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Wespath's HealthFlex Summit

Kathy Hohner | October 11, 2023

Emerging Pharmacy Trends

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Drivers of Trend:

- New indications for expensive drugs
- Highly effective drugs like GLP-1s to treat diabetes, weight loss, potential indication for CV, GLP pipeline

Future Potential Costs:

- Over 250 new drugs are expected to launch within the next five years and contribute over $100B in new healthcare spending
- Gene therapy pipeline is strong, including for relatively prevalent conditions such as sickle cell disease

What Else to Watch:

- The political landscape continues to drive change in the pharmacy benefit space with States taking the lead but also activity at the Federal level

Source; IQVIA https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-2022

Wespath Pharmacy Cost Trend

Wespath Pharmacy Cost Trend

Top 4 Disease States = 64% of Spend

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Wespath's trend (1H 2022 vs 1H 2023) was 7.8%

- Wespath's costs PMPM are higher than benchmark
- More utilizers with chronic diseases than benchmark
- Wespath's trend is lower than the benchmark

Top contributors to trend:

- Inflammatory Conditions (28% of total plan paid)
- Diabetes (24% of total plan paid)
- Weight Loss (4% of total plan paid, *122% trend*)

Top Disease States by Total Plan Paid

1. Inflammatory Conditions

$58.18 PMPM	18.0% Trend
58.3% over benchmark	Top Driver: Utilization

2. Diabetes

$50.39 PMPM	20.5% Trend
106.9% over benchmark	Top Driver: Drug Mix

3. Oncology

$14.15 PMPM	-16.4% Trend
36.9% over benchmark	Top Driver: Cost

4. Asthma/COPD

$8.01 PMPM	-1.2% Trend
69.9% over benchmark	Top Driver: Drug Mix

GLP-1s and Weight Management

GLP-1s: Why all the concern?

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	Saxenda	Wegovy	Ozempic	Mounjaro
Active Ingredient	liraglutide	semaglutide	semaglutide	tirzepatide
Annual Cost	$16,412	$17,537	$12,165	$13,300
Route	Self-Administered injection	Self- Administered injection	Self-Administered injection	Self-Administered injection
Dose Timing	Daily	Weekly	Weekly	Weekly
FDA Approval	Obesity	Obesity	Type II Diabetes	Type II Diabetes; Obesity, pending
Mean % Weight Loss	5.4% - 7.4%	9.6% - 16%	5-10%	Up to 20%

The good…

- Highly effective
- Tolerable side effects
- High media attention
- Positive impact to other related chronic conditions

The bad…

- Costly drug
- High consumer demand
- Some not approved for obesity
- High off-label use impacting supply issues
- When drug is stopped, weight is re-gained unless lifestyle changes occur

The results…

- ❑ GLP-1 spend rose by 40% in 2022
- ❑ Projected GLP-1 spend to reach $71B by 2032
- ❑ Ozempic alone represents 4%-5% of total plan cost
- ❑ Diabetes treatments account for ~18% of the total cost for pharmacy plans (24% for Wespath)

Source: IPD Analytics

Weight Loss Coverage Considerations

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Weight loss is often carved out of benefits, citing lifestyle or cosmetic reasons.

- Fully insured groups typically do not have access to weight loss drugs.
- Self-funded employer groups must opt in and pay additional costs for coverage.

- What other plans covered in 2022:
  - IFEBP says 22% of employers covered
  - PSG says 43% cover, and 28% may add
  - Business Group on Health reports that 59% cover
- Only 8% of those who cover have measures in place to measure and report outcomes.

