Demystifying Pharmacy

October 12, 2023





Pharmacy Landscape

- Senate panel challenges traditional pricing
- State legislation challenges traditional pricing, incentivized mail, and exclusive specialty



Specialty

- Gene therapy products cost in the millions per patient
- Rare disease drugs >\$100,000 per year
- Pharma coupon funding challenges
- More specialty generics
- Biosimilar contracting strategies

- "Big Three" have 80% of market
- PBM/carrier impact to contracting options
- Pharma consolidation and impact to pipeline
- PBMs form rebate aggregators

Market Consolidation

Low **Net Cost**

- PBMs offering low/ no-rebate formularies and the traditional rebatedriven formularies
- Biosimilars increasing in availability in the market
- Rebates in medical benefits

PBM Legislation

Federal

Pharmacy Benefit Manager Reform Act

- Would ban spread pricing
- Would require 100% of rebates to be passed through to plans

Other key focuses of federal attention

- Delinking PBM compensation from the price of the drug (pushed by pharma)
- Transparency reporting requirements for PBM
- Copay adjustment programs (all amounts) paid by pharma should accumulate toward member OOP)
- Community pharmacists are pushing for federal legislation to carve-out PBM exemption

State

Resulting in patchwork of legislation

US Supreme Court decision, Rutledge v. PCMA, resulted in confusion over ERISA preemption

OK case, PCMA v. Mulready, will have impact on ERISA preemption once decided

Common state provisions include:

- Banning spread pricing
- Reimbursing based on acquisition cost
- Removing network restrictions
- Limitations on utilization management programs
- Removing copay accumulator programs

Prescription Drug Reform Act

Florida SB 1550

Effective 7/1/23

- Licensing and reporting requirements of PBMs
 - Requires PBM to get Certificate of Authority and report certain investment/ownership information
- Annual attestation
- Retail networks may not limit or direct to affiliated pharmacies
- Restricts use of step therapy
- Prohibits mandatory mail
- Requires pharma to report certain price increases
- Requires 60-day continuity of care period for certain formulary changes made during the plan year
- Network requirements
- Note: not all PBMs agree this applies to self-funded **ASO** groups

Contracts renewed/amended on or after July 1, 2023, between PBM and plan: No spread pricing, and 100% pass-through of all manufacturer rebates

Contracts renewing after July 1, 2023, between the PBM and the network pharmacies also have requirements

Vendor Landscape

BUNDLED PBMs

- **BUCA Carriers**
- Preferred TPA **Partnerships**

COLLECTIVES

- **RxBenefits**
- **Employers Health**
- Health Action Council
- National CooperativeRx
- CoreTrust

TRADITIONAL PBMs

- CVS Caremark
- **Express Scripts**
- Optum



EMERGING PBMs

- Capital Rx
- SmithRx
- Ventegra
- Navitus

SPECIALTY CARVE-OUT

- Archimedes
- **RxResults**
- VIVIO

INNOVATIVE SOLUTIONS

- Pharmacogenomics
- RxResults
- Alternative Funding (Payer Matrix, Paydhealth)
- Condition Management (Tria Health)
- GoodRx
- Amazon RxPass
- Cost Plus

PBM Verticals

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



- 1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. IN Dec. 2021, Walgreen
- 2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit subsidiary as Centene Pharmacy Sevrices. 3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
- 4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans
- 5. Previously known as Evernorth Care Group and Cigna Medical Group. 6. In 2021, Cigna's Evernorth business acquired MDLive.
- 8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023. 9. Previously known as IngenigRx.
- 11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced plans to close a majority of its SeniorBridge home care locations Source: The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 234. Companies are listed alphabetically by corporate name.



May 2023

Anti-Obesity Medications



MEDICATIONS AND WEIGHT LOSS

- GLP-1 Wegovy & Saxenda: 10%-16% loss.
- Mounjaro (pending): 20%+ loss.
- GLP-1 also approved for diabetes.
- Intended for patients with BMI >30 or BMI >27 and co-morbid conditions.
- · Weight likely to return if medication stopped; results of clinical trials included intensive lifestyle modification programs.



COST

- GLP-1 average price \$1,200 per month.
- Priced significantly higher than oral appetite suppressants (e.g., Xenical, Contrave, Qsymia).
- · According to ICER, GLP-1 price needs to be reduced by 40-50% to be cost effective.
- Obesity medications now in plan cost top 10 therapy class.



OUTLOOK

- GLP-1 use has expanded quickly. Wegovy/Saxenda for obesity. Ozempic and other diabetes medications are used off-label 25% or greater.
- Expected to be chronic medications. Manufacturers indicate therapies to be used lifelong.
- Mounjaro expected approval for weight loss in 4Q23.
- 60% of health system employers and 40% of other employers cover AOM; seeing increase in coverage.

GLP-1 Place in Therapy

Relative to APPETITE SUPPRESSANTS

- Substantially superior efficacy.
- Substantially higher cost.

RECOMMENDED STRATEGIES

- Diabetic GLP-1 PA to prohibit off-label use.
- If cover AOM, require prior authorization and lifestyle modification program.



- Humalog, Novolog, Levemir, and Lantus are primary brands used today.
- Insulin represents 5% of brand claims and 1% of overall claims.
- 0%-1% net plan sponsor savings with reduction in AWP and loss of rebates.
- Lower ingredient cost and lower rebates to plan sponsor.

