

**An Introduction to
Managed Care 2010**

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Pharm 542 UW

What Is “Managed Care”

Presentation Outline

- Birth of Managed Care
- Types of systems
- US Managed care vs. other systems
- Early pharmacy programs
- Key players in 2009
- What PBMs do
- Historical silos: Medical vs. pharmacy
- Terminology basics

Birth of Managed Care

- Traveling armies, e.g. George Washington
- Railroad and lumber camps
- Western Clinic, Tacoma WA
- 1920's and 30's: birth of the Blues
- Kaiser projects in the depression and WWII

Birth of Managed Care, continued

- HIP (Health Insurance Plan of Greater New York)
- Group Health Cooperative
- Insurance programs

Types of Managed Care Systems *and some examples*

- Staff models - Group Health
- Group Models - Kaiser
- IPA systems - The Blues
- OWAs - CIGNA

US Managed Care vs. Single Payers

- Common features
 - All use formularies
 - All focused on costs, health outcomes, value
 - All struggling with increased health costs, aging populations, biologics, comparative effectiveness

Single Payers

- Common throughout the world (not US!)
- Centralized formulary reviews
 - Great Britain NICE, Canada CADTH, Europe EMEA, etc
 - Experts in Modeling
- Reviews based on societal impact – so interested in direct (Rx and Medical) and indirect costs (e.g. productivity)
- Very interested in QALYs – to guide health care trade-offs

US Managed Care

- Hundreds of MCO's across US
- Each with its own formulary (or use PBM formulary) and review (P&T) committee
- Many different (often hundreds) of Medical and Pharmacy Benefits for each MCO
- More interested in direct Rx and Medical costs than in indirect costs or QALYs
- Many don't have modeling experts

Early Pharmacy Programs

- Pharmacy costs would not be manageable
- GHC in 1950: trial based on hospital practice
- Formulary concept adopted
- Kaiser, HIP etc added pharmacy programs
- Birth of PBMs

Key Players: 2009

- President Obama, Congress, CMS
- MCOs
- PBMs
- Pharmacies – Retail, Specialty, Hospital
- Infusion Centers
- Patients
- Physicians
- Pharmaceutical Manufacturers
- Etc.

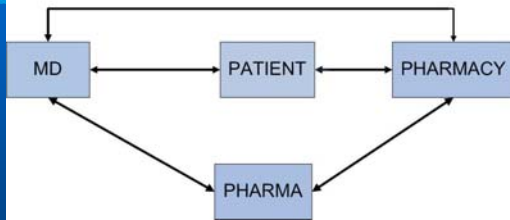
What PBMs Do

- All or none, vs. menu selection
- Claims processing
- Formulary development, maintenance and management
- Manufacturer contracting
- Network management
- Reports
- Mail order/specialty pharmacy
- Benefit management

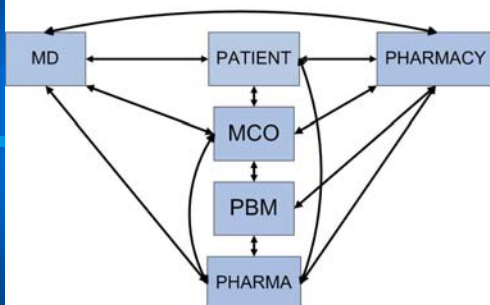
How PBMs Make Money

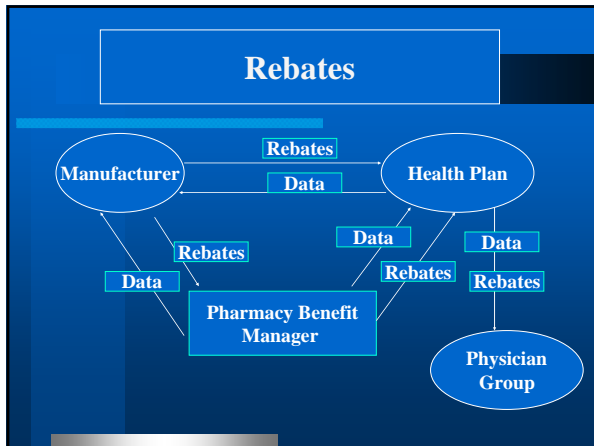
- Rebates (much more transparent now)
- Custom report generation
- Claims processing fees
- Sales of data and information
- Sidelines, e.g. mail service, specialty pharmacy, etc.

"THEN"



"NOW"





Managed Care Jargon

- “Member” = person with health insurance coverage from MCO
- “Benefit” = the health insurance policy (“contract”); what the MCO will provide
- “Provider” = MD (sometimes pharmacist, nursing home, etc)
- “Pharmacy Benefit” = typically means the retail drug coverage, copays, formulary status, associated policies, etc.

