

# **Real World Data: Moving Beyond Clinical Trials: The WellPoint Outcomes-Based Formulary**

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# Presentation Objectives

- Provide an overview of WellPoint NextRx
- Review the WellPoint NextRx Outcomes-Based Formulary Process
- Provide examples of data and analyses used to support formulary decisions (emphasis on observational data)
- Provide highlights of the WellPoint Health Technology Assessment Guidelines
- Presentation summary

## Vision

***WellPoint NextRx will transform our industry and become the most trusted and valued Pharmacy Benefits Manager (PBM)***



## Mission

***We deliver integrated pharmacy and health solutions providing exceptional value to our customers***



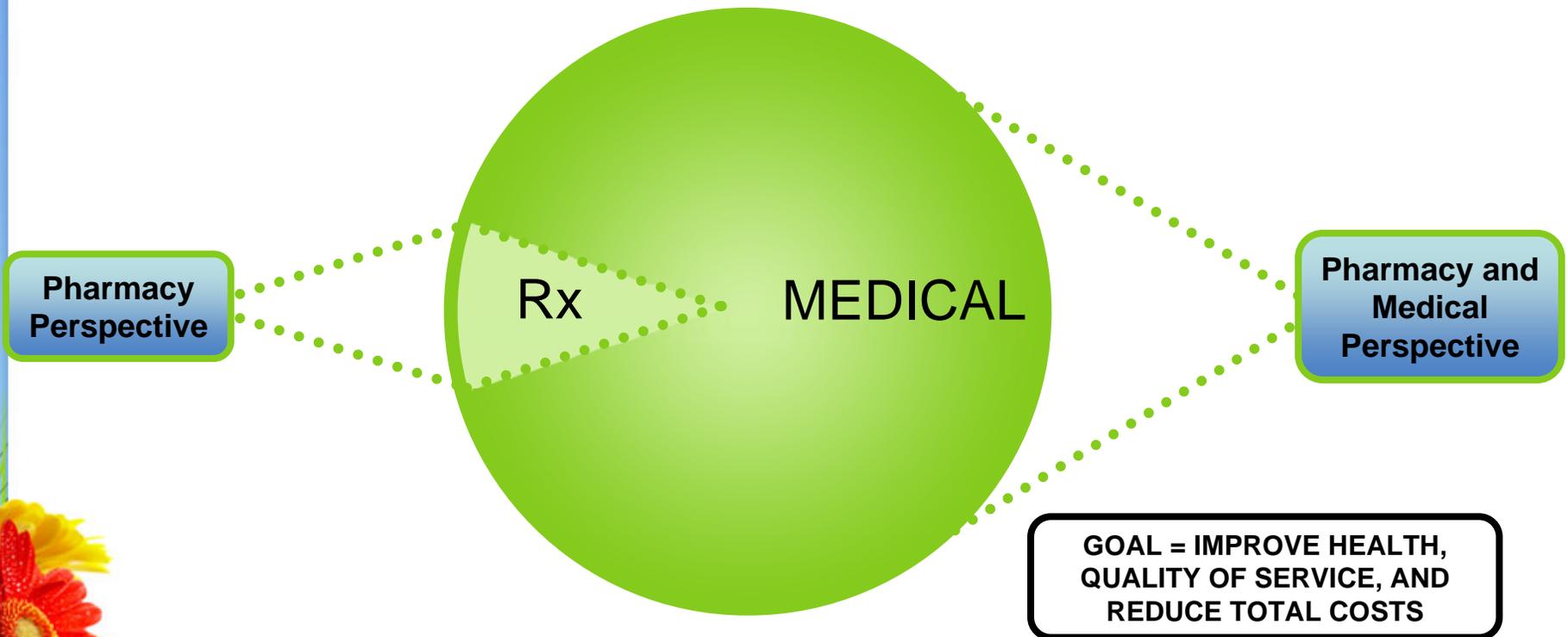
## Differentiating Strategies

***Leader in affordable quality care  
Most trusted choice for consumers***



# The Value of Integration

*The integration of pharmacy and medical data can provide information for the improvement of health, and better management of total health care cost.*



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## General Approach

### *Consider the complete burden of disease*

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Clinical Burden

Epidemiology

Natural History of Disease

Total Cost of Care

Productivity Impact

Quality of Life Impact

### *Leverage the formulary process to improve patient outcomes*

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Improve Quality of Care  
(clinical status, quality of life)

Reduce Total Cost  
(pharmacy, medical, ancillary, home health, nursing home, etc.)

Optimize Care  
(cost effectiveness)

Improve Productivity

# P & T Process and 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

**Clinical  
appropriateness  
FIRST**

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

**Financial  
considerations  
SECOND**

# A Critical Review of Clinical Trial Data

**Each clinical trial and guideline is carefully critiqued before being included in the drug monograph**

- Only high quality evidence material is included in the monograph
- Many studies fall short

**The focus of decision-making is based on patient-oriented clinical outcomes**

- Outcomes that are understood and desired by patients (e.g. decreased risk of heart attack/stroke/death)
- Many studies fall short here too

# Common Pitfalls of Clinical Trial Data

- High-drop out rates or missing data, with no sensitivity analysis
- Use of post-hoc analysis to draw cause and effect conclusions
  - Subgroup analysis where subgroups were not determined in advance.
- Non-significant findings or power calculation is not clear
- Non-ITT analysis (>5% of patients excluded from the primary outcome analysis)
- Inadequate dosages
- Use of non-validated scoring methods
- Disease oriented outcomes only (BP lowering vs. CV mortality)
- Unclear quality assessment methods for meta-analysis studies
- Study duration too short for endpoint (e.g. 6 weeks HbA1c)
- Use of other medications that may influence or confound the effect of the primary drug on outcomes

## Pharmacoeconomic and Outcomes Data

How well does the drug perform in the real world (effectiveness vs. efficacy)?

Are we achieving the outcomes we expect based on clinical trial data?

Is the drug being used properly (right patient, dose, duration, etc.)?

