Value Based Formulary Design: Is Premera A Voice Crying in the Wilderness?

ISPOR 20th Annual International Meeting
avalere.com

Background/ Issues

- Payers in many other countries routinely use sophisticated value-based decision making principles when designing formularies
- However, few US payers employ this philosophy to the extent that it is being used by Premera BlueCross BlueShield
- Is Premera on the leading edge of a c-change in formulary development in the US, or is it an outlier, proceeding at a pace that will not be replicated?
- Will more VBFD tools be used by payers in the US or not?
- If so, what tools will these be, and how, when, and by whom will they be used?
- What will be the implications for pharmaceutical manufacturers?
- This panel explores trends in VBFD from multiple constituent perspectives.

Panelists

Panelist 1: Moderator/Contact Person: **Kathleen E. Hughes, MBA** **Vice President, Health Economics and Outcomes Services** **Avalere Health LLC** **1350 Connecticut Avenue, NW** **Washington, DC 20036** **Phone: 202.207.1309** **Email:** khughes@avalerehealth.net	**Panelist 2: Payer (with VBFD) Panelist:** **Dan Danielson, MS, RPh** **Pharmacy Manager, Clinical Services** **Premera Blue Cross MS 432** **7001 220th St SW** **Mountlake Terrace, WA 98043-2124** **Phone: 425-918-6659** **Email:** Dan.danielson@premera.com
Panelist 3: Other Payer Panelist: Edmund J. Pazella, MD, MPH National Medical Director, Pharmacy Management Aetna, Inc. 151 Farmington Ave Hartford, CT 06156-0001 Phone: (860) 273-0123 Email: PezallaE@aetna.com	**Panelist 4: Manufacturer Panelist:** John Graham, VP, VEO, CVM-NS Global Value Evidence and Outcomes RD Projects Clinical Platforms & Sciences GlaxoSmithKline 2301 Renaissance Boulevard King of Prussia, PA 19406 Phone: 610.787.3863 Email: john.3.graham@gsk.com

Avalere

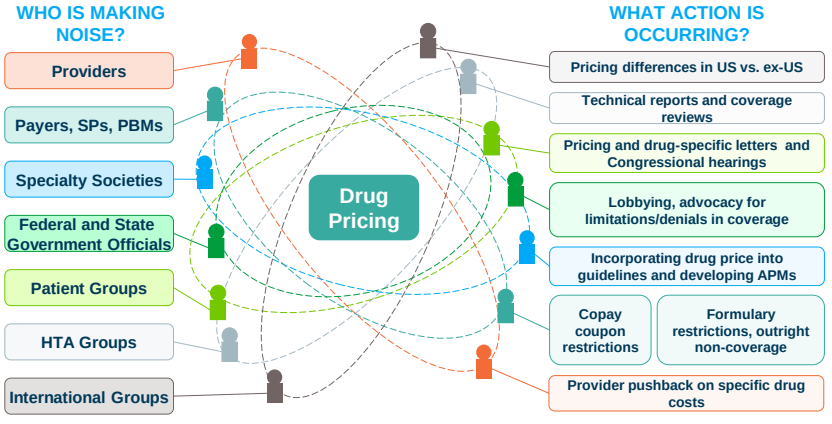
Background

Kathy Hughes
Vice President
Avalere Health

Background

- Drug Pricing and Cost
- Shift to Tiering and Cost-Sharing
- Background on Value-Based Insurance Design (VBID)
- International Health Technology Assessments (HTAs)
- U.S. HTAs and Novel Means of Demonstrating Value
  - HTAs
    - Veteran Affairs (VA)
    - Academy of Managed Care Pharmacy (AMCP) Guidelines
    - Wellpoint Guidelines
    - Centers for Medicare & Medicaid Services (CMS)
  - Performance-based Risk Sharing Agreements (PBRSAs)
- Future U.S. Trends

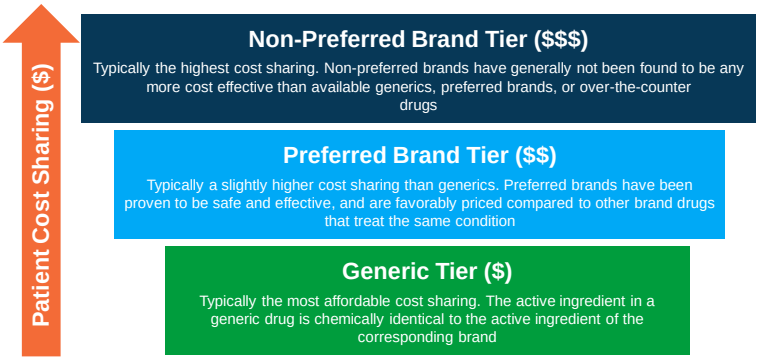
The Market Is Consistently Focused on Drug Pricing and Costs



