

The role of actuarial science in US manufacturers' potential budget impact and cost-effectiveness value propositions

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MAY 18, 2022

Outline

Introductions

- Why would a drug or device manufacturer use an actuary?

Patient population modeling

- Denominators

Service and population costs

- Payer types
- Per member per month—the foundational actuarial pricing unit

Pricing strategy considerations

- Understanding US pricing structures
- Alternative contracting methods
- Regulatory and customer factors

Product launch support

Summary and conclusions

Introductions

Presenters



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David has been a senior healthcare consultant in the Hartford office of Milliman since 1999. His clients include medical device manufacturers, employers, insurers, physicians and hospitals. He uses big data and data science to help his clients.

David started his career as the Director of Medical Economics with Kaiser Permanente in Southern California and the Northeast, and helped MedSpan, a provider sponsored HMO, get their start.



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Tracy specializes in evaluating health benefit programs for insurance companies, employers, pharmacy benefit managers, Medicare plan sponsors, and government entities. She supports drug manufacturers with optimizing pricing and formulary placement from a payer perspective in Medicare and commercial markets. Tracy enjoys helping clients assess and understand strategic considerations in response to regulatory and market changes.

Global reach, local knowledge

Actuaries apply mathematical and statistical methods to real world data to assess financial risk. These methods can be applied in a variety of business contexts where understanding the likely financial impact of possible future outcomes is beneficial.

Who is Milliman?

- We are one of the largest actuarial consulting firms in the world and the global market leader in actuarial consulting.
- We work extensively with many of the world's largest pharmaceutical companies, including support for their value-based contracting efforts.

Key contacts



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Actuarial value proposition



Who are actuaries?

Focus on quantifying and managing risk and uncertainty through a control cycle approach.

Adhere to strict professional and ethical standards to ensure users can rely on the work.



What is actuarial analysis?

- Financial
- Conducted with an emphasis on managing financial risk
- Apolitical
- Projections of the future based on historical experience, adjusting for known differences and poor data
- Sensitivity testing of assumptions



What do health actuaries do?

- Historical experience analysis and benchmarking
- Risk adjustment and equalization calculations
- Predictive modelling
- Analysis / comparison of contracts and reimbursement mechanisms
- Return on investment, e.g., for disease management programs

Merging the actuarial and clinical perspective



Modeling

Leveraging real-world datasets

Balance between actuarial modeling and the statistical rigor many manufacturers desire (e.g., statistical significance causation)



Bring in the doctor, pharmacist, or other clinician

Well-versed in: Clinical drug names, pipeline products, new launches / patent expirations, a medication's specific diagnoses / patient cohort



Actuarial + Clinical = A happy marriage

Layering in actuarial modeling capabilities with clinical knowledge brings a unique and valuable perspective a manufacturer may not have internally

Patient population modeling

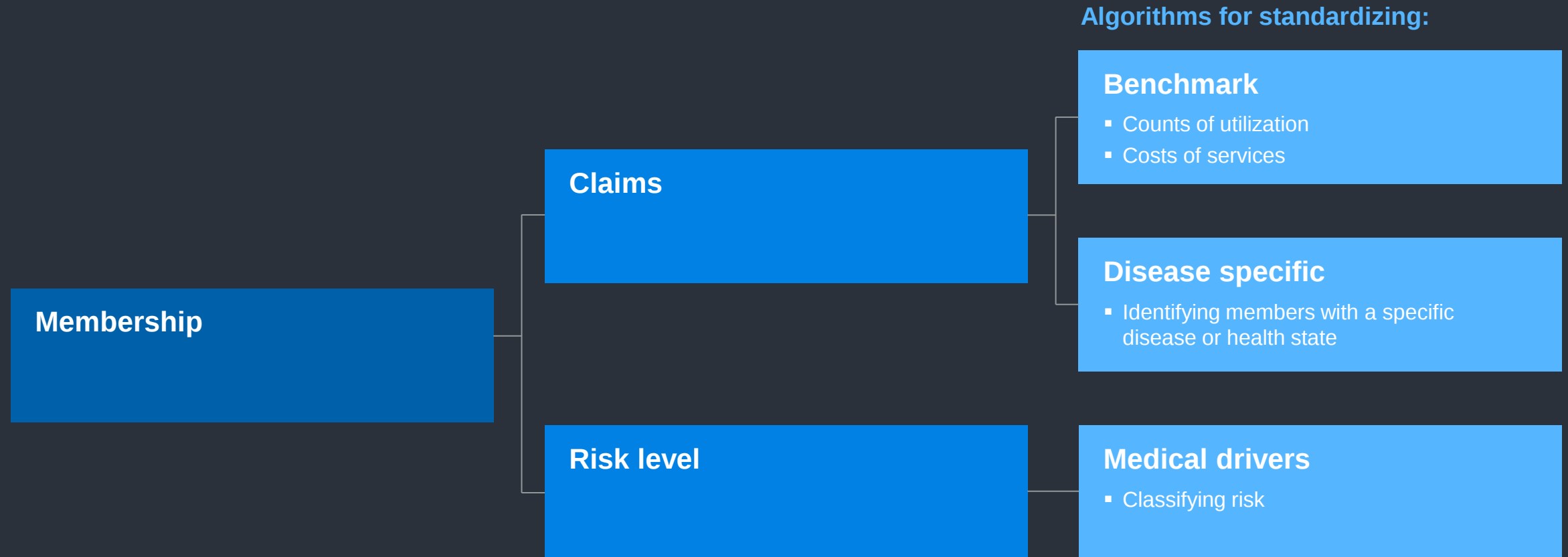
Poll

Question 1

Hospital billed amounts for a Health Technology Assessment (HTA)

- a) Reflect what hospitals get paid for services
- b) Accurately represent a broad financial perspective of a patient's healthcare experience
- c) Represent the societal cost of care for an inpatient stay
- d) None of the above

Real word data (RWD)



