinical practice patterns
- Are the results valid?
  - Study meets all or most evaluation criteria

Studies will be rated as useful, possibly useful or not useful

Comparative Effectiveness Research guidelines can be found as in the press release

Comparative Effectiveness Research
WellPoint's Rating

CER and Observational Data Usefulness Rating	Criteria for Evaluation of a Comparative Effectiveness Research or Observational Study
Useful	• Scientifically credible and appropriate methodology used, AND • Relevant to the WellPoint population and includes all relevant treatment comparators, AND • Meets ALL specified criteria requirements and the results are valid
Possibly Useful	• Scientifically credible and methodology is appropriate, AND • Relevant to the WellPoint population and includes relevant treatment comparators, BUT • Only meets SOME of the specified criteria requirements and there is some uncertainty around the results
Not Useful	• Not considered scientifically credible, OR • Not relevant to the WellPoint population or does not include relevant treatment comparators, OR • Not meet the specified criteria requirements such that the results are deemed invalid

WELLPOINT
Health. Care. Value.

CER Data Sources

"Identifying and Eliminating the Roadblocks to Comparative Effectiveness Research," NEJM, June 2, 2010

- Roadblocks in this study and anticipated road blocks:
  - Differing drug copays, which can impact results
  - Masking drug identities to patients
  - Coordinating logistics among hundreds of insurance plans for studies involving patients of all ages

The NEW ENGLAND JOURNAL of MEDICINE