- Top reasons for excluding weight loss medications from coverage:
  - ✓ Consider the medications to be lifestyle drugs – which are excluded from coverage
  - ✓ Too expensive to cover for all members for whom the medication would be prescribed

Some plans discontinuing coverage for weight loss in 2024 because costs are unsustainable

Weight Loss Coverage Considerations

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- Forecasted growth from 2023 to 2027 is +378% (+$8.1B) in spend
- Prior Authorizations
  - Initial coverage period to assess effectiveness
    - Periodic re-assessment for continuation of coverage
  - Weight support program for initial and ongoing lifestyle change:
    - Once target weight goal is met (or close) ongoing follow up with physician, including for discontinuation of the medication
    - Refer to program for ongoing lifestyle change support
- Refill-too-soon thresholds modifications
- Behavior and lifestyle modification programs
- Case management for complex situations
- Integration of programs impacting weight management

Legislative Impacts

State Mandates on PBMs

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In Rutledge v. Pharmaceutical Care Management Association (140 S. Ct. 812 (2020)), the US Supreme Court unanimously held that "ERISA does not pre-empt a state law". The Arkansas statute at issue regulates only the relationship between PBMs and pharmacies.

- Self-funded and fully insured group health plan sponsors concerned their Rx plans will be required to comply with multiple and varied state regulations - effectively reduce cost savings.

- Possible widespread impact that includes PBM regulation, transparency, MAC pricing, spread pricing, mail order use, exclusive specialty pharmacy use, rebate pass through and others.

- Proposed mandates by state include Alabama, Illinois, Indiana, Louisiana, Minnesota, Montana, New Hampshire, Oklahoma, South Carolina, Tennessee, Texas and West Virginia.

HOT OFF THE PRESS

- SB1550 Florida restricts ability for clients to administer traditional pharmacy cost saving programs like mandatory mail.

HOT OFF THE PRESS

- PCMA vs. Mulready – Oklahoma's Patient's Right to Pharmacy Choice Act (the Act) is preempted by ERISA.

Medicare Drug Rebate Cap Elimination
Why it Matters to a Commercial Plan

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- American Rescue Plan Act eliminates the Medicaid Drug Rebate Cap. Certain manufacturers are exposed with 100%+ rebate obligation to Medicaid effective 1/1/2024
  - Highest impacts to products that have been in the market for years that are single source brands with no generic competition (insulin, asthma products)
- Manufacturers (Eli Lilly, Novo Nordisk, Sanofi) announced list price decreases *for all buyers* for some insulin products to minimize their obligations to Medicaid
  - Rebates for these products will be minimal

Manufacturer Drug Rebate Program

Drug manufacturers are required to pay rebates to Medicaid via the Medicaid Drug Rebate Program (MDRP) in exchange for coverage of their drugs. Helps offset costs for Medicaid

Affordable Care Act (ACA) of 2010

Capped the total statutory Medicaid rebate at 100% of AMP, even if the manufacturer continues to take prices increase exceeding the rate of inflation

American Rescue Plan Act of 2021

- Enacted on March 11, 2021 during COVID public health crisis
- Aimed at mitigating the effects of the COVID-19 pandemic through new funding
- Eliminates the rebate cap of 100 percent of the AMP starting January 1, 2024

What Does This All Mean?

- Starting Jan 1, 2024, Manufacturers may be required to pay rebates to the Medicaid program that exceed the list price of the drug, due to cap being removed
- In other words, manufacturers may have certain drugs where they pay Medicaid to use the product(s)
- This creates a new liability for drug manufacturers that did not previously exist

Biosimilars and Formulary Placement

Biosimilars

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What is a biosimilar?

- A biosimilar is highly *similar* to an existing biological product (reference product).
- A reference brand may have several distinct biosimilars associated with it.

What's the latest news on biosimilars?

- Biosimilars are new - first biosimilar approved by FDA for Neupogen in 2015
- **43** biosimilars are available for **10** different biologic brands
- Biosimilars account for **24%** of total volume of reference molecules prescribed and **46% ($260B)** of spending in the U.S.
- Savings projected to exceed **$180B** over the next 5 years
- So far there is almost **no adoption** of Amgen's Amjevita, the first Humira biosimilar

Biosimilars and Formulary Placement

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Practical considerations for formulary placement:

- Maintain clinical quality of care, flexibility, & choice
- Improve client net cost in category
- Ensure stability of supply from manufacturer(s)
- Physician acceptance
- Minimize patient disruption

OptumRx Decision Criteria:

- Clinical review & product attributes
- Pricing and plan savings (Net Cost)
    - Lower drug cost and lower rebates
- Ability to move market share
- Manufacturing capabilities