Are there quality of life or productivity benefits?

Are there medical cost offset benefits

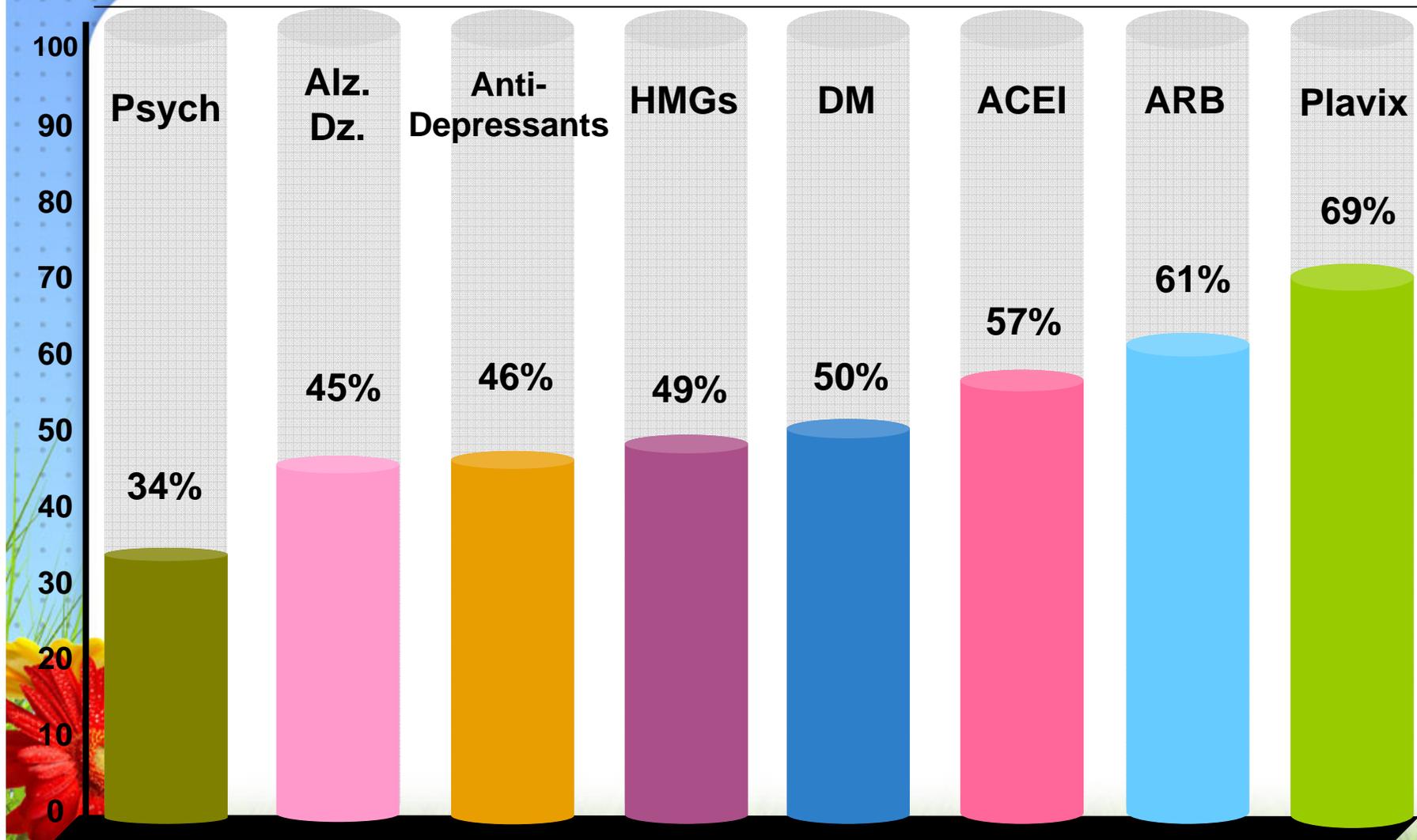
# Efficacy vs. Effectiveness

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

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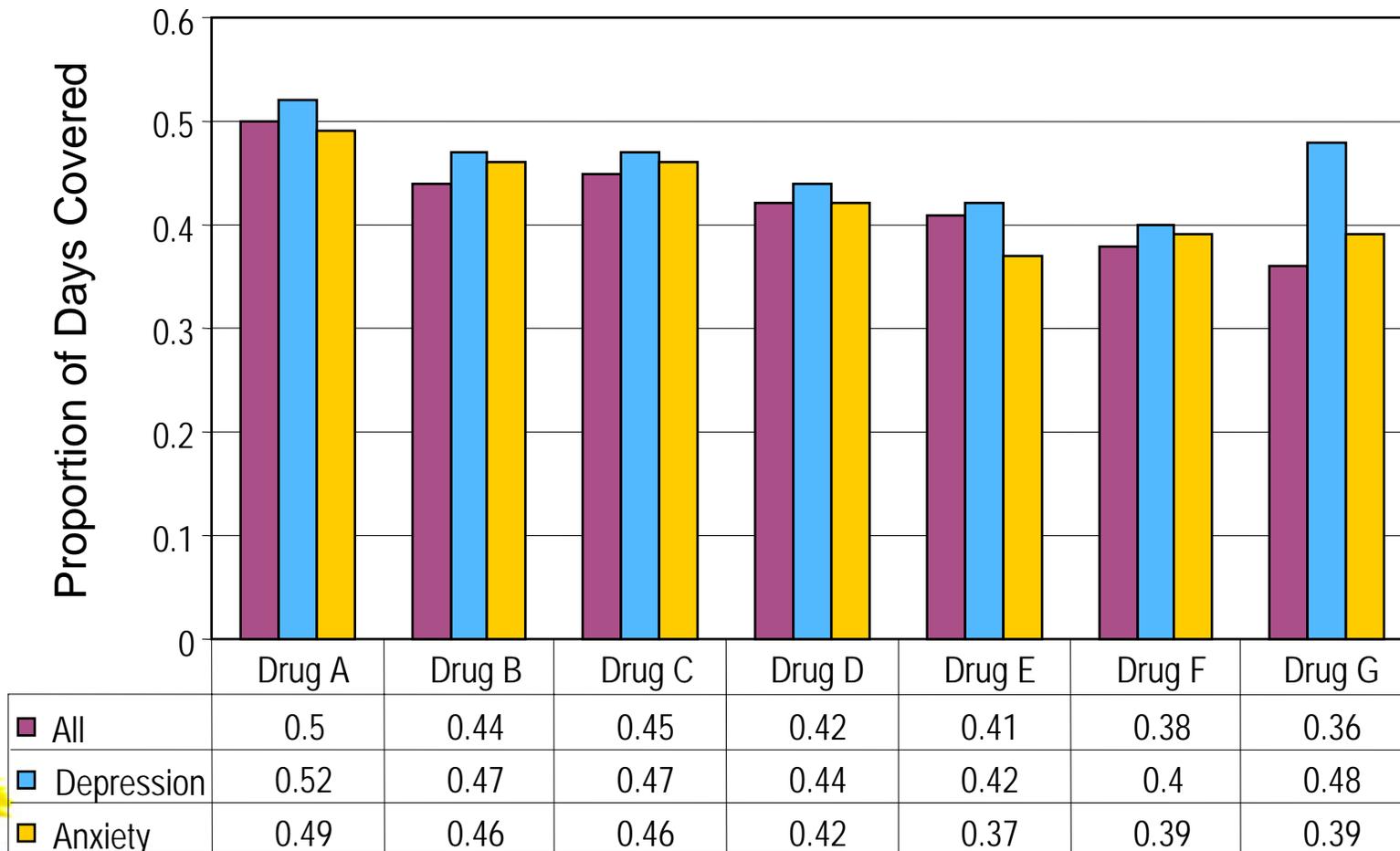
# Compliance Varies Significantly by Therapeutic Category