Managed Care Jargon, continued

- “Medical Benefit” = includes office visits, hospitalizations, lab tests, etc, as well as drugs administered by doctor, in hospital, in nursing home, etc.
- “Copay” = the member contribution to receive a service
- “Coinsurance” = a copay based on a % of normal selling price
- “Exclusions” = what’s not covered or provided

...and more Jargon!

- “Tier” = a benefit design term denoting what level of copay is due for a given drug
- “Exclusion” = a benefit design term denoting that a service, product, etc. is not covered
- “Prior Authorization” = a requirement that the health plan approve a drug or service before being provided the patient
- “Step Therapy” = a process requiring a patient to try drug A before receiving B

Managed Care: your worst nightmare, or your best friend?

“Managed care has done too good of a job making pharmaceuticals easily available.”

Pharmaceutical Company President

What Managed Care Does *and how it “manages”*

1. Health Insurance Basics
2. What the Pharmacy Department Does

Health Insurance Basics

- ### Presentation Outline
- Concept of insurance
 - Tragedy of the Commons
 - Develop and sell insurance products
 - Design benefits (hundreds per company)
 - Focus on all health care – until Part D
 - ASO BoB
 - In some cases, provide care
 - In some cases, manage care

- ### The Concepts Behind Insurance
- Spread the Risk
 - Reward (or penalty) for the risk-takers
 - The insurers
 - The insured
 - A "Population" approach
 - Is there really a free lunch?
 - Etc.

The Basic Dilemma of Health Care Insurance: The Tragedy of the Commons

- A resource management issue
- Multiple people acting in their own individual self interest will ultimately destroy a shared limited resource, even when they know it's in no ones interest to let this happen.

Hardin G. The tragedy of the commons. Science. 1968;162:1243-1248

Insurance Products

- Seek to be the "norm;" Avoid adverse selection
- Sometimes reward positive behavior
- Meet demands from:
 - Customers
 - Consumers
 - Providers
 - Regulators
- Most health insurers have several hundred insurance products/benefit packages

Other General Issues

- Focus on "total" health care (virtually all inclusive)...
- But, MMA spawned insurance for drugs only
- Exceptions to coverage:
 - Experimental therapies
 - Cosmetic treatments
- Mandated coverage
- State insurance commissioners

Who Bears the Risk?

- The insurance company, or the employer?
- ASO = Administrative Services Only: The insurance company provides claims processing, and sometimes care management; The employer bears the risk

Beyond Just Insurance...

- Some health insurers and provide care:
 - Group Health Cooperative
 - Kaiser
 - Intermountain
- Others "only" manage care:
 - The Blues (and most health insurance plans in existence)

What the Pharmacy Department Does

Presentation Outline

- The “New Era”
 - A wide range of key roles
 - Increasingly Pharmacy Dept is responsible for “retail,” “medical,” and specialty Rx
- Rx Management Programs

Changing Roles for MCO Pharmacy Departments

- Old View
 - Began to change in the late 80's
 - Just control retail drug costs
 - Use the PBM's formulary and rebates
 - Big rebates are 'job 1'
 - Minimize impact on the member
 - Keep doctors happy

The New Era for MCO Pharmacy Directors and Their Staffs

- Responsible for both 'retail' and 'medical drugs'
- Overall goal: clinically sound, cost effective drug therapy
- Manages the formulary
 - Reviews AMCP dossiers and other evidence
 - Creates evidence from data – e.g. number needed to treat
 - Prepares summaries for the MCO's P&T committee
 - Coordinates and schedules P&T meetings, may or may not have a vote

New Era, continued

- Carefully reviews utilization & cost reports
- Responsible for managing biologics and high cost specialty drugs
 - *but still searching for the best approach and benefit design*
 - Contracts with specialty pharmacy, monitors service
- Manages rebates but recognizes that % generics reduces overall costs better
 - Rebate contracting themselves, or through PBM

New Era, continued

- Monitors PBM's services
 - Contracting with PBM
 - Are we getting reports we need?
 - Are benefits and membership changes getting loaded into computer promptly?
 - When there is a problem, do we get super-fast service?
- Responsible for Pharmacy networks
 - Either build their own (most common), or use PBM's
- Contracts with Mail Order service
 - And monitors service

Rx Management Programs

- #1 in importance – the Formulary, & clinically sound, cost effective Rx program
- Physician education
 - “Report cards” – how your prescribing (e.g. % generics) compares with your peers
 - Newsletters about new drugs – effectiveness relative to other drugs, and costs
 - Important (but not all MCOs do it) – letters before formulary changes begin

Rx Management Programs, continued

- **Rx benefits**
 - Works with MCO Actuaries, Medical Directors, Marketing
 - Goal: benefits that will sell to employer groups, control costs, be solid clinically, minimize member and physician angst
- **Member Education**
 - Advance notice about formulary changes
 - Programs to improve patient compliance (a huge US problem)
- **Wellness & Disease management programs**