The Latest on Humira Biosimilars

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Table: Reflects current pricing for select Humira biosimilars

Product	Optum Preferred	Annual Therapy Cost (WAC)	Discount to Humira	Interchangeable	Concentration	Citrate Free
Humira/AbbVie	**Reference**	$89,994.06	–		HIGH	Yes
Amjevita/Amgen – High WAC	**X**	$85,494.24	5%	Approved, not launched	LOW	Yes
Amjevita/Amgen – Low WAC	**X**	$40,497.39	55%	Approved, not launched	LOW	Yes
Cyltezo/Boehringer-Ingelheim	**X**	$85,494.24	5%	Yes	High Pending Q2 2024	Yes
Unbranded/Boehringer-Ingelheim		$17,098.87	81%	Yes	High Pending Q2 2024	Yes
Hyrimoz/Sandoz	**X**	$85,494.24	5%	Yes	HIGH	Yes
Unbranded/Sandoz	**X**	$17,098.87	81%	Yes	HIGH	Yes
Yusimry/Coherus		$12,935.00	85%	No	LOW	Yes
Yusimry/Cuban Cost Plus Drug cash price		$7,400.00	92%	No	LOW	Yes

High concentration and citrate free are most acceptable to patients.
Currently 89% of the Humira utilization is high concentration.

Humira reformulation

- Reformulated in 2019
- Citrate free
- Higher concentration, lower volume
- Thinner needles
- Reduced injection site pain
- Available as pen device and prefilled syringe

Humira biosimilars

- Most FDA approved 2023 target biosimilars are low concentration, higher volume
- Some are citrate free, some not
- Most have a pen device and prefilled syringes
- Expected to have approved indications for the majority of Humira utilization

Source: IDP Analytics

Major Biosimilars Through 2025

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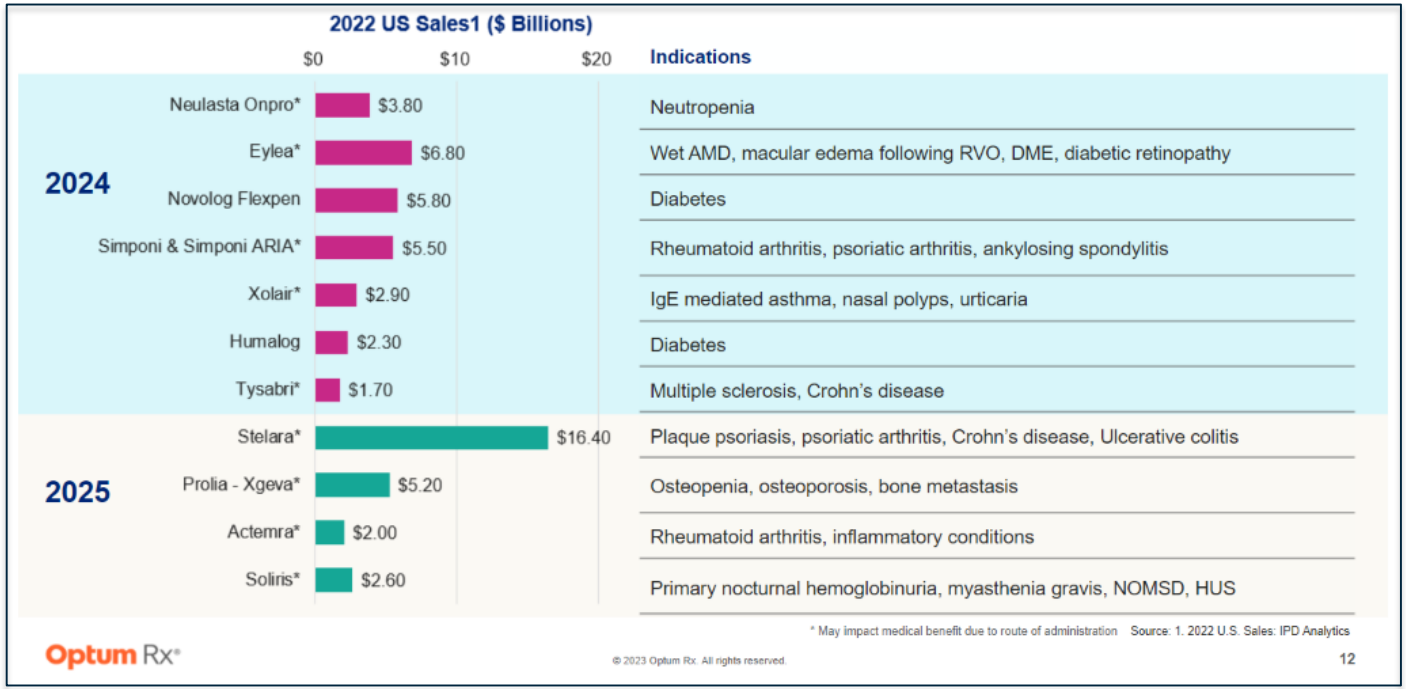