SOURCE: Internal Claims Database Analyses – WellPoint NextRx 2008

# Antidepressant Compliance

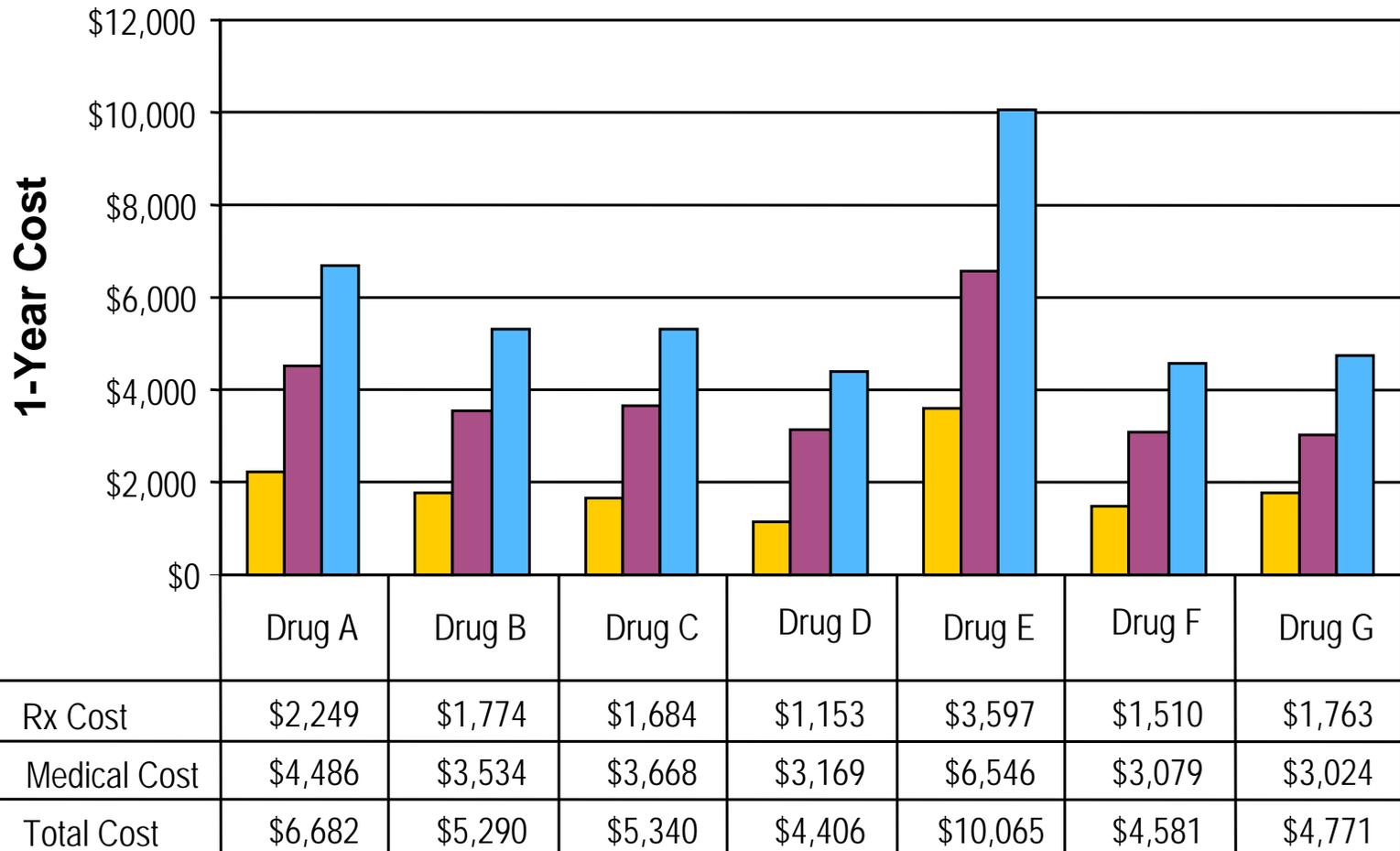
(Proportion of Days Covered Over a 1-Year Period)