VALUE

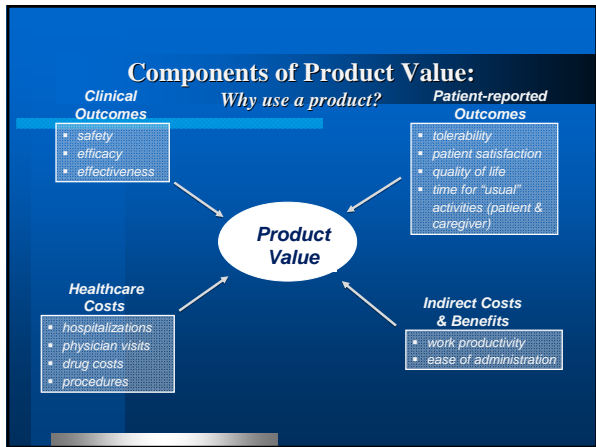
Why it has become so important

Presentation Outline

- **What is “Value” in Healthcare**
 - Well known to this audience!
 - 2009 forces of change
 - What evidence Formulary Directors want to see

What is Value in Health Care?

- Comparative Effectiveness
 - Does a medical intervention (drug, device, program, surgery) improve health outcomes relative to existing interventions?
 - Big Investment (> \$1B) by Pres Obama and Congress
- Cost Effectiveness
 - Is the incremental benefit enough to justify the additional cost?



2010 Forces of Change

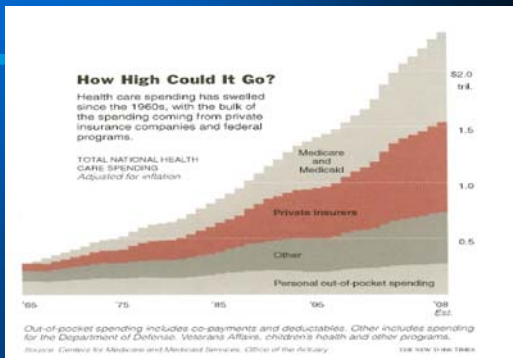
- Value dossiers are being requested worldwide
 - US AMCP, Great Britain NICE, Canada CADTH, Europe EMEA, Australia PBAC...
- What has happened – why all the interest in value?
 - Worldwide: Healthcare \$\$ squeeze. Aging populations. Big costs for biotech drugs (even though overall Rx cost trend has gone down)
- Big focus on comparative effectiveness internationally.

More forces of change – emphasis on value

- US Payers (MCOs, PBMs, government programs) are making evidence-based formulary decisions
 - AMCP Dossiers have had an enormous role
 - Efficacy, Safety, Health Outcomes, Total Cost of Care
- In the US: boomers ready to 'break the bank' for Medicare medical and Rx costs. Employers demanding value in their health insurance.
- Employers want to know what they are getting for their health insurance investment

New York Times: March 1, 2009

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SPECIAL REPORT

Show Us the Value

David B. Salzman and Michael J. Fava

A NEW SURVEY REVEALS WHAT MCOs AND PBMs REALLY WANT: PRODUCTS WITH VALUE — AND THE CLINICAL PROOF THAT DEMONSTRATES THEIR WORTH.

Affordable health care has become a leading political and social issue in the United States, and managed care organizations (MCOs) have responded by seeking to reduce pharmaceutical expenses to minimize rising costs. Historically more aggressive, MCOs are now behaving like true consumers and demanding that new drugs bring value to the overall healthcare system, relative to the cost and effectiveness of a cheaper, older alternative.

That seemingly simple objective — to link pharmaceutical value to secondary costs — has resulted in a dramatic paradigm shift that encourages pharmaceutical R&D to

Pharmacy Directors Want Full Information about Value

- Product PI, safety and efficacy aren't enough in formulary reviews. MCO's, PBM's and government programs want to evaluate:
 - Health outcomes (e.g. impact on hospitalizations and overall medical costs). Clinically solid economic models are important for new drugs.
 - Place in therapy – how a new drug compares with other drugs, not just placebo

Pharmacy Directors and Value continued

- Studies that aren't in the PI – e.g. latest clinical data just presented at ASCO, economic studies
- Economic models (discussed by Sean Sullivan tomorrow)
 - For US decision makers, “clinically sound and understandable” is more important than “robust and elegant.” More interested in direct costs (Rx and medical) than QALYs
 - And US decision makers tend to be a little suspicious of models...