RWD assets

Large population medical claims data

Sample sources	Content	Lines of business	Years	2020 volume (lives)
Proprietary research datasets	Medical and prescription drug claim line detail with membership	- Commercial - Individual - Medicare Advantage - Medicare Part D - Managed Medicaid	12+ 12+ 12+ 10 12+	64 Million (M) 6 M 2 M 7 M 7 M
Marketscan		Commercial	12+	30 M
CMS 100% Research Identifiable Files		- Medicare Fee-for-service - Medicare Advantage - Medicaid	15+ 5 6	63 M 23 M 83 M
State discharge	Inpatient discharge detail, no membership	All	15+	N/A, 100% of admissions

The alphabet soup of medical coding

- CPT-4 (Current procedural terminology)
- HCPCS (Healthcare common procedure coding system)
- RVU (Relative value units)
- DRG & APR-DRG
(Diagnostic related group; all payer-DRG, Tricare)
- ICD-10
(International classification of diseases version 10)
- Ambulatory payment classification (APC) codes
- Modifiers
- Place of service
- Specialty
- Bill type
- Revenue codes
- National drug code (NDC) and therapeutic class
- Clinical classification software (CCS)
- Cost categories and bundles
- Risk scores
- Costs: Billed, allowed, paid, and coordination of benefits (COB)

Example: Identification of patients who experience seizures

Questions to explore

1. How may patients experience seizures by seizure type?
2. How do I define the population using Real World Data (RWD)?



Market size

Disclaimer: This information is for illustrative purposes only and is not appropriate for any other purposes

3.4M



People in the US experience epileptic seizures²

4th

Most prevalent neurological disease, more than multiple sclerosis, cerebral palsy, and Parkinson's combined



Typical audience and uses

- CEO
- Board
- Potential investors
- Size of the opportunity
- Addressable market
- Market entry
- Penetration

Market size segmentation by payer type and disease category

Disclaimer: This information is for illustrative purposes only and is not appropriate for any other purposes

Seizure category	Medicare aged	Disabled	Medicaid	Commercial	Total
Grand mal not intractable	11,000	11,000	15,000	19,000	56,000
Grand mal intractable	7,000	13,000	13,000	19,000	52,000
Motor seizures not intractable	270,000	238,000	269,000	522,000	1,299,000
Motor seizures intractable	55,000	82,000	92,000	182,000	411,000
Post traumatic not intractable	3,000	2,000	4,000	7,000	16,000
Post traumatic intractable	-	-	-	-	-
Non motor seizures not intractable	49,000	30,000	76,000	105,000	260,000
Non motor seizures intractable	3,000	2,000	7,000	10,000	22,000
Other convulsions	90,000	58,000	173,000	312,000	633,000
Febrile convulsions	-	-	36,000	39,000	75,000
Psychogenic non-epileptic seizures (PNES)	-	-	1,000	1,000	2,000
Total	488,000	436,000	686,000	1,216,000	2,826,000

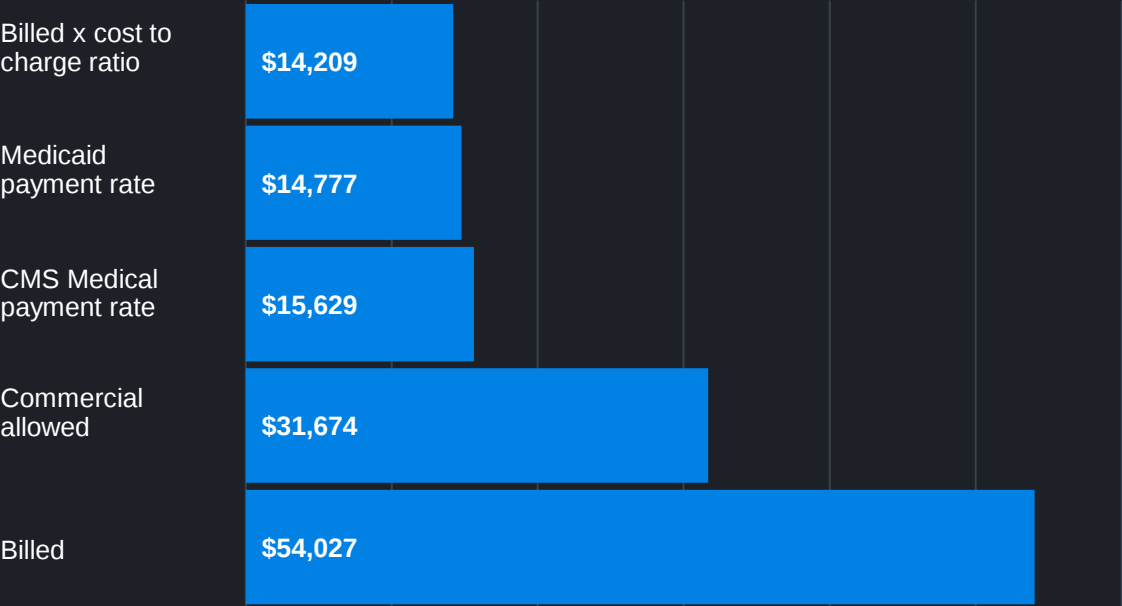
Intractable: Difficult to control. Not-Intractable: Current treatment is working

Service and population costs

Service costs vary by payer type

Disclaimer: This information is for illustrative purposes only and is not appropriate for any other purposes

- Hospital average allowed cost by payer type
- Major hip and knee joint replacement MS-DRG 470
- North Carolina, 2021



- Variability of costs
- Major hip and knee joint replacement MS-DRG 470
- North Carolina, 2021

Percentile	Allowed	Billed
20th	\$14,558	\$46,213
40th	\$26,524	\$53,177
50th	\$29,191	\$56,848
60th	\$33,945	\$63,144
80th	\$43,295	\$76,750