Source: Data on file – WellPoint NextRx, 2008

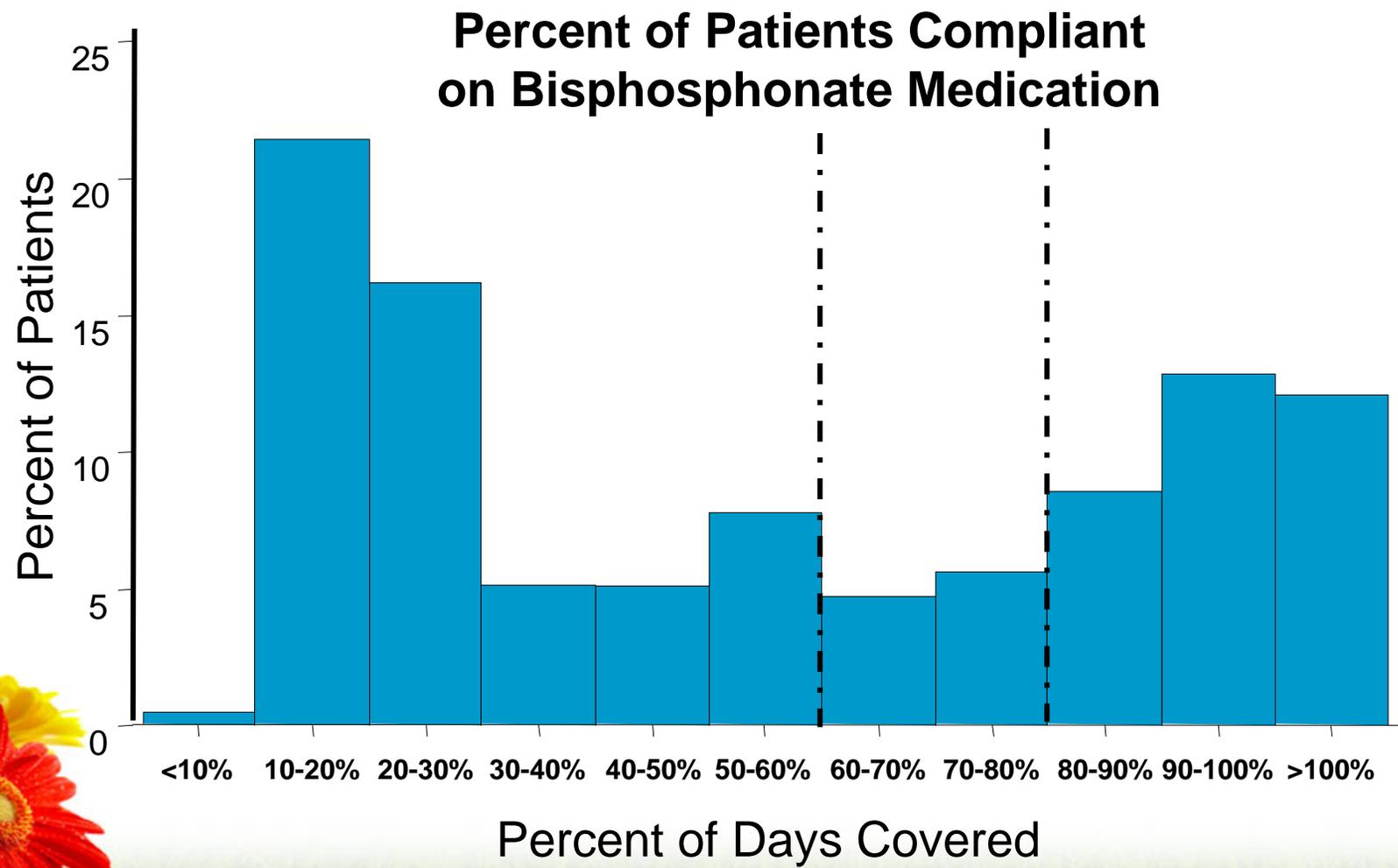
# Antidepressant Total Cost

(Pharmacy and Medical Cost Over a 1-Year Period)