What's next?

- Biosimilars expected in 2024 up to $28B in sales
- Stelara ($16.4B in sales) will be Humira Round 2
- Stelara lost patent Sept 2023 but patent agreement with J&J to delay launch until 2025

Source: OptumRx

Highly Anticipated Biosimilar for Stelara

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Stelara is one of the top-selling drugs in the U.S. with over $10B in annual sales.

A recent agreement between Janssen and Amgen will result in further Stelara biosimilar launch delays.

Previously expected to face biosimilar competition in late 2023, but now Stelara biosimilars will not reach market until after 1/1/2025.

Table: 2025 Anticipated Stelara Biosimilars

Biosimilar Name	Manufacturer(s)	Status	Estimated U.S. Approval	Estimated Launch
ABP 654	Amgen	Pending approval	2H 2023	Jan. 1, 2025
AVT04	Alvotech, Teva	Pending approval	October 11, 2023	2025
CT-P43	Celltrion	Phase 3	2024	2025
SB17	Samsung Bioepis	Phase 3	2024	2025
Bmab1200	Biocon	Phase 3	2024	2025
BMB-3115	Accord, Intas, Dong-A, Meiji Seika	Phase 3	1H 2024	2025
FYB202	Formycon AG, Fresenius Kabi	Phase 3	3Q 2024	2025
BAT2206	Bio-Thera Solutions, Hikma	Phase 3	2025	2025

Source: IDP Analytics

Member Affordability

Member Affordability
OptumRx's Price Edge Program

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GoodRx and other discount programs - How do they work?

- Consumer compares their out-of-pocket cost using the discount card with their out-of-pocket cost using their plan's benefit
- Consumer may find a lower price, *because GoodRx aggregates the network rates they receive from multiple PBMs (including OptumRx)*
- GoodRx receives a payment for each coupon that patients use. Pharmacies pay GoodRx directly for these referrals
- GoodRx partners with almost all PBMs to negotiate deals, and PBMs collect a fee from GoodRx for each Rx

How can Wespath take advantage of these discounts and improve member satisfaction?

OptumRx is offering a new discount program called Price Edge

- OptumRx's system scans discount card market pricing and provides competitive on-benefit pricing to members for generics that are covered by the plan
- Also provides cash discount pricing for non-covered generic drugs
- No action is needed by the member – Wespath members will automatically receive the lowest available price

Member Affordability and Engagement

Doesn't OptumRx already do this?

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Consumers expect their physician to tell them what costs to expect for a new prescription they are ordering *but most physicians don't know.*

Plan Sponsors expect their PBM to recommend lower cost options *but the PBM's incentives don't always align with this expectation.*

- Technology solutions layer on top of existing pharmacy benefits to uncover clinically sound ways to spend less on prescriptions
- Engagement tool that takes the burden off the member to help them take advantage of savings opportunities
  - If member wants to makes a switch, they quarterback that switch
  - Reduces costs for members and the plan
- Works within the formulary and integrates within the existing benefit structure, but still might suggest a non-rebateable alternative

Example savings opportunities:

- $ Similar medication that treats the same condition
- $ Different form of the same medication (like a tablet vs. a capsule)
- $ A generic version

Gene Therapy

Gene Therapy Drugs

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Gene therapy modifies a person's genes to treat or cure disease.
They are administered in a hospital setting and covered under the medical benefit.

