

2018 HEALTH
MEETING
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Session 16OF, Drug Pipeline Impact on Future Claims Costs

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2018 SOA Health Meeting

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Drug Pipeline Impact on Future Claims Cost

June 25, 2018



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Information about unapproved medications is not an opinion predicting if these products will eventually be approved or their launch price. This information is provided to create awareness of the current status in the drug development process.

Agenda

- Background
- Problems
- FDA Approval Process
- Pipeline Overview
- Creating Solutions
- Reinsurance Impact
- Questions

Background



2013 Hepatitis C headlines...

Forbes

Dec 26, 2013

"Analyst forecast Sovaldi will generate as much as \$3 billion in annual sales in 2014..."

FiercePharma

Apr 22, 2014

"We can officially say Gilead Sciences pulled off the fastest drug launch on record... Sovaldi's Q1 total:

\$2.27 billion."

The New York Times

Feb 4, 2015

"Together Sovaldi and Harvoni achieved \$12.4 billion in sales..."

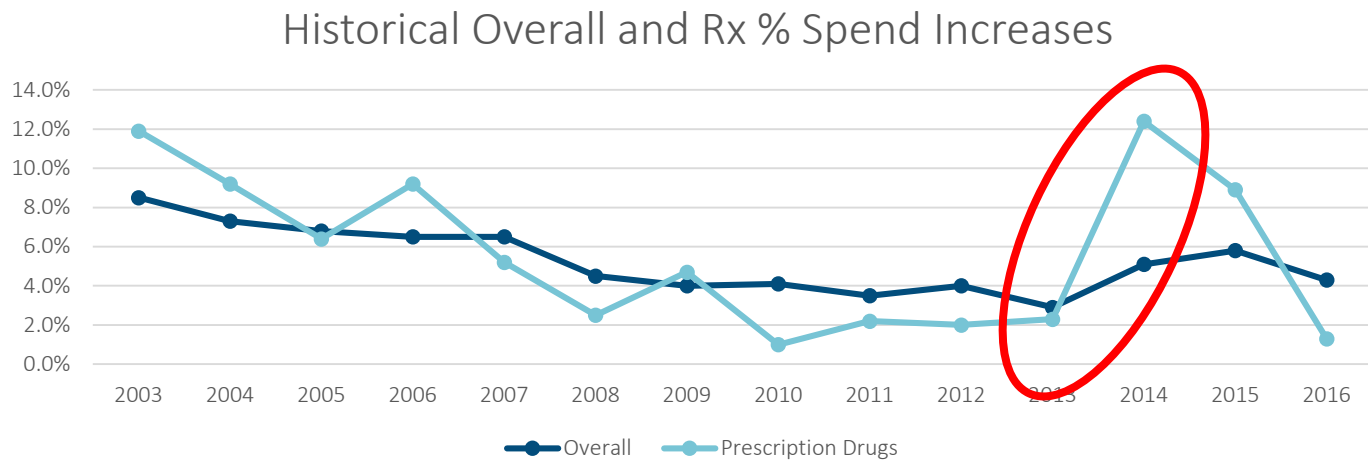
Source:

<https://www.forbes.com/sites/matthewherper/2013/12/26/the-most-important-new-drug-of-2013/#70e61921bb16> Accessed June 14, 2018.

<https://www.fiercepharma.com/marketing/it-s-official-gilead-s-sovaldi-zooms-past-previous-records-fastest-ever-drug-launch> Accessed June 14, 2018.

<https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html> Accessed June 14, 2018.

Why are we here?



Source: National Health Expenditure Data: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> June 15, 2018

Orphan Drugs

Are rare diseases really that rare?

Conditions that affect fewer than 200K people in the U.S. are called “orphan” or rare diseases. The individual diseases may be rare, but collectively affect 1 in 10 Americans and present **critical cost and care challenges** for payers as well as patients.

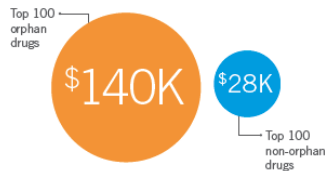
Alarming realities

These diseases have a high early mortality rate and cause catastrophic social, emotional and financial burdens for patients and their families.

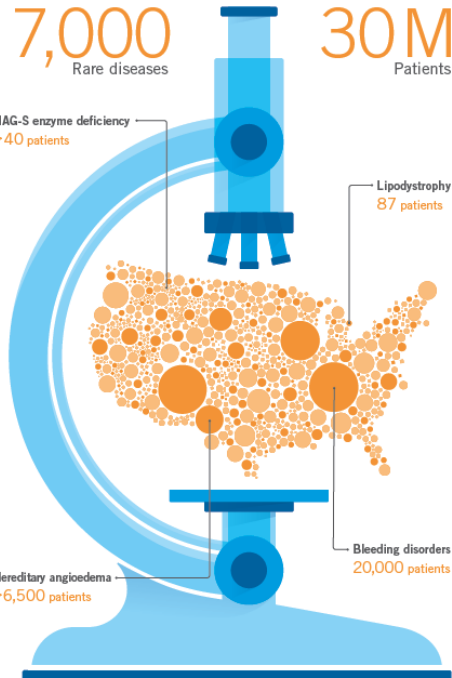
- Difficult to diagnose** – On average, patients wait nearly 5 years for an accurate rare disease diagnosis and see 7 physicians during that time.
- High mortality rate** – 30% of children with rare diseases won't live to see their 5th birthday.
- High costs** – Annual costs per patient are more than 5x higher than non-orphan drugs.

Financial exposure

Average cost per patient in 2016



441 FDA-approved orphan drugs
35% of specialty drugs in the pipeline are orphan
95% of rare diseases don't have an FDA-approved therapy



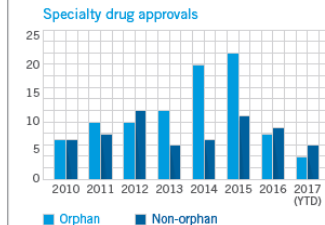
Good news/bad news

It's life-changing for patients when new therapies become available, but the costs can be staggering. Here are just a few examples ...

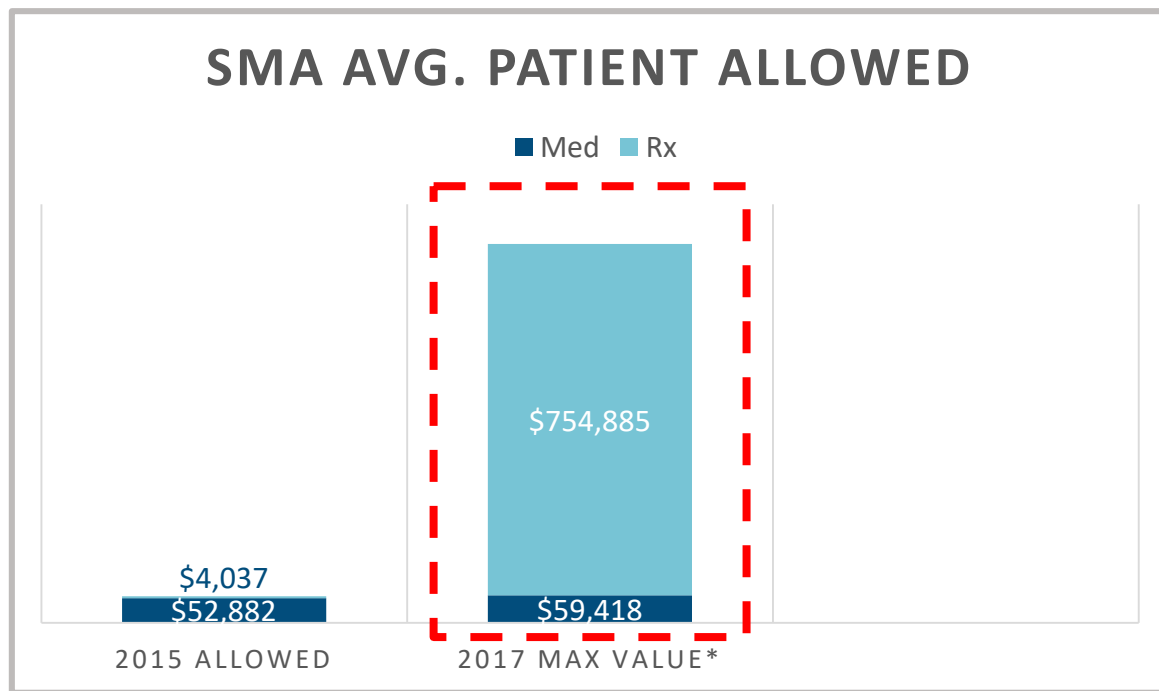
Rare disease conditions	Average spend per patient
Bleeding disorders (factor)	\$1,603,783
Hereditary angioedema	\$3,090,961
Rare congenital and acquired general lipodystrophy	\$1,011,022

Rapid increase in approvals and cost

The Orphan Drug Act of 1983 created financial incentives to promote development of breakthrough therapies. Some manufacturers used those incentives to capitalize on the profitability of orphan drugs, which led to broader investigations regarding the act.



Case Study – nusinersen (Spinraza®)



*Results based on 2015 Market Scan and Milliman Commercial data

Assumptions & Description

- Per Pt. Annual Cost of Spinraza - \$750k
- Annual Trends: Med – 6% Rx – 10%
- SMA = Spinal Muscular Atrophy
- FDA Approved 12/23/16
- Approx. 9k patients in US have disease

Why are we here – Pipeline is still robust

- Pipeline has over 7,700 products in development as of June 2018
 - 5,400 in January 2013
- Correlates to 10,800 drug-indication combinations
- 74% were potentially first-in-class in July 2017
- 1037 were orphan drug designation

Sources:

The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, The Analysis Group, July 2017

The BioMed Tracker Drug Intelligence Platform [Accessed at <https://www.biomedtracker.com> on June 18, 2018]

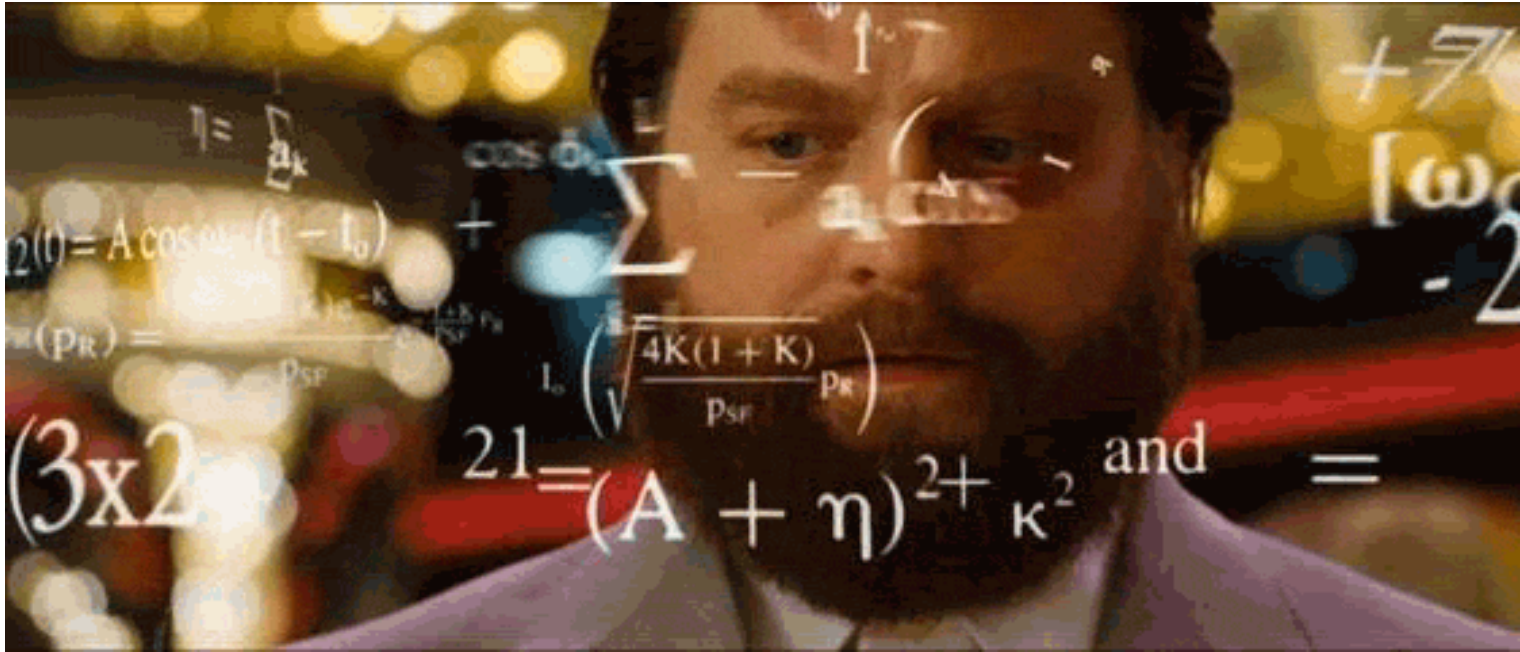
Problems



new drugs, minimal visibility



complex to track



Challenges in identifying patients who may be eligible for pipeline treatments



FDA Approval Process



Drug approval process

Pre-clinical

- 1,000's molecules
- toxicity
- IND submission

Phase I

- 20 to 100 healthy individuals
- Lasts several months
- 70% move to Phase II

Phase II

- 100's with disease
- Several months up to 2 years
- 33% move to Phase III

Phase III

- 1000's with disease
- Several months up to 2 years
- 25-30% get approved
- NDA/BLA submission

Time

Drug approval process

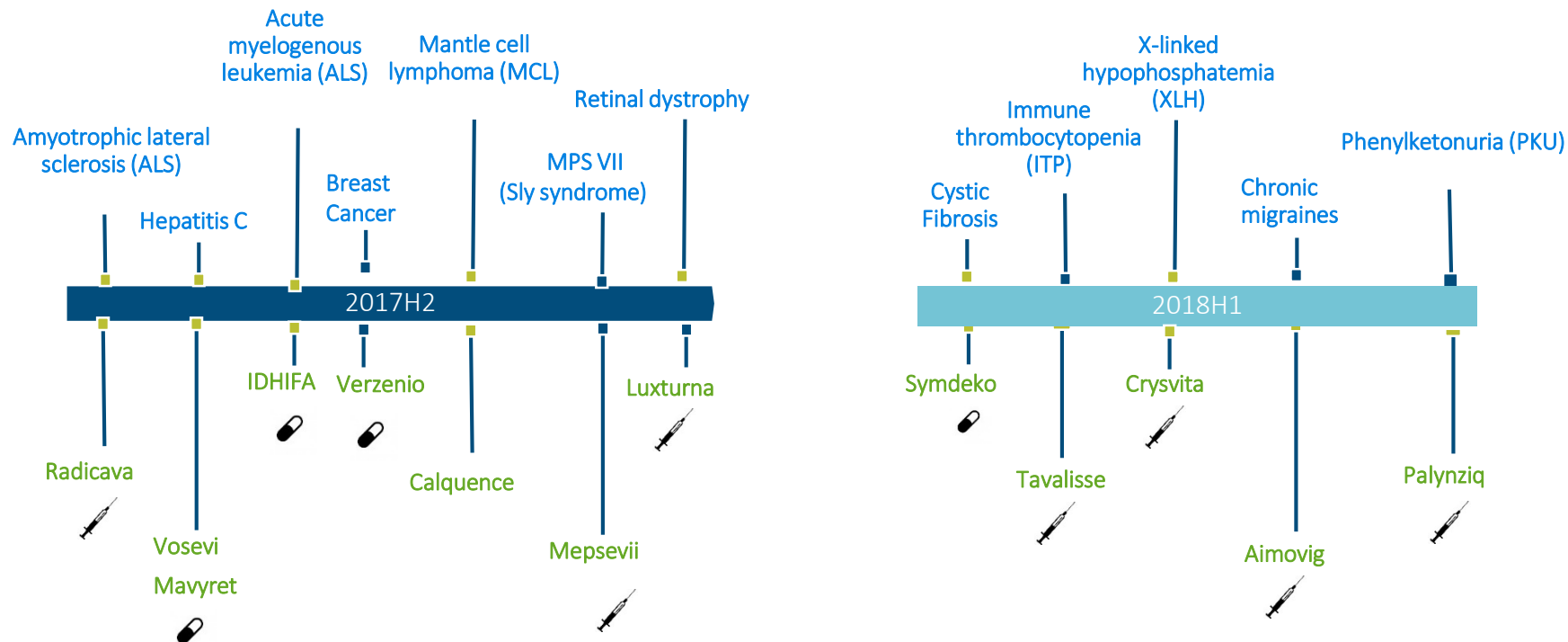
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Pipeline Overview

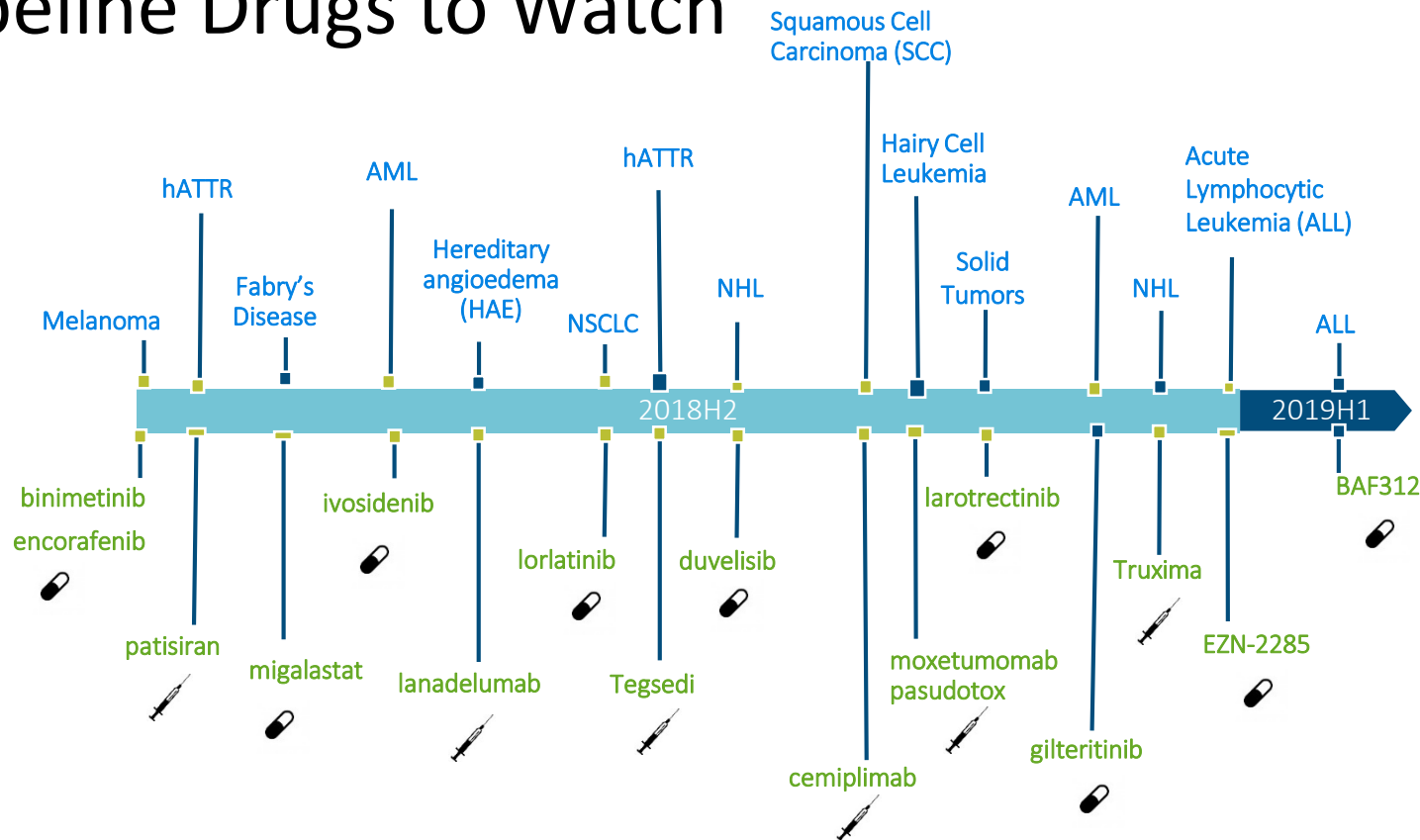


2017 & 2018 FDA Drug Approvals



Source: 2017 New Drug Therapy Approvals <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM591976.pdf>
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm> Accessed June 14, 2018.

Pipeline Drugs to Watch

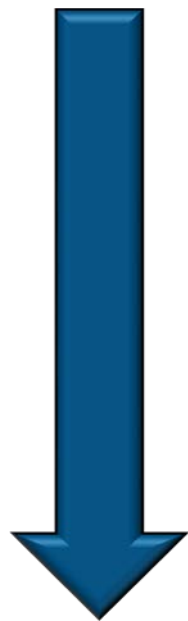


hATTR = hereditary amyloidosis (transthyretin [TTR]-related) NSCLC = non-small cell lung cancer AML = acute myeloid leukemia NHL = Non-hodgkin lymphoma

Source: The BioMed Tracker Drug Intelligence Platform Accessed at <https://www.biomedtracker.com> on June 18, 2018.

CAR-T therapy

Increasing number
of patients eligible
for treatment



\$475,000

Kymriah™

8/30/2017

Pediatric
ALL



5/1/2018

DLBCL



CLL/SLL

MM

\$373,000

Yescarta®

10/17/2017

DLBCL



MCL

Indolent
NHL

ALL

CLL/SLL

\$???,000

JCAR-017 &
others

Multiple
myeloma

ALL

DLBCL

NHL

CLL/SLL

\$???,000

100+ Other
CAR-T agents

sarcoma

Brain
cancer

AML

NSCLC












Solid
tumors

ALL = Acute lymphoblastic leukemia
DLBCL = Diffuse large B-cell lymphoma
MCL = Mantle Cell Lymphoma
MM = Multiple myeloma
NHL = Non-hodgkin lymphoma
AML = Acute myelogenous leukemia
NSCLC = Non-small cell lung cancer
CLL / SLL = Chronic lymphocytic leukemia / small lymphocytic

Creating Solutions



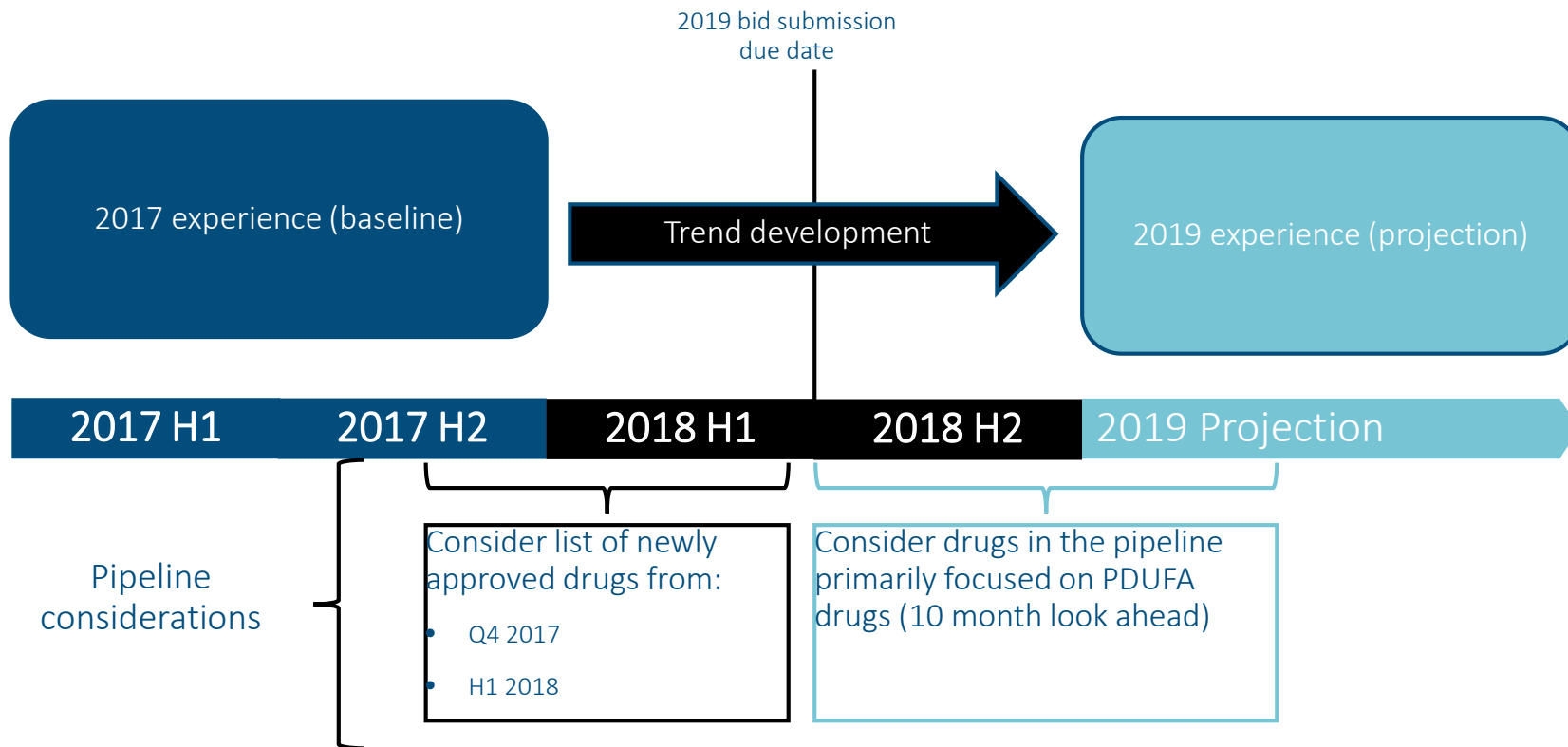
Sources of Pipeline Information

Primary	Secondary	Tertiary
<ul style="list-style-type: none">- Press releases from manufacturer    	<ul style="list-style-type: none">- News or Organizations    	<ul style="list-style-type: none">- Pipeline databases   

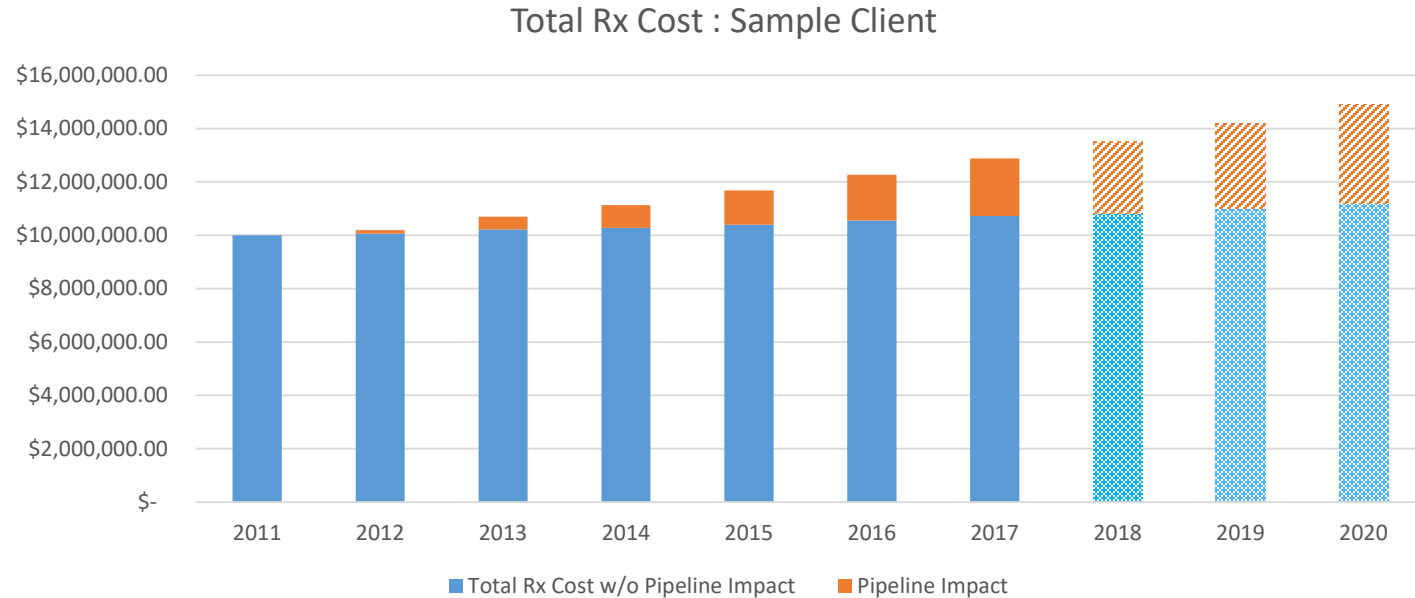
Goals and considerations of projecting pipeline costs

- Focus on understanding incremental costs and/or utilization incurred by pipeline drugs
- Address the following assumptions:
 - Launch date of pipeline drugs
 - Launch price of pipeline drugs
 - Expected pipeline drug uptake within the population eligible to receive treatment
- Pipeline drug uptake should take into consideration the following:
 - Novel therapy – significantly impacts current treatment landscape
 - Add-on therapy – drug is added to current treatment protocols
 - Replacement – drug displaces current drugs used to treat condition

Timing considerations



Client Case Study



*Results based on a random group sample from historical MarketScan and Milliman Commercial data

Sample client solution – financial impact

Summary of Base 2017 and Projected 2019 Pharmacy Costs By Medication and Condition									
Condition	Medication	Estimated Effected Members	Base Period			Projected Period			Total Cost of New Medication
			Total Rx Cost	Total Medical Costs	Total Cost	Total Rx Cost	Total Medical Costs	Total Cost	
Amyotrophic Lateral Sclerosis (ALS)	Radicava	5	\$ 26,529	\$ 347,807	\$ 374,336	\$ 26,529	\$ 533,571	\$ 560,100	\$ 185,764
Behcet Syndrome	Otezla	7	\$ 232,325	\$ 221,812	\$ 454,138	\$ 260,325.43	\$ 199,631	\$ 459,957	\$ 5,819
Immune Thrombocytopenic Purpura (ITP)	Tavalisse	27	\$ 409,082	\$ 2,126,049	\$ 2,535,130	\$ 744,541	\$ 2,126,049	\$ 2,870,590	\$ 335,459
Cystic Fibrosis	Semdeko	15	\$ 4,342,771	\$ 1,460,430	\$ 5,803,201	\$ 5,009,079	\$ 1,314,387	\$ 6,323,465	\$ 520,264
Duchenne's Muscular Dystrophy	Eteplirsen	11	\$ 105,486	\$ 1,595,193	\$ 1,700,679	\$ 205,486	\$ 1,483,530	\$ 1,689,016	\$ (11,664)
Fabry's Disease	Migalastat	8	\$ 1,129,068	\$ 3,342,327	\$ 4,471,395	\$ 1,849,068	\$ 3,074,941	\$ 4,924,009	\$ 452,614
Hereditary Angioedema (HAE)	Ianadelumab	6	\$ 3,429,622	\$ 331,488	\$ 3,761,109	\$ 3,789,622	\$ 298,339	\$ 4,087,961	\$ 326,851
Leber's Congenital Amaurosis	Luxturna	1	\$ 3,901	\$ 5,100	\$ 9,002	\$ 700,000	\$ 5,100	\$ 705,100	\$ 696,099
X-Linked Hypophosphatemia (XLH)	Crysvita	1	\$ 6,751	\$ 347,363	\$ 354,115	\$ 180,000	\$ 347,363	\$ 527,363	\$ 173,249

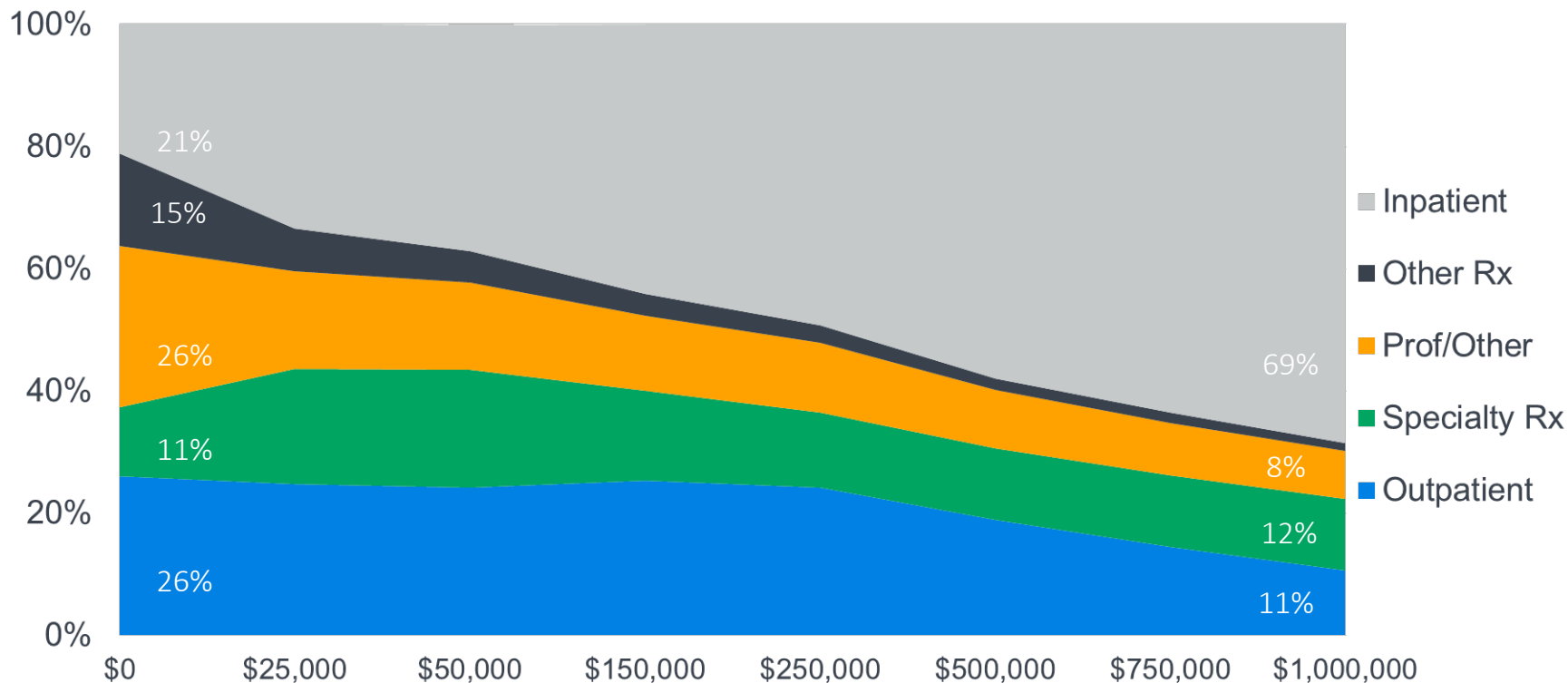
Credit to MIT Center for Biomedical Innovation

NEWDIGS Research Brief 2018F206-V022-Patient Mobility and 2018F205-V021-ORBM

Downstream Impact - Reinsurance



Distribution of Stop Loss Cost by Type of Service



Source: Truven MarketScan Research Database 2011-2015 Commercial data.

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Reinsurance applies across all payers



Commercial

- Group or individual insurance purchased by individuals or employers
- Fully insured by HMO / insurance company **or self-funded by the employer**
- Public exchange introduced 1/1/2014 to improve access, particularly to individuals and small employer groups
- Payors negotiate with providers for payment terms



Medicare

- Federal government program administered by CMS
- Health insurance for elderly or younger people with specific diseases: End Stage Renal Disease or ALS
- Government retains risk for traditional Medicare or transfers the risk to the private sector (HMOs) via Medicare Advantage
- Federal government defines Medicare Allowable payments for all participating providers.



Medicaid

- Jointly run by federal and state government; varies by state
- Health insurance for low income or disabled individuals
- More than half of Medicaid risk is transferred to private sector HMOs or providers (Managed Medicaid)
- States determine qualifications for Medicaid coverage and some states have expanded coverage.
- Each state defines Medicaid Allowable payments for providers

Basic insurance and reinsurance terminology

- **Health Insurance**

A type of insurance that covers the cost of an insured person's medical treatment, services, supplies or pharmaceutical expenses. Insurance companies or Health Maintenance Organizations (HMOs) are licensed by the states to write Health Insurance.

- **Reinsurance**

When an HMO or insurance company passes all or part of their risk to another insurance company.

- **Self-Funded Employer**

An employer who assumes the financial risk of providing health insurance to its employees and their dependents. The employer typically contracts with a TPA and provider network.

- **Stop Loss Insurance**

A type of insurance sold to a Self-Funded Employer to protect against very large claims on any one person (Specific Stop Loss) or higher than expected claims overall (Aggregate Stop Loss).

3 types of reinsurance: Quota-Share, Excess, Aggregate

- **Proportional Reinsurance (Quota Share)**

Reinsurer shares in a percentage of each risk on a underlying policy. Reinsurer shares all premiums and losses accordingly. The reinsurer shares a portion of every claim.

Example: With a 75% quota share reinsurance agreement, the reinsurer is paid 75% of all premium (less a ceding allowance to cover the insurance company's expenses) and the reinsurer is liable for 75% of all claims.

- **Non-Proportional Reinsurance (Excess Reinsurance or Specific Stop Loss)**

(Re)insurer assumes liability for losses that exceed a specified retention (deductible) per person. The (re)insurer only has liability on losses for individuals who have large claims.

Example: HMO or Self-Funded Employer retains the first \$200,000 of risk per person. The reinsurer or Stop Loss carrier is liable for claims that exceed \$200,000 on any one person for all claims in any 12 month period.

- **Aggregate Reinsurance (or Aggregate Stop Loss)**

Aggregate coverage caps the aggregate amount of losses that a ceding company or self-funded employer is responsible for to an amount referred to as the attachment point.

Example: Ceding company retains risk up to 125% of expected claims in aggregate. If expected claims for the 12 month period are \$10,000,000, the ceding company's attachment point is \$12,500,000. The reinsurer is liable if total claims for all covered individuals exceed \$12,500,000.

High Cost Claims – Pre ACA

- Limited coverage (\$1M caps)
- Higher uninsured population

High Risk Pools

- Effective January 1 2014, the Exchanges were formed and insurers were required to provide guaranteed issue insurance with no exclusions for pre-existing conditions.
- ~35 states had High Risk Pools covering ~300,000 people across the U.S.
- These individuals had medical claims that were 3-4 times higher than the insured population.
- Following ACA, **most High Risk Pools have shut down** since these individuals can now buy Health Insurance either through the Exchange or directly from HMOs or Insurance Companies.

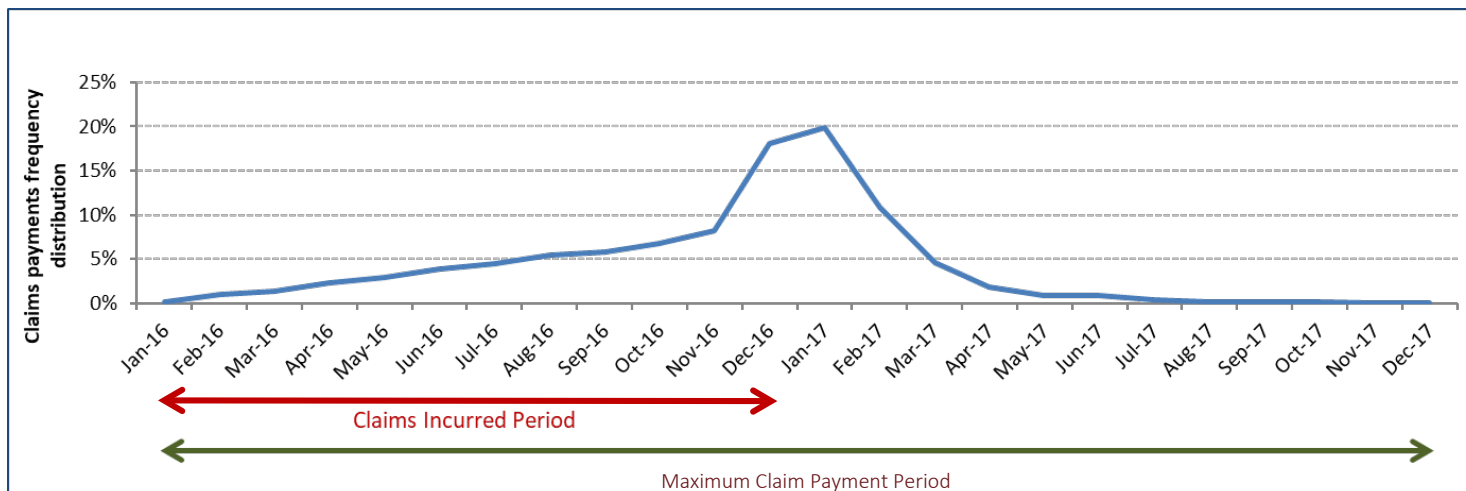
Reinsurance policy structure

Technical Features

- Reinsurer covers claims incurred by a member over a **12 month period**
- If a member is hospital confined at the end of the policy year, the Reinsurer claim terminates and client must meet their deductible again in the following policy year – if renewed (not automatic)
- Many stop loss policies will be written on an “incurred and paid” basis where the claim must be both incurred and paid in the 12 month period
- Claim reporting and submission deadlines are specified and usually do not exceed 12 months following termination date of the reinsurance policy

Contract Characteristics

- **1 year product**
- **Rates & terms change annually**
- Very short tail
- **High deductibles** (> \$50,000 per claimant)
- Excess reinsurance is **for unknown claims**
- Higher deductible or exclusions included for large known ongoing claims (“lasers”)
- **“Run in” provision** reduces timing issues



Specialty Drugs

- For new drugs entering the market, there is minimal visibility into
 - The drugs coming out,
 - The costs of these drugs,
 - What conditions they treat, and
 - Who in the member population is potentially impacted
- The number of new specialty drugs entering the market is increasing
 - Tracking pipeline movement is time consuming and complex
- When looking at a specific employer, it is difficult to
 - Identify people in a plan that are impacted by new drugs entering market, and
 - How drug and medical costs will change

New Gene Therapies create challenges for Insurance, Reinsurance and Stop Loss carriers

- Business model is to pool expected claims over a group of people.
- Reinsurance and Stop Loss Insurance are 1 year contracts covering services that are delivered in a 12 month period. Spreading the cost of Gene Therapy drugs over several years means the Reinsurer or Stop Loss Insurer would only be liable for a portion of the cost.
- While contracts are for 1 year, Reinsurers and Stop Loss Insurers desire long term relationships and are interested in treatments that reduce cost over a longer period of time.
- Reinsurers and Stop Loss Insurers need to anticipate new technologies or treatments that are high cost and may impact their expected claims. Reinsurance and Stop Loss premiums will increase if high cost new drugs are expected.
- Reinsurance and Stop Loss are intended to cover unknown claims. Ongoing known claims are typically “lasered” and remain the risk of the Health Insurer or Self-Funded Employer.
- Clients may change their Reinsurer or Stop Loss Insurer each year making longer term payment methods or refunding a challenge.
- Rebates / refunds that can be attributed to a person reduce Reinsurer or Stop Loss claims but current claim deadlines are short.

Excluding Claims

■ “Experimental” sample definition

- Medical services, supplies or treatments provided or performed in a special setting for research purposes, under a treatment protocol or as part of a clinical trial (Phase I, II, or III). The covered service will also be considered Experimental in any setting if the Covered Person is required to sign a consent form that indicates the proposed treatment, procedure, medical service, supply, drug, device or biological product is part of a scientific study or medical research to determine its effectiveness or safety. Medical treatment which is not considered standard treatment under the particular medical circumstances by the majority of the medical community or by Medicare, Medicaid or any other government financed programs or the National Cancer Institute regarding malignancies, will be considered Experimental. Off-label usage of any drug will be considered Experimental. A drug, device or biological product is considered Experimental if it does not have FDA approval.

■ “Medically Necessary” sample definition

- A treatment, service, supply or drug that:
 1. Is appropriate and essential for the diagnosis or treatment of the Covered Person’s symptoms;
 2. Is within the scope, duration or intensity of that level of care which is needed to provide safe, adequate and appropriate diagnosis or treatment;
 3. Is in accordance with generally accepted current professional medical practice, based on consultation with an appropriate service Provider;
 4. Involves only the use of drugs or substances that are not Experimental.
- A treatment, service, supply or drug will not be considered Medically Necessary if:
 1. It is part of a treatment plan that is considered to be Experimental or for research services; or
 2. It is provided primarily as a convenience to the patient or the patient’s family or the Provider.

The fact that a physician may prescribe, order, recommend or approve a treatment, service, supply or drug does not, of itself, make it Medically Necessary.

Excluding claimants - Lasering

- What does “laser” mean?

- A laser is the practice of assigning a higher deductible (or excluding the individual from Reinsurance or Stop Loss Insurance completely) for an individual with a known condition that is likely to exceed the deductible.

- Why do Stop Loss Insurers and Reinsurers “laser” individuals?

- Stop Loss Insurance and Reinsurance is for unknown claims
- If an individual is likely to incur a large claim due to an ongoing condition or treatment, the Stop Loss Insurer or Reinsurer must increase their premium rates to cover these expected claims.
- The result is that the cost to the Self-Funded Employer or ceding company is higher than it would be if they retained the risk themselves.

Laser “look back period” is generally 1 year to identify “ongoing claims”

Typical conditions / treatments that are lasered

- Hemophilia
- Hereditary angioedema
- Spinal muscular atrophy
- Leukemia
- Hodgkin Lymphoma
- Multiple Myeloma
- Cystic Fibrosis
- Duchenne Muscular Dystrophy
- Urea Disorders
- Crohn's Disease
- Advanced Cancers
 - Breast
 - Colon
 - Lung
 - Bone

Other Issues

- Specialty inflation – leveraged trend
- Rebates
- Pay for performance contracts
 - Patient mobility
 - Payer, reinsurer, broker mobility
- Final rates → Disclosure

Cost Control Strategies

- Prior authorization
- Step therapy
- Pre-certification
- Network steerage
- Centers of Excellence
- Reference-Based Pricing (Medicare)
- Direct provider contracting

Open Discussion



Thank you!

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