Source: Data on file – WellPoint NextRx, 2008

# A Small Percentage of Patients Newly Started on Bisphosphonate Therapy are > 80% Compliant

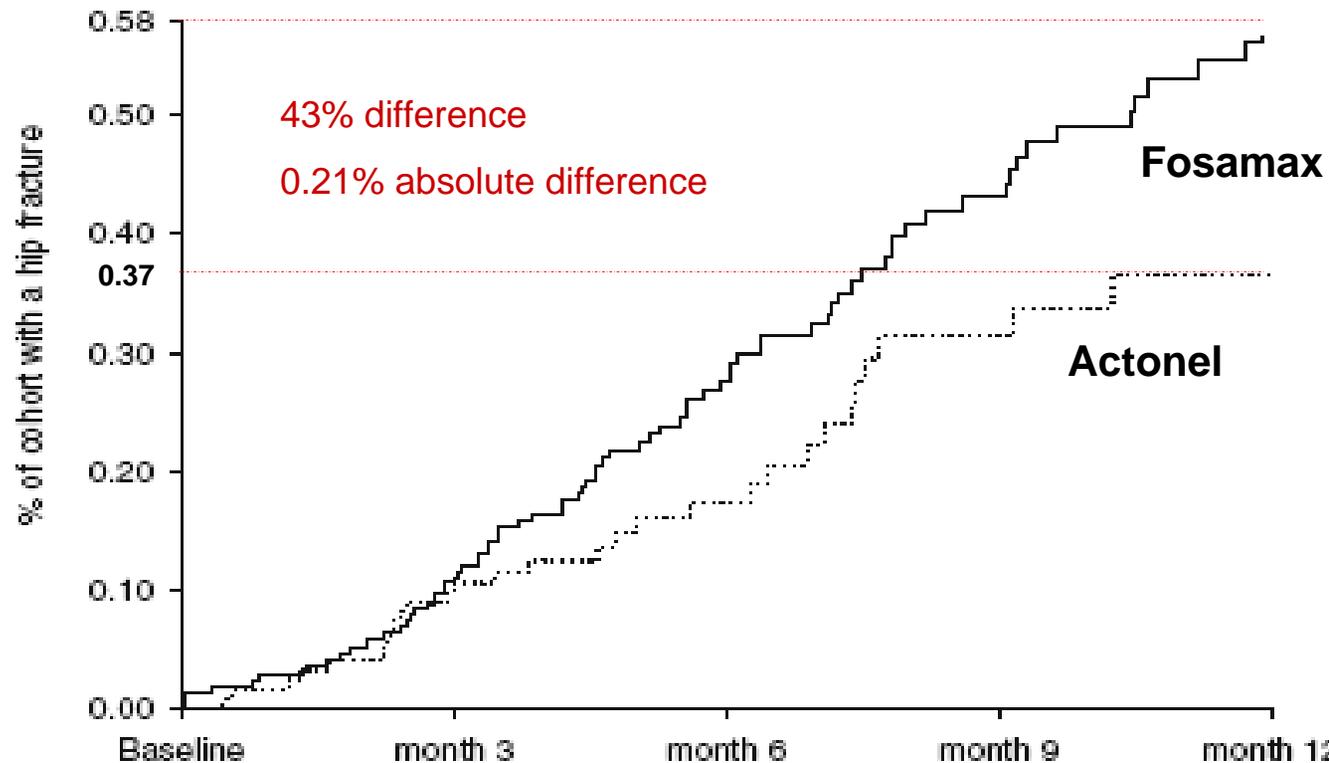


Source: Data on file – WellPoint NextRx, 2008

# REAL Study

## Incidence of Hip Fractures 1-Year Post Index

### Cumulative Incidence of Hip Fractures



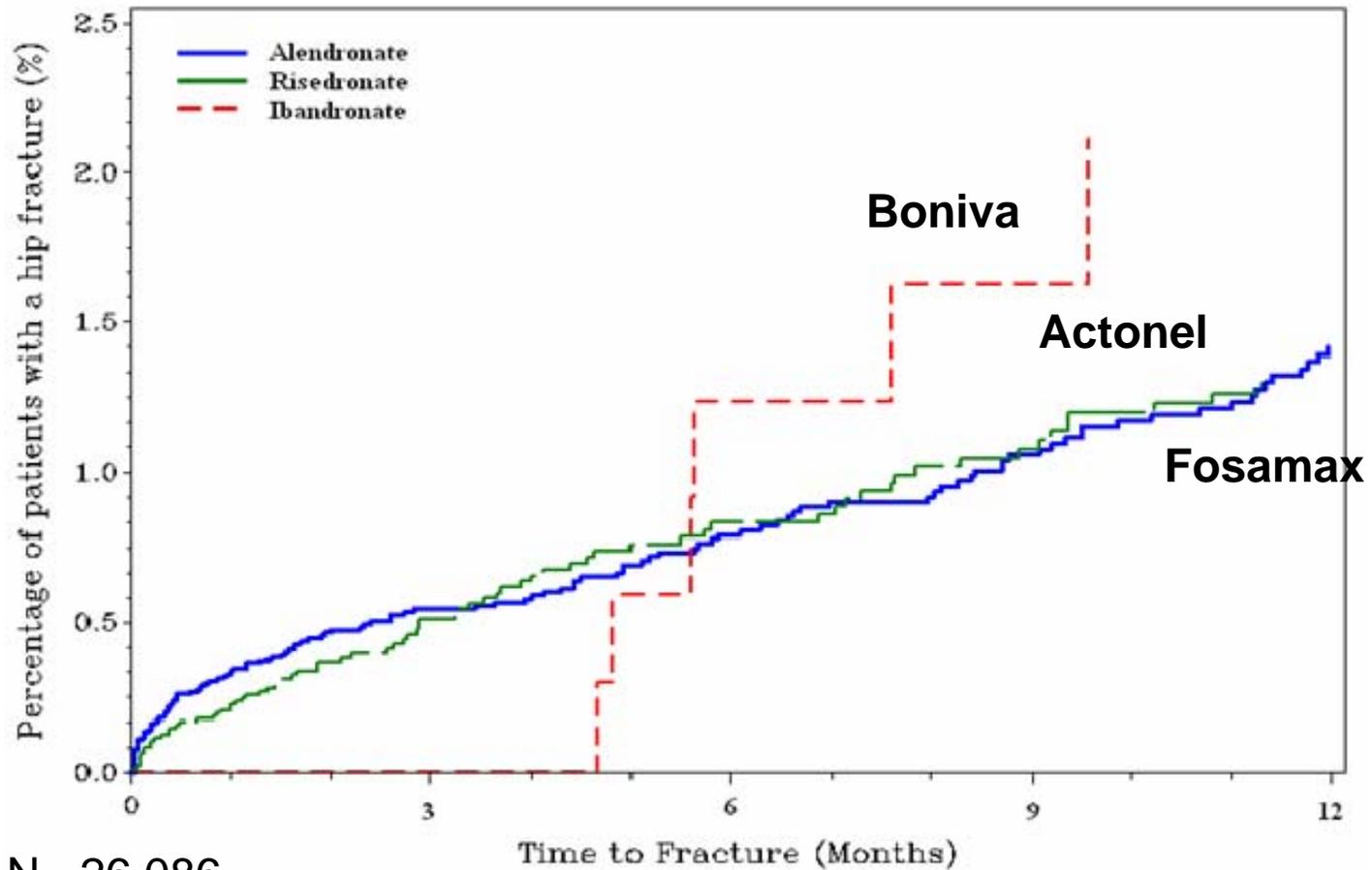
#### Patients at risk (fracture events)

Alendronate	21615 (0)	21590 (25)	12993 (54)	8677 (69)	5582 (80)
Risedronate	12215 (0)	12202 (13)	6847 (19)	4319 (27)	2584 (29)

Silverman SL, Watts NB, Delmas PD, Lange JL, Lindsay R. Osteoporos Int (2007) 18:25–34