SP: Specialty Pharmacy
PBM: Pharmacy Benefit Manager
APM: Advanced Payment Model

Commercial Payers Use Cost Sharing Differentials via Tiering to Steer Patients Towards Less Expensive Therapies

- Historically, insurers have applied a tiered cost-sharing structure to the pharmacy benefit design, which results in different payments for different medications depending on whether a medication is a generic, a preferred brand, or a non-preferred brand1. In addition, historically the tiers were all copayment tiers--the biggest change has been the creation and expansion of coinsurance tiers

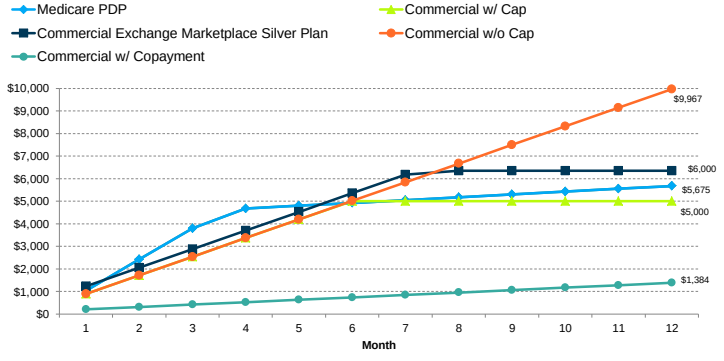


Insurers are increasingly adding additional tier(s) with high associated cost sharing for specialty medications

1. There are additional variations on formulary tiering; this represents the most common tiering design among commercial plans. Medicare Part D plans are more often adopting 5-tier designs with a preferred and non-preferred generics tier and/or an injectable tier, in addition to a specialty tier.

High Drug Prices Place Cost Sharing Burden on Both Payers and Patients

TOTAL ANNUAL OOP COSTS BY PLAN TYPE FOR A DRUG WITH A PRICE OF $2,500 FOR 30-DAY SUPPLY ($30,000 ANNUAL)



As patient cost sharing increases, coupled with an uncertain future for the viability of manufacturer-sponsored cost sharing assistance in all markets, the patient voice will become even louder in the high drug cost discussion

Notes: Medicare PDP plan assumes $310 deductible, $2,850 initial coverage limit (with 33% coinsurance), followed by coverage gap (with 47.5% coinsurance), up to $4,550 total OOP before catastrophic coverage (5% coinsurance); Commercial w/ Cap assumes $100 deductible, $5,000 OOP limit on prescription drug spending, and 33% coinsurance; Health Marketplace Silver Plan assumes $600 deductible, $6,000 OOP limit (assumed to be exclusively comprised of drug costs), and 33% coinsurance; Commercial w/o Cap assumes $100 deductible and 33% coinsurance.
Source: Avalere Health Proprietary Model, 2014. PDP – Part D Plan

Value-Based Insurance/Formulary Design

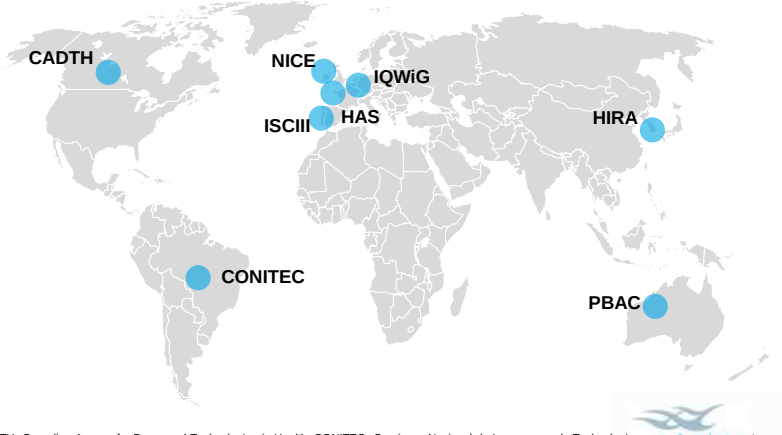
VBID SEEKS TO ENCOURAGE THE APPROPRIATE USE OF HIGH-VALUE MEDICAL SERVICES

- VBID recognizes that:
  - Medical services differ in the benefit provided
  - Clinical benefic of certain medical services differ between the patient, provider and site of care
- Higher cost sharing for drugs have been associated with lower rates of adherence and increase in the discontinuation of therapy
- Applied to drugs, value based formulary design (VBFD) attempts to structure a formulary that reflects the value of drug rather than cost
  - VBFD seeks to align co-pay for drugs with their value in hopes of obtaining better clinical outcomes and economic benefit
- To date most value-based plans have targeted chronic medical conditions such as diabetes, hypertension, hyperlipidemia, and asthma