Name	Approved Date	Therapy Cost - WAC	Indication
Luxturna	(12/19/2017)	$850K	Inherited retinal disease
Zolgensma IV	(05/24/2019)	$2.1M	Spinal Muscular atrophy
Zynteglo	(08/17/2022)	$2.8M	Beta Thalassemia
Skysona	(09/16/2022)	$3M	Cerebral adrenoleukodystrophy
AMT-061	(11/22/2022)	$3.5M	Hemophilia B
SRP-9001	(6/22/2023)	$3.2M	Muscular Dystrophy
Roctavian	(6/29/2023)	$2.9M	Hemophilia A

Source: IPD Analytics

Gene Therapy Development
Pipeline for Rare Diseases

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- Rare diseases represent:
  - 370 diseases
  - 8.4M U.S. patients, more than 50% are children
  - Annual health cost of $2.2 trillion
    - Cost to treat rare and orphan diseases ranges from $500K- $1M per patient
    - Cost to treat highly prevalent conditions is $266,000 per patient
- By 2025, the FDA expects to approve 10-20 gene therapies each year
- Cancer gene therapy industry revenue is projected to hit $4.3 billion by 2024
- Gene therapy target primarily cancer therapy and rare diseases with limited or no treatment options:

• Hemophilia A and B	• Gaucher disease
• Duchenne muscular dystrophy	• Sickle cell → high prevalence!

Source: IPD Analytics

Gene Therapy
What more can you be doing?

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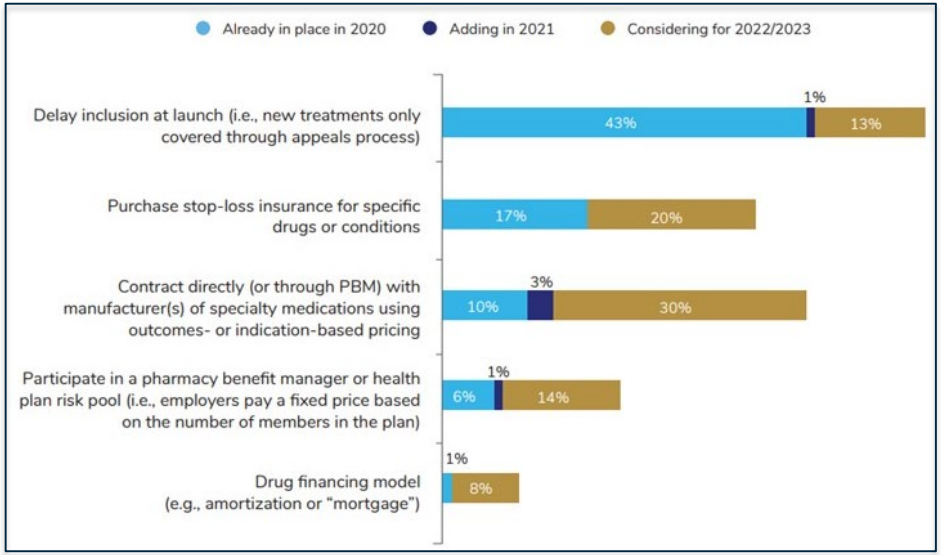
1. Monitor the pipeline and request that plan partners provide:
   - Advanced notification when an anticipated high-priced therapy may come to market
   - Their strategy related to the therapy's safety, efficacy, and the plan's coverage considerations
2. Evaluate the plan exposure via member claims
3. Monitor spend under the medical benefit and discuss pricing and rebates
4. Create urgency with plan partners on total cost of care forecasting
5. Discuss Centers of Excellence and bundled payments for the administration and follow-up of complex therapies
6. Evaluate value-based, outcomes-based and/or risk-sharing payment models that are being considered
   - Definitions of value vary by stakeholder
   - Extended outcome evaluation periods may be needed for long-term durability of curative efficacy

Figure 1: Employer Concerns About High-cost Therapies



Source: Business Group on Health

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Thank you!

Kathy Hohner
Kathy_Hohner@ajg.com
Phone: 201.571.3851
Mobile: 847.567.3512