# WellPoint Data: Incidence of Hip Fractures 1-Year Post Index

Kaplan-Meier cumulative incidence of hip fractures (1 year post-index)

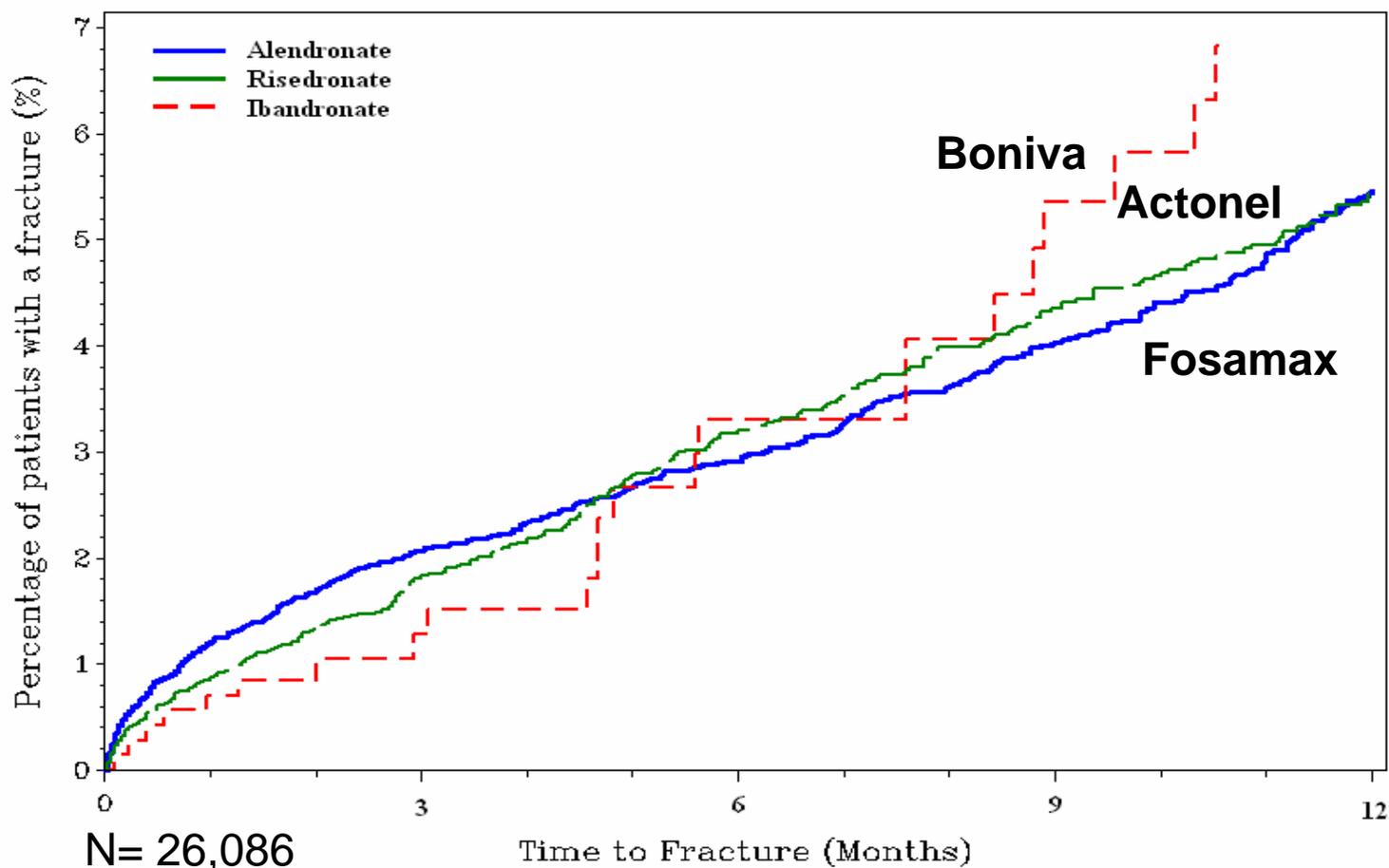


N= 26,086

Source: Data on file, WellPoint NextRx 2008

# WellPoint Data: Incidence of All Fractures 1-Year Post Index

Kaplan-Meier cumulative incidence of all fractures (1 year post-index)