1. Supporting Consumer Access to Specialty Medications Through Value-Based Insurance Design, A. Mark Fendrick, MD, Jason Buxbaum, MHSA, Kimberly Westrich, MA, University of Michigan Center for Value-Based Insurance Design
2. 2. Sullivan SD, Yeung K, Vogeler C, Ramsey SD, Wong E, Murphy CO, Danielson D,Veenstra DL, Garrison LP, Burke W, Watkins JB. Design, implementation, and first-year outcomes of a value-based drug formulary. J Manag Care Spec Pharm. 2015 Apr;21(4):269-75

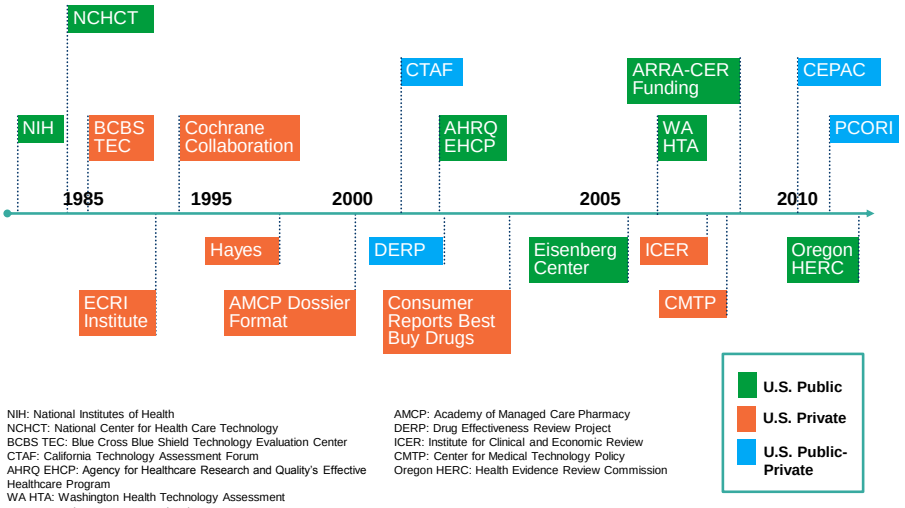
HTAs Play Critical Roles In Supporting the National Decision-Making Process in Many Countries

HTAS EXAMINE SEVERAL ASPECTS OF HEALTH TECHNOLOGY INCLUDING SAFETY, EFFICACY, PATIENT REPORTED OUTCOMES, REAL WORD EVIDENCE, COST AND COST-EFFECTIVENESS



CADTH: Canadian Agency for Drugs and Technologies in Health CONITEC: Comissao Nacional de Incorporaca de Technologias HAS: Haute Autorité de Santé HIRA: Health Insurance Review and Assessment Service IQWiG: Institute for Quality and Efficiency in Health Care ISCIII: Instituto de Salud Carlos III NICE: National Institute for Health and Clinical Excellence PBAC: Pharmaceutical Benefits Advisory Committee

Public and Private HTA Agencies Have Been Supporting Drug Coverage and Reimbursement Decisions for Payers



NIH: National Institutes of Health
NCHCT: National Center for Health Care Technology
BCBS TEC: Blue Cross Blue Shield Technology Evaluation Center
CTAF: California Technology Assessment Forum
AHRQ EHCP: Agency for Healthcare Research and Quality's Effective Healthcare Program
WA HTA: Washington Health Technology Assessment
ARRA: American Recovery and Reinvestment Act
CEPAC: New England Comparative Effectiveness Public Advisory Council
PCORI: Patient-Centered Outcomes Research Institute

AMCP: Academy of Managed Care Pharmacy
DERP: Drug Effectiveness Review Project
ICER: Institute for Clinical and Economic Review
CMTP: Center for Medical Technology Policy
Oregon HERC: Health Evidence Review Commission

Veterans Affairs

THE SECRET FORMULA

"Double secret probation" HTA process
+ Legal/regulatory ability to effect discounts
+ Supplementary discounting practices