FORMULARIES

Presentation Outline

- Pharmacy management tactics
- All about formularies
- Who decides formulary status/coverage
- The P and T process
- The *AMCP Format for Formulary Submissions*

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Pharmacy Management Tactics

- Formularies; The P and T process
- PA, step edits, restrictions
- Benefit design
- Contracting
- Pharmacy networks and mail order
- CME; profiling
- Member education; profiling
- Disease management
- Other

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Definition: Formulary

- List of medications
- Medication-related information
- Usually indicates tiers
- Regularly updated
- Represents the clinical judgment of physicians, pharmacists, and others
- Utilization management tool

Coalition Working Group. Principles of a Sound Drug Formulary System.
October 2000.

Types of Formulary Benefits

- Typically just 1 formulary per MCO, but it can be administered in several ways:
 - Open – educational, all drugs covered
 - Closed – Non-formulary drugs are not covered unless “medically necessary”
 - Partially/Selectively Closed – Certain drugs &/or classes excluded
 - Tiered – open/closed with variable coverage

What Formularies Should Do

- Promote the safest, most effective drugs, related products, and therapies that will provide the desired goals of therapy at the most reasonable cost
- Vehicle for communication of health promotion information

Definition: Formulary System

- Ongoing evidence-based process
- Carried out by health care professionals
- To establish policies on the use of drugs, related products, and therapies
- Identifies drug products and therapies most medically appropriate and cost-effective for the health interests of a given population
- Periodic reanalysis

P&T Committee Functions

- Objectively evaluate and select drugs for formulary
- Establish policies and procedures to educate practitioners about drug products, usage, and committee decisions
- Oversee quality improvement and DUE
- Implement generic substitution and therapeutic interchange programs
- Develops policies and procedures for access to non-formulary drug products

Coalition Working Group, Principles of a Sound Drug Formulary System, October 2000.

Background / History

- 1950's Hospitals
- Health plans rapidly adopted use
- 1991 Australian PBAC & Canadian CCOHTA formulary guidelines developed
- 1998 Regence BlueShield
- 1999 NICE formulary guidelines and tech assessments developed
- 2000-1 AMCP/RBS formulary guidelines adopted nationally

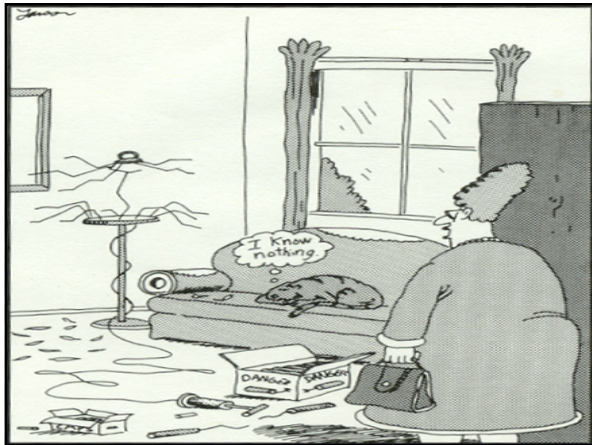
The Formulary Process: Who Decides Coverage?

- The P and T Committee
or
- The "Pharmacy Business Committee"
 - P and T determines clinical merit
 - If equivalent, then business issues are the determining factor

Typical P and T Members

- Membership can vary considerably
- MDs – variety of specialties
- MCO Medical director (vote ?)
- MCO Pharmacy director (vote ?)
- Community pharmacist ?
- Ethicist?
- Public member?
- Attorney?
- Other?

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Three Basic Questions:

- Is the drug under review more effective, equal to, or less effective than comparators?

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Three Basic Questions:

- Is the drug under review safer, equal to or less safe than its comparators

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Three Basic Questions:

- If equivalent to the comparators, which drug is the best overall deal?

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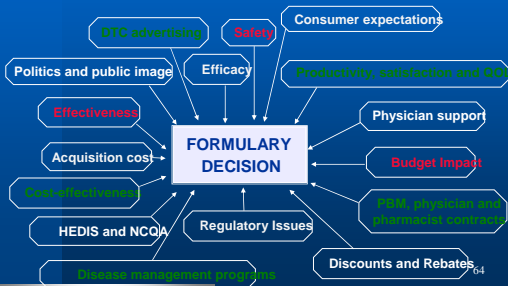
Past Method of Evaluation

(for some MCOs)

- Anecdote and bias
- Incomplete information
- Drug impact only (cost, rebate)
- Evidence based decision-making
- Total medical costs: cost offsets
- Total health impact
- Total value

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Factors That Can Impact a Decision



Committee Capabilities

- **Highly variable**
- **Movement towards EBM (a “buzz word?”)**
 - Some are very capable and practice it religiously
 - Others claim to use it, but don’t understand it.
- **Lots of detractors**

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The Environment: Current Limitations

- **Inadequate safety and efficacy data**
 - Evidence-based assessments difficult
 - Few studies available at time of review
 - FDA accelerated review process
- **Lack of unpublished studies**
- **Lack of off-label use data**
- **Lack of QOL, functional status, and cost-effectiveness data**

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What's Needed to Make the Best Decisions?