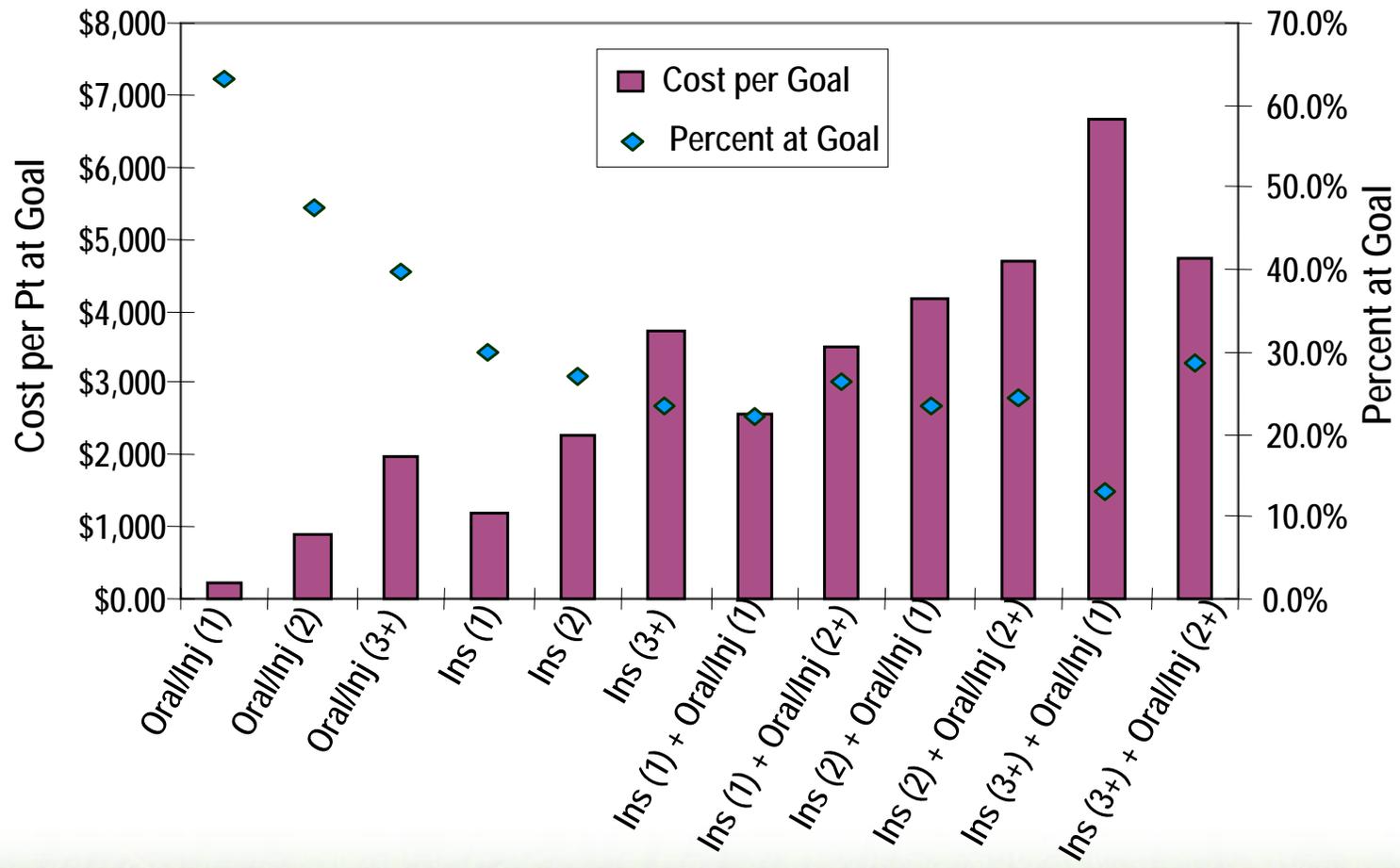


N= 26,086

Time to Fracture (Months)

Source: Data on file, WellPoint NextRx 2008

# Proportion of Patients at HbA1c Goal (<7) and Cost per Patient at HbA1c Goal



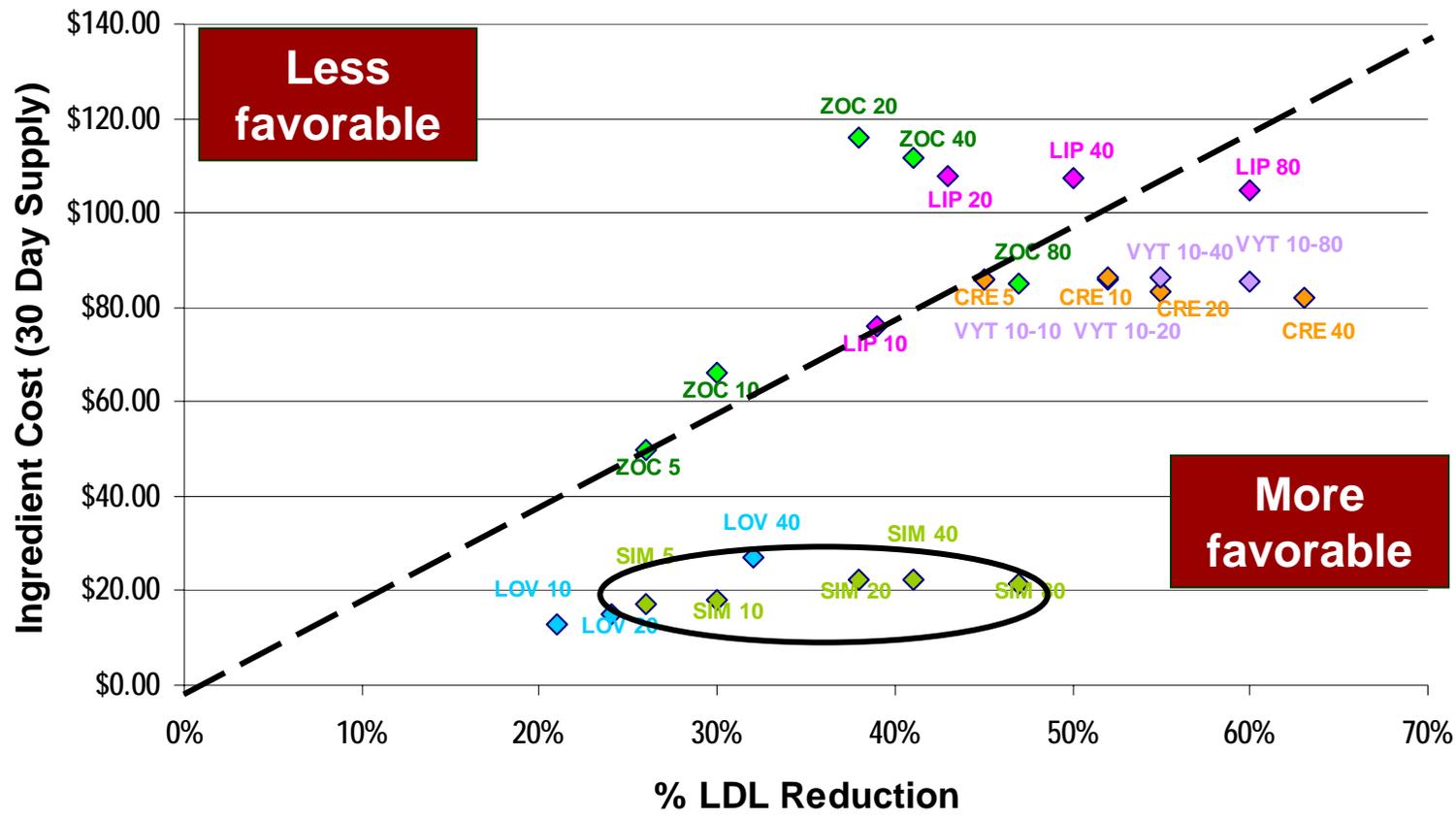
Source: Data on file – WellPoint NextRx, 2008

