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world-class expertise + individual attention

Ethica Pharmacy Advisors

State of the Rx Industry for FEI





Agenda

- Rx trends and statistics
- Current PBM Market and the Influence of Transparency
- Impact of Specialty Drugs
- Focus on Biosimilars
- Gene Therapy
- Obesity and the Role of GLP-1 Agonists
- Legislative Update

National Rx Trends + Statistics

More than

1 in **4**

adults taking prescription drugs report difficulty affording their medication.

Average Annual Cost of a Specialty Drug

\$84,000

\$4.25m

per Lenmeldy dose (for MLD)
The most expensive medication in the U.S.

Pharmacy Trend Increases:

6%-10%

Utilization:

6+%

910 Brand drugs had price increases in January 2024 averaging +4.7%

\$14.50

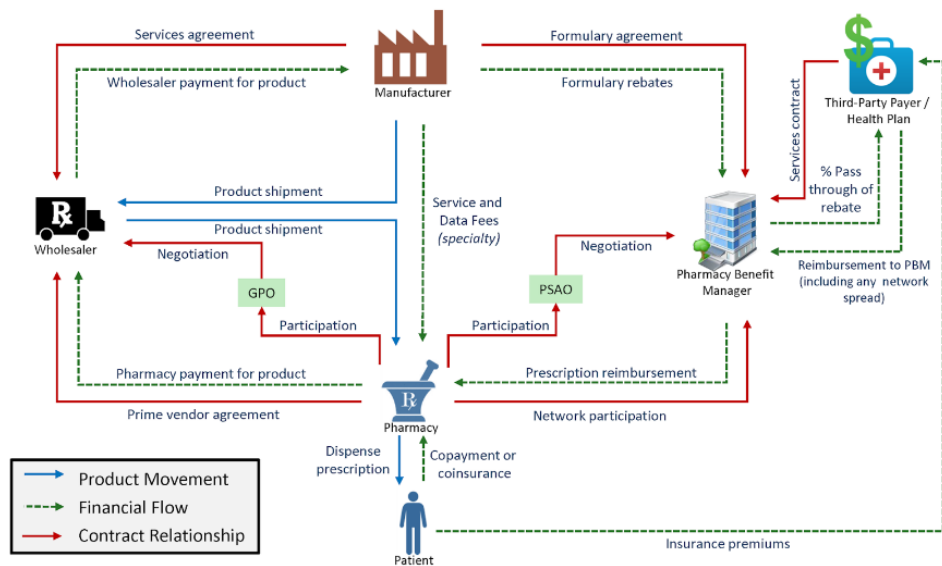
PMPM or 5% of an entire drug spend budget

The impact of GLP-1s on overall pharmacy costs.

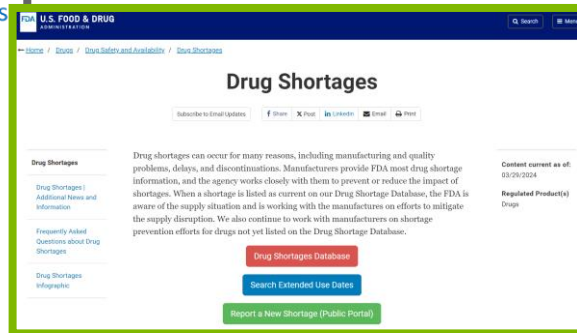
86%+ Generic Dispensing Rate

Complexities and Opaqueness

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



Source: Fein, Adam J., *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017. Chart illustrates flows for **Patient-Administered, Outpatient Drugs**. Please note that this chart is illustrative. It not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
 GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization



DRUG CHANNELS

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023



THE WALL STREET JOURNAL

HEALTH | PHARMA

Florida Is First State Allowed to Import Drugs From Canada in Bid to Reduce Costs

FDA's decision could change the way Americans obtain prescription medicines

By Liz Esley Whyte | Follow

Updated Jan. 5, 2024 5:52 pm ET

Transparency in PBM Contracting

- What does it really mean to be transparent?