- EBM expertise
- Appropriate committee membership
- Capable staff support
- Evidence
- A rigorous process
- Support of the organization

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What's Meant by "Evidence?"

- Randomized controlled trials
- Peer reviewed publications
- Data on file
- Anecdotal information
- Comparator information
- Economic information
- Expert opinion

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Is the Evidence Relevant?

- Are studies (of any type) well designed and conducted?
 - relevant study populations?
- Are head to head comparisons relevant to clinical practice?
- Are multiple measures of efficacy and effectiveness presented?
- Is focus on primary endpoints or final outcomes?

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Is the Evidence Relevant? (continued)

- Are costs associated with introduction of the drug addressed?
- Is long term impact addressed (beyond clinical trial periods)?
- Is impact on sub-groups addressed?
 - differing cost-effectiveness characteristics (age, sex, physiological response)

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Take Home Messages

- Expenditure trends strongly suggest that the “squeeze” will continue.
- MCO’s have to get out of silo Rx decisions
- The process for selecting and managing the use of pharmaceuticals by MCOs must be improved.
- MCOs need to employ rigorous technology assessment programs to evaluate evidence of benefit, safety and value of new compounds.

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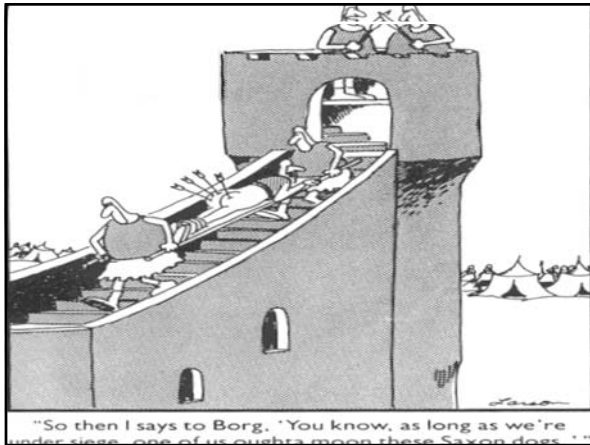
Pharmaceutical companies have said...

- There is no consistent way MCOs evaluate medications
 - The formulary approval process has been criticized as lacking scientific basis
- Decisions still based too heavily on the cost of the medication
- MCOs do not accept the value argument for their products
 - There is a lack of expertise in MCOs relating to pharmacoeconomic data or outcomes studies

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MCOs Have Said...

- Value arguments are typically “smoke and mirrors”
- Evidence for new drugs is usually insufficient and biased
- Marketing plays too much of a role in drug selection



Limitations of the Traditional Process

- Adequate data not available in a timely fashion
- Unpublished data not easily obtained
- Outcomes data and modeling not routinely supplied
- Excessive staff time spent in gathering and summarizing material
- Glossy formulary kits lack relevance for the plan and its members

So, What's really Happening Out There???

- Are your drugs given a fair hearing
- Do those making decisions know what they are doing
- Are patients being harmed
- What do the payers think

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The Need for Improvement

- Given the current environment there is a real need for change in many MCOs
- Given the diversity in evaluation processes, there is still a substantial need for standardization

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The AMCP Dossier Format

History

- AMCP Dossier process began in 1998
 - Started as “Regence Blue Shield Formulary Guidelines”
 - Published 1998 Fullerton, Sullivan, Atherly, Mather
 - Fullerton was VP at Regence Blue Shield Seattle (1.1 million members); Sullivan P&T Chair; Atherly Formulary Director; Mather UW Fellow
 - Why we began US dossiers in 1998 – to get more complete information for evidence-based formulary decisions

FDA & Regulatory Issues

- AMCP dossiers (1998 Regence; 2000 AMCP) not part of FDA charter (FDAMA – 1997)
 - FDA has no regulatory authority over dossiers
 - Unsolicited request essential!
 - Section 114 (Economic data) – discussed tomorrow
- AMCP careful to communicate with FDA
- FDA staff understands evidenced needs for MCO/PBM formulary decision makers
 - Including off-label data and models with stated assumptions

Unsolicited Requests

- Can not just offer an AMCP dossier
- Can make a statement “ENDO is fully supportive of the AMCP dossier process”
- Pipeline presentations can fuel requests for dossiers
- Be sure to keep a paper trail
- A practical caution...

Who can discuss dossier content?

- Here are some observations
- About 65% of a dossier is on-label
- Regence experience
- Two extremes
 - 1) Account Execs can't say a word about dossier; or
 - 2) Account Execs can discuss everything in dossier
- Somewhere in the middle makes sense!