# Observed Percent Change in LDL-C by Different Statin Doses



<b>Drug and Dose</b>	<b>Sample Size (Obs. Data)</b>	<b>Mean % LDL-C Reduction (Observational Data)</b>	<b>Mean % LDL-C Reduction in STELLAR Clinical Trial</b>	<b>Package Insert</b>
Atorvastatin 10	21,495	-35	-37	-39
Atorvastatin 20	11,518	-38	-43	-43
Atorvastatin 40	3,072	-40	-48	-50
Atorvastatin 80	528	-38	-51	-60
Rosuvastatin 5	121	-30	---	-45
Rosuvastatin 10	2,015	-39	-46	-52
Rosuvastatin 20	213	-37	-52	-55
Rosuvastatin 40	16	-43	-55	-63
Simvastatin 5	84	-21	---	-26
Simvastatin 10	1,377	-28	-28	-30
Simvastatin 20	6,050	-32	-35	-38
Simvastatin 40	4,589	-34	-39	-41
Simvastatin 80	477	-30	-46	-47

# Simvastatin is Associated With a Lower Cost Per Percentage LDL Reduction



# COPD Health Care Utilization (1)

12 months post-index date

	Spiriva N=3,030	Atrovent N=1,463	Combivent N=4,206
<b>COPD-Related utilization</b>			
<b>ER Visits</b>			
≥ 1 ER visit %	9	12	11
Mean# of ER visits	0.1(0.6)	0.2(0.6)	0.1(0.5)
<b>Inpatient hospitalization</b>			
≥ 1 inpatient stay %	26	36	31
Mean# of hospital stay	0.4(0.9)	0.6(1)	0.4(0.9)
<b>Outpatient visits</b>			
≥ 1 outpatient visit %	100	92	93
Mean# of outpatient visits	8(10)	8.7(10.3)	7.4(9.5)

# COPD Health Care Utilization (2)

12 months post-index date

	Spiriva N=3,030	Atrovent N=1,463	Combivent N=4,206
<b>All-Cause Utilization</b>			
<b>ER Visits</b>			
≥ 1 ER visit %	23	28	27
Mean# of ER visits	0.4(1.3)	0.5(1.6)	0.4 (1)
<b>Inpatient hospitalization</b>			
≥ 1 inpatient stay %	33	44	40
Mean# of hospital stay	0.6(1.2)	0.9(1.5)	0.7 (1.2)
<b>Outpatient visits</b>			
≥ 1 outpatient visit %	100	99	100
Mean# of outpatient visits	28.1(22.6)	28.6(23)	27.5(21.8)

# COPD Health Care Utilization (3)

## 12 months post-index date

	Spiriva N=3,030	Atrovent N=1,463	Combivent N=4,206
<b>All-Cause unadjusted cost</b>			
Medical	\$10,378*	\$14,316 <sup>§</sup>	\$11,182
Pharmacy	\$2,584*	\$1,927	\$1,952 <sup>¶</sup>
Total (Medical + Pharmacy)	\$13,007*	\$16,093 <sup>§</sup>	\$13,116
<b>COPD-related adjusted cost</b>			
Medical	\$4,317*	\$6,612 <sup>§</sup>	\$4,782 <sup>¶</sup>
Pharmacy	\$324	\$310 <sup>§</sup>	\$171 <sup>¶</sup>
Total (Medical + Pharmacy)	\$5,172*	\$7,226 <sup>§</sup>	\$5,224

Adjusters are prior year cost, age, gender, health plan Charlson Comorbidity index, hypertension, depression, asthma, and stroke

\* p<0.05 pairwise comparison between spiriva and atrovent

§ p<0.05 pairwise comparison between atrovent and combivent

¶ p<0.05 pairwise comparison between spiriva and combivent

# Quality of Life Summary

- Some diseases are associated with significant QoL burden
- Some treatments can result in significant improvement in QoL
  - QoL consistent with disease in remission
  - QoL approaches that of the US population norm
- QoL is an important endpoint from a patient perspective



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# **Revised WellPoint Guidelines for Formulary Submissions: 2008**

## **Standards and Recommendations**



# WellPoint Outcomes Based Formulary



- Supports WellPoint's leadership position in the provision of a high-quality pharmacy benefit that is evidence-based
- Formulary decisions are based on high quality evidence focused on patient outcomes
- Studies should be representative of WellPoint patient populations
- Product choice *and continuing formulary support* should be supported by clinical evidence and product value (e.g. cost-effectiveness)
- Patient focused claims are judged by their impact in a naturalistic environment and should be monitored on an ongoing basis, validated and reported on by manufacturers

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# Presentation Summary (1)

## WellPoint NextRx strategy

- Transform our industry. . .
- Deliver integrated pharmacy and health solutions. . .
- Leader in affordable quality care. . .

## Outcomes-based formulary

- Understand the complete burden of disease
- Leverage the formulary process to improve patient outcomes
  - Improving quality of care (clinical status, quality of life)
  - Reducing total cost of care (pharmacy, medical, total)
  - Optimize care (cost effectiveness)
  - Leverage both clinical trial data and observational data

## Compliance challenges

- Generally poor (~50%)
- Leverage tier placement and other tools to drive utilization towards drugs associated with better outcomes (quality and total cost)

## Presentation Summary (2)

Efficacy and effectiveness data to be used to make formulary decisions

There are differences in performance of drugs within the same therapeutic category

- Goal is to identify the “best” performing drugs

Health Technology Assessment Guidelines

- Inform manufacturers regarding information most useful to WellPoint

Expected Outcomes

- A pharmacy benefit that is high quality and cost effective
- Better quality of care
- Improved cost-effectiveness of care