= Greatest discounts of any purchaser

Academy of Managed Care Pharmacy Guidelines to Support Formulary Listing

- Focused on pharmaceutical care in managed health care environments, including:
  - Creating scientifically designed methodologies using evidence-based clinical studies
  - Promoting evaluation of products based on effectiveness in improving health outcomes, not cost
- Format for formulary submissions
  - Created to help health systems that evaluate medications for use by their patients
  - Establishes guidelines for process and content of formulary submissions drug companies can use to prepare submissions to a P&T Committee
  - First published in 2000, revised in 2002 (version 2.0), 2005 (version 2.1), 2009 (version 3.0) and 2012 (version 3.1)
  - Format requires manufacturers to provide product dossiers that contain information on study design, research protocols, analytic methods, and results
  - Accepted industry standard

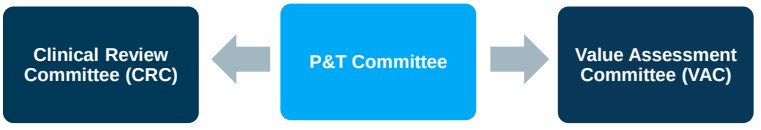
AMCP guidelines provide an opportunity for pharmaceutical manufacturers to demonstrate the value of their product through evidence

AMCP Format for Formulary Submissions, http://www.amcp.org/slidedecks/

WellPoint Health Technology Assessment Guidelines

WELLPOINT SOUGHT TO LINK PHARMACY AND MEDICAL DATA IN ORDER TO IMPROVE OUTCOMES AND BETTER MANAGE OF TOTAL HEALTH CARE COST

- WellPoint's Outcomes-Based Formulary Approach was designed to consider both the complete burden of disease and to utilize the formulary to improve patient outcomes
- P&T process involved a critical evaluation of the evidence ***first***, followed by a review of clinical, outcomes and financial data before making a final decision on tier placement



- In 2008, Wellpoint became the first health benefits company to publish its health technology assessment guidelines for use in evaluating pharmaceuticals with an emphasis on potential medical cost offsets, effects on PROs and QoL, and effects on productivity

The WellPoint OutcomesBased Formulary: Health Technology Assessment Guidelines, http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=12235

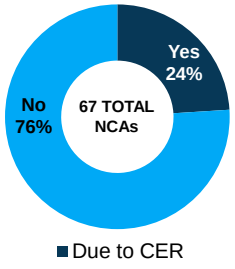
PRO: Patient Reported Outcomes
QoL: Quality of Life

CMS Uses CER for Medicare National Coverage Determinations

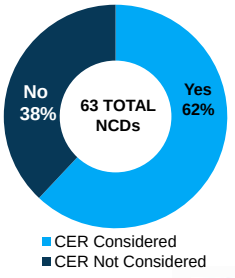
- Funding for CER has enabled CMS and other payers to subject new and existing treatments to more intensive scrutiny than they have received in the past
- CMS may choose to determine coverage and reimbursement for medical products at a national level by opening a national coverage analysis (NCA) and establishing a national coverage determination (NCD)

A RECENT AVALERE HEALTH ANALYSIS IDENTIFIED THAT CER MAY BE A TRIGGER FOR OPENING NCAS AND DETERMINING NCDS

Number of NCAs Initiated due to CER (2007-2014)



Number of NCDs That Considered CER (2007-2014)