AMCP's *Format for Formulary Submissions*: Components

- Product information
- Supporting clinical and economic information
- Modeling report
- Product value and overall cost
- Supporting information

Product Information

- Product description
 - Approved Indications
 - Off label Uses
 - Pharmacology and Pharmacokinetics
 - AEs and Interactions
 - Comparator Drugs

Product Information (Continued)

- **Place in Therapy**
 - Epidemiology
 - Pathophysiology
 - Societal and Economic Impact
 - Approaches to Treatment
 - Place in Treatment
 - Expected Outcomes

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Supporting Clinical and Economic Information

- Key Clinical and Economic Studies (published or not) in text and evidence table formats
- Outcomes Studies and Economic Evaluation Supporting Data
- Meta-analyses and Systematic reviews

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Modeling Report

- To predict system-wide consequences of the drug
- Helps define the drug's role in the MCO
- Should be relevant to the MCO, based on their
 - Costs
 - Demographics
- Overall, aids the decision-making process

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Product Value and Overall Cost

- **A Value Argument Based on:**
 - Summary of all the data presented
 - Expected unit cost
 - Estimated expenditures for the drug
 - Anticipated effects on clinical and HRQL outcomes
 - Economic consequences for the MCO, members, and clients

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Supporting Information

- **References (Copies of publications or other documents)**
- **Spreadsheet models**
- **Anything else that may be pertinent but does not fit elsewhere.**

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Understanding the Process

- **AMCP Dossier process almost 10 years old**
- **Dossier means “data”**
- **No frills or “pizza boxes”**
 - Good: Clinically solid, interesting to read, professional appearance
 - Not good: Reads like a marketing piece or formulary kit
- **Communication is vital**
- **New environment requires new thinking**
- **Evolution is needed from both the pharmaceutical industry and the managed care industry**

PIZZA

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Use and Abuse of a Dossier

- Easy to request, but difficult to analyze
- Staff support capabilities??
 - Clinical
 - Economic
 - Business
- Staff support time is limited
- Courage to make the tough decisions

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AHRQ Study

(Harvard, UW, Tufts, Premera Blue Cross)

- Carefully reviewed 35 dossiers
 - Submitted to Premera Blue Cross between January 2002 and September 2005
- Quality lacking, especially with economic analyses
- Off-label indications often not supported very well with clinical data
- Only 46% included an economic analysis
- *"We found no evidence of improvement in the quality over time."*

Colmenero, Sullivan, Watkins, Neumann et al.
Amer J Managed Care. Jul 2007;13(7):401-407.

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Dossiers vs Formulary Kits

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Dossiers

- Much more than a formulary kit!
- Science & evidence based (everything backed up with data, references)
- Not limited to on-label, so includes treatment guidelines, economic modeling, unpublished data
- Only to PharmD / MD formulary decision makers in response to unsolicited request

Formulary Kits

- More marketing focused in content and style
- Largely centered around label
- General distribution okay

What An MCO Does With Dossiers

- Quick review for completeness
- Request for any incomplete sections
- In-depth analysis
- Preparation of P&T monograph with/without recommendation
- P&T review and decision
- Implementation

Types of Formulary Decisions

- Add/Don't add
- Remove
- Defer
- Prior authorization
- Step edits (contingent therapy)
- Therapeutic interchange
- Mandatory generic substitution
- Communication requests

Reality Check for MCOs

- Formulary decisions need justification
- Decision making has often been weak
- Drug spending continues to increase
- Employers want evidence of ROI
- Manufacturers need to comply
- MCOs need to coordinate all of this to make better decisions

Where is All of This Going?

- Will the drug benefit survive?
- If so, in what form
- Will it get more restrictive?
- Will Pharma be able to align incentives with MCOs?

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Pharmacy Benefits

Presentation Outline

- Benefit trends 2009
- Tiers
- A Sample Rx Benefit
- What a drug costs MCO
- Medicare Part D

Benefit Trends 2009

- Benefits not keeping up with very high cost drugs (NY Times)
 - Huge problem for members who need biologics and other super high-cost Rx
 - Prices for 1 month of treatment
 - Gleevec (cancer; oral) \$3600
 - Betaseron (MS, self inject) \$1000
 - Pegasys (Hep C, inject abdomen or thigh) >\$3000
 - Cerezyme (Gaucher disease, infused) \$20,000

Benefit trends, continued

- “Pharmacy” Rx and “Medical” Rx still are usually in separate benefits
 - “Retail” = oral, topical, self injectable
 - “Medical” = physician administered
 - Patients often caught in the middle between “retail” and “medical” coverage – NY Times

NY Times: *“Because it was a pill, I had to pay – not the insurance”*

Important: find out what the most common Rx benefits are!