Insulin Market

Some manufacturers announced a 70%-78% reduction in list price for late 2023 and 2024 for many products.

Rebates expected to be eliminated.

High-cost options expected to remain on the market for rebate-focused formularies (e.g., Tresiba).

Lilly and Sanofi capping patient price at \$35 per month.

Favorable to patients.



Biosimilar Update: Humira

- First biosimilar (Amjevita, Amgen) launched end of January 2023, having two different pricing structures:
 - High list price + rebates
 - Low list price + low or no rebates
- Up to 11 more products/formulations launching in 2023
- Formulary decision announcements from PBMs/carriers are coming out now
- Each PBM is handling contract and rebate ramifications differently
- Be alert that Humira's manufacturer field sales reps may attempt to convince prescribers to transition long-stable Humira patients to "successor products" Rinvoq or Skyrizi

Biosimilar Update: Humira

Product/Manufacturer	Citrate- Free?	Interchangeable?	Launch Date	Annual WAC	Discount Off Brand Humira
50 mg/mL Concentration (40 mg/0.8 mL)					
Humira/AbbVie	No	_	2002	\$89,994	_
Amjevita (high WAC)/Amgen	Yes	No ^a	1/31/2023	\$85,494	-5%
Amjevita (low WAC)/Amgen	Yes	No ^a	1/31/2023	\$40,497	-55%
Abrilada/Pfizer	Yes	Seeking ^b	Not launched ^b	_	_
Cyltezo/Boehringer Ingelheim	Yes	Yes	7/1/2023	\$85,494	-5%
Hadlima/Samsung Bioepis; Organon	No	Seeking ^c	7/1/2023	\$13,494	-85%
Hulio/Biocon	Yes	Seeking ^c	7/1/2023	\$85,494	-5%
Adalimumab-fkjp (unbranded Hulio)/Biocon	Yes	Seeking ^c	7/1/2023	\$12,935	-86%
Hyrimoz/Sandoz	No	No	Not launched	_	_
Idacio/Fresenius	Yes	No	7/1/2023	\$85,494	-5%
Yusimry/Coherus	Yes	No	7/1/2023	\$12,935	-86%
Yusimry (Mark Cuban Cost Plus Drug Company)/Coherus	Yes	No	7/1/2023	\$7,400 ^d	-92%
100 mg/mL Concentration (40 mg/0.4 mL)					
Humira/AbbVie	Yes	_	2015	\$89,994	_
Hadlima HC/Samsung Bioepis;Organon	Yes	Seeking ^c	7/1/2023	\$13,494	-85%
Hyrimoz HCF/Sandoz	Yes	No	7/1/2023	\$85,494	-5%
Adalimumab-adaz (unbranded Hyrimoz HCF)/Sandoz	Yes	No	7/1/2023	\$17,099	-81%
Yuflyma/Celltrion	Yes	Seeking ^c	7/2/2023	\$85,494	-5%
AVT02/Alvotech; Teva	Yes	Seeking ^e	1H 2024 (CRL ^e)	_	_
Amjevita HC/Amgen	Yes	Seeking	2023–2024 (Phase 3)	-	-
Cyltezo HC/Boehringer Ingelheim	Yes	Seeking	2H 2023–2024 ^f	_	_
Yusimry HCg/Coherus	TBD	TBD	TBD	_	-

Considerations

- High WAC retain rebates
- Low WAC no/low rebates
- Availability of patient copay cards
- Interchangeability
- Patient acceptance
 - Pain of injection
 - Cost



Biosimilar Update: Stelara

- Eight pending versions (no high concentration vs. low concentration issue as with Humira).
 - Two products were initially expected in 2023, but now, due to patent litigation, the earliest we expect Stelara biosimilars is 2025.
 - Six remaining products in Phase III clinical trials.
- Caution seven years elapsed between FDA approval and biosimilar product launch for Humira, due to legal delays and entanglements.
- Far too early to know anything about definitive launch dates, pricing, formulary placement, etc.
- Be alert that Stelara's manufacturer field sales reps may attempt to convince prescribers to transition long-stable Stelara patients to "successor product" Tremfya.

Hemophilia Gene Therapy

Hemophilia A

Hemophilia A is more common and more likely to be severe; two-thirds of patients are estimated to have severe disease.

- Prevalence: 1 out of 5,000 male births
- **Roctavian** was approved by the FDA in July 2023
- · Not considered a cure or lifelong benefit
- Price of \$2.9M for a 1x IV infusion

Hemophilia B

Hemophilia B is less common and only 50% have severe disease.

- Prevalence: 1 out of 25,000 male births
- **Hemgenix** (etranacogene dezaparvovec) HOPE-B trial showed an 80% reduction in bleeding; manufacturer submitted to the **FDA**
- Approved Nov. 2022
- Price of \$3.5M-\$4.2M
- Most expensive drug on the market

Current average annual cost of therapy is \$160,000. Severe cases can exceed \$1M per year.



Specialty Copay Card Challenges

J&J sues SaveOnSP

AbbVie blocks copay cards for patients enrolled in variable copay programs

15 states require copay assistance to count toward indemnities*

*State regulated plans

Biosimilars in the market

Independence changes everything.