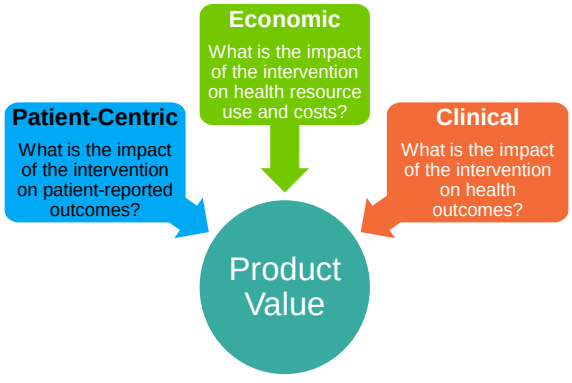


CER: Comparative Effectiveness Research

Payers Are Attempting to Reward Drugs with Better Value in Future Payment Models

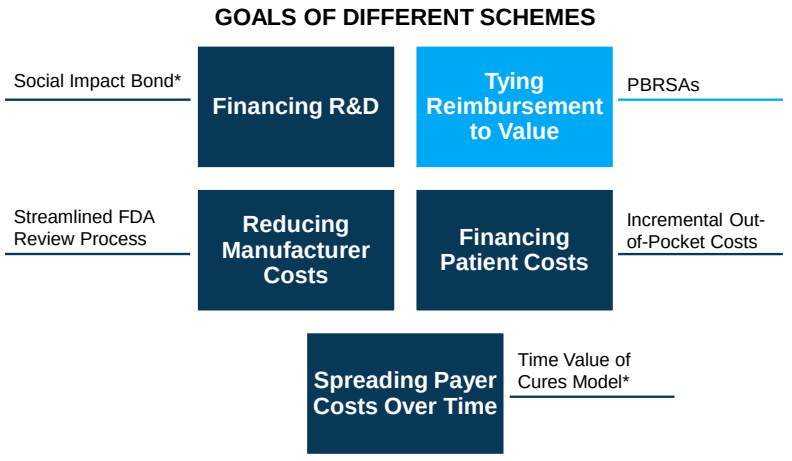
FUTURE:
Payment Rewards Value

- Value-based purchasing
- Public reporting
- Bundled payments
- Direct link between payment and outcomes
- Performance-Based Risk-Sharing Agreements (PBRSAs)



The increased focus on value provides opportunities to engage payer and provider customers in unique contracting and reimbursement relationships that may optimize market access

PBRSAs Are One of the Many Contracting Schemes Stakeholders Are Exploring



*This model is in early discussion stages. Gottlieb S, Carino T (2014). Establishing New Payment Provisions for the High Cost of Curing Disease. *American Enterprise Institute*. www.aei.org/publication/establishing-new-payment-provisions-for-the-high-cost-of-curing-disease/

The Future of Value Based Formulary Design in the U.S.

Are we going to see a shift to VBFD?

What will these new VBFDs look like?

How much will we see?

How will VBFDs impact overall health plan costs?

Will VBFDs lead to long term cost savings without affecting patient adherence and health?

VALUE BASED FORMULARY DESIGN (VBFD):
IS PREMERA A VOICE CRYING IN THE WILDERNESS?

2015 ISPOR Annual Meeting
ISPOR Issue Panel
20 MAY 2015
Dan Danielson MS, RPh.

Concept:

Align out-of-pocket costs with the value of health services

- Application: pharmaceuticals assigned to one of four Value-Based Formulary (VBRx) tiers based on ICERs
  - ICERs documented in economic monographs drawn up by Premera staff
    - Brief clinical review
    - Review of current economic evidence
  - Evidence presented to an evaluated by an independent Value Assessment Committee
    - Accept and/or modify staff recommendations
    - Send back for more analysis

Formulary has been in operation since July 2010

Value-Based Formulary Tiers

Standard Thresholds*

Tier 1: Highly Cost-effective:
<$10,000/QALY

Tier 2: Cost-effective:
<$50,000/QALY

Tier 3: Somewhat cost-effective:
<$150,000/QALY

Tier 4: Minimally cost-effective:
>$150,000/QALY, *or insufficient evidence to determine cost-effectiveness*

*Tier thresholds are explicit but flexible. A "preventive list" similar to those used by other plans is included with VBRx. More liberal thresholds are applied to ultra-orphan drugs.

Environment

Competitive commercial insurance environment, complicated by implementation of Affordable Care Act

- Offered to Self Funded Employer Groups
- Current customers
  - Premera Associates
  - 2 Washington state healthcare provider organizations
- Interest in adoption of VBRx for many employers was cooled by uncertainties surrounding
  - 2012: SCOTUS decisions on "ObamaCare" and US Presidential Election
  - 2012-Present: no hard evidence to address effectiveness in controlling/mitigating healthcare cost trends
  - 2013-2014: Implementation of ACA

First Year Results

Developing the Proof Points using Premera Associate experience

- Plan pharmacy payments reduced
  - $6.87 PMPM (3%) year over year in terms of actual spend
- Average member cost-shares increase
  - 12% on average
  - Significantly less for diabetics, users of blood pressure and cholesterol medications(5%, 8%, and 2% respectively)
- No negative changes to adherence to these drug therapies

Sullivan SD et. al. Design, Implementation, and First-Year Outcomes of a Value-Based Formulary, J Manag Care Spec Pharm. 2015 Apr;21(4):269-75.