- A MCO will usually have hundreds of Rx benefits, but focus sales on just a few
 - Thank goodness for modern claims processing computers!
 - What you need to find out: what are the most common Rx benefits; and likely changes for the future

Tiers

- Just about all health plans now use tiers
 - Tier 1 = generics (e.g. \$5 copay or free)
 - Tier 2 = preferred brands (e.g. \$25)
 - Tier 3 = non-preferred brands (e.g. 50% or \$50)
 - Tier 4 = biologics, specialty (e.g. 20%)
 - Tier 5, Tier 6 = ??

Pharmacies Specified in MCO Benefits

- MCO usually contracts with 3 kinds of pharmacies (described in benefits)
 - Retail pharmacies (usually many!)
 - Mail order pharmacy (usually just 1 or 2)
 - Specialty pharmacy (next topic)

Components of a Rx Benefit

- Maximum Coverage per year
 - Retail drugs \$5000/person per year; example 2: \$20,000 per year – e.g. for a self insured employer group
 - Medical drugs (not including hospital) \$10,000
- Copays/coinsurance
 - Retail drugs: Tier 1 = \$5; Tier 2 = \$25; Tier 3 = 50%; Tier 4 = 20%. All drugs: \$25 or 50%, which ever is higher – non-participating pharmacy
 - Medical drugs: \$20 Example 2: 20%

Discussion: What do you think about these parts of the benefit?

Sample benefit, continued

- **Deductibles**
 - \$200 (copays/coinsurance) retail drugs
 - \$250 medical drugs
- **Formulary**
 - Often available on the MCO's web site; and tiers shown; also usually shows which drugs must be prior-auth
- **Pharmacies**
 - Must use a participating pharmacy, or much higher copays
 - Walgreens mail order pharmacy (3 months for 2 copays)
 - Specialty drugs (listed) – must use Caremark

Sample benefit, continued

- **Maximum out of pocket**
 - Per Rx or Per year
 - Many MCO's don't have a max
- **Exclusions (common examples)**
 - Drugs not FDA approved
 - OTC drugs; and Rx drugs with OTC equiv.
 - Investigational/experimental drugs (*but some health plans will pay for FDA approved oncology drugs for off-label indication if part of a NCI study*)
 - Cosmetic drugs (e.g. Botox for wrinkles)
 - Fertility drugs
- **Appeals process**

What the Retail Drug Costs the MCO

Example: \$80 WAC, \$100 AWP
Tier 2 preferred brand

- **Pharmacy contract specifies AWP less 15% = \$15**
Net: $\$85 + \$2.50 \text{ disp fee} = \87.50
- **Tier 2 Member Copay = \$25**
Net that MCO pays Pharmacy = **\$62.50**
Note: if 25% coinsurance, $25\% \times \$85 = \21.25
- **Rebates calculated later – usually not shared with member or pharmacy, but sometimes with employer group (negotiated with MCO)**

Medicare Part D Rx Benefit

- Started June, 2004
- Administered by private MCOs
 - MCO doesn't have to be a "Medicare Advantage" provider
- Seniors now under formularies
 - MCO almost always has a separate formulary (structure set by CMS)

Medicare Part D, *continued*

- For 2009 (need to confirm)
 - Base monthly premium (about \$31)
 - \$300 deductible (member pays 100%)
 - 25% coinsurance up to \$2920 total drug costs
 - "Donut Hole" (100% coinsurance) up to \$4650 out of pocket (\$6596 total \$)
 - After that, coinsurance is 5%

Specialty Pharmacy

Presentation Outline

- **What is “Specialty Pharmacy”**
 - Focus on high cost oncology drugs, biologics, drugs that need special training or monitoring
- **Huge growth of SP**
- **SP Services**
 - Base Services
 - Options

What is “Specialty Pharmacy”

- Pharmacy that specializes in high cost drugs, and therapy for less common, complex medical conditions
 - High cost oncology drugs
 - Biologics (they are all high cost!)
 - Drugs that need special training and/or experience for the pharmacist

Top Specialty Drug Spend

- **Cancer drugs**
- **Rheumatoid Arthritis**
- **Multiple Sclerosis**
- **Anemia, neutropenia**

The Growth of Specialty Pharmacy

- More than 50% of drugs in development are considered SP drugs
- Greatly increased research funding by manufacturers
- New hope for patients
- MCOs and CMS complaining, but still willing to pay very high costs
 - Have had to back away from some Average Selling Prices (ASP) – complaints particularly from oncologists

Average Rx Costs for A Large MCO

- Average Retail Rx: \$68.85
 - Generic \$26
 - Brand \$140
 - Specialty \$1736
- SP drug trend is 2-5 times higher than traditional drugs during last 5 yr
- In 2003, SP drugs were about 9% of total drug spend; now 15-20% - but <1% of total Rx

Specialty Pharmacy's Services

Base Services

- Maintains inventory of very high cost drugs
- Ships directly to MD or to patient
- Detailed Reporting
- Bills MCO based on contracted price and discount
 - Retail drugs often processed directly with PBM on-line

Specialty Pharmacy Services, *continued*

Options

- Makes sure patient meets MCO-approved criteria before dispensing
- Communications with MD and patient as needed, including patient compliance
- Nurse case managers can monitor particular drugs or patients
- Help avoid waste and over-usage
 - Negotiates rebates with manufacturers
 - Rebates are usually small with SP drugs

Communicating with Payors

Presentation Outline

- Background for understanding your audience
- Where/How your presentation fits in
- How to present to MCOs

Here's the Situation: You're going to an MCO to give an clinical/value/outcomes presentation...

- What's your audience's perspective? Where are they coming from? Who's responsible for what (e.g. dossier review, P and T, Formulary, etc.)
- How do they make formulary decisions, and where does your message fit in? What's been their history?
- What will resonate with them? Evidence? Value? Etc.
- How can you communicate with them?
- What factors influence how your information is accepted?
- Appearances count!!!

The Pharmacy Director/Clinical Pharmacist/Formulary Manager as Your Audience

- New drugs can be wonderful, but...
- How will we pay for them
- Outcomes are the right measure, but I'm measured on drug spend
- What does this drug do for quality
- What do our clients want/need
- Is there a compelling value argument? Can I sell it to my boss(es)? – or will it fall into the black hole of skepticism?
- How should benefit design evolve to deal with biologics?

Pharmacy Director Frustrations

- He/she understands the need to:**
- Assess the health plan impact of new products
 - Improve formulary decision making
 - Become less reliant on RCT (i.e. broaden the scope of evidence
 - Maximize the use of outcomes and economics data in the formulary process

The Clinical Pharmacist

(P and T staff support – if there is one)

- Where's the evidence of:
 - Efficacy
 - Effectiveness
 - Safety
 - Outcomes (and Value if you're lucky)
- How does it compare to related agents
- Will organizational/client/other "politics" get in the way of the right decision

The Medical Director

(Rarely available!!)

- Defers drug issues to pharmacy director
- Total medical costs are the thing; therefore a value message may resonate especially well
- We need to maximize ROI
- How does this drug impact quality?
- How does it impact outcomes?
- How knowledgeable are they about outcomes, economics, etc?

Managed Care's Dilemma – 1

(That your presentation may help fuel)

- "If you use our newer (and more expensive) drug, your members will achieve better and faster outcomes, such that total medical costs go down"

Typical presentation

Managed Care's Dilemma - 2

- “You’re doing a great job controlling drug expenses, but if we’re too aggressive, won’t we shoot ourselves in the foot?”

GHC RVP

Managed Care's Dilemma - 3

- “I’m happy to see that the expense of this new drug you’ve added to the formulary will be more than offset by medical cost savings. How much will we save and when can we put it in the bank? And by the way, you’re now responsible for documenting these savings.”

MCO CFO

Presenting Your Message

Remember:

- Tell me what you’re going to tell me
- Tell me
- Then tell me what you told me.
- And finally, the “KISS” principle

What to Articulate

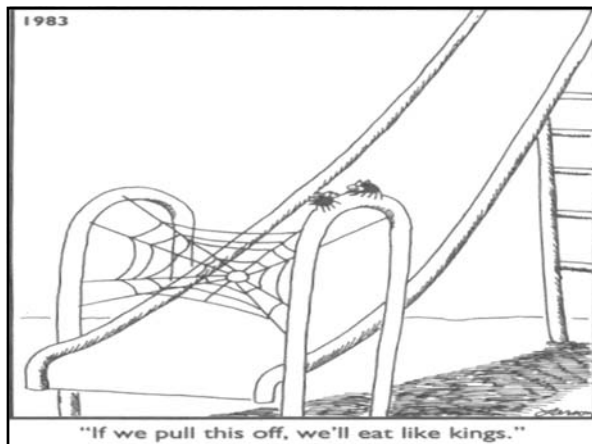
- Key value message(s) – the 30 second elevator speech – mesh with the AMCP dossier!
- Evidence summary bullets
- Applicability to the MCO
- Impact on health outcomes and total cost of care
- “Actionability”

What to Demonstrate to and Quantify for an MCO

(i.e. the unsophisticated pharmacy director)

If added to the formulary in a preferred position:

- Spending for this drug will be minimal, or
- Our drug costs less on a per day, per year, or per treatment course, or
- There will be an increase in drug spend, but savings of \$_____ will accrue elsewhere, or
- There will be a net increase in total medical costs, but it's worth it, as quantified by_____.



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**Other Topics, Questions
and Lessons Learned**