Per member per month

Example: Emergency room visit

$$\text{PMPPM} = \frac{\text{AvgCost} \times \text{Util Rate}}{12}$$

$$\text{Average cost per visit} = \$900$$

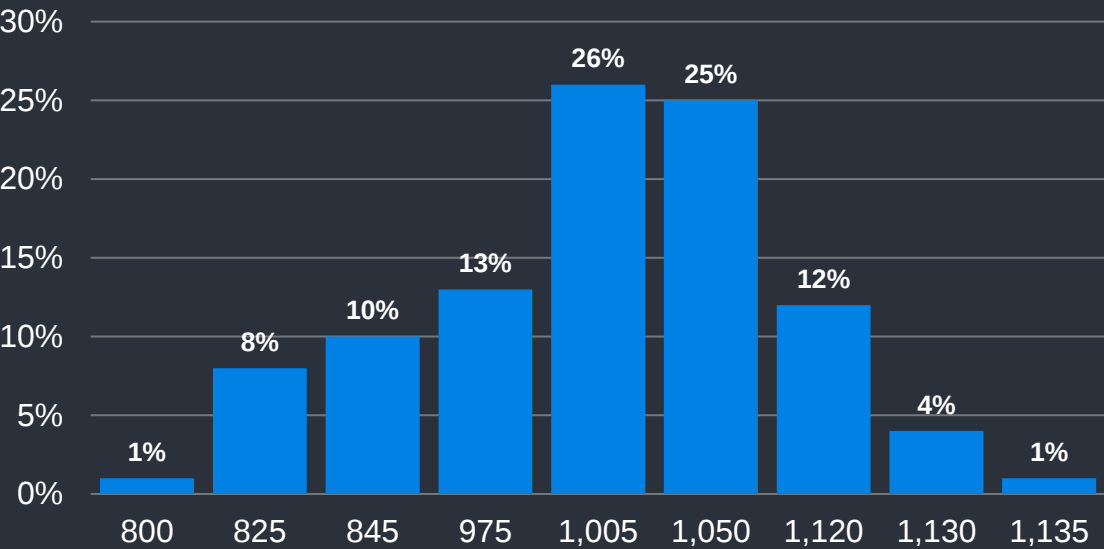
$$\text{Utilization per 1,000 members} = 150$$

$$\text{PMPPM} = 900 \times .15 / 12 = \$11.25$$

Medical claims are volatile

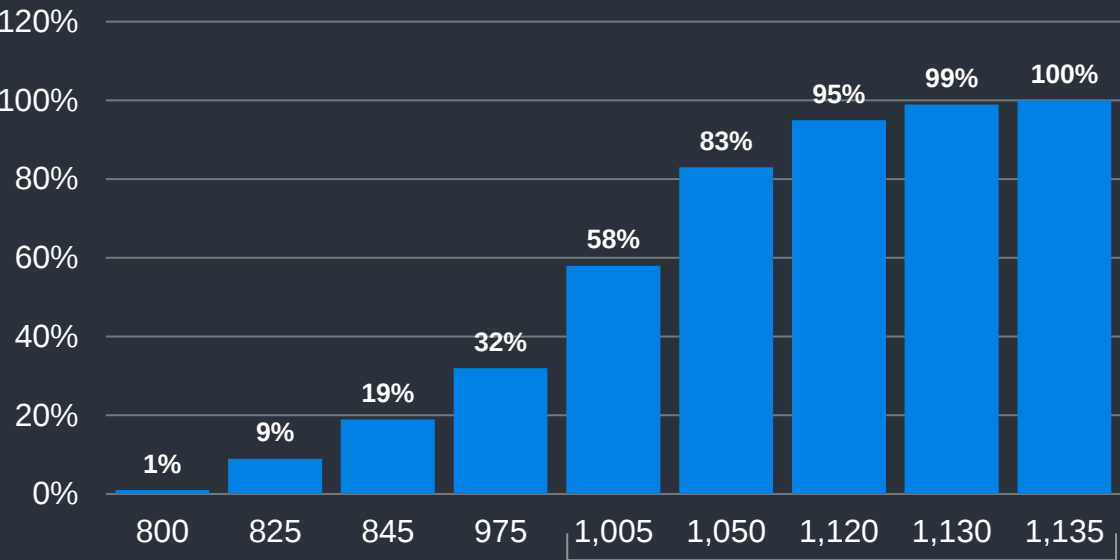
What if real world data looks like this

Probability of number of emergency department (ED) visits for your population of people with diabetes



Using real world data shows distribution of the number of ED visits for your population

Cumulative probability of ED visits for your population of people with diabetes



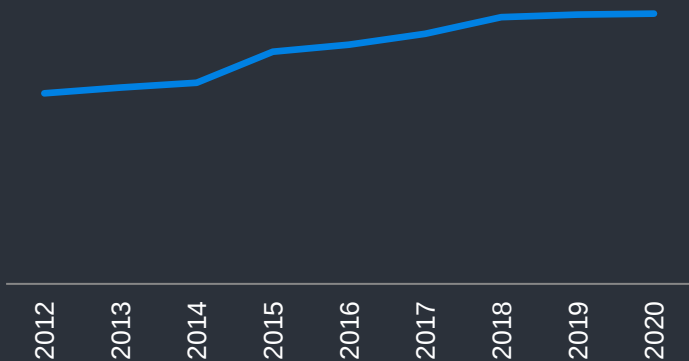
Cumulative probability shows that 68% of the time, number of visits exceeds mean of 1,000.

Trend

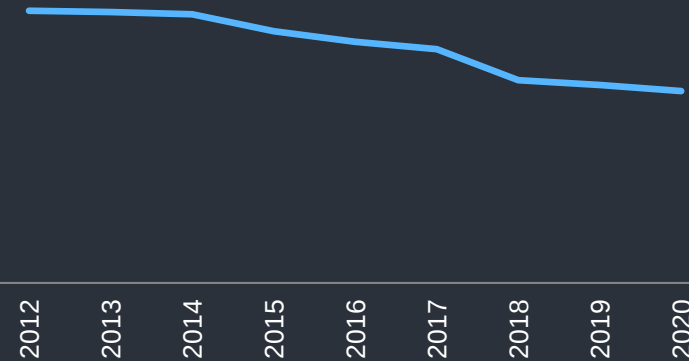
How are the number of visits changing year over year

ED visits over time

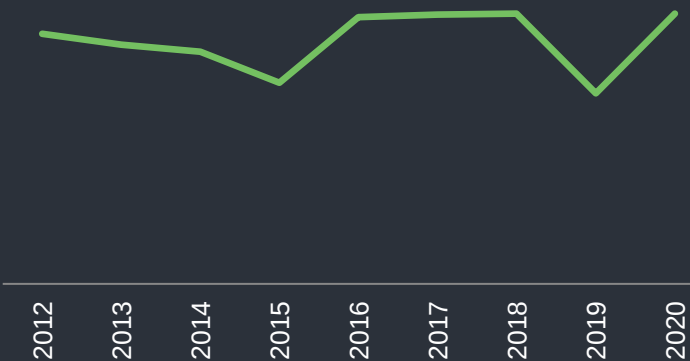
Scenario 1



Scenario 2



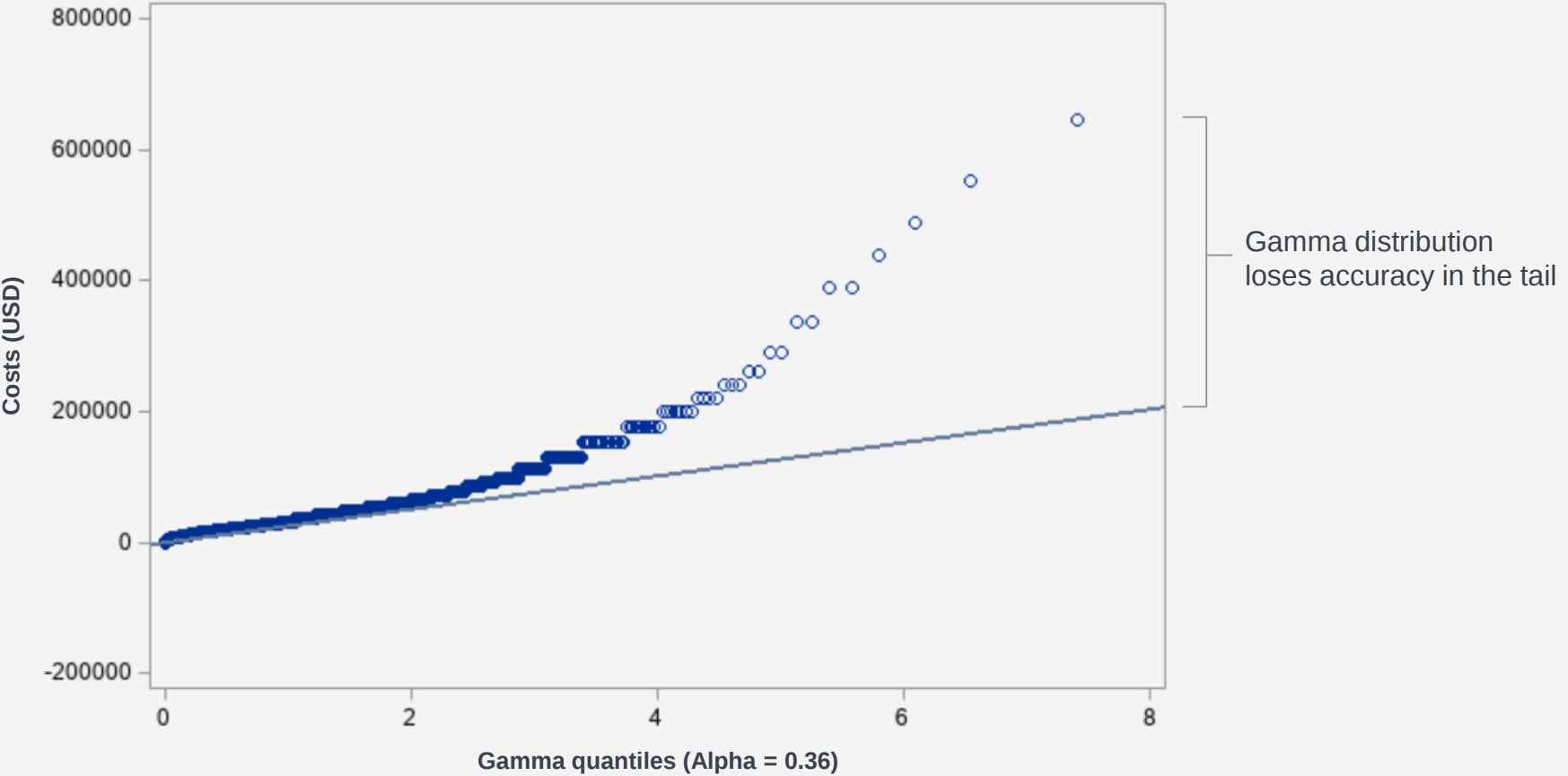
Scenario 3



Outliers can make a difference

Empirical distribution vs. theoretical gamma distribution

Gamma
quantile-quantile
(Q-Q) plot



Long or short horizon value proposition varies by payer type

Who has the longer time horizon for “returns”—the private insurance system or the government system?



Return on investment (ROI)

- Approach looks purely at financial costs and benefits: usually used by private payers.
- The fundamental question for private payers is, “will this new medicine or technology increase or decrease my claims cost and how can I mitigate the financial risks associated with claims cost inflation?”



Cost effectiveness analysis (CEA)

- Approach looks at incremental quality of life benefit metrics versus incremental costs for a new medicine or technologies relative to the existing treatment regime.
- The fundamental question for government payers here is, “is paying for this new technology or medicine going to give me more ‘health’ for my population relative to other ways I could spend my limited health budget?” This is intrinsically value-based!

Quiz: Budget impact of new technology

A health technology assessment (HTA) of a new drug determines a \$30,000 quality-adjusted life year (QALY) and the acceptance threshold is \$50,000.

The new drug is expected to cost **\$80,000**, involves 1 year of treatment, and will potentially impact **50,000** people (**5,000** per year) over ten years with an average age of 35.

⁽¹⁾ There are 220 million commercially insured lives in the U.S.



Question 1

How much must a commercial insurer with **1 million** covered lives increase their monthly premium?



Answer

About \$0.15 assuming they are all commercially insured.

- Budget impact to the insurer is \$1.8m per year over 10 years
- Per member per month cost = $\left(\left(\frac{50,000}{10} \right) / 220,000,000^{(1)} \right) \times 80,000 / 12 = \0.15 PMPM
- Budget impact = $\text{PMPM} \times 12 \times 1,000,000 = \$0.15 \times 12 \times 1,000,000 = \1.8M

Quiz: Budget impact of new technology

A health technology assessment (HTA) of a new drug determines a \$30,000 quality-adjusted life year (QALY) and the acceptance threshold is \$50,000.

The new drug is expected to cost **\$80,000**, involves 1 year of treatment, and will potentially impact **30,000,000** people **6,000,000** per year) over ten years with an average age of 35.



Question 2

How much must a commercial insurer with **1 million** covered lives increase their monthly premium?



Answer

- Per member per month cost =
$$\frac{((30,000,000 / 10) / 220,000,000^{(1)}) * 80,000}{12} = \$90.91 \text{ PMPM}$$
- Budget impact = PMPM x 12 x 1,000,000 =
$$\$90.91 \times 12 \times 1,000,000 = \$1.1\text{B}$$

⁽¹⁾ There are 220 million commercially insured lives in the U.S.

Quiz: Budget impact of new technology

A health technology assessment (HTA) of a new drug determines a \$30,000 quality-adjusted life year (QALY) and the acceptance threshold is \$50,000.

The new drug is expected to cost **\$6,000**, involves 1 year of treatment, and will potentially impact **30,000,000** people **6,000,000** per year) over ten years with an average age of 35.

⁽¹⁾ There are 220 million commercially insured lives in the U.S.



Question 3

How much must a commercial insurer with **1 million** covered lives increase their monthly premium?



Answer

- Per member per month cost =
$$\frac{((30,000,000 / 10) / 220,000,000^{(1)}) * 6,000}{12} = \$6.82 \text{ PMPM}$$
- Budget impact = PMPM x 12 x 1,000,000 =
$$\$6.82 \times 12 \times 1,000,000 = \$81.8\text{M}$$

How might these numbers change if it were a Medicare payer?

Merging the actuarial and clinical perspective



Modeling

Market-specific medical and pharmacy claim data

Determine appropriate approach for measuring disease burden and healthcare experience



Bring in the doctor, pharmacist, or other clinician

Guidance on disease pathology and healthcare experience for patients identified with disease state



Actuarial + Clinical = A happy marriage

Estimate disease burden and healthcare utilization and costs for a manufacturer's various customer types

Pricing strategy considerations

Pricing strategy considerations

1

**Understanding US
pricing structures**

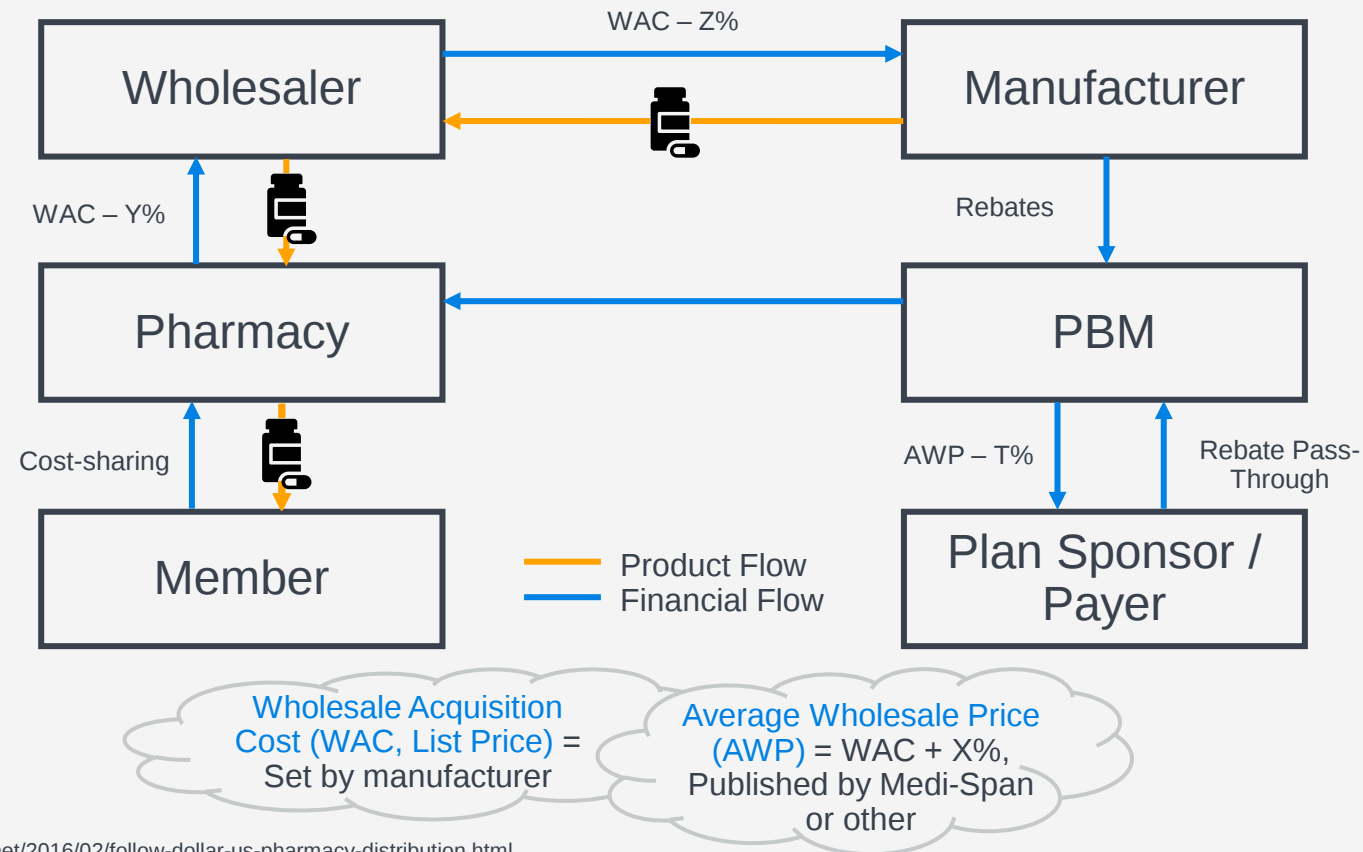
2

**Alternative contracting
methods require
specialized valuation**

3

**Regulatory changes
and customer perception
affect pricing**

Complex reimbursement structure in US



Source: Adapted from <http://www.drugchannels.net/2016/02/follow-dollar-us-pharmacy-distribution.html> and <https://www.usatoday.com/story/news/2016/10/03/how-prescription-drug-middlemen-make-their-money/91461918/>

How do payers think?



Commercial



Medicare



Medicaid



**Self-funded
employers**



**Pharmacy Benefit
Managers (PBMs)**



**Other government
payers**

Poll

Questions 2 and 3



Question 2

A **Medicare Part D plan** is negotiating formulary access for two high-cost products: Product X costs \$30,000 with a \$5,000 rebate and Product Y costs \$75,000 with a \$50,000 rebate. Which product would the plan prefer?

- a) Product X, the lower priced product
- b) Product Y, the higher priced product
- c) Either X or Y – the plan is indifferent because the costs net of rebates are equivalent



Question 3

A **pharmacy benefit manager (PBM)** is negotiating **commercial** formulary access for two high-cost products: Product X costs \$30,000 with a \$5,000 rebate and Product Y costs \$75,000 with a \$50,000 rebate. Which product would the PBM prefer?

- a) Product X, the lower priced product
- b) Product Y, the higher priced product
- c) Either X or Y – the PBM is indifferent because the costs net of rebates are equivalent

Example: Discounts or rebates?

Rebates may be more valuable than discounts for reducing payer liability

- Both scenarios include the same amount of total price concessions.
- The higher discount is shared between the payer and the member, while the rebate is used to directly reduce the payer's responsibility.

Item	Lower discount, with rebate	Higher discount, no rebate
Average Wholesale Price (AWP)	\$250	\$250
AWP discount	(\$50)	(\$110)
Discounted cost	\$200	\$140
20% Member coinsurance	(\$40)	(\$28)
Rebate	(\$60)	\$0
Net payer responsibility	\$100	\$112
Total price concession (discount + rebate)	\$110	\$110

Pricing structure examples



Traditional fee-for-service (FFS) payments



Discounts off billed charges or average wholesale price (AWP)



Prospective payment systems, where several aspects of service are bundled into one payment, such as Medicare bundled payment arrangements



Risk-based payments, where the provider is rewarded with bonus payments if they operate within certain performance standards, such as shared savings arrangements



Population-based capitated services, where a provider is paid a per member per month (PMPM) amount for each enrolled or allocated member regardless of the services used



Other payments in lieu of or in addition to those above, such as post-point of sale rebates

Which reimbursement structure is best?



The ideal reimbursement structure to achieve target product use and revenue may vary by payer type



Administrative claims data provides valuable insight into how payers may view various types of reimbursement



For example, drug manufacturers use actuarial models with real world data (RWD) to help develop pricing and rebate strategy

- Models estimate payer liability reflecting a "full medicine cabinet" for members taking a given medication
- Allows for viewing payer impact of changes in medication price and rebate
- Important to consider all medications because payer liability often varies throughout the year based on a member's total accumulated cost

Alternative contracting

“The goal of Value-Based Insurance Design (VBID) is to decrease the cost of health care while increasing the effectiveness of health services.”

– CDC Issues Brief, 2015

“Colorado implements accountability for Novartis on outcomes of two new drugs.”

– State of Reform, March 2022

“Amgen snags another Enbrel outcomes-based payment deal as it seeks to prop up aging blockbuster.”

– Fierce Pharma, December 2019

“Like it or not, value-based contracting is coming for drugs and medical devices.”

– MedCity News, April 2021

“Takeda launches value-based pricing program for lung cancer med Alunbrig.”

– Fierce Pharma, November 2021

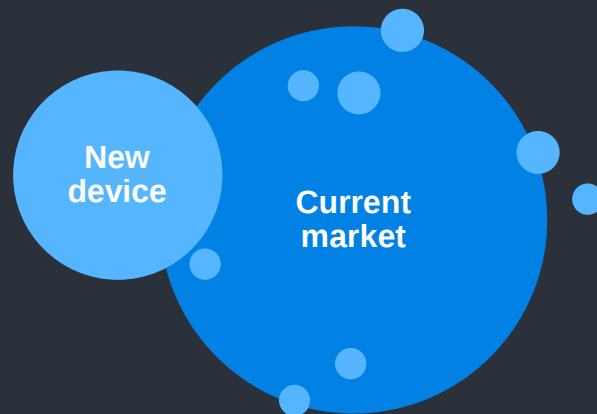
“Access Vascular Inc. partners with Healthcare Insights to develop new MedTech value-based care program.”

– Access Vascular Inc, February 2022

Why enter into a value-based contract?

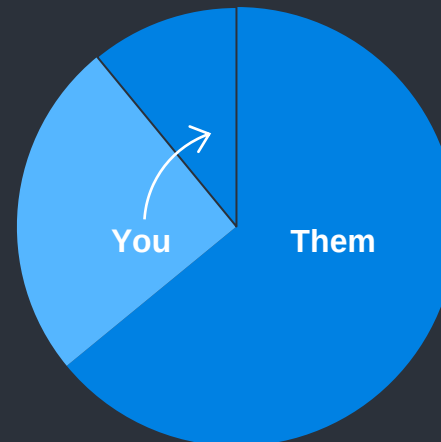
Introduce new product to the market

Example: Product will prevent hospitalizations or replace an expensive diagnostic tool



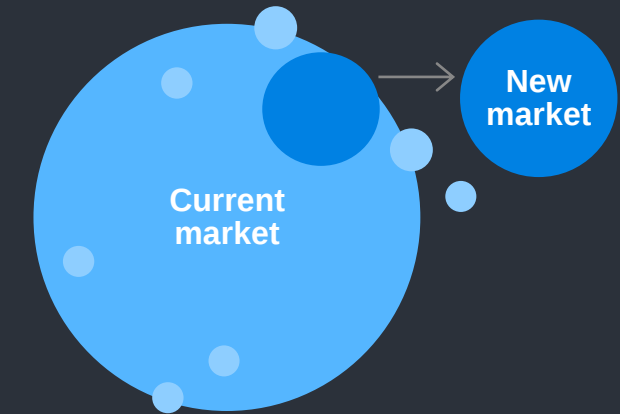
Increase market share

Example: Product works as effectively or better for another condition

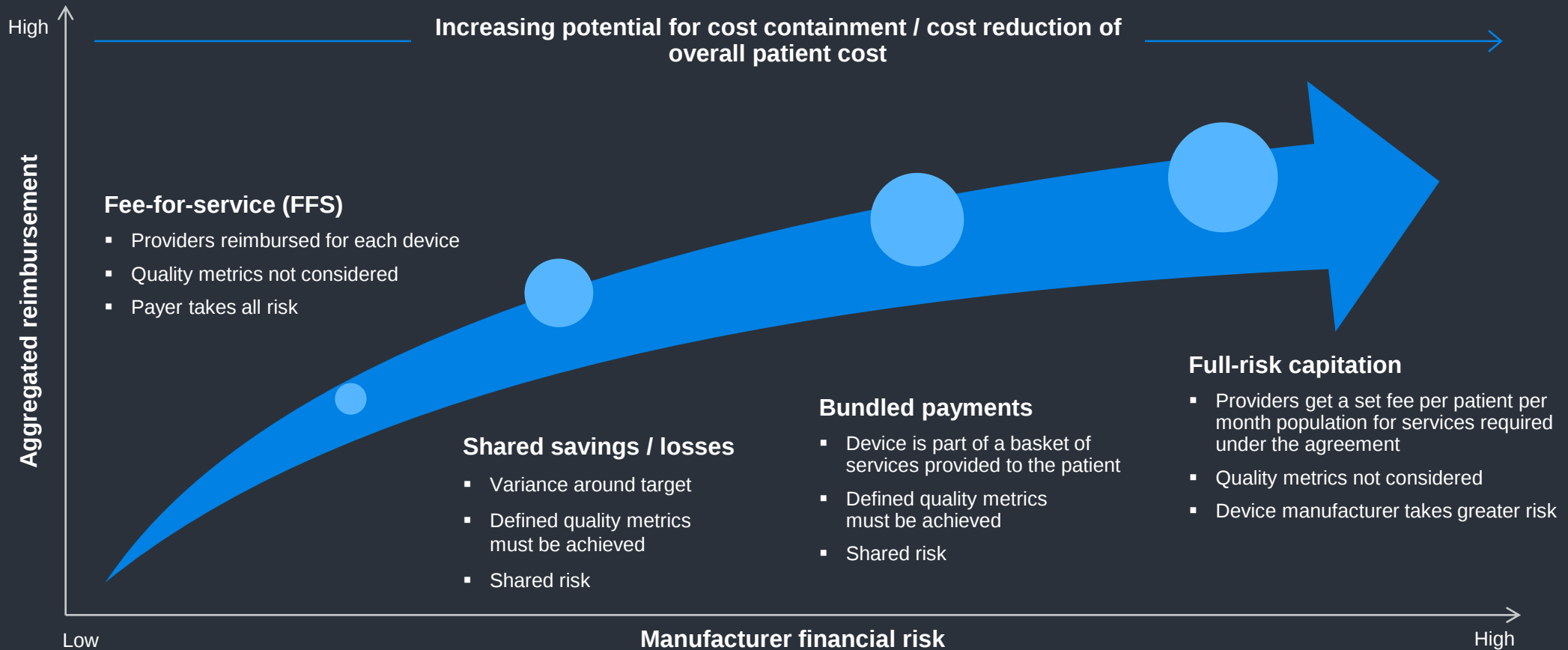


Introduce existing product into new market

Example: Product outperforms others used to treat the same condition in reducing readmissions



Alternative contracting



**If you are taking on risk,
you need an actuary.**

Alternative contracting



**Define
the population**



**Define
the services**



**Set historical
baseline
and trends**



**Apply risk
adjustment**



**Monitor performance
and define risk
share / gain share
provisions**



Requires an understanding of:

- Expected volume of product relative to administrative complexity of arrangement
- Whether based on outcomes related to approved indications for product, measurable in readily available data source(s), realized in acceptable time frame
- Willing and able partners

Regulatory and other contributing factors



Legal, regulatory, and policy considerations include an understanding of pharmacy or device-specific legislation, especially as it relates to contracting:

- FDA guidelines for contracting “on label”
- Formulary construction regulations
- Medical versus pharmacy benefit
- 340B
- New contracting strategies, e.g., moving rebates to the point of sale



What if the rules change?

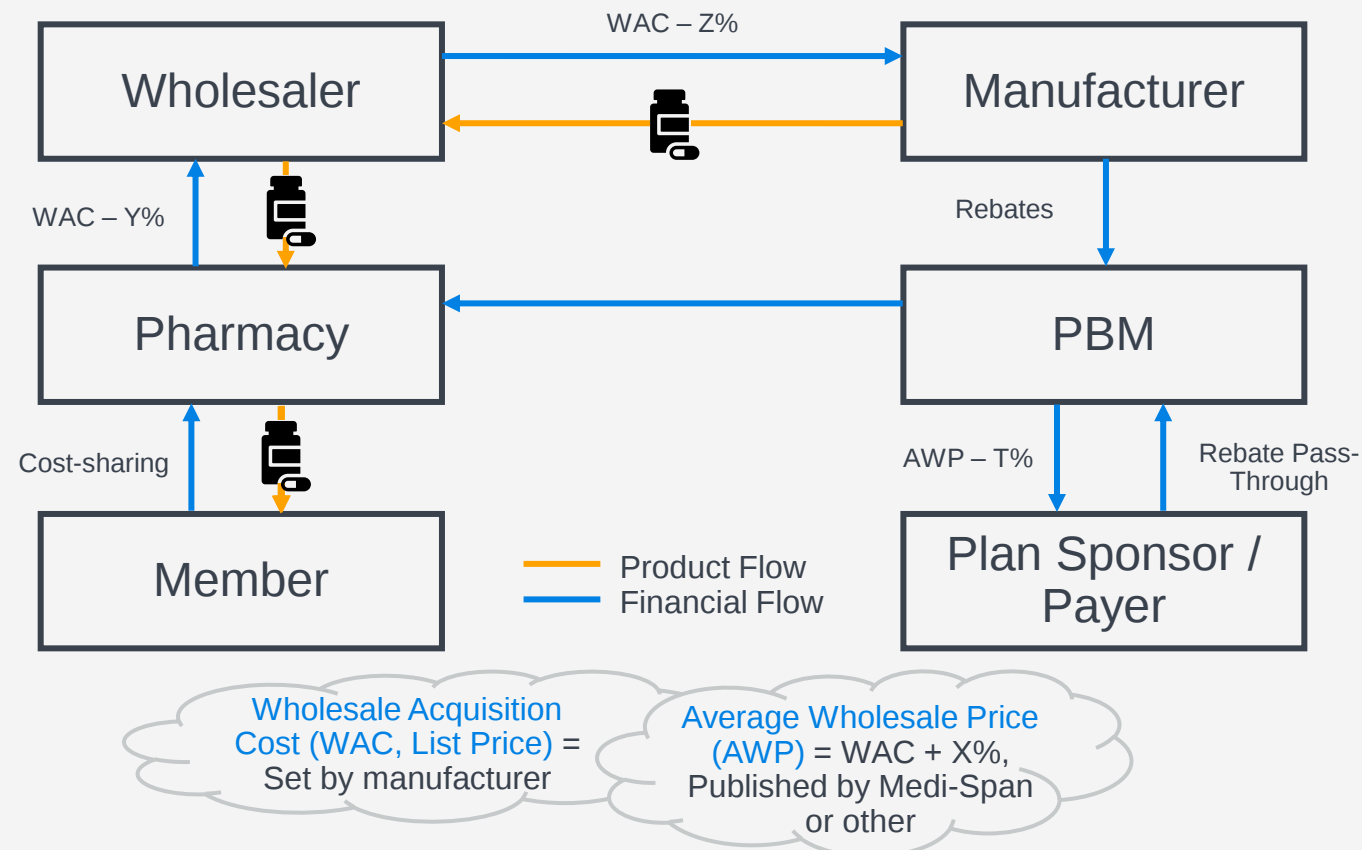
Example: Using RWD to assess the impact of policy changes on stakeholder costs

- The proposed Build Back Better Act would redesign the Medicare drug benefit
- For manufacturers, how would this policy change affect:
 - out-of-pocket cost for beneficiaries using their product?
 - payers’ perception of their product’s cost structure?
 - the manufacturer’s Medicare discount program payments?
 - market perception and costs relative to competitors?

Where does the patient fit in?

- Majority of members (patients) are presented with a single or limited option(s) for a technology and are responsible for out-of-pocket cost sharing.
- Acceptance of cost may be influenced by demand.

Source: Adapted from <http://www.drugchannels.net/2016/02/follow-dollar-us-pharmacy-distribution.html> and <https://www.usatoday.com/story/news/2016/10/03/how-prescription-drug-middlemen-make-their-money/91461918/>



Merging the actuarial and clinical perspective



Modeling

- Market-specific medical and pharmacy claim data
- Factors for prevalence, disease severity, treatment duration, and costs



Bring in the doctor, pharmacist, or other clinician

Guidance on treatment patterns, medications, therapies, or other interventions in the market



Actuarial + Clinical = A happy marriage

Estimate disease burden and cost implications for a manufacturer's various customer types

Product launch support

Payer and market access



Understand payer knowledge management

- Disease burden
- Treatment paradigm
- Unmet need
- Competitive assessment
- Access landscape



Identify payer knowledge gaps

- Therapeutic area and emerging pipeline
- Payers' decision-making processes
- Stakeholder thought-leadership



Develop value platform to close gaps

- Prioritize areas of differentiation:
- Current / future market
 - Clinical, economic, and humanistic value



Prioritize payer customers

- Size, region, and capabilities
- Adapt to meet needs



Train account directors

- Competency model development
- Training plan development
- Content development
- Training delivery

Payer value proposition

Once your product is on the market, how do you expand?

Actuarial analysis can support payer value proposition by using data to demonstrate benefits.

- Examples:
 - For alternative contracting arrangements, is your device or drug producing desired outcomes?
 - How do payer costs compare for patients using your product vs. not?
 - How do payer costs compare for patients pre- and post-product adoption?
 - Does the product reduce use of other healthcare services, such as emergency visits?
 - Are patients using the product profitable for the payer?



Payer value proposition

Example: Profitability of members taking Drug X

- When deciding whether to cover a new product, payers may review whether patients using the product are profitable
- Actuaries estimate the revenue and costs associated with members using a given product, considering all other medical and/or pharmacy claims for those members

Members taking Drug A

They are profitable to payers in this market.
Analysis promotes payer coverage adoption.

Members taking Drug B

They are not profitable to payers in this market.
Analysis identifies that potential pricing structure changes could improve product attractiveness.

	Drug A	Drug B
Revenue	\$100	\$100
Drug X allowed	\$90	\$130
Other allowed	\$500	\$600
Net paid	\$95	\$145
Loss ratio	95%	145%

Summary and conclusions

At what stage do you involve actuaries?

Possible starting points

Discovery



Preclinical
research
prototype



Premarket
application



Market
trials



Coverage
determination



Full market
launch and
beyond



- What: Patient profile
- Audience: Internal
- Use: Considerations when developing randomized controlled trial (RCT)

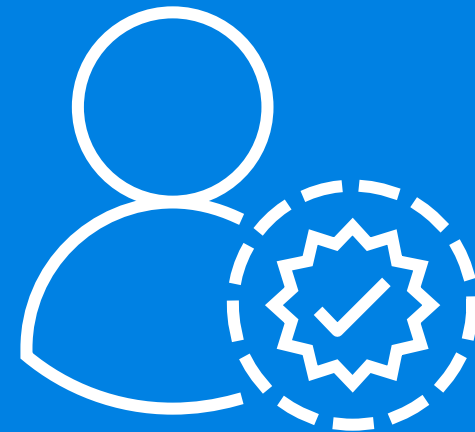
- What: Patient profile, cost and clinical effectiveness
- Audience: Internal
- Use: Preparation for billing and market launch

- What: Value demonstration
- Audience: CMS, Insurer's Technology Committees
- Use: Sales deck – value and effectiveness

The role of actuarial science

Actuaries can help inform

- Patient population modeling
- Pricing strategy considerations
- Product launch support



Caveats and limitations

The information contained in this presentation has been prepared for the ISPOR 2022 conference breakout session given on May 18, 2022. The views expressed in this presentation are those of the presenters, and not those of Milliman or ISPOR.

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Questions?





Thank you

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