Coming Soon: Independent, comprehensive Three Year Analysis

Manufacturer Responses

to modeling requests has been variable; trend is toward easier access to manufacturer models

Themes:

- Manufacturer Corporate Compliance policies impact access to models
  - Leave behind
  - Medical Science Liaison supervised only
- Differences among manufacturers in integration levels of US and Global Outcomes divisions
- Highly variable model quality
  - Some manufacturers open to our advice and consultation
  - Others create poor models and then “go dark”
  - Still others don’t provide modeling of any kind

Future directions

Depend on independent assessment of VBRx performance

- Re-launch
  - Sales efforts will be data driven, not theoretical
  - Expand cadence and quality of our economic monographs
- Reconfigure
  - Based on opportunities for improvement brought forward
- Retire
  - If found to be dominated by standard plan designs in terms of programmatic value

Re-launch appears to be the most likely scenario
Retirement seems highly unlikely

aetna

Value-based approaches to healthcare

Edmund J. Pezalla, MD, MPH
VP, Pharmaceutical Policy and Strategy

May 2015

There are two sides to value-based insurance

Demand

- **Encouraging adherence through reduction in copay**
- **Encouraging use of preferred or generic products through copay differentials**

Supply

- **Structuring formularies based on clinical or economic value**
- **Constructing outcomes or at-risk contracts**

Demand side VB design is meant to impact patient behavior

Adherence to evidence-based medications prescribed after myocardial infarction (MI) remains poor

Within 2 years of initiating therapy, only half of patients remain adherent to their prescribed statins, beta-blockers, or ACEI/ARBs

Drug costs appear to be a central reason for medication underuse

Even among patients with insurance, utilization varies according to the comprehensiveness of coverage

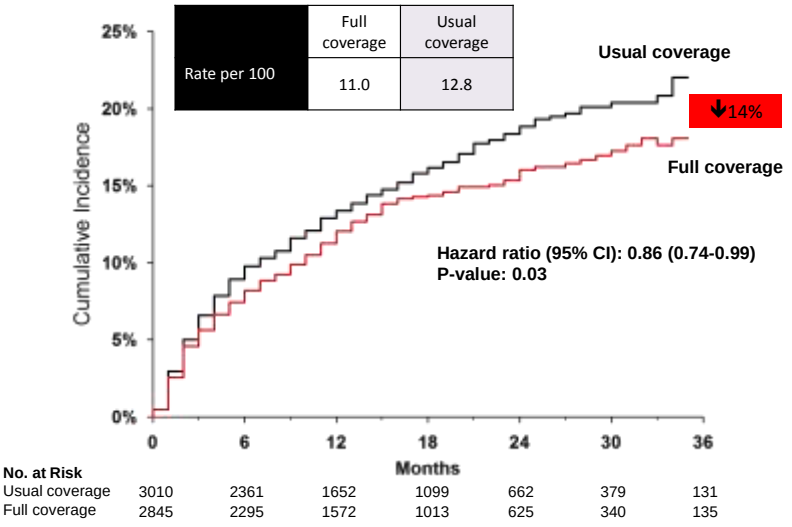
Eliminating out-of-pocket costs for evidence-based therapies may promote adherence and improve outcomes

Referred to as "value-based insurance design" or "evidence-based plan design"

Observational studies support the ability of this strategy to increase adherence but its impact on health outcomes and spending has not been rigorously evaluated

Major vascular events (Fatal or nonfatal MI, unstable angina, CHF, stroke)

MI FREEE



No. at Risk							
Usual coverage	3010	2361	1652	1099	662	379	131
Full coverage	2845	2295	1572	1013	625	340	135

On the supply side most of our work has been in value-based provider contracts

- **Providers are rapidly evolving into ACO, PCMH and other risk bearing entities**
- **This is an industry trend following the lead of CMS**
- **Value-based contracts or outcome based contracts are rare in the US**
  - Difficult and expensive to measure outcomes
  - Meaningful risk amounts will cause readjustments of BEST PRICE

VALUE BASED FORMULARY DESIGN (VBFD): IS PREMERA A VOICE CRYING IN THE WILDERNESS?

John Graham, Pharm.D.
Vice President
Value Evidence and Outcomes
GlaxoSmithKline

Value Must be Demonstrated

- Premera (VBF) is only unique in the U.S..
  - NICE, IQWiG may be the most well known, but all countries need to evaluate value
- Improved evidence generation is the foundation of value
  - Robust and Valid
  - Specific and Impactful
  - Informed

Premera provides an example of the importance of collaboration

- Open dialogue leads to improved understanding
  - Proactively address challenges
  - Models are specific and useful
  - Data package is comprehensive