Impact of Specialty Drugs

SPEND

50% to 60%

Specialty drug costs represent **more than half** of total pharmacy spend.

TRAJECTORY

2/3 of new drugs launches

Specialty Drugs will represent at least 2/3 of new drug launches through the next 5 years.

GROWTH

8%

Growth is anticipated to be 8% per year through 2025.

COST

\$84,000/year

The average cost of a specialty drug annually is approximately \$84,000.

Defining Specialty Drugs:

- Biologic in origin and produced using recombinant technology
- Usually injected but oral therapy becoming more available
- Intensive clinical monitoring often needed (weight-based dosing)
- Special handling and supplies may be required, along with administration training



Specialty Drug Management Waterfall

SPECIALTY DRUG ACCESS

1. Open Formulary
2. Preferred/Exclusive Channel
3. Site of Care Steerage
4. Medical Channel Strategy
5. Direct Contracting via COEs such as HTCs
6. Carve-out to Specialty Drug PBM
7. Reimportation from outside the US*
8. Exclude Specialty Drugs from Benefit to Maximize Copay Assistance*

CONTRACTING

1. Spread Pricing versus Pass-Through versus Acquisition Cost +
2. Drug Discount versus OED versus Specialty Generic/Brand Discount Guarantees
3. True Accumulation Programs
4. Copay Assistance or Variable Copay Programs
5. Stop Loss
6. Reclaiming Medications*

CLINICAL MANAGEMENT

1. Day Supply Limits
2. Prior Authorization (PBM)
3. Prior Authorization (Carve-out)
4. Specialty Drug Formulary
5. Biosimilar Strategy
6. Clinical Effectiveness Research/ICER
7. Specialty Drug Adherence and Coordination
8. Case Management

* May present a compliance risk. Suggest Plan's internal or external legal counsel review each program prior to implementation of benefit consideration

The Biosimilar Opportunity

DEFINITION

A Biosimilar is...

An FDA approved biological product that has been compared to an FDA approved biologic known as the 'reference' or innovator product. Reference and biosimilar products are:

- Large and complex molecules
- Produced from living organisms
- Carefully monitored to ensure consistent quality

CLASSIFICATION

Criteria to Qualify

Structure and function of an approved biosimilar are compared to the reference product including:

- Purity
- Molecular structure
- Bioactivity

Must NOT have any clinically meaningful difference compared to the reference product in the below ways:

- Pharmacokinetic or pharmacodynamics
- Immunogenicity

VALIDATION

FDA Approval

A biosimilar is approved by the FDA after rigorous evaluation and testing:

- Meets FDA's rigorous standards for approval
- Are manufactured in FDA-licensed facilities
- Are tracked as part of post-market surveillance to ensure ongoing safety



Value of Biosimilars

SAVINGS

Projected to exceed savings of \$181 Billion through 2027

OPTION FOR TREATMENTS

Over 100 Biosimilars are currently in development

ENHANCED ACCESS

The FDA has approved 45 Biosimilars

Plan Sponsors can maximize the use of Biosimilars to lower overall cost through a variety of ways:

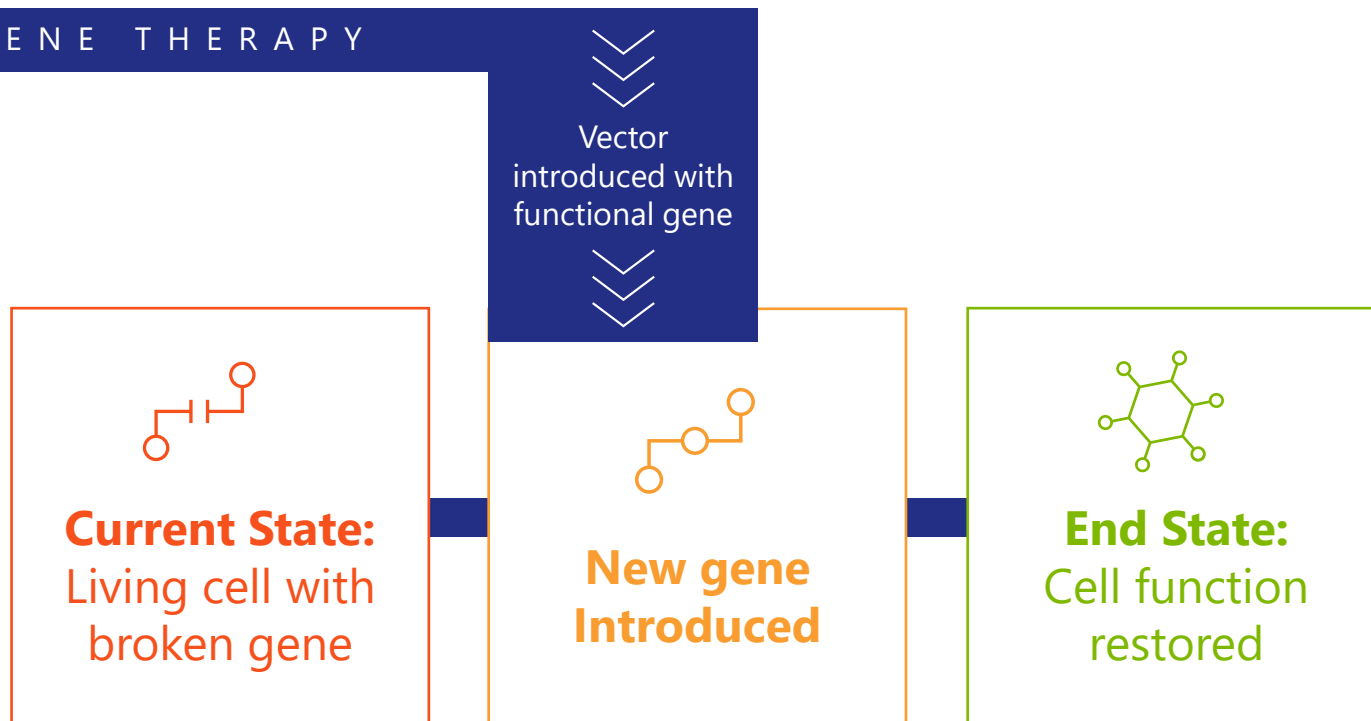
- Benefit design
- Formulary selection
- Integration options
- Utilization management
- Member education
- Transition plans for members

yes and

Gene and Cell Therapy

- **Gene therapy** modifies the genome of a cell through a ‘viral vector’ and can treat, modify, reverse or cure a life-threatening disease.
- Unlike gene therapy, **cell therapy** works as targeted cells are removed from the patient and altered before readministered to the patient. The cells are enhanced in a lab and returned to the patient as functioning cells.

GENE THERAPY



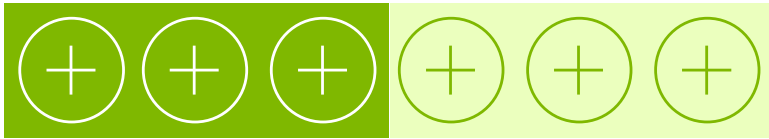
Gene Therapy Market

- 32 gene and cell therapies are currently approved by the FDA
- Average cost per dose is \$1 Million - \$2 Million
- Expect 10-20 new approvals per year
 - Oncology and central nervous system most common therapy area for study

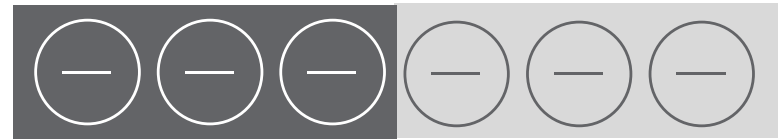


**not an inclusive listing*

PROS + CONCERNS



- ⊕ Overall cost savings versus lifetime expense
- ⊕ One time administration
- ⊕ Improves quality of life



- ⊖ Substantial one-time cost
- ⊖ Possible risk of producing antibodies
- ⊖ Long term effectiveness or variability among members still unknown

Research demonstrates that gene therapy may offer overall savings compared to traditional treatments over the lifespan of the member

- These findings are particularly relevant for hemophilia
 - Traditional factor replacement for hemophilia over a lifetime is expected to be **\$21.5M** whereas the cost of gene therapy including indirect costs is approximately **\$3.8M**

WEIGHT LOSS: The BIGGEST News in Rx

More than

2 in **5**

adults have obesity
(42.4%)

9.2%

of all adults
are considered
severely obese

34.1%

of men are overweight

27.5%

of women are overweight

GLP - 1 s

Rx Management Considerations

Consider approaching Rx management from two perspectives: Diabetes versus Weight Loss

Revisit the organization's philosophy on overall well-being, healthy living and weight loss

1. Do you have a well being vendor partner today?
2. Do you cover bariatric or gastric bypass surgery?
3. Do you cover anorexiant under the drug benefit?
4. Have you considered discounts on healthy meal choices/delivery or Weight Watchers-type programs
5. Do you provide discounts on local fitness centers or provide onsite facilities?

Cost

- Average monthly cost of a GLP-1 medication is \$1,000 (average range of \$900-\$1,300)

Getting to Know GLP-1 Agonists

GLP-1 agonists work by triggering insulin release and reducing glucose production in the liver (making a person feel 'full')

Drug Name	Indication	Dosing	Dosage Form	Other Uses
Bydureon	Type 2 Diabetes	Weekly	Injection	Weight Loss
Byetta	Type 2 Diabetes	2x Daily	Injection	Weight Loss
Mounjaro	Type 2 Diabetes	Weekly	Injection	Weight Loss
Ozempic	Type 2 Diabetes	Weekly	Injection	Weight Loss, Other
Rybelsus	Type 2 Diabetes	Daily	Tablet	Weight Loss
Saxenda	Weight Loss	Daily	Injection	N/A
Trulicity	Type 2 Diabetes	Weekly	Injection	Weight Loss, Other
Victoza	Type 2 Diabetes	Daily	Injection	Weight Loss, Other
Wegovy	Weight Loss	Weekly	Injection	N/A
Zepbound	Weight Loss	Weekly	Injection	N/A

Considerations for Coverage

Whether you cover GLP-1s for Type 2 Diabetes or weight loss, it is important to note that the most effective management of both also includes:

- Living a healthy lifestyle
- Diet modifications
- Exercise

Sample Prior Authorization for Diabetes

- Confirmed Type 2 diabetes diagnosis
- Clinical markers like HbA1c
- Use or failure of first line therapies such as Metformin
- Use of clinical edits (quantity limits, step care edits)

Sample Prior Authorization for Weight Loss

- Confirmed body mass index threshold met
- Confirmed failure on diet and exercise
- Inability to lose sufficient weight for improvements in health
- Use of clinical edits (quantity limits, step care edits)
- Continuous enrollment in behavioral modification program
- Duration checks regarding success



THE IMPACT

The Impact on the Pharmacy Benefit based on Legislation

Pharmacy Networks

- Eliminating preferred options
- Increases plan sponsor cost at retail by 4.2%*

Specialty Pharmacy

- Restricts or eliminates use
- Increases plan sponsor cost by 4.6%*

Mail Order

- Restricts use
- Increases plan sponsor cost by 13.3%
- Increases member cost by 9.4%*

Pharmacy Reimbursement

- State mandates increase dispensing fee and reimbursement
- Increases plan sponsor cost by 9.6%*

More than **650 bills** were **introduced in 2023** specifically related to the pharmacy benefit.

Expect a similar volume in 2024.

**Estimates provided by CVS Health based on their book of business*

KEEPING Rx PRICING REASONABLE

Legislative Considerations

Limiting how much Pharma can increase cost

88%

Ease for generic drugs to come to market

88%

Allowing the government to negotiate for Rx pricing

83%

Reimportation of drugs

78%

Increase taxes on Pharma where Rx pricing is not negotiable

72%

Ending the tax break to Pharma for advertising

56%



yes
and

Thank you.
